DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413, 494, and 512

[CMS–1805–F]

RIN 0938–AV27

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, 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 2025. 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 Conditions for Coverage for ESRD Facilities, ESRD Quality Incentive Program, and ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2025.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Nicolas Brock at (410) 786–5148 for issues related to the ESRD Prospective Payment System (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 Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

ESRDQIP@cms.hhs.gov, 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:

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

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Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary

A. Purpose

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 Conditions for Coverage for ESRD facilities, the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this rule finalizes and discusses policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. For example, we are finalizing the proposal to allow Medicare payment for home dialysis for beneficiaries with acute kidney injury, which would assist this vulnerable population with transportation and scheduling issues and allow them to have flexibility in their dialysis treatment modality. Additionally, we discuss the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, which will expand access to these drugs to the 21 percent of the ESRD PPS population who do not have Part D coverage. Our internal data show that a significant portion of ESRD beneficiaries who lack Part D coverage are African American/Black patients with ESRD. Our policy objectives include a commitment to advancing health equity, which stands as the first pillar of the Centers for Medicare & Medicaid Services (CMS) Strategic Plan,[1] and reflect the goals of the Administration, as stated in the President's Executive Order 13985.[2] 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, socioeconomic status, geography, preferred language, or other factors that affect access to care and

[1] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity*.

[2] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

health outcomes.'' [3] In the calendar year (CY) 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, African American/Black, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this final rule, we continue to address health equity for beneficiaries with ESRD who are members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, racial and ethnic minorities, and American Indians and Alaska Natives. The term 'underserved communities' refers to populations sharing a particular characteristic, including geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.[4]

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 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 percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule finalizes updates to the ESRD PPS for CY 2025.

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 final rule updates the AKI payment rate for CY 2025. Additionally, this rule extends payment for home dialysis and the payment adjustment for home and self-dialysis training to renal dialysis services provided to beneficiaries with AKI.

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 establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This rule finalizes our proposals to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy measure topic and to remove National Healthcare Safety Network (NHSN) Dialysis Event reporting measure beginning with Payment Year (PY) 2027. This rule also discusses feedback received in response to our requests for public comment on two topics relevant to the ESRD QIP.

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

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center). The ETC Model 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.'' Subsequently, the ETC Model has been updated three times in the annual ESRD PPS final rules for calendar year (CY) 2022 (86 FR 61874), CY 2023 (87 FR 67136), and CY 2024 (88 FR 76344).

This final rule makes certain changes to the methodology CMS uses to identify transplant failure for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. We also solicited input from the public through a Request for Information (RFI) on topics pertaining to increasing equitable access to home dialysis and kidney transplantation. Feedback we receive from the public will be used to inform CMS' thinking regarding opportunities and barriers the Innovation Center may address in potential successor models to the ETC Model.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2025:* The final CY 2025 ESRD PPS base rate is $273.82, an increase from the CY 2024 ESRD PPS base rate of $271.02. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.988600), and a productivity-adjusted market basket percentage increase of 2.2 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $273.82 (($271.02 × 0.988600) × 1.022 = $273.82).
- *Modification to the wage index methodology:* We are finalizing a new ESRD-specific wage index that will be used to adjust ESRD PPS payment for geographic differences in area wages on an annual basis. Beginning for CY 2025, we will change our methodology to use mean hourly wage data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and full time equivalent (FTE) labor and treatment volume data from freestanding ESRD facility Medicare cost reports to produce an ESRD-specific wage index for use, instead of using the hospital wage index values for each geographic area, which are derived from hospital cost report data. Additionally, we are finalizing updates to the wage index to reflect the latest core-based statistical area (CBSA) delineations determined by the Office of Management and Budget (OMB) to better account for differing wage levels in areas in which ESRD facilities are located.
- *Annual update to the wage index:* For CY 2025, we are finalizing updates to the wage index using the new methodology based on the latest available data. This is consistent with

[3] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[4] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

our past approach to updating the ESRD PPS wage index on an annual basis but uses the new wage index methodology based on data from BLS and freestanding ESRD facility Medicare cost reports.

- *Modifications to the outlier policy:* We are finalizing several proposed revisions to the outlier policy. For the outlier payment methodology, we are finalizing the use of a drug inflation factor based on actual spending on drugs and biological products rather than the growth in the price proxy for drugs used in the ESRD Bundled (ESRDB) market basket. We are also finalizing the use of the growth in the ESRDB market basket price proxies for laboratory tests and supplies to estimate CY 2025 outlier spending for these items. Additionally, we are finalizing our proposal to account for the post-TDAPA add-on payment adjustment amount for outlier-eligible drugs and biological products during the post-TDAPA period. Lastly, we are finalizing the expansion of the list of eligible ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to establishment of the ESRD PPS.
- *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and the final methodology changes previously discussed. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2025 using the latest available CY 2023 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2023 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023. For pediatric beneficiaries, the final FDL amount will increase from $11.32 to $234.26, and the MAP amount will increase from $23.36 to $59.60, as compared to CY 2024 values. For adult beneficiaries, the final FDL amount will decrease from $71.76 to $45.41, and the MAP amount will decrease from $36.28 to $31.02. We note that the inclusion of composite rate drugs and biological products will cause a significant increase in the final FDL and MAP amounts for pediatric patients due to high-cost composite rate drugs furnished to pediatric beneficiaries; this is discussed in further detail in section II.B.3.e of this final rule. The 1.0 percent target for outlier payments was achieved in CY 2023, as outlier payments represented approximately 1.0 percent of total Medicare payments.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2025:* The final CY 2025 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.22. This final offset amount reflects the application of the final productivity-adjusted ESRDB market basket update of 2.2 percent ($10.00 × 1.022 = $10.22). There are no capital-related assets set to receive the TPNIES in CY 2025 for which this offset would apply.
- *Update to the Post-TDAPA Add-on Payment Adjustment amounts:* We calculate the post-TDAPA add-on payment adjustment in accordance with § 413.234(g). The final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.4601 per treatment, which will be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2025. The estimated post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0096 per treatment, which will be included in the calculation for only the fourth quarter of CY 2025. We are finalizing our proposal to publish the final post-TDAPA add-on payment adjustment amount for drugs and biological products that do not have a full year of utilization data at the time of rulemaking after the publication of the final rule through a Change Request (CR). For CY 2025, this will be the case for Jesduvroq.
- *Update to the Low-Volume Payment Adjustment (LVPA):* We are finalizing our proposal to modify the LVPA policy to create a two-tiered LVPA whereby ESRD facilities that furnished fewer than 3,000 treatments per cost reporting year will receive a 28.9 percent upward adjustment to the ESRD PPS base rate and ESRD facilities that furnished 3,000 to 3,999 treatments will receive an 18.3 percent adjustment. We are also finalizing that the tier determination would be based on the median treatment count over the past 3 cost reporting years.
- *Inclusion of oral-only drugs in the ESRD PPS bundled payment:* Under 42 CFR 413.174(f)(6), payment to an ESRD facility for oral-only renal dialysis service drugs and biological products is included in the ESRD PPS bundled payment effective January 1, 2025. In this final rule, we are providing information about how we will operationalize the inclusion of oral-only drugs into the ESRD PPS as well as budgetary estimates of the effects of this inclusion for public awareness. After reviewing public comments, we are finalizing a $36.41 increase to the monthly TDAPA amount for claims which utilize phosphate binders to account for operational costs related to ESRD facilities providing phosphate binders that were not addressed when the ESRD PPS base rate was developed for CY 2011.

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

- *Update to the payment rate for individuals with AKI:* We are finalizing an update the AKI payment rate for CY 2025. The final CY 2025 payment rate is $273.82, which reflects the final CY 2025 ESRD PPS base rate of $273.82 reduced by the home and self-dialysis training add-on payment budget-neutrality adjustment of $0.00 (as detailed in section III.C.3 of this final rule).
- *Payment for home dialysis for beneficiaries with AKI:* We are finalizing our proposal to allow Medicare payment for beneficiaries with AKI to dialyze at home. Payment for home dialysis treatments furnished to beneficiaries with AKI will be made at the same payment rate as in-center dialysis treatments. We are finalizing our proposal to permit ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI, and to implement this adjustment in a budget neutral manner with a $0.00 reduction to the AKI base rate. We are finalizing modifications to the ESRD facility conditions for coverage (CfCs) to implement this policy change.

3. ESRD QIP

Beginning with PY 2027, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, on which facility performance is scored on a single measure based on one set of performance standards, with a Kt/V Dialysis Adequacy measure topic, which would be comprised of four individual Kt/V measures and scored based on a separate set of performance standards for each of those measures. We are also finalizing our proposal to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027. We are discussing feedback received in response to our request for public comment on a potential health equity payment adjustment and our request for public comment on potential future updates to the data validation policy.

4. ETC Model

Beginning for CY 2025, we are finalizing the proposed modification to

the methodology used to attribute ESRD Beneficiaries to the ETC Model, specifically, to the definition of an ESRD Beneficiary at 42 CFR 512.310. Under the ETC Model, CMS attributes ESRD beneficiaries to the ETC Model that meet several criteria including having a kidney transplant failure less than 12 months after the transplant date. We are refining the methodology we use to identify ESRD Beneficiaries with a kidney transplant failure to reduce the likelihood that CMS is overestimating the true number of transplant failures for the purposes of the model. We provide more detail on the finalized modification and its rationale in section V.B of this final rule.

We also sought input from the public through a RFI on the future of the ETC Model, potential successor Models and other approaches CMS may consider to support beneficiary access to patient-centered modalities for treatment of ESRD.

C. Summary of Costs and Benefits

In section VII.C.5 of this final rule, we set forth a detailed analysis of the impacts that the final changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VII.C.5.a of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2025 compared to estimated Medicare payments in CY 2024. The overall impact of the CY 2025 payment changes is projected to be a 2.7 percent increase in Medicare payments. Hospital-based ESRD facilities will have an estimated 4.5 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.6 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $220 million in CY 2025 compared to CY 2024 as a result of the proposed payment policies in this rule. Because of the projected 2.7 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2025, which translates to approximately $40 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 certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this final rule, since no new items were approved for the TPNIES for CY 2024 (88 FR 76431) there are no continuing TPNIES payments for CY 2025. In addition, since we did not receive any applications for the TPNIES for CY 2025, there will be no new TPNIES payments for CY 2025. As discussed in section II.E of this final rule, the TDAPA payment periods for Jesduvroq and DefenCath®, will continue into CY 2025. As described in section VII.C.5.b of this final rule, we estimate that the combined total TDAPA payment amounts for Jesduvroq and DefenCath® in CY 2025 will be approximately $25,633,599, of which, $5,126,719 will be attributed to beneficiary coinsurance amounts.

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

The impact table in section VII.C.5.c of this final rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2024. The overall impact of the CY 2025 changes is projected to be a 2.3 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities will have an estimated 3.4 percent increase in Medicare payments compared with freestanding ESRD facilities that will have an estimated 2.3 percent increase. The overall impact reflects the effects of the final Medicare payment rate update and the final CY 2025 ESRD PPS wage index, as well as the policy to extend payment for AKI dialysis at home, which is not expected to have any impact on payment rates. As discussed in section III.C.3, we are finalizing our proposal to extend the ESRD PPS home and self-dialysis training add-on payment adjustment to AKI patients; however, that adjustment is required to be implemented in a budget neutral manner for AKI payments, so it will not have any impact on the overall payment amounts for AKI renal dialysis services and therefore is not included in these estimates. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2025 ESRD PPS base rate, will increase by $1 million in CY 2025 compared to CY 2024.

3. Impacts of the PY 2027 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing in this final rule, the overall economic impact of the PY 2027 ESRD QIP will be approximately $154 million. The $154 million estimate for PY 2027 includes $136.1 million in costs associated with the collection of information requirements and approximately $17.9 million in payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The final change to the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model is not expected to have a net effect on the model's projected economic impact.

II. Calendar Year (CY) 2025 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) (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 (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase 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 [5] (excluding oral-only ESRD-

[5] 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

Continued

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 percentage increase 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.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) 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 drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

nomenclature. We use the term ''biological products'' in this final rule except where referencing specific language in the Act or regulations.

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 an individual 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 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)(1)).

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 six 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)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients (§ 413.235(b)(2)); and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

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 appeared in the August 12, 2010, issue of 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.

Most recently, we published a final rule, which appeared in the November 6, 2023, 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 2024 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2024. We also finalized a post-TDAPA add-on payment adjustment; a TPEAPA for pediatric ESRD patients for CYs 2024, 2025, and 2026; administrative changes to the LVPA eligibility requirements to allow additional flexibilities for ESRD facilities impacted by a disaster or other emergency; clarifications on TPNIES eligibility requirements; and, effective January 1, 2025, requirements for ESRD facilities to report time on machine for in-center hemodialysis treatments, and to report discarded amounts of renal dialysis drugs and biological products from single-dose containers or single-use packages. For further detailed information regarding these updates and policy changes, see 88 FR 76344.

B. Provisions of the Proposed Rule, Public Comments, and Response to the Comments on the CY 2025 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'' (89 FR 55760–55843), referred to as the ''CY 2025 ESRD PPS proposed rule,'' appeared in the July 5, 2024 issue of the **Federal Register**, with a comment period that ended on August 26, 2024. In that proposed rule, we proposed to make a number of updates and policy

changes for CY 2025, including annual updates to the ESRD PPS base rate, a new ESRD PPS wage index methodology, changes to the list of eligible ESRD outlier services, several methodological changes to the outlier policy, changes to the LVPA structure, updates to the post-TDAPA add-on payment adjustment amounts, and updates to the offset amount for the TPNIES.

We received 212 public comments on our proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and dialysis coalitions. 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; 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). Of these 212 public comments, approximately 70 were unique and approximately 130 were either duplicative submissions or were solely a form letter. We received approximately 110 comments from unique submitters, which reflected a form letter expressing support for a piece of ESRD-related draft legislation which would delay the inclusion of oral-only drugs into the ESRD PPS. We note that we do not comment on draft legislation in this rule will not be directly responding to the support for this draft legislation in this rule, but we are interpreting these letters as expressing support for a delay to the inclusion of phosphate binders into the ESRD PPS bundled payment and have responded to comments which express this sentiment in section II.B.7 of this final rule. Additionally, we note that many of the form letters we received appear to be duplicative submissions based on many names and contact information repeating, so we wish to encourage organizers of these and future campaigns in the future to avoid such duplication as it creates additional operational considerations when reviewing comments.

We received numerous comments on policies for which we did not make any proposals, including mandatory charity care requirements in dialysis clinics, care for undocumented patients, staff assistance for home dialysis, addressing disparities in the kidney transplant process, elevating and integrating patient and caregiver perspectives through a needs navigation model, dialysis commercials for ESRD and AKI, the continuation of TPEAPA, removing the budget neutrality requirement for TPEAPA, both replacing and preventing the replacement of nephrology nurses with other health professionals for prolonged care, including physician assistants or physician associates within the minimum requirement for a dialysis facility's interdisciplinary team, addressing the need for emergency planning for dialysis services in the event of power outages or extreme weather conditions, removing the prospective payment system for home dialysis patients, increasing Medicare Advantage (MA) program payments to beneficiaries in certain geographic areas, restructuring the functional categories for renal dialysis drugs and biological products, aligning CMMI voluntary model benchmarks with the ESRD PPS and its respective add-on payment adjustments, recognizing the mandatory network fee in cost-reports for independent dialysis facilities, removing or mitigating outdated barriers to the use of digital health technology solutions in the ESRD PPS, changing how ESRD patients pay copays, eliminating copays for home dialysis, adding codes for dialysis training onto the telehealth list, and the general need for statutory and regulatory refinements to the ESRD PPS bundled payment. While we are not providing detailed responses to these comments in this final rule because they are out of scope of the proposed rule, we thank the commenters for their input and will potentially consider the recommendations for future rulemaking.

We received several comments related to the requirement at § 413.198(b)(5)(i) to report ''time on machine'' data effective January 1, 2025. These comments generally requested that CMS amend or eliminate the requirement. Some commenters reiterated their concern that this requirement would be burdensome and potentially hazardous. Commenters also requested that CMS identify a consensus definition for time on machine, define time on machine based on ''clock time,'' exclude home dialysis claims from reporting requirements, and designate a claims-based code for an inability to report time on machine data. We did not include any proposals in the CY 2025 ESRD PPS proposed rule to modify the time on machine reporting requirement, and therefore we are not addressing these comments in this rule. We refer commenters to the CY 2024 ESRD PPS final rule (88 FR 76344 through 76507), and the additional guidance CMS posted on November 22, 2023.[6] However, we will consider these comments for potential future refinements to the requirement for reporting of ''time on machine'' data.

We received several comments not related to policies we proposed regarding the TDAPA, TPNIES, TPNIES for capital-related assets that are home dialysis machines, the post-TDAPA add-on payment adjustment, or other potential areas where commenters thought similar policies could be beneficial. Several commenters expressed concern that the ESRD PPS does not sufficiently incentivize innovation in dialysis care or reimburse for innovative technologies. Commenters' suggestions included extending the TDAPA and TPNIES payment periods from 2 years to 3 years, extending the duration of the post-TDAPA add-on payment adjustment to make it permanent, refining base rate-setting exercises based on TDAPA utilization and price data, and adjusting the base rate at the end of the TPNIES payment period. Commenters also suggested revisions to existing TPNIES policies such as expanding the TPNIES for capital related assets beyond home dialysis machines to include in-center dialysis machines or other equipment and supplies that are capital related assets. Commenters suggested that CMS further clarify the TPNIES substantial clinical improvement criteria, clarify whether software can be eligible for the TPNIES, and urged CMS to incentivize more manufacturers to apply for TPNIES. Several commenters suggested that CMS create a pathway for new clinical laboratory tests related to the treatment of ESRD either through an expansion of TPNIES or adoption of a parallel Transitional Laboratory Add-on Payment Adjustment, which the commenters called TLAPA. Commenters suggested changes to the ESRD facility cost reports and billing procedures that would allow for line-item reporting of TDAPA, post-TDAPA, and TPNIES related costs. We received several comments stating that the MA and ESRD PPS regulatory processes should be coordinated to ensure that beneficiaries with ESRD that are enrolled in MA can access items approved for the TDAPA and the TPNIES under the ESRD PPS. Finally, we received several comments on Medicare coverage for certain Humanitarian Use Devices.

[6] *https://www.cms.gov/files/document/mm13445-esrd-acute-kidney-injury-dialysis-cy-2024-updates.pdf.*

We are not providing detailed responses to these comments in this final rule because they are not related to the policy proposals of the CY 2025 ESRD PPS proposed rule. We thank the commenters for their input and will potentially consider the recommendations for future rulemaking.

Lastly, a commenter suggested that CMS had not allowed for a 60-day comment period for the proposed rule because the beginning of the comment period was calculated from the date the proposed rule was made available for public inspection on the **Federal Register** website rather than the date that it appeared in a print issue of the **Federal Register**. The commenter stated that the public comment deadline should have been September 4, 2024. We disagree with the commenter's assertion that we did not allow for the appropriate comment period for this rule. Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of Federal Register) on June 27, 2024. We believe that beginning the comment period for the proposed rule on the date it became available for public inspection at the Office of the Federal Register fully complied with the statute and provided the required notice to the public and a meaningful opportunity for interested parties to provide input on the provisions of the proposed rule.

1. CY 2025 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

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 percentage increase 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 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. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

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.

b. CY 2025 ESRD Market Basket Update

We proposed to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the CY 2025 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.b.(3) of this final rule, we are calculating the final market basket update for CY 2025 based on the final market basket percentage increase and the final productivity adjustment, following our longstanding methodology.

(1) CY 2025 Market Basket Percentage Increase

Based on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket, the proposed CY 2025 market basket percentage increase was 2.3 percent. We also 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 percentage increase), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase in the final rule. Accordingly, based on IGI's third quarter 2024 forecast of the 2020-based ESRDB market basket, the final CY 2025 ESRDB market basket percentage increase is 2.7 percent.

(2) 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 ESRDB market basket percentage increase 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 fiscal year (FY), year, cost reporting period, or other annual period) (the ''productivity adjustment'').

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), 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 would not affect the data or methodology.[7] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We refer readers to *https://www.bls.gov/productivity/* for the BLS

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

historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we would continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2024 forecast, the proposed productivity adjustment for CY 2025 (the 10-year moving average of TFP for the period ending CY 2025) was 0.5 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 final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 productivity adjustment in the final rule. Accordingly, based on IGI's third quarter 2024 forecast, the CY 2025 final productivity adjustment remains unchanged at 0.5 percentage point.

(3) CY 2025 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2025 market basket percentage increase on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket. We proposed to then reduce the market basket percentage increase by the estimated productivity adjustment for CY 2025 based on IGI's first quarter 2024 forecast. Therefore, the proposed CY 2025 ESRDB market basket update was equal to 1.8 percent (2.3 percent market basket percentage increase reduced by a 0.5 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 percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase and productivity adjustment in the final rule. Accordingly, the final CY 2025 ESRDB market basket update is calculated using the final CY 2025 ESRDB market basket percentage increase, based on IGI's third quarter 2024 forecast of the 2020-based ESRDB market basket, and the final productivity adjustment, based on IGI's third quarter 2024 forecast. Therefore, the final CY 2025 ESRDB market basket update is equal to 2.2 percent (2.7 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment).

(4) Labor-Related Share

We define the labor-related share 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. For the CY 2025 ESRD PPS payment update, we proposed, and are finalizing, to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

(5) Public Comments on the ESRDB Market Basket Increase Factor, Productivity Adjustment, Annual Update and Labor-Related Share

We invited public comment on our proposals related to the ESRDB market basket update and labor-related share. Approximately 25 unique commenters including large dialysis organizations (LDOs); small dialysis organizations (SDOs), patient advocacy organizations; nonprofit dialysis associations; two coalitions of dialysis organizations; professional organizations; and MedPAC commented on the proposed update. The following is a summary of the public comments received on these proposals and our responses.

Comment: Commenters generally supported increasing the ESRD PPS base rate and the utilization of the most recent data available (for example, a more recent estimate of the market basket or productivity adjustment) to determine the final CY 2025 ESRD PPS update. MedPAC recommended that the ESRD PPS base rate increase for CY 2025 should be updated by the amount determined under current law, and commented that analysis reported in the March 2024 Report to the Congress: Medicare Payment Policy concluded that this increase is warranted based on its 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). Most other commenters, however, expressed concerns regarding the proposed productivity-adjusted ESRDB market basket update, the proposed ESRD PPS base rate and payment adequacy under the ESRD PPS.

Response: We appreciate commenters' support for an increase to the ESRD PPS base rate and MedPAC's support of the proposed update amount. We acknowledge that many commenters expressed numerous concerns related to the proposed payment rates and payment adequacy within the ESRD PPS. We agree with MedPAC that increasing the payment rate according to the established ESRD PPS methodology is the most appropriate course of action. We have summarized and addressed commenters' specific concerns regarding the payment rate and payment adequacy below.

Comment: Numerous commenters expressed concerns regarding payment rates within the ESRD PPS and the CY 2025 ESRDB market basket update. The general opinion of commenters was that the current ESRD PPS payment rate was not adequate. Many of these comments specifically indicated a belief that the proposed CY 2025 ESRDB market basket update was not a sufficient increase given inflation, specifically pointing to rising costs including labor costs. Many of these concerns were presented in concert with a request for a ''forecast error adjustment,'' which we discuss later in this section of the preamble. Some commenters included comparisons between the ESRD PPS payment rates or ESRDB market basket increases, and other figures not directly related to the furnishing of renal dialysis services such as other Medicare payment systems, overall healthcare costs and overall inflation. Most of these comments requested that CMS take some action to alleviate the perceived concern regarding payment rates. Commenters often cited certain costs which have contributed to the rising costs faced by ESRD facilities including costs related to labor and wages, costs related to training nurses and technicians, supply costs often resulting from limited competition for supplies or limited purchasing power for supplies, supply costs associated with receiving goods in geographically isolated areas, and costs of home dialysis supplies and equipment. Some commenters detailed the potential implications of inadequate ESRD PPS payments including worsened health outcomes, health equity concerns, access to care issues often resulting from ESRD facility closures or reduction of shifts, and inability for ESRD facilities to recruit and retain high quality staff. Several comments quoted MedPAC's estimated 2024 Medicare margins for ESRD facilities which were 0.0 percent as

published in the March 2024 Report to Congress.[8]

Response: We thank commenters for their insight into the payment adequacy of the ESRD PPS and the costs faced by ESRD facilities. We recognize that the input prices that ESRD facilities face have increased in recent years at a rate higher than the ESRDB market basket forecasts have predicted. We address commenters' related requests for a ''forecast error adjustment'' later in this section of the preamble. Payment rates under the ESRD PPS are established based on a methodology dictated by statute, which means the CY 2025 ESRD PPS base rate reflects the CY 2011 ESRD PPS base rate updated by each year's ESRDB market basket update. The ESRD PPS base rate has also been routinely adjusted by certain budget-neutrality factors, for example, budget neutrality adjustment factors related to the annual update to the wage index or related to various payment adjustments like the case mix adjustments or the LVPA. However, we note that the construction of these budget-neutrality factors is calculated to offset the effect of certain other updates and adjustments on total spending under the ESRD PPS and thereby maintain the level of overall payments, so we do not believe that the budget-neutrality factors have had a negative impact on the total payments under the ESRD PPS. Since CY 2011, the only time the ESRD PPS base rate was increased other than as part of a routine update or adjustment was in the CY 2021 ESRD PPS final rule, when we first incorporated calcimimetics into the bundled payment and increased the base rate by $9.93 (85 FR 71410). In summary, the ESRD PPS base rate is based on a longstanding, data driven method provided for by statute. We did not propose, and are not finalizing, any changes to the ESRD PPS payment update methodology.

We agree with commenters that payment adequacy is important as it has a wide variety of impacts both on ESRD facilities and ESRD patients, many of which have been described by commenters. We intend to continue monitoring the performance of the ESRD PPS, and any changes to the ESRD PPS payment rate or ESRDB market basket would be made through notice and comment rulemaking.

We recognize that MedPAC has found that the Medicare FFS margins for ESRD facilities are projected to be 0.0 percent for 2024. We wish to add that MedPAC found that Medicare marginal profit for ESRD facilities was approximately 18 percent for 2022.[9] We understand that the Medicare FFS margin is lower than many interested parties may believe would be appropriate; however, we believe that payments are sufficiently high relative to marginal costs to support the profitable operation of ESRD facilities generally. While we believe MedPAC margin estimates are generally a reasonable metric, we note that the ESRD PPS payment rate is based on the change in prices of a fixed bundle of goods and services, not based on continuously re-aligning payment with costs directly.

Comment: Several commenters discussed the current difficulties of recruiting and retaining healthcare workers. Commenters often characterized this as a healthcare labor shortage and stated that the accompanying increase in wage inflation was a major source of increased costs for ESRD facilities. Many commenters indicated a belief that the proposed CY 2025 ESRDB market basket update or the proposed CY 2025 ESRD PPS base rate were insufficient given this increase in labor costs. One analysis cited by commenters found that labor costs for ESRD facilities rose by 23.7 percent between 2017 and 2023 whereas the ESRD PPS base rate rose by only 14.7 percent during that same period.

Response: We appreciate the commenters' evaluation of labor costs for ESRD facilities. We acknowledge that many ESRD facilities are having increased difficulty in hiring due to overall trends present in the healthcare industry. We note that the ESRDB market basket includes several price proxies for the various cost categories of the ESRDB market basket, including labor. We agree with commenters that labor costs are a significant driver of overall rising costs for ESRD facilities; however, they are not the only costs faced by ESRD facilities and, therefore, are not the only component of the ESRDB market basket. As labor is a substantial driver of the overall input price increase, generally the other input prices faced by ESRD facilities are increasing less than labor prices, so the overall ESRDB market basket increase for a given year is less than the amount by which labor prices have increased. Our analysis of the ESRDB market basket increases from 2017 to 2023 has found that the ESRDB market basket forecasted compensation prices increased by a cumulative 20.9 percent over this time period. The actual ESRDB market basket compensation price growth (based on historical data) over this time period is 23.7 percent. This suggests the ESRDB market basket price proxies are projecting the increased price of labor faced by ESRD facilities with reasonable accuracy, and we believe that the data presented by the commenters supports this belief.

Comment: Several commenters, representing numerous industry interests, stated they believe that the ESRDB market basket is systemically flawed, because the market basket fails to accurately capture the changes over time in the prices in the goods and services included in renal dialysis services. The commenters believed the flaws are due to problems with the weights and price proxies used to assess the changes in costs year-over-year.

The commenters cited analysis from a contractor that suggests possible flaws in the market basket cost weights and price proxies. First, the commenters noted that the cost weights for capital costs are significantly higher in the ESRDB market basket compared to other CMS market baskets. They suggested that while 31 percent of the overall capital costs are determined to be labor-related, the price proxy for capital costs does not use a labor-related price proxy. The commenters suggested that the price proxy for capital costs should be a blended proxy that also includes a price proxy for labor. Another area of concern was that the weight for the ''All Other Goods and Services'' cost category is much larger than in other CMS market baskets—a weight of 11.1 percent is assigned to this category in the ESRDB market basket—and that similar categories under the inpatient prospective payment system (IPPS) and skilled nursing facility (SNF) PPS have weights of 1.2 percent and 0.3 percent, respectively. The commenters stated that further refining the category's definition under the ESRD PPS could reduce the weight and result in a more accurate update factor reflective of ESRD-specific costs.

Response: We appreciate the commenters' suggestions for areas that could benefit from technical improvements in the design and methodology for the ESRDB market basket cost weights and price proxies. We did not propose to rebase or revise the ESRDB market basket in the CY 2025 ESRD PPS proposed rule and further note that we finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141). At the time of the CY 2023 rulemaking cycle, the 2020 Medicare cost report data was the most recent, fully complete

[8] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

[9] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

cost data available and reflected cost data as submitted by freestanding ESRD facilities.

The share of capital costs referenced by the commenter are related to the allocation of a portion of the capital cost weight to the labor-related share since fixed capital costs (for example, construction or improvements to a building) would include costs associated with labor to perform the construction in the initial price, and that price is financed over time or incorporated with the lease contract. This methodology of allocating a portion of the market basket capital cost weight to the labor-related share is consistent across the other CMS PPSs such as those for SNFs, inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs), and long-term care hospitals. For the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized the continued use of the Producer Price Index (PPI) Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120), to measure the price growth of the Capital-Related Building and Fixtures cost category. This PPI reflects the prices of leases for nonresidential buildings (including professional and office buildings). The North American Industrial Classification System (NAICS) definition for this industry comprises establishments primarily engaged in acting as lessors of buildings (except mini-warehouses and self-storage units) that are not used as residences or dwellings. Included in this industry are: (1) owner-lessors of nonresidential buildings; (2) establishments renting real estate and then acting as lessors in subleasing it to others; and (3) establishments providing full service office space, whether on a lease or service contract basis. The establishments in this industry may manage the property themselves or have another establishment manage it for them. We continue to believe that this is an appropriate price proxy, as it reflects the lease or replacement value of nonresidential buildings that would be influenced by both labor prices, such as those associated with construction costs, as well as other nonlabor factors, such as building supplies and interest rates.

In response to the concerns related to the ESRDB market basket cost weight for All Other Goods and Services, as stated in the CY 2023 ESRD PPS final rule (87 FR 67145), the All Other Goods and Services cost weight was derived by disaggregating the Administrative and General cost weight (calculated using the freestanding ESRD Medicare Cost Report data) using the 2012 Service Annual Survey data, which was the most recent year of detailed expense data (inflated to 2020 levels) published by the Census Bureau for NAICS Code 621492: Kidney Dialysis Centers. Though the resulting weight for this category may differ from the weight calculated for other indices, it appropriately reflects the cost distributions associated with providing ESRD services, as prescribed by law.

We note that changing the composition of the ESRDB market basket or changing the price proxies used for the ESRDB market basket would likely not have had a significant impact on the past forecast errors of the ESRDB market basket, since those forecast errors were calculated by comparing the forecasted ESRDB market basket update available at the time of rulemaking to the ''actual'' ESRDB market basket update based on that same index. Any change to the weights or price proxies in the ESRDB market basket would not by itself mitigate a forecast error. The forecast error would only be different or mitigated if the forecasts of alternative price proxies were more accurate than those for the current price proxies used in the ESRDB market basket.

CMS is open to hearing from the commenters and discussing any data or analysis the industry may provide regarding ways to ensure the Medicare payments are appropriate and that the market basket price proxies and weights are accurate. We welcome any publicly available and representative input cost data that reflects total and category-specific costs for the ESRD industry the commenters could provide. We will consider the commenters' suggestions when we propose to rebase and revise the ESRDB market basket in the future and note that any such proposal would occur through notice and comment rulemaking. We rebase and revise the CMS market baskets approximately every 4 to 5 years so that the cost weights reflect recent changes in the mix of goods and services that ESRD facilities purchase to furnish renal dialysis services between base periods. We last rebased in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67153).

Comment: Several commenters expressed concern that the ESRDB market basket updates are disproportionately lower than for all other Medicare providers reimbursed under a PPS. The commenters stated they understand that different cost structures influence this outcome; however, they noted it is important to note these discrepancies given that all these healthcare sectors draw from the same labor pools, and lower ESRD PPS updates erode ESRD facilities' ability to attract caregivers in the current labor market. One commenter noted that the price proxy for buildings utilized by IPPS and SNF is the ''BEA—Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care—vintage weighted 27 years'' which the commenter stated is growing at a faster rate than the price proxy ''PPI Industry for Lessors of Nonresidential Buildings'' which is used by the ESRD PPS.

Response: The 2020-based ESRDB market basket percentage increase is equal to the weighted price change of the individual price proxies based on their respective cost weights. The cost weights are primarily derived using data from the freestanding ESRD facility Medicare cost reports and reflect relative shares of input costs needed to provide renal dialysis services to ESRD beneficiaries. Similarly, the other CMS PPS market baskets, such as the 2022-based SNF market basket and 2018-based IPPS market basket, reflect the relative share of input costs needed to provide skilled nursing and hospital care to Medicare beneficiaries based on the data reported on the respective provider cost reports.

While we understand that commenters may compare the annual updates in the ESRDB market basket to other Medicare payment system market baskets, the ESRDB market basket is developed in accordance with section 1881(b)(14)(F)(i) of the Act requiring that the index reflect the composition of costs associated with providing renal dialysis services. These costs (and the subsequent cost distributions) are reported by ESRD facilities on the Medicare cost reports and may differ (appropriately) from the relative distribution of costs of other medical care providers, such as inpatient hospitals or skilled nursing facilities. Additionally, the price proxies used in the ESRDB market basket are intended to reflect the price pressures faced by ESRD facilities. While some price proxies may be similar to those used across other CMS market baskets, in most cases they are appropriately different because they reflect the price pressures faced by ESRD facilities. For example, the rate of increase in the ESRDB market basket compensation category reflects the weighted average of the price increase for occupations employed by ESRD facilities.

At the time of the CY 2025 ESRD PPS proposed rule, based on the IGI's first quarter 2024 forecast with historical data through the fourth quarter of 2023,

the 2020-based ESRDB market basket increase was forecasted to be 2.3 percent for CY 2025, reflecting forecasted compensation price growth of 3.6 percent. In the CY 2025 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 2025 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 2025. Based on IGI's third quarter 2024 forecast with historical data through the second quarter of 2024, we are projecting a CY 2025 ESRDB market basket increase of 2.7 percent (reflecting forecasted compensation price growth of 3.8 percent). Therefore, for CY 2025 a final ESRDB productivity-adjusted market basket update of 2.2 percent (2.7 percent less 0.5 percentage point for the productivity adjustment) will be applicable, compared to the 1.8 percent productivity-adjusted market basket update that was proposed.

Comment: Several commenters raised concerns about the labor-related share of the ESRD PPS. These commenters suggested that adjusting the labor-related share could better recognize changes in labor costs and result in a higher overall market basket update for the ESRD PPS. Some commenters noted that the ESRD PPS labor-related share for CY 2025 is 55.2 percent while the labor-related share for SNF PPS is 70.1 percent and 67.6 or 62 percent for IPPS.

Response: The purpose of the labor-related share is to reflect the proportion of the national ESRD PPS base payment rate that is adjusted by the wage index. 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 wages and wage-related costs in the geographic area in which the ESRD facility is located. The purpose of the labor-related share is to allocate ESRD payment between a labor-related portion and non-labor-related portion for purposes of geographic adjustment and the labor-related share does not directly impact the market basket update.

We define the labor-related share 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 costs that are related to, influenced by, or vary with the local labor market. In the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154), we detailed the use of the 2020-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Specifically, effective for CY 2023, a labor-related share of 55.2 percent was determined based on the sum of Wages and Salaries, Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees, and 46 percent of the weight for Capital-related Building and Fixtures expenses, which, with the exception of the Professional Fees (0.7 percent) cost weight, were derived from the ESRD Medicare cost reports (CMS Form 265–11, OMB NO. 0938–0236).

While the conceptual definition of the labor-related share used for the ESRD PPS is similar to that used for SNF PPS and IPPS, the cost structures for the various providers differ substantially. Thus, we believe the ESRD labor-related share of 55.2 percent is appropriate, and we are finalizing our proposal to continue to use this labor-related share for CY 2025 ESRD PPS payments.

We note that the labor-related share, as previously discussed, is used to determine the portion of the ESRD PPS base rate which is related to labor for the purposes of applying the ESRD PPS wage index. We believe some of the commenters who requested a higher labor-related share may have believed that increasing the labor-related share would change the proportion of the ESRDB market basket to which price proxies related to labor are applied. As discussed in the CY 2023 ESRD PPS final rule, the ESRDB market basket cost weights are derived from cost report data and, therefore, are the most appropriate measures of the proportion of the ESRDB to which we apply each pricy proxy. It would not be appropriate to apply one of the labor price proxies to other non-labor cost weights in the ESRDB market basket.

Comment: One commenter stated that while they understand CMS does not have authority to waive the application of the productivity adjustment, they were concerned that applying a one-size-fits-all approach in an effort to incentivize efficiencies fails to recognize the unique challenges facing ESRD facilities.

Response: Section 1881(b)(14)(F)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(xi)(II) of the Act. As required by statute, the CY 2025 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending CY 2025. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to section 1881(b)(14)(F)(i) of the Act to apply the specific productivity adjustment described here and do not believe it can be removed from the calculation of the market basket update. As such, we are not finalizing any changes to the use of the productivity adjustment in the CY 2025 ESRDB market basket update.

As stated in the CY 2025 ESRD PPS proposed rule (89 FR 55765), the United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of annual economy-wide, private nonfarm business total factor productivity (previously referred to as annual economy-wide, private nonfarm business multifactor productivity). IGI forecasts total factor productivity consistent with BLS methodology by forecasting the detailed components of TFP. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. We believe our methodology for the productivity adjustment is consistent with sections 1881(b)(14)(F)(i)(II) and 1886(b)(3)(B)(xi)(II) of the Act, the latter of which states the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

The CY 2025 proposed productivity adjustment of 0.5 percent was based on IGI's forecast of the 10-year moving average of annual economy-wide private nonfarm business TFP, reflecting historical data through 2022 as published by BLS and forecasted TFP for 2023 through 2025. The final productivity adjustment for CY 2025 is also 0.5 percentage point for this final rule and is slightly higher than the productivity adjustment for CY 2024 (0.3 percent). This higher productivity adjustment is primarily a result of incorporating BLS revised historical data through 2022, the preliminary historical growth rate in TFP for 2023, and an updated forecast for TFP growth for 2024 reflecting higher expected growth in economic output.

Comment: Commenters reported that the IGI forecast continues to significantly underestimate the increasing costs ESRD facilities incur when providing services to Medicare

beneficiaries and that the market basket increases provided by CMS have not kept up with the rising costs of doing business, particularly labor costs. Commenters stated that while they recognize that updates to the ESRDB market basket are set prospectively, and some degree of forecast error is thus inevitable, they also believe that ESRD facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors. Many commenters urged CMS to reconsider its decision not to adopt a forecast error policy. They stated that a forecast error adjustment for the ESRD PPS would be needed to ensure the funding that the Congress intended ESRD facilities to receive would be available to support patient care and help address health inequities.

The commenters stated that the CMS contractor that determines forecasted price growth for the bundled ESRD PPS market basket has failed to provide an accurate update for the last 4 years resulting in an approximately negative 7 percent forecast error since 2019. They further stated that they believe that the existing methodology will produce an inaccurate annual payment update for CY 2025. Furthermore, they stated that the forecast errors in the ESRD PPS are disproportionately worse than the forecast errors in the other Medicare payment systems and continue to urge CMS to address what they describe as the past underfunding of the payment system.

A few commenters stated that the failure to correct the known forecast errors over the last several years is contrary to the statutory requirement at section 1881(b)(14)(F)(i) of the Act to update the ESRD PPS payment rate based on the change in prices of the ESRDB. The commenters stated that the CMS response in the CY 2024 ESRD PPS final rule was that its market basket update forecast ''misses'' for CY 2021 and CY 2022 were largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 Public Health Emergency (PHE) and that an analysis of the forecast error of the ESRDB market basket over a longer period shows the forecast error has been both positive and negative. The commenters highlighted our past statement that the difference between the projected and actual market basket increases can be both positive and negative. The commenters claimed that this is not the reality of the current situation, and that it would be unlikely that the forecast errors would ''miss'' to the same extent in the future. The commenters also noted that it appears that the under-forecast of the ESRDB market basket updates have continued into 2023, and they stated that preliminary evidence shows even into 2024.

The commenters requested that CMS reconsider its decision not to adopt a forecast error adjustment for the ESRD PPS to account for the underestimates from CMS' forecasted market basket updates in prior calendar years, and to eliminate the risk of further substantial forecast errors going forward by adopting a forecast error adjustment policy for future years modeled after the forecast error adjustment policy in the SNF PPS. Some commenters supported CMS finalizing a forecast error adjustment in this final rule effective for CY 2025, whereas other commenters supported CMS proposing a forecast error adjustment effective for CY 2026. The commenters further stated that addressing these forecast errors is essential to fulfill CMS's statutory obligation to ensure that the ESRD PPS market basket update reflects actual changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

Several commenters noted that when CMS first introduced the forecast error adjustment for SNFs, the agency explicitly determined that this type of adjustment would not be providing a source of new industry funding. Instead, the commenters noted that CMS stated that we were correcting an under-forecast of pricing levels that resulted in lower payments than we would otherwise have made if actual, instead of forecast, data were used. One commenter further stated that on the contrary in the CY 2024 ESRD PPS final rule, CMS justified not implementing stakeholder calls for a forecast error adjustment for the ESRD PPS by explaining that the cumulative under-forecast of the SNF market basket increases was not due to a PHE, which was the case for the ESRD PPS's under-forecast in recent years. However, the same commenter noted that CMS finalized a forecast error adjustment for the SNF payment system due to the rapid increase in the price of labor and because CMS concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs. The commenter further rationalized that while the forces driving the under-forecast of the ESRDB market basket today may differ from those impacting the SNF market basket in 2003, the outcomes for providers are presenting in the same manner. Commenters stated that they believe implementation of a retroactive cumulative forecast error adjustment and continued forecast error adjustment in the future is within CMS's existing statutory authority under section 1881(b)(14)(F)(i) of the Act. Commenters referenced perceived similarities between this statutory language for the ESRD PPS and the statutory language for the SNF PPS annual update at section 1395rr(b)(F)(i)(I) of the Act, which CMS utilized when finalizing the SNF PPS forecast error adjustment.

Based on what the commenters characterized as the same statutory obligation and an even larger and longer record of forecast errors, the commenters requested CMS adopt the same retrospective forecast error adjustment and future forecast error adjustment process for the ESRD PPS. They provided further context for this request by referencing the justification of the forecast error adjustment policy in the SNF PPS as precedent.

Some commenters urged CMS to implement a one-time retrospective adjustment to the ESRD PPS base rate in the amount of the current cumulative forecast error calculated from the beginning of the ESRD PPS, while others requested such an adjustment for the period of 2019 or 2020 through 2023. Additionally, most commenters also supported the implementation of a forecast error correction policy for future years that would be triggered when the absolute (positive or negative) error is equal to or exceeds a 0.5 percentage point threshold. One commenter also requested that CMS acknowledge that the current forecast methodology has failed to produce accurate updates for 4 years and work with IGI to minimize forecast misses in the future. One commenter requested more transparency regarding the methodology for developing the price forecasts that are used in the CMS market baskets.

Response: 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 2025 market basket update in this final rule reflects historical data through the second quarter of CY 2024 and forecasted data through the fourth quarter of CY 2025. While there is no precedent to adjust for market basket forecast error in the ESRD PPS payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year to the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred

since the implementation of the ESRD PPS in CY 2011. Over most of this history the forecast errors were small in magnitude, with the largest error (in absolute terms) prior to 2021 being an over-forecast (the actual market basket increase was less than the forecasted market basket increase) of 0.8 percentage point in 2017. More recently the ESRDB market basket has been under-forecast, as noted by the commenters, with larger errors occurring for 2021 through 2023. The cumulative forecast error since ESRD PPS inception (CY 2012 to CY 2023) is an under-forecast of 4.3 percent.[10] These recent forecast errors were largely a function of uncertainty in the overall economy and the health sector specifically due to the nature of the COVID–19 PHE and the unforeseen inflationary environment.

We thank the commenters for their continued feedback on the ESRDB market basket. In the CY 2024 ESRD PPS proposed rule we explained why we did not believe a forecast error adjustment was appropriate at that time. We did not propose a forecast error adjustment in the CY 2025 ESRD PPS proposed rule for these same reasons and are not finalizing a forecast error adjustment at this time. Specifically, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations, and forecast error calculations are unpredictable (88 FR 76356 through 76358). Historically, the positive differences between the actual and forecasted market basket increase have offset negative differences over time. Although we acknowledge that this has not been the case in recent years, we note that it may take a longer period of time for forecast errors to balance out. For example, in CY 2016 the cumulative forecast error for the ESRDB market basket since CY 2012 was 0.4 percent, and in each year from CY 2012 to CY 2016, the cumulative forecast error was positive, ranging from 0.2 percent to 0.5 percent. Then, beginning in CY 2017, the cumulative forecast error was negative, which continued through CY 2020, ranging from −0.4 percent to −0.6 percent. These examples illustrate that over time positive and negative differences between the actual and forecasted market basket increase have tended to balance out. Therefore, in accordance with our longstanding ESRD PPS payment update methodology, we are finalizing to update the CY 2025 ESRD PPS base rate without the application of a forecast error adjustment to the ESRDB market basket.

Given the concerns raised by the commenters, we intend to continue to monitor the pattern of the ESRDB market basket forecast errors to observe if the historical experience (where errors have balanced out) continues. Any changes to the ESRD PPS payment update methodology, including any forecast error adjustment policy, would be proposed through notice and comment rulemaking. We acknowledge the commenter's request for more transparency regarding the ESRDB market basket forecast methodology and have shared details in prior and this year's rules on these methods; however, we are limited in the amount of information we can provide regarding the forecast methodology, which is proprietary to IGI.

Comment: Some commenters expressed concern about whether CMS was adhering to Social Security Act and the Administrative Procedure Act requirements in declining to adopt a forecast error adjustment. One commenter stated that, given the past forecast errors, they did not believe our methodology fulfilled the requirement to update the payment system based on the change in prices of the ESRDB market basket. This commenter further stated a belief that because CMS had determined that a forecast error adjustment was appropriate for the SNF PPS in 2004, we would be in violation of the ESRD PPS's similarly worded statute unless we were to implement a forecast error adjustment for the ESRD PPS, due to the similarities between the circumstances of SNF PPS in 2004 and the ESRD PPS presently.

Response: We strongly disagree with the commenter's assertion that CMS's position regarding an ESRD PPS forecast error payment adjustment conflicts with any of the statutory requirements for the ESRD PPS. As we have discussed previously, we believe that the ESRDB market basket forecast reflects the change in prices of an appropriate mix of goods and services included in renal dialysis services, as required by statute. We note that the circumstances of the ESRD PPS in the present are not identical to the circumstances of the SNF PPS when we finalized a forecast error adjustment. The cumulative under-forecast of the SNF market basket increases in 2004 was based on a rapid increase in the price of labor, not due to a PHE that rapidly increased the price of most of the goods and services in the ESRDB market basket. Additionally, the increase in the price of labor uniquely impacted the SNF PPS at that time as the SNF PPS had only existed for a few years and had numerous under-forecasts in that short timeframe. This is unlike the current ESRD PPS environment, where the ESRD PPS had a decade of reasonably accurate forecasts, followed by a PHE resulting in multiple Medicare payment systems facing similar forecast errors. We continue to believe these differences in circumstances are relevant in evaluating the forecast errors in the ESRD PPS in recent years and their implications for the future performance of the payment system. We note that when CMS finalized a forecast error adjustment for the SNF payment system, we concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs; not that it was required under the statute (68 FR 46057). For these reasons, we disagree with the commenter's stated belief that a forecast error adjustment would be required to fulfill the ESRD PPS statutory requirements, and, at this time, for the reasons discussed previously, we do not believe that a forecast error payment adjustment would be appropriate for the ESRD PPS. We also disagree with the commenter's assertion that by not implementing a forecast error adjustment we are in violation of the Administrative Procedure Act; as discussed previously, our established ESRDB market basket methodology has been set and revised through notice and comment rulemaking (75 FR 49151 through 49162, 79 FR 66129 through 66136, 83 FR 56951 through 56964, 87 FR 67141 through 67154). For the CY 2025 ESRD PPS proposed rule we provided a 60-day comment period, and we have considered and responded to all relevant comments in this final rule explaining our reasoning for the policies we are finalizing.

Comment: One coalition of dialysis organizations disagreed with CMS's evaluation that a forecast error adjustment would make ESRD PPS payments less predictable. The commenter stated that under the current payment system providers are uncertain whether the ESRDB market basket forecast would be accurate for a given year.

Response: We appreciate this commenter's perspective on predictability within the ESRD PPS as we work to improve the payment system. Our current view on predictability is that it is important for ESRD facilities to be able to plan for future years with the most complete information possible, which we believe would likely not be the case if the ESRD PPS base rate would be lowered in a given year due to an over-forecast in the prior year. We will take this input into consideration for future rulemaking.

[10] This figure does not include a forecast error for CY 2015, as section 1881(b)(14)(F)(i)(III) of the Act required a 0.0 percent update for that year.

Final Rule Action: We did not propose and are not finalizing any changes to the ESRDB market basket methodology for CY 2025. Thus, the final ESRDB market basket update for CY 2025 is 2.2 percent, representing a ESRDB market basket percentage increase of 2.7 percent reduced by a 0.5 percentage point productivity adjustment.

2. CY 2025 ESRD PPS Wage Indices

a. 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, we established a policy to adjust the labor-related portion of the ESRD PPS 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. Under current policy, we use the Office of Management and Budget's (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/*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there are 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 have computed the average wage index value of all hospitals in urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For rural areas with no hospital data, we have computed the wage index using the average hospital 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).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the US Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further 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) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a labor-related share of 55.2 percent. 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 that same rule, 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. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2025, as discussed in section II.B.1.b.(4) of this final rule, the final labor-related share to which the wage index would be applied is 55.2 percent.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). The ESRD PPS wage index values have historically been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix.

b. Methodology Changes for the CY 2025 ESRD PPS Wage Index

CMS has received feedback on our longstanding ESRD PPS wage index methodology from interested parties through comments on routine wage index updates in the annual ESRD PPS proposed rules. Commenters often suggested specific improvements for the ESRD PPS wage index. In the CY 2024 ESRD PPS final rule (88 FR 76359 through 76361), we discussed the comments on the routine wage index proposals from the CY 2024 ESRD PPS proposed rule (88 FR 42436); commenters, including MedPAC, suggested that we 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. MedPAC specifically suggested that CMS implement the recommendations discussed in its June 2023 Report to Congress,[11] which recommended moving away from the current IPPS wage index methodology in favor of a methodology based on all employer wage data for all Medicare PPSs with industry specific occupational weights. Additionally, MedPAC suggested that the new methodology reflect local area level differences in wages between and within metropolitan statistical areas and statewide rural areas and smooth wage index differences across adjacent local areas. MedPAC stated that, compared to the current IPPS wage index methodology, a methodology based on all employer wage data with industry-specific occupational weights would improve the accuracy and equity of payments for provider types other than inpatient acute care hospitals, such as ESRD facilities.

In past years some interested parties have contended that the methodology used to construct the current ESRD PPS wage index does not accurately reflect the ESRD facility labor market. These interested parties have noted that the ESRD PPS wage index has been based on the IPPS wage index, which uses hospital data, which commenters have stated may not be applicable for ESRD facilities. More specifically, commenters have suggested that the types of labor used in ESRD facilities differ significantly from the types of labor used by hospitals, which may result in the use of relative wage values across the United States that do not accurately match the actual relative wages paid by ESRD facilities. For example, if ESRD

[11] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf*.

facilities have a different proportion of registered nurses (RNs), technicians and administrative staff compared to hospitals, and if wages for each of those labor categories vary differentially across the country, it is possible that relative wages for ESRD facilities, given their occupational mix, would vary differently from relative wages for hospitals across CBSAs. Because of this, some commenters have specifically requested that CMS develop an ESRD PPS wage index based only on data from ESRD facilities. Additionally, some commenters have criticized the time lag associated with using the IPPS wage index, which is generally based on data from four FYs prior to the rulemaking year (see, for example, 88 FR 58961).

(1) December 2019 Technical Expert Panel (TEP)

In response to feedback from interested parties on the ESRD PPS wage index, CMS's data contractor hosted a Technical Expert Panel (TEP) in December of 2019.[12] During this TEP, the contractor presented a potential alternative approach to the wage index, which utilized BLS data to address the concerns of commenters, to initiate a discussion on the ramifications of a potential new ESRD PPS wage index that would combine two sources of existing data to more closely reflect the occupational mix in ESRD facilities. The methodology presented at this TEP utilized publicly available wage data for selected occupations from the BLS OEWS survey and occupational and fulltime equivalency (FTE) data from freestanding ESRD facility cost reports (Form CMS 265–11, OMB No. 0938–0236). Specifically, this approach used the freestanding ESRD facility cost reports to determine the national average occupational mix and relative weights for ESRD facilities. Next, the contractor applied the estimated county-level wages based on BLS OEWS[13] to obtain occupation-specific wages in each county. The BLS OEWS data is updated annually using sample data collected in six semiannual survey panels over the prior 3-year period, which allows for the inclusion of more recent data than the hospital cost report data that is utilized by the IPPS wage index. Therefore, as noted during the TEP, this new methodology would allow CMS to adjust wage index values to reflect relative changes in wage conditions in a timelier fashion compared to the current ESRD PPS wage index methodology. Additionally, as noted during the TEP, by utilizing FTE data reported on the freestanding ESRD facility cost reports, this methodology is likely more reflective of the occupational mix employed by ESRD facilities than the hospital wage index.

Panelists at this TEP generally indicated their preference for the presented alternative wage index methodology, because it utilized more recent wage data from the BLS OEWS program. Panelists also favored how the alternative methodology was more targeted to ESRD facilities by utilizing FTE data from ESRD facility cost reports in determining the occupational mix. Some panelists voiced concerns about using publicly available BLS geographic area data, as the data do not disaggregate wages by health care sector, and therefore wages from acute care hospitals are not differentiated from outpatient care centers and other non-hospital health care settings. Some panelists noted that this would result in a wage index based on the publicly available BLS OEWS data having some of the same limitations for which the use of the IPPS wage index has been criticized—mainly that it includes wage data from hospitals.

(2) Proposed New Methodology for Using BLS Data To Calculate the ESRD PPS Wage Index

Based on feedback we received in response to past ESRD PPS proposed rules and from the December 2019 TEP, we developed a new ESRD PPS wage index methodology that we believe better reflects the ESRD facility labor market, which we proposed in the CY 2025 ESRD PPS proposed rule (89 FR 55766 through 55782). Similar to the methodology presented in the December 2019 TEP, this new methodology utilizes two data sources: one for occupational mix and one for geographic wages. First, we determine a national ESRD facility occupational mix (NEFOM) based on cost report data from freestanding ESRD facilities. Second, we extract and use data from the publicly available BLS OEWS survey on the average wages in each CBSA for each labor category present in the NEFOM. We note that because the publicly available BLS data are available at the Metropolitan Statistical Area (MSA), non-MSA and New England City and Town Area (NECTA) levels, and the wage index is designated at the CBSA level (which uses MSAs and other area designations that differ from non-MSAs and NECTAs), we use the area definition dataset[14] that accompanies the BLS data to assign wages at the county level, and map counties to CBSAs using a crosswalk. This crosswalk is included in Addendum B, 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*.

(a) Description of Data Sources Utilized in the Proposed Methodology

In the CY 2025 ESRD PPS proposed rule we discussed the data sources which we utilized for the proposed new ESRD PPS wage index methodology. We described the data sources in detail alongside explanations of the ways in which we proposed to use the data, potential benefits and weaknesses compared to the IPPS wage index data, and the lag associated with the data.

(i) Data From the BLS OEWS Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates

The BLS OEWS program publishes annual estimates of employment and wages by occupation. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates, published in April 2023, are based on six semiannual survey panels from November 2019 to May 2022. We proposed to use publicly available mean hourly wage data at the MSA level,[15] which is available online at *https://www.bls.gov/oes/*. OEWS wage data collected in earlier survey panels are ''aged'' or updated to the reference date of the estimates based on adjustment factors derived from the OEWS survey data using a regression model. The BLS OEWS mean hourly wage data that was presented in the CY 2025 ESRD PPS proposed rule and was utilized for the proposed new wage index methodology described in detail later in this section of this final rule reflect these wage aging adjustments. Table 1 shows the

[12] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-may-2020.pdf*.

[13] The OEWS program produces estimates of employment and wages by occupation based on a survey of business establishments. OEWS data are released annually with a May reference date. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates are based on six semiannual survey panels from November 2019 through May 2022. We note that we use a crosswalk between counties and MSAs, non-MSAs and NECTAs to get county level wage estimates.

[14] For more information on MSAs and non-MSAs please see: *https://www.bls.gov/oes/current/msa_def.htm*. For more information on the most recent CBSA delineations (as discussed later in this section) please see: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

[15] We use the territory-level data for Guam and Virgin Islands, since the MSA and non-MSA level data is not available.

occupation codes based on the Standard Occupational Classification (SOC) and the corresponding occupational title for each SOC, alongside the common name that we use to refer to workers in specific occupations throughout this final rule. The ESRD PPS common names match the FTE categories captured on Worksheet S–1, lines 23 through 30 of the freestanding ESRD facility cost report form. The SOC System is a United States government system for classifying occupations. It is used by Federal Government agencies collecting occupational data, enabling comparison of occupations across data sets. When we considered the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. For many of these occupations, the corresponding BLS code was straightforward. For example, BLS code 29–1141 is for ''Registered Nurses'' which matches the category on the cost reports from which the NEFOM is derived exactly. For the occupations that were not necessarily specific to the healthcare field, for example administrative staff, we used BLS codes that were specific for healthcare, such as code 43–6013 for ''Medical Secretaries and Administrative Assistants.'' In the proposed rule, we explained that we believe that these are the most appropriate codes, as a more general code may not capture the specifics of the healthcare labor market.

TABLE 1: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports Occupation Classifications

ESRD PPS Colloquial Name	BLS Occupation Title	Occupation Code
Registered Nurses (RN)	Registered Nurses	29-1141
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29-2061
Nurse Aides	Nursing Assistants	31-1131
Technicians	Health Technologists and Technicians, All Other	29-2099
Social Workers	Healthcare Social Workers	21-1022
Dietitians	Dietitians and Nutritionists	29-1031
Administrative Staff	Medical Secretaries and Administrative Assistants	43-6013
Management	Medical and Health Services Managers	11-9111

The BLS OEWS data used for the analysis presented in the proposed rule included mean wages by occupation for all industries combined located in a MSA (or non-MSA area or NECTA), including the hospital industry. While interested parties have criticized the current ESRD PPS wage index methodology's sole reliance on hospital data, we stated that inpatient hospital data is appropriate to include in this analysis for several reasons. Principally, as explained later in this section, the wage data is being weighted based on an occupational mix that is specific to ESRD facilities, which makes this methodology more accurate to the wage environment of ESRD facilities regardless of the source of the wage data. Additionally, ESRD facility data is included in the BLS data, while ESRD facilities generally are not included in the hospital cost report data used in the IPPS wage index (with the exception of hospital-based ESRD facilities). Lastly, hospitals are a major contributor to labor markets, and it is reasonable to believe that ESRD facilities compete with hospitals (as well as other healthcare facilities) when it comes to hiring labor; as such, the inclusion of hospital data would provide additional insight into the labor markets of these areas.

In the proposed rule, we discussed that a limitation of the publicly available BLS OEWS data is that the survey only includes information on the wages that employers paid to their employees. Therefore, the OEWS does not include self-employed contract labor wages or benefits paid to employees, which are reflected in the IPPS wage index. Nevertheless, we believed, and we continue to believe, that this data source would be an improvement over the use of the IPPS wage index for the ESRD PPS, as its purpose is to identify geographic differences in wages. In the proposed rule, we noted that assuming wages spent on self-employed contract labor wages and employee benefits vary similarly to employee wages, we would not expect any significant difference arising from this limitation of the BLS data. We anticipated that most traveling nurses and technicians would be employed by a staffing agency, and therefore would be included in the OEWS estimates; however, as worksite location reporting is optional,[16] we note it is possible that some of the wages for these traveling nurses and technicians could be included in the MSA in which their employing agency is located, rather than the MSA in which they worked. However, we noted that we would not anticipate that this would have an appreciable impact on the OEWS estimates used for this methodology. Additionally, we noted that the OEWS would only include the wages paid by the contract agency to these contract workers, so the OEWS estimates would likely not include the full cost of the contract labor paid by the ESRD facilities to the contracting agency. We could not separately estimate the prevalence of self-employed contract labor at ESRD facilities from the rest of contract labor, which we believe would still provide some insight into the potential limitation of the exclusion of self-employed contract labor wages from the BLS OEWS. We noted that all contract labor costs represent approximately 5 percent of compensation costs in the 2020-based ESRDB market basket (87 FR 67143). As discussed in the CY 2025 ESRD PPS proposed rule, our analysis of freestanding ESRD facility cost report FTE data indicated that approximately 1.3 percent of RN hours and 1.1 percent

[16] *https://www.bls.gov/respondents/oes/instructions.htm#online.*

of technician hours were contract labor in 2022. Additionally, our data showed that the share of contract labor hours has been relatively stable over time but has increased slightly over the past few years.

In the proposed rule, we discussed that one potential concern about use of the BLS OEWS data is that in some cases, the BLS OEWS may not have usable data for a county for an occupation, which is used in the construction of the new ESRD PPS wage index according to the methodology presented later in this section. This occurs when BLS is unable to publish a wage estimate for a specific occupation and area because the estimate does not meet BLS quality or confidentiality standards.[17] For reference, among the 25,808 unique county-occupation combinations in the May 2022 BLS OEWS data used in the analysis in the proposed rule, the wage information missing rate was 5.2 percent. To impute the missing data for the methodology presented in the proposed rule, we performed a regression using the most similar (by mean hourly wage) occupation (of the occupations we proposed to include in the wage index methodology, presented in Table 1) for which there was no missing data. For dietitians we used RNs, for technicians we used LPNs and for nurses' aides we used administrative staff. The regression included controls for whether the county is rural, the census region in which the county is located, and the natural logarithm of the treatment count of the county. For the wage index presented in the CY 2025 ESRD PPS proposed rule, we only had to impute missing county-level data for dietitians, technicians, and nurses' aides; however, for future years, we noted that we may have to impute data for other occupations and will be sure to note any imputations through notice and comment rulemaking.

In the proposed rule, we presented an analysis on historical BLS OEWS data for the occupations presented in Table 1.[18] We found that mean hourly wages for these categories are increasing over time, consistent with what we would expect given the ESRD PPS market basket increases. Given this analysis, we stated that the BLS OEWS data are reasonably stable and appropriately reflect general wage inflation trends that ESRD facilities face.

(ii) Data From Freestanding ESRD Facility Cost Reports

Under § 413.198(b)(1), all ESRD facilities must submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively. Generally, these cost reports have a time range of January 1 to December 31 of a given year, but they can represent any 12-month period. Included in these cost reports is information on the number of full-time equivalent (FTE) positions employed by the ESRD facility. FTEs are stratified by occupation type, such as RNs, LPNs, technicians, and administrative staff. For the purpose of these cost reports, an FTE represents a 40-hour work week averaged across the year. Specifically, the cost reports define FTEs as the sum of all hours for which employees were paid during the year divided by 2080 hours. The cost reports also state personnel involved in more than one activity must have their time prorated among those activities. For example, an RN who provided professional services and administrative services is counted in both the RN line and the administrative line according to the number of hours spent in each activity.

For the methodology presented in the proposed rule, we proposed to use FTEs to calculate the occupational mix for all freestanding ESRD facilities. For the purposes of this proposal, we used the term ''freestanding ESRD facilities'' to mean ESRD facilities that complete the independent renal dialysis facility cost report (Form CMS 265–11, OMB No. 0938–0050). We noted that these ESRD facilities are a subset of ''independent'' facilities as defined at § 413.174(b), as cost-reporting is only one of 5 criteria used in the determination of whether an ESRD facility is independent or hospital-based as listed at § 413.174(c). For the purposes of this proposal, we referred to ESRD facilities that complete the hospital cost report (Form CMS 2552–10, OMB No. 0938–0050) as ''ESRD facilities that are financially integrated with a hospital,'' per the criteria at § 413.174(c)(5). The occupational mix data presented in the proposed rule represented the average proportion of hours spent on the duties of that occupation at all freestanding ESRD facilities nationally for CY 2022. This national mix includes FTE data on both staff and contract labor from freestanding ESRD facility cost reports for each occupational category.

Table 2 presents the NEFOM calculated from the freestanding ESRD facility cost report data from cost reporting periods beginning on or after January 1, 2022, and before December 31, 2022 (2022 cost report data), with four decimal places of precision. For the purposes of comparison, Table 2 includes both the occupational mix we presented in the CY 2025 ESRD PPS proposed rule, as well as an updated version of this occupational mix with more complete CY 2022 cost report data. In the proposed rule, we noted that CY 2022 would be the most recent complete year of cost reporting data for both the proposed rule and for this CY 2025 ESRD PPS final rule, as the latest 2022 cost reports could have begun in December 2022 and ended in December 2023, although some 2022 cost reports were not yet available at the time of the analysis for the proposed rule. For the approximately 1.7 percent of freestanding ESRD facilities without 2022 cost report data available at the time of rulemaking for the proposed rule, 2021 cost report data was used. At the time of proposed rulemaking, we anticipated that we would have complete CY 2022 cost report data; however, this has proved not to be the case. For this final rule, some CY 2022 cost report data was still not available, so 2021 cost report data was used for 126 ESRD facilities. The occupational mix weights used in the proposed new wage index methodology are presented in terms of the number of FTEs per 1000 treatments, although we note that the specific denominator does not impact the calculation, as these are relative weights. Table 2 also includes percentages that represent the percent of FTEs for each occupation in the NEFOM. For example, RNs represent approximately 30 percent of the NEFOM, which means that across the nation, 30 percent of all hours worked by employees at freestanding ESRD facilities are worked by RNs. We note that we did not include FTEs that were reported as ''other'' occupations in the cost reports in this occupational mix, because we could not determine what occupation(s) this represented and, therefore, could not get appropriate wage estimates. ''Other'' occupations would have accounted for 3.8 percent of the NEFOM if included.

[17] *https://www.bls.gov/oes/oes_ques.htm.*

[18] We note that the BLS OEWS wage data is not intended to be used as a time-series analysis, but rather as cross-sectional estimate of wages in a geographic area (*https://www.bls.gov/oes/oes_ques.htm#other*). We reviewed and presented this data primarily to demonstrate the stability of the methodology by evaluating the robustness of the input data source.

TABLE 2: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	Freestanding Facilities 2022 Occupational Mix (FTEs/1000 treatments) as Presented in the Proposed Rule	Freestanding Facilities 2022 Occupational Mix Percentage as Presented in the Proposed Rule	Updated Freestanding Facilities 2022 Occupational Mix (FTEs/1000 treatments)	Updated Freestanding Facilities 2022 Occupational Mix Percentage
Registered Nurse	0.4208	29.9690%	0.4234	29.9628%
Licensed Practical Nurse	0.0566	4.0310%	0.0568	4.0224%
Nurse Aide	0.0339	2.4131%	0.0341	2.4130%
Technicians	0.5350	38.1040%	0.5381	38.0815%
Social Worker	0.0661	4.7078%	0.0666	4.7098%
Administrative staff	0.1505	10.7194%	0.1520	10.7565%
Dietitian	0.0635	4.5220%	0.0639	4.5237%
Management	0.0777	5.5337%	0.0781	5.5301%

We note that the NEFOM is calculated as a part of the proposed wage index methodology described in detail later in this section of this final rule, from freestanding ESRD facilities cost reports, and that the NEFOM is not an input in the wage index calculation. However, we presented the NEFOM in the proposed rule to inform the calculation process for any interested parties which wish to replicate the calculation.

For this methodology, we proposed to only utilize data from freestanding ESRD facilities, which comprise the vast majority of ESRD facilities. ESRD facilities that are financially integrated with a hospital represent approximately 4.5 percent of ESRD facilities. It was necessary to make this distinction, as ESRD facilities that are financially integrated with a hospital complete a different cost report form (Form CMS 2552–10, OMB No. 0938–0050), which does not include all the occupational categories included on the freestanding facility cost report (Form CMS 265–11, OMB No. 0938–0050). Specifically, ESRD facilities that are financially integrated with a hospital do not include administrative and management staff hours in their cost reports. FTE data for administrative and management staff are necessary for this analysis, so we proposed to exclude hospital-integrated cost reports. We stated that we believe that the occupational mix for freestanding ESRD facilities is likely similar to the mix for ESRD facilities that are financially integrated with a hospital (which, as noted earlier, make up a small proportion of all ESRD facilities), such that we would not expect significantly different results if we were able to include ESRD facilities that are financially integrated with a hospital in this analysis.

As discussed in the proposed rule, we conducted additional analyses to ensure that this occupational mix data would be appropriate for the construction of an ESRD facility wage index. First, we reviewed the occupational mix for ESRD facilities on a regional level to determine if the use of a single national occupational mix was appropriate. While we found some variation across regions, the variation was relatively small between regions, with the weight values for each occupation being within a few percentage points. The main exceptions to this were in the United States Territories, which had higher variation in occupational mix, likely due in large part to the relatively few ESRD facilities in those regions. Additionally, we found that lower volume ESRD facilities tended to have slightly different occupational mixes, requiring relatively more administrative and management staff FTEs, likely due to the lack of economies of scale for these occupations at lower treatment volume levels. Second, we conducted an analysis on the change in the national occupational mix over the past 5 years and found little variation over this time period. Both of these analyses indicate that the use of a single national occupational mix is appropriate for constructing an ESRD facility wage index as the occupational mix is reasonably similar to most region's occupational mixes and relatively stable over time.

Additionally, we proposed to use treatment volume data from freestanding ESRD facilities as reported on freestanding ESRD facility cost reports. This treatment volume data is used in the proposed wage index methodology as a weight on the county level wages when calculating the wages for a CBSA. The calculation is described in further detail in section II.B.2.b.(2)(b) of this final rule.

In the proposed rule, we emphasized the importance of accurate cost report data for this proposed policy as well as other current and potential policies under the ESRD PPS, such as facility-level or case-mix adjustment refinement. We strongly urged ESRD facilities to carefully review cost report data to ensure continued accuracy so that future refinements to the ESRD PPS are based on the best data possible.

(iii) IPPS Hospital Wage Index

As discussed in the proposed rule, the proposed new wage index methodology used the established ESRD PPS wage index methodology, which is based on the IPPS hospital wage index, for the purposes of standardizing the new wage index (step 6 in the methodology described in section II.B.2.b.(2)(b)). Consistent with our established ESRD PPS methodology, we use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS. For the purposes of the proposed new wage index methodology, we referred to this older wage index methodology as the ''ESRD PPS legacy wage index.'' The ESRD PPS wage index values under the legacy methodology are calculated without regard to geographic reclassifications authorized for acute care hospitals 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 2025, the updated wage data are generally for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data). Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Consistent with our established policy of updating wage indices in the final rule, we stated in the CY 2025 ESRD PPS proposed rule that we intend to use the most recent IPPS wage index for the construction of the CY 2025 ESRD PPS legacy wage index for the final rule (89 FR 55771). We noted that the purpose of calculating the ESRD PPS legacy wage index is solely for standardizing the new ESRD PPS wage index, ensuring that the treatment weighted average of the new ESRD PPS wage index is the same as it would have been under the established methodology. This would ensure that the changes associated with the proposed new wage index methodology are contained to the wage index, whereas changes associated with shifts in utilization would be reflected in the wage index budget neutrality factor. For example, if the new methodology resulted in a significant increase in the number of high-wage index facilities, the standardization factor would decrease wage index values across the board to keep the treatment-weighted average of the legacy and new wage index methodologies the same; in contrast, if utilization trends resulted in a significant increase in the number of treatments furnished by ESRD facilities in high-wage index areas, the treatment weighted average of both the legacy and new wage index methodologies would increase, which would need to be accounted for by the wage index budget neutrality adjustment factor. This is described in more detail in step 6 of the proposed new wage index methodology described in section II.B.2.b.(2)(b) of this final rule.

(iv) Time Lag Associated With New Data Sources

One concern expressed by interested parties about the current ESRD PPS wage index methodology is that the IPPS wage index, used as its basis, uses data from approximately 4 fiscal years prior. Interested parties have opined that this delay makes the ESRD PPS wage index less responsive to certain changes in wages, such as inflation.[19] In the proposed rule, we noted that the purpose of the wage index is to reflect geographic difference in the area wage levels, and that national trends in wages, including wage inflation, are accounted for by the ESRDB market basket percentage increase. We noted that the IPPS wage index is generally responsive to geographic variation in wages, including variation stemming from local or regional inflation. However, as interested parties have raised concerns about the time lag associated with our use of the IPPS wage data, we discussed the difference between the time lag associated with our use of the IPPS wage index for the ESRD PPS and the proposed new ESRD PPS wage index methodology.

As previously discussed in this section, the new ESRD PPS wage index methodology that we proposed would use data from BLS OEWS and freestanding ESRD facility cost reports. BLS publishes OEWS data annually with a May reference date, with estimates typically released in late March or early April of the following year. Each set of OEWS estimates is based on six semi-annual survey samples spanning the prior 3 years. Wages collected in earlier survey panels are updated to the reference date of the estimates based on wage adjustment factors derived from the OEWS survey data using a regression model. The freestanding ESRD facility cost report data that can be analyzed at the time of rulemaking are generally from 2 CYs prior. Specifically, for the proposed wage index presented in Addendum A of the ESRD PPS proposed rule, the BLS OEWS data represent wages as of May 2022 (based on survey panels collected from November 2019 through May 2022), and the cost report data generally covered cost reporting periods beginning on or after January 1, 2022, and before December 31, 2022.[20] The publicly available BLS OEWS data is an average using data collected over a 3-year period due to the large sample involved in the survey. This pooled sampling improves stability and predictability of the OEWS estimates over time. In the CY 2025 ESRD PPS proposed rule (89 FR 55772), we noted that, should the proposed methodology be finalized, we would use the most recent update of BLS OEWS data for the ESRD PPS final rule. Under this new proposed methodology, BLS OEWS estimates for May 2023 would be utilized for the final CY 2025 ESRD PPS wage index.

Both the ESRD facility cost report data and the BLS OEWS data are more recent than the data used for the IPPS wage index. Additionally, the purpose of using the freestanding ESRD facility cost report data in this proposed methodology would be to establish a national occupational mix for ESRD facilities, which we are calling the NEFOM. In the proposed rule, we stated that we intend to present the NEFOM annually to reflect the latest complete year of cost report data at the time of rulemaking to inform the public of the relative weights assigned to each occupation. Given that freestanding facility cost reports are submitted on a rolling basis, the most recent data would generally be obtained from cost reports beginning in the CY three years prior to the CY for which we are setting rates (that is, for the CY 2025 proposed rule, the latest complete year of cost report data are from cost reports beginning in CY 2022). Based on our analysis of prior years' cost report data, we did not anticipate that the national occupational mix would change much from year-to-year. Additionally, we noted that the use of a single national occupational mix for all ESRD facilities would limit the impact of changes in employment patterns on the wage index, as all ESRD facilities would be similarly impacted by a change in the NEFOM. As the wage index is a relative value, the main way that a change in the NEFOM would impact an ESRD facility's wage index would be if the CBSA in which that ESRD facility is located has relatively high or low wages for an occupation that experiences growth or shrinkage in the NEFOM. Thus, the main driver in changes from year-to-year under the proposed new wage index methodology likely would be the BLS OEWS data, which, for the final rule, would be based on estimates with a reference date of the May prior to the rulemaking year.

We noted that, at the time of the analysis conducted for the proposed rule, the May 2023 BLS OEWS estimates were not yet available; however, they were available at the time of the analysis conducted for this final rule. As previously discussed, some ESRD

[19] In accordance with section 1886(d)(14)(E)(1) of the Act, the IPPS wage index is required to employ data based on ''a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States.'' The IPPS is based on the most current audited hospital wage data from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date of September 30, 2025) (see, for example, 88 FR 58961).

[20] In cases where 2022 freestanding cost report data were not available at the time of the proposed rule, 2021 data was used. This was the case for 131 ESRD facilities, approximately 1.7 percent of the ESRD facilities in this analysis. In calculating the wage indices for this final rule there were 126 ESRD facilities for which 2021 cost report data was used.

facilities' CY 2022 cost reports were not available for the proposed rule but are available now for the final rule; however, we still do not have complete CY 2022 data, so we must utilize some CY 2021 cost reports for this final rule. In the proposed rule, we stated that should the proposed new wage index methodology be finalized, we would update the wage index values based on the most recent BLS OEWS data available. We also proposed to use most recent cost report data available for cost reporting periods beginning in CY 2022 and update the NEFOM in Table 2 accordingly in the final rule (89 FR 55772). Using the most recent 2022 data available for the calculation of the new ESRD PPS wage index methodology in the final rule would be consistent with our established ESRD PPS wage index methodology of updating ESRD facility wage indices between the proposed and final rules.

In the proposed rule, we noted that our proposed new wage index methodology does use the IPPS wage index to create the ESRD PPS legacy wage index, which is used to standardize the results of the new ESRD PPS wage index methodology. We recognized the concerns we have heard regarding the data lag associated with our use of the IPPS wage index for the ESRD PPS. However, as the ESRD PPS legacy wage index would only be used to calculate a treatment-weighted average of the legacy wage index to standardize the wage index values derived under the proposed new methodology, the proposed new ESRD PPS wage index would continue to reflect the relative differences in area wages based on the more recent BLS OEWS data. Therefore, any effect of any data lag of the ESRD PPS legacy wage index on the proposed new ESRD PPS wage index would be minimal.

(v) Comparison Between Proposed New Wage Index Methodology Data Sources and Hospital Wage Index Data

The other main concern that interested parties have raised about our current ESRD PPS wage index methodology is that the IPPS wage index is based on hospital cost report data. As previously discussed, interested parties have stated that hospital cost report data is not necessarily the most appropriate source for estimating geographic differences in wages paid by ESRD facilities. These interested parties predominantly point to the different occupational mix employed by ESRD facilities as the main differentiator between inpatient hospitals and ESRD facilities; however, there may also be differences in wages paid for the same occupational labor category in the two settings. Differences in wages within the same occupation could arise from any number of factors, including differences in duties, hours, required experience, or desirability of the position.

In the proposed rule we presented Table 3 in the context of the proposed new wage index methodology. Table 3 compares the national average occupational mix and corresponding wages for occupations employed by freestanding ESRD facilities to that of hospitals from IPPS data. The source of average wages used here for ESRD facilities is the BLS OEWS mean hourly wage data, which is then weighted by ESRD PPS treatment count in the geographical area. Average IPPS wages are derived from the IPPS occupational survey (Form CMS–10079) as presented in the fiscal year (FY) 2024 IPPS Public Use File (PUF),[21] representing data from 2019. The mean hourly wage data from BLS is from the May 2022 OEWS estimates, which are based on six panels of survey data from November 2019 through May 2022.

TABLE 3: Comparison of Occupational Mix and Mean Hourly Wages for Selected Occupations between Freestanding ESRD Facilities and Acute Care Hospitals

Occupation (Column A)	**Freestanding Facilities Occupational Mix** (Column B)	**Mean Hourly Wage – BLS** (Column C)		**Occupation** (Column D)	**Acute Care Hospitals Occupational Mix** (Column E)	**Mean Hourly Wage – IPPS** (Column F)
Registered Nurse	30.0%	$42.97		Registered Nurse	28.2%	$44.42
Licensed Practical Nurse	4.0%	$27.30		Licensed Practical Nurse	2.6%	$26.85
Nurse Aide	2.4%	$17.34		Nurse Aide	7.8%	$18.53
Medical Aide	-	-		Medical Aide	1.5%	$19.51
Technicians	38.1%	$24.42		Other	60.0%	$34.92
Social Worker	4.7%	$30.61				
Administrative staff	10.7%	$19.42				
Dietitian	4.5%	$32.63				
Management	5.5%	$60.45				

In discussing this data in the proposed rule, we noted that the hospital wage data (column F) in Table 3 presents the wages paid by hospitals to employees, as derived from the IPPS occupational survey data, for the purposes of comparing to the BLS data. This data is used to adjust the hospital average hourly wage, calculated using hospital cost report data, based on the provider-specific occupational mix. This differs from the hospital cost report

[21] Files related to the FY 2024 IPPS final rule are available online at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page.*

data used for the IPPS wage index, as that does not break down all wages and related costs by occupation.

Compared to hospitals, ESRD facilities generally use slightly higher proportions of RNs and LPNs and significantly fewer nurse aides and medical aides (column B). Additionally, the freestanding ESRD facility cost reports include additional occupational categories to reflect the labor mix employed by ESRD facilities.

(b) Construction of the New ESRD PPS Wage Index

In the proposed rule, we presented these general steps, which we stated we would use when constructing a wage index based on the proposed new ESRD PPS wage index methodology; for a more detailed look at the specific computational steps we execute in the code to calculate the wage index according to the proposed methodology, including steps related to data collection and cleaning, we provided the supplementary document Addendum C of the proposed rule.

1. We calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA. We weight mean hourly wage by treatment count to ensure that the mean hourly wage for the CBSA is proportional with the actual wages paid by ESRD facilities in the CBSA. This avoids a situation where a particularly high or low wage county within a CBSA has no ESRD facilities but still has a large impact on the wage index for that CBSA. This reasoning extends to each instance in which we weight values by treatment counts. We use a crosswalk that relates counties to MSAs, non-MSAs and NECTAs.

2. We calculate the ESRD facility mean hourly wage in each CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for a given CBSA with the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

3. We calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

4. We calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

5. We divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level (that is, a wage index that has not been normalized as described in step 6).

6. We multiply the raw wage index level for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS Medicare cost report data and divide the product by the treatment weighted average of raw wage indices, which equals 1 by construction.[22] This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices. By ensuring the weighted average of the new wage index is the same as the weighted average of the pre-floor pre-reclassification IPPS wage index we have normalized the new wage index such that it is more comparable to the former ESRD PPS wage index methodology. This prevents the possibility that the treatment-weighted average of the new wage index is significantly different than the treatment-weighted average of the established methodology. We include this step because our goal in establishing the proposed new wage index methodology is not to alter the significance of the wage index in determining each ESRD facility's payment, but rather to ensure that the wage index values better reflect relative labor costs that affect ESRD facilities specifically. We note that because we apply a wage index budget neutrality adjuster (discussed in section II.B.4.b), the new wage index methodology would not increase total payments to ESRD facilities even absent this step.

7. We apply the 0.6000 floor to the wage index by replacing any wage index values that fall below 0.6000 with a value of 0.6000, which is the wage index floor for the ESRD PPS as established in the CY 2023 ESRD PPS final rule (87 FR 67166).

After following these steps, we would obtain the wage index values for each CBSA (based on the new OMB delineations as discussed later in this section of the preamble) according to the proposed ESRD PPS wage index methodology described previously. In the proposed rule, we noted that the 5 percent cap in year-over-year decreases in wage index values would be applied for each ESRD facility after the new wage index is calculated based on the proposed methodology for the CBSA in which the ESRD facility is located and, therefore, is not reflected in the proposed wage index value for a CBSA in Addendum A of the proposed rule, 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* under the page for CMS–1805–P. This was necessary as this cap protects ESRD facilities in the rare circumstances when changes in policy related to the wage index methodology or CBSA delineations cause an ESRD facility to be in a significantly lower wage index area in a given year when compared to the previous year (87 FR 67161). As discussed later in this section, for CY 2025 we proposed to adopt new OMB delineations of CBSAs relative to those used in the CY 2024 ESRD PPS wage index. As this 5 percent cap applies to an ESRD facility, and not to a CBSA, it would protect any ESRD facility that is delineated into a much lower wage-index CBSA for CY 2025.

(c) Methodological Alternatives Considered

While developing the proposed new wage index methodology, we considered several different alternatives regarding both data sources used for the new wage index methodology and construction of the wage index itself. We considered the feasibility of requesting the use of confidential BLS OEWS data. This was one suggestion from the December 2019 TEP. Confidential data would have some benefits over public data, primarily that it would provide greater disaggregation of wages by employer type, such as wages paid by ESRD facilities. Additionally, confidential BLS data could have a timeframe other than the 3-year pooled sample used in the public data, for example, using only the most recent year's data. However, we noted that the OEWS survey sample is designed to be statistically representative only when all 3 years of the sample are combined, so the use of an alternative or shorter timeframe may not be appropriate. We determined that the publicly available BLS data would be the most appropriate for our wage index, as it still provides precise estimates of wages and would allow for far better transparency. Additionally, we

[22] Treatment weighted averages of wage indices are calculated by multiplying the wage index value for each CBSA by the treatment count in the CBSA and dividing by the aggregate national treatment count.

stated that we believed that the inclusion of data from other employers (meaning employers that are not ESRD facilities) would improve the robustness of the methodology, as ESRD facilities compete for labor against these other employers.

When considering the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. As discussed previously, for many of these occupations, the corresponding BLS code was straightforward as many of the occupations present in the freestanding ESRD facility cost reports matched a single BLS code. However, for technicians employed by ESRD facilities we gave further consideration to two different BLS codes. As presented in Table 1, we proposed to use code 29–2099 for ''Health Technologists and Technicians, All Other'' for the construction of the methodology to account for the labor costs of technicians. This is the most appropriate category, as ''technicians'' in the freestanding ESRD facility cost reports generally refers to dialysis technicians, which do not fall into any of the other BLS codes for health technologists and technicians. Additionally, we noted that the SOC uses ''dialysis technician'' as an illustrative example for code 29–2099.[23] However, we had some concerns about using this category, as it does not specifically represent dialysis technicians, but rather all health technicians that do not fit in the other categories. Because the category is non-specific, also known as a ''residual'' category, we were concerned with the impact of the inclusion of other, non-dialysis technicians in this category. To avoid any issues arising from the use of a residual category, we considered using code 29–2010 for ''Clinical Laboratory Technologists and Technicians.'' Although this category does not fit dialysis technicians as well, it had the benefit of not being a residual category, and it had fewer counties with missing data. However, we determined that it was most appropriate to use the most similar category for dialysis technicians, being the category in which data for dialysis technicians would be included, which is code 29–2099 ''Health Technologists and Technicians, All Others.''

As an alternative to using a single national occupational mix for ESRD facilities we considered using regional or state-level occupational mixes. The considered alternative would use a similar methodology to the construction of the NEFOM, but with a different occupational mix for each census region or state and would apply the occupational mix in the same way in the construction of the wage index. That is, the BLS data for a CBSA would be weighted by the occupational mix for the region or state in which that CBSA is located. This alternative was considered, in part, because of a suggestion from a panelist at the December 2019 TEP who pointed out that different states have different laws regarding staffing requirements for ESRD facilities, which was not reflected in the methodology presented at the TEP. We conducted an analysis comparing a state-level occupational mix wage index to the national occupational mix wage index methodology presented previously. This analysis found some notable differences, including higher wage index values for ESRD facilities in the Pacific census region, but many regions experienced little change. We decided against the use of state-level or regional occupational mixes for three main reasons. The first is that the use of different occupational mixes for different ESRD facilities made the methodology significantly more complicated and difficult to understand. The second is that this methodology made it so that one ESRD facility could be in an area with higher wages for all occupations compared to another ESRD facility but receive a lower wage index value due to having an occupational mix which favored lower-paying occupations. In the proposed rule, we noted that this could be perceived as being inconsistent with the intent of the wage index to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located (83 FR 56967). Lastly, we were concerned about the possibility that, should we use anything other than a national occupational mix, the state-level or regional occupational mix could be manipulated. This would be especially relevant for states or regions with few ESRD facilities and, therefore, individual ESRD facilities would have an outsized impact on the occupational mix for that state or region. Accordingly, we did not propose this alternative because we believed that the use of a single national occupational mix is the most appropriate for this new ESRD facility wage index methodology.

We considered proposing a ''phase-in'' policy for this wage index methodology change, which could be implemented in addition to the 5 percent cap on wage index decreases. One potential example of a phase-in policy could be a 50/50 blended methodology, where an ESRD facility would receive the average of their wage indices from the proposed new and legacy methodologies for the first year of implementation. However, we decided that such a phase-in policy was unnecessary in light of the 5 percent cap on year-to-year wage index decreases for ESRD facilities. We believed that an additional, or alternative, phase-in policy would further complicate this change. Additionally, a phase-in policy could hurt ESRD facilities that would receive a higher wage-index under the new methodology, which we do not believe would be appropriate, as we believe the new methodology based on BLS data is the best approximation of the labor costs those ESRD facilities face.

We considered setting the NEFOM through rulemaking separately from the routine wage index update. Under this alternative, we would periodically update the NEFOM, for example every 2 years, with potentially more years of freestanding ESRD facility cost report data. This would mean that the NEFOM would be a rounded input in the wage index methodology, rather than a figure precisely calculated as an intermediary step in the methodology. This would slightly simplify the calculation steps and would allow for complete transparency on the NEFOM. However, we have decided to instead derive the FTEs per 1,000 treatments for each occupation as the weights as a part of the wage index calculation as that would increase the precision of this calculation. Additionally, given the transparency of the FTE data derived from publicly available cost reports, we noted that we could still publish the NEFOM for the coming year in rulemaking alongside the updated wage index; however, we note that the NEFOM we publish would have a lower precision so replications using the published NEFOM as an input may be slightly off. Furthermore, compared to setting the NEFOM through rulemaking less frequently than annually, the proposed methodology to calculate the NEFOM as a part of the wage index methodology annually would be more responsive to national trends in occupational mix for ESRD facilities.

Finally, we considered whether it was most appropriate to use something other than the mean hourly wage for the BLS OEWS data for the construction of the wage index. We noted that there were always concerns when using the mean of a data set that the figure could be unduly influenced by outliers. One potential alternative would be to use the

[23] *https://www.bls.gov/soc/2018/major_groups.htm.*

median hourly wage data instead. The median hourly wage is available by occupation in publicly available BLS data, and the median is not as influenced by outliers as the mean. We also considered using the geometric mean, instead of arithmetic mean, as that is also less influenced by outliers; however, the geometric mean is not provided in publicly available BLS data. Ultimately, we determined that the mean hourly wage is the most appropriate for this new wage index methodology, as any outliers are relevant data points insofar as some ESRD facilities may pay wages significantly higher than the average.

c. Example Calculation Using the Proposed New Wage Index Methodology

Table 4 is an example of a calculation of the wage index for a hypothetical ESRD facility in a hypothetical CBSA under the proposed new methodology which was presented in the CY 2025 ESRD PPS proposed rule. This CBSA contains three counties, each with a different mean hourly wage and treatment count. Table 4 presents the mean hourly wage and treatment count used in the calculation.

TABLE 4: Hypothetical BLS Data for Example

	County 1	County 2	County 3
Treatment count	200 treatments	300 treatments	500 treatments
RN wage	$45	$40	$50
LPN wage	$30	$30	$35
Nurse aide wage	$15	$20	$10
Technicians wage	$30	$35	$25
Social worker wage	$30	$25	$35
Administration wage	$20	$25	$20
Dietitian wage	$35	$30	$30
Management wage	$60	$65	$50

Step 1. Calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA.

RN wage = [(200 * $45) + (300 * $40) + (500 * $50)]/1000 = $46.0

LPN wage = [(200 * $30) + (300 * $30) + (500 * $35)]/1000 = $32.5

Nurse aide wage = [(200 * $15) + (300 * $20) + (500 * $10)]/1000 = $14.0

Technicians wage = [(200 * $30) + (300 * $35) + (500 * $25)]/1000 = $29.0

Social worker wage = [(200 * $30) + (300 * $25) + (500 * $35)]/1000 = $31.0

Administration wage = [(200 * $20) + (300 * $25) + (500 * $20)]/1000 = $21.5

Dietitian wage = [(200 * $35) + (300 * $30) + (500 * $30)]/1000 = $31.0

Management wage = [(200 * $60) + (300 * $65) + (500 * $50)]/1000 = $56.5

Step 2. Calculate the ESRD facility mean hourly wage in the CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for the CBSA with the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. The NEFOM for CY 2025 that we presented in the CY 2025 ESRD PPS proposed rule is presented again in Table 5. For the purposes of ensuring the calculation in this section is as easy to understand as possible we are using the percentage values from the NEFOM rounded to the nearest tenth of a percent. This makes the wage values calculated in this step and step 4 more intuitive as they would represent a weighted average of the wages in the CBSA. We note that in the actual calculation of the wage index, as described in Addendum C, we calculate the number of FTEs per 1000 treatments for each occupation and use those as the weights, so that the weights have a higher level of precision.

TABLE 5: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	**ESRD Freestanding Facilities FTE Percentage as Presented in the Proposed Rule (rounded)**
Registered Nurse	30.0%
Licensed Practical Nurse	4.0%
Nurse Aide	2.4%
Technicians	38.1%
Social Worker	4.7%
Administration	10.7%
Dietitian	4.5%
Management	5.5%

ESRD facility mean hourly wage for this CBSA = (0.300 * $46.0) + (0.040 * $32.5) + (0.024 * $14.0) + (0.381* $29.0) + (0.047 * $31.0) + (0.107 * $21.5) + (0.045 * $31.0) + (0.055 * $56.5) = $34.75

Step 3. Calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

To simplify this calculation, assume there are 3 CBSAs as presented in Table 6:

TABLE 6: Hypothetical Wage Data for 3 CBSAs in Example

	CBSA 1	CBSA 2	CBSA 3	Calculated National
Treatment count	1000 treatments	800 treatments	1550 treatments	3350 treatments
RN wage	$46	$42	$50	$46.90
LPN wage	$32.5	$28	$35	$32.58
Nurse aide wage	$14	$20	$21	$18.67
Technicians wage	$29	$35	$33	$32.28
Social worker wage	$31	$30	$35	$32.61
Administration wage	$21.5	$20	$18	$19.52
Dietitian wage	$31	$35	$30	$31.49
Management wage	$56.5	$60	$55	$56.64

Step 4. Calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. Similarly to step 2, we are using the percentages from the NEFOM as weights for the purposes of this example calculation.

National average ESRD facility wage = (0.300 * $46.90) + (0.040 * $32.58) + (0.024 * $18.67) + (0.381 * $32.28) + (0.047 * $32.61) + (0.107 * $19.52) + (0.045 * $31.49) + (0.055 * $56.64) = $36.27

Step 5. Divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level.

Raw wage index value = $34.75/$36.27 = 0.95809

Step 6. Multiply the raw wage index for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS data and divide the product by the treatment weighted average of raw wage indices (which equals 1 by construction). This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices (for the purpose of this hypothetical calculation we have used a value of 1.00679).

Pre-floor wage index value = 0.95809 * 1.00679/1 = 0.9646

Step 7. Apply the 0.6000 floor to the wage index by replacing any wage index values which fall below 0.6000 with 0.6000.

Final wage index value = 0.9646

d. Estimated Impacts of Change to Wage Index Methodology

In the proposed rule, included a discussion on the estimated impacts of the new wage index methodology (89 FR 55778 through 55780). We discussed that this methodological change would be associated with significant changes in wage index values, and therefore payment amounts, for ESRD facilities. Full impacts for the final CY 2025 ESRD PPS wage index, alongside the updated CBSA delineations and rural transition policy discussed in section II.B.2.f of this final rule, are presented in Table 19 in section VII.C.5.a of this final rule, including application of the 5 percent cap on year-to-year wage index decreases. In the proposed rule we presented a table which included the impacts of this change with and without the 5 percent cap on wage index decreases. This table demonstrated how the application of the 5 percent cap mitigates negative changes for CY 2025 associated with the new wage index methodology.

We noted that the 5 percent cap on wage index decreases would apply to ESRD facilities that are located in a CBSA (based on CY 2025 CBSA delineations) with a wage index value 5 percent lower than the CY 2024 wage index value for their CBSA (based on CY 2024 CBSA delineations). The table in the proposed rule was presented for the sole purpose of illustrating the potential long-term ramifications of the proposed new wage index methodology once sufficient time has passed such that the 5 percent cap on year-over-year decreases would no longer constrain the overall effect of this new methodology on wage index values.

In the proposed rule, we discussed our analysis comparing the hypothetical results of applying this new wage index methodology in past years to the actual ESRD PPS wage index methodology based on the IPPS wage index for those years. We found that the application of the new wage index methodology consistently yields mean and median wage index values slightly higher than the actual mean and median wage index values used for those years, implying that the wage index resulting from this new methodology is relatively stable. Additionally, we found that the payment impacts based on facility type did not change much when using data from claim years 2019 through 2022, with most facility types that are projected to receive a payment increase for CY 2025 associated with the new wage index methodology seeing a payment increase in past years. Similarly, most facility types that are projected to receive a payment decrease in CY 2025 associated with the proposed new wage index methodology were found to have received payment decreases in our hypothetical analysis of past years. Therefore, we determined that this new wage index methodology is relatively stable when analyzing the differences between the new proposed wage index and the ESRD PPS legacy wage index.

e. CY 2025 ESRD PPS Wage Index

For CY 2025, we are updating the wage indices to account for updated wage levels in areas in which ESRD facilities are located. We proposed to use the new wage index methodology described previously, in subpart b of this section, according to the most recent available data. We believe that the use of this new wage index methodology is appropriate and responds to the feedback we have received from interested parties regarding the limitations of the current wage index. Specifically, the use of BLS OEWS data would allow for this new wage index methodology to be more responsive to differences in ESRD facility wage levels across the country. Additionally, by using occupational mix data from the freestanding ESRD facility cost reports, this new wage index methodology would better reflect the actual wage costs incurred by ESRD facilities and be most appropriate to use for the ESRD PPS due to several reasons specific to ESRD facilities. First, freestanding ESRD facility cost reports contain detailed occupational FTE data, which allows CMS to create a wage index that is tailored to the wage costs faced by ESRD facilities based on their unique staffing needs. Dissimilarities between hospital occupation mix and ESRD facility occupational mix make the use of the IPPS data less appropriate for ESRD facilities. In addition, the ESRD PPS has a lower labor-related share than most other Medicare payment systems.[24] This new ESRD PPS wage index methodology addresses these specific circumstances.

In the proposed rule, we recognized that there were several methodological limitations to using a wage index based on publicly available BLS OEWS data. Specifically, the BLS OEWS data source lacks information on employee benefits and the full cost of contract labor and includes information from hospitals and other healthcare providers. However, we stated that we believed that the benefits of using this new wage index methodology would outweigh these limitations, as the use of BLS OEWS wage data weighted by an occupational mix derived from freestanding ESRD facility cost report data would allow for a wage index that is more representative of the geographic variation in wages faced by ESRD facilities.

For CY 2025, we also proposed to use OMB's most recent CBSA delineations as published in OMB Bulletin No. 23–01, which are based on the data from the 2020 decennial census, for the purposes of the CY 2025 ESRD PPS wage index and rural facility adjustment. This was consistent with our historical practice of updating the CBSA delineations periodically according to the most recent OMB delineations, most recently in the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434). We discuss this policy in greater detail in section II.B.2.f of this final rule. For more information on the OMB delineations, we refer readers to the OMB Bulletin No. 23–01: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

To implement the proposed change in wage index methodology, we proposed to amend the regulations at 42 CFR 413.196(d)(2) and 413.231(a). Effective January 1, 2025, the amended § 413.196(d)(2) would state that CMS updates on an annual basis ''[t]he wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent complete calendar year of Medicare cost reports submitted in accordance with § 413.198(b).'' The amended § 413.231(a) would state that ''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 (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.''

For CY 2025, we proposed to update the ESRD PPS wage index to use the most recent BLS OEWS wage data and the most recent CY 2022 freestanding ESRD facility cost report occupational mix and treatment volume data available. At the time the analysis was conducted for the proposed rule, the most recent BLS OEWS wage data available represented May 2022. We proposed that if more recent data become available after the development of this ESRD PPS rule and before the publication of the ESRD PPS final rule (for example, the April 2024 release of May 2023 OEWS data, which was published after the analysis performed for the proposed rule), we would use such data, if appropriate, to determine the CY 2025 ESRD PPS wage index in the ESRD PPS final rule.

(1) Alternative CY 2025 ESRD PPS Wage Index Using Established Methodology

In the proposed rule, we presented a version of the current ESRD PPS wage index constructed using our established methodology with the most recent available data, which we referred to as the ESRD PPS legacy wage index methodology. The purpose of presenting the legacy methodology with modifications was to illustrate an alternative to the new methodology described previously for consideration by interested parties to facilitate comments on the proposed rule. The inclusion of a CY 2025 version of the ESRD PPS legacy wage index methodology allowed for interested parties to compare wage index values under the current methodology and proposed new methodology. For the reasons previously discussed, we believed and continue to believe that the proposed new wage index methodology based on BLS OEWS data and ESRD Medicare cost report data is the most appropriate for ESRD facilities; however, we considered commenters' input on this proposal and the alternative wage index based on the established methodology (updated with the most recent data) when making a determination about the best approach in this final rule.

In the CY 2025 ESRD PPS proposed rule we presented the ESRD PPS legacy wage index, which is based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS, as an alternative wage index. Please see the proposed rule (89 FR 55781) for a detailed description of this alternative wage index, which followed our legacy methodology.

(2) Request for Comments on This Proposal

In the proposed rule, we explained our belief that our new ESRD PPS wage index methodology more accurately estimates the geographic variation in wages paid by ESRD facilities when compared to the current ESRD PPS wage index based on the IPPS wage index. We acknowledged that this new methodology would represent a significant change to the established ESRD PPS wage index methodology, both by changing the data sources and the calculations for the wage index. We requested comments on all aspects of the new methodology, including the use of BLS OEWS data for CBSA-level wage estimates, the use of mean hourly wage (rather than median hourly wage), the use of freestanding ESRD facility cost reports for deriving occupational mix weights based on FTEs for each occupation per 1000 treatments as presented in the NEFOM, the use of the ESRD PPS legacy wage index for standardization, and the computational steps used to calculate the wage index.

[24] For example, under section 1886(d)(3)(E) of the Act, the IPPS applies a labor-related share of 62 percent for each hospital unless this would result in lower payments to the hospital than would otherwise be made.

We welcomed any insights into potential methodological improvements, particularly related to some of the limitations of the new data sources discussed previously, including the absence of the cost of employee benefits and the full cost of contract labor in the BLS data, and the inability of this methodology to capture differences in ESRD facility occupational mix across different geographic areas. In the proposed rule we stated that we would consider modifying the methodological steps used to calculate the wage index in the final rule, depending on the comments we received. Additionally, we requested comments on the proposed use of the new wage index methodology compared to the established wage index methodology based on the IPPS wage index which was used to create the alternative ESRD PPS legacy wage index. We also requested comments on the distributional implications of this wage index proposal, with specific consideration to rural areas and remote or isolated areas such as the United States Territories in the Pacific. Lastly, we requested comments on our proposal to begin using our new wage index methodology beginning on January 1, 2025.

We invited public comment on our proposal for our new ESRD PPS wage index methodology and its use for CY 2025. Approximately 20 commenters including LDOs, SDOs, provider advocacy organizations, coalitions of dialysis organizations, a professional organization, several ESRD facilities, and MedPAC commented on the proposed new ESRD PPS wage index methodology. The following is a summary of the public comments received on these proposals and our responses.

Comment: Most commenters who expressed an opinion on the new ESRD PPS wage index methodology, including a coalition of kidney organizations, several LDOs and MedPAC, stated that the use of the IPPS wage index within the ESRD PPS was flawed. Some commenters specified reasons why the IPPS methodology was not appropriate for the ESRD PPS including data lag and the fact that it is based on hospital cost report data. The majority of these commenters indicated that they believed the new wage index methodology would be an improvement over the IPPS wage index for the ESRD PPS. Many commenters supported the wage index proposal and requested that CMS finalize the proposal for CY 2025.

Response: We thank commenters for their opinions on the proposed new wage index methodology as well as their opinions on the ESRD PPS's current use of the IPPS wage index. We agree that the ESRD PPS wage index proposed for CY 2025 has advantages over use of the IPPS wage index when applied to the ESRD PPS. We appreciate the support for the new ESRD PPS wage index methodology, which we are finalizing in this rule.

Comment: Many commenters expressed concerns over some of the impacts of the proposed new ESRD PPS wage index methodology. Among these comments, the most frequently mentioned impact was the wage index budget neutrality adjustment factor. Multiple commenters requested that we implement this new wage index methodology in a non-budget neutral manner. Several commenters noted that there was no statutory requirement for budget neutrality for the ESRD PPS wage index. Some commenters expressed concerns about payment adequacy within the ESRD PPS and stated a belief that the corresponding decrease to the ESRD PPS base rate would lead to inadequate payments. One commenter attributed the budget neutrality reduction to the occupational mix used in calculating the new wage index methodology.

Response: We appreciate the thoughtful comments on the impacts of the proposed new ESRD PPS wage index methodology. We acknowledge that the new wage index methodology, implemented budget neutrally, would decrease the ESRD PPS base rate for CY 2025 relative to use of the legacy wage index methodology for CY 2025. However, as discussed in the proposed rule, we note that this decrease to the CY 2025 ESRD PPS base rate is predominantly due to the application of the 5 percent cap on year-over-year wage index decreases under § 413.231(c), which raises the average ESRD PPS wage index. Although the ESRD PPS base rate would be decreased for CY 2025, as this cap becomes less impactful (that is, in future years, as fewer facilities would quality for the application of the 5 percent cap as a result of the change in wage index methodology), the ESRD PPS base rate would increase over time, eventually attaining the level at which it would have been otherwise. The occupational mix has minimal impact on the budget neutrality adjustment factor, as the NEFOM serves as weights for the wage index, which are applied equally to the individual CBSA wages and national wages in the wage index calculation and, therefore, are essentially cancel out concerns on their impact on the average wage index value.

Although there is no explicit statutory requirement to implement the ESRD PPS wage index in a budget neutral manner, our longstanding philosophy within the ESRD PPS is that when we adjust for relative resource use and the costs for which we are adjusting are already included in the ESRD PPS base rate, those adjustments should be implemented budget neutrally. Under section 1881(b)(14)(A) of the Act our payment system is based on total costs from ESRD facility cost reports from 2007 and is increased annually based on the ESRDB market basket reflecting the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. Labor-related costs, including wages and benefits, were included in the cost reports used in the initial analysis (75 FR 49071 through 49083); therefore, we generally believe it is appropriate to implement any adjustment factors which are based on the allocation of those costs in a budget neutral manner.

We have received many comments regarding concerns about payment adequacy in response to our proposed rule, many of which were combined with calls to implement the new ESRD PPS wage index in a non-budget neutral manner. While we acknowledge commenters' concerns about payment adequacy and address them in section II.B.1.b and below in section II.B.4 of this final rule, we note that the purpose of the ESRD PPS wage index is to estimate geographic variation in wages. It would not be appropriate to make changes to the ESRD PPS wage index methodology to attempt to increase total payments to address the commenters' perceived inadequacies. We note that the construction of the wage index budget neutrality factor ensures that the change in the CY 2024 and CY 2025 wage indices does not result in an increase or decrease of estimated aggregate payments. Although for CY 2025 the wage index budget neutrality factor is lower than it has been in the past years, resulting in a larger decrease to the ESRD PPS base rate, this does not change the fact that aggregate payments are estimated to be unchanged implementing the wage index methodology for CY 2025. As noted previously, the main driver of the lower-than-typical budget neutrality factor is the application of the 5 percent cap in wage index decreases, which raises the average wage index value for CY 2025. Although each year's wage index budget neutrality factors are independent, they are derived using the prior year's wage index. The higher-than-typical average wage index value of CY 2025 results in

a smaller budget-neutrality factor. The smaller budget-neutrality factor results in a larger decrease to the ESRD PPS base rate. Consequently, this would likely lead to a higher budget-neutrality factor in future years where the average wage index value would be lower than in CY 2025, as ESRD facilities that received the 5 percent cap in CY 2025 would receive lower wage index values in CY 2026. This will likely result in an increase to the ESRD PPS base rate in CY 2026 related to the wage index budget neutrality factor.

Comment: MedPAC reiterated support for their wage index methodology, which was described in the June 2023 Report to Congress, as discussed earlier.[25] MedPAC noted that their recommended methodology would include two features which our proposed new wage index methodology lacked: a methodology to smooth wage index values across adjacent CBSAs and a methodology to allow for variation in wage index values within a single CBSA.

Response: We thank MedPAC for their recommendations. We did not propose a smoothing methodology across CBSAs because we do not believe it would serve the purpose of the ESRD PPS wage index, which is to estimate geographic differences in area wages. Furthermore, a smoothing methodology would increase the complexity of the methodology and likely involve parameter choices that could be seen as arbitrary. The fact that ESRD facilities which are near each other but located in different CBSAs would have different wage index values is unavoidable and persists within the ESRD PPS legacy wage index. Under the stated rationalization for a smoothing methodology, ESRD facilities in different CBSAs which are geographically near each other would compete for labor. We agree with this evaluation of local labor markets, but we note that should these ESRD facilities and other healthcare employers in the area be competing for labor, their wages would likely reflect that, which would in turn be reflected in the BLS OEWS data and used in the new wage index methodology. As for the recommendation to allow variation within a single CBSA, we acknowledge that such a fine level of detail would have certain advantages if the precision of the wage index could be maintained. However, we do not believe that there is any way to allow such variation without using data sources which would be lower quality, when applied to the ESRD PPS, than the BLS OEWS. In addition, MedPAC recommends the use of American Community Survey (ACS) data, which could allow for some information on average wages, but that information would not be specific to the types of labor used in ESRD facilities. We proposed this new wage index methodology to create a wage index that is specific to ESRD facilities, so the use of such nonspecific data, like the ACS data, would not align with our goals of creating an ESRD-specific PPS wage index. Additionally, similar to the smoothing methodology, utilizing ACS data to allow for further variation of wage index values would increase the complexity of an already complex methodology. We believe that our new ESRD PPS wage index methodology as proposed, without either of these methodological steps (that is, not incorporating either smoothing across CBSAs or variation within CBSAs), strikes a balance between simplicity and accuracy by estimating geographic wages at the CBSA level using the highest quality, publicly-available data, without arbitrary model parameters. We did not propose and, for the reasons stated previously, we are not finalizing in this rule either of the commenter's suggestions of smoothing across CBSAs or accounting for variation within CBSAs.

Comment: Several commenters expressed support for the use of the IPPS wage index for the ESRD PPS. Some commenters highlighted the lack of hospital-based ESRD facility data used in constructing the NEFOM and stated a belief that due to this lack of data the IPPS wage index would be more appropriate for hospital-based ESRD facilities. One commenter stated that this omission would unfairly penalize hospital-based ESRD facilities, particularly pediatric hospital-based ESRD facilities. One commenter requested we make changes to the methodology to utilize hospital-based ESRD facilities' cost report data in the occupational mix, as hospital-based ESRD facilities have hiring practices and occupational mixes more similar to hospitals. One commenter stated that the omission of hospital-based ESRD facility data would have distributional implications due to varying ranges of hospital-based ESRD facilities in different geographical areas.

Response: We appreciate commenters' insight into the extent to which the ESRD PPS legacy wage index based on IPPS data is appropriate for ESRD facilities. We note that we generally agree that the use of the IPPS wage index for the ESRD PPS has historically been reasonably appropriate for estimating geographic variation in wages for many of the reasons the commenters stated, however, this does not change our belief that the new ESRD PPS wage index is more appropriate for the ESRD PPS moving forward compared to the legacy methodology based on the IPPS wage index. Many of the objections these commenters raised to the new methodology revolved around the fact that the NEFOM was based solely on freestanding ESRD facility cost reports and, therefore, did not include data from hospital-based ESRD facilities. While we agree that including data from hospital-based ESRD facilities into the NEFOM would be an improvement, we could not incorporate data from hospital-based ESRD facility cost reports into the NEFOM in an appropriate way. As we explained in the proposed rule (89 FR 55770), hospital-based ESRD facilities lacked certain occupational categories which are present in freestanding ESRD facility cost reports, and therefore, in the NEFOM. The omission of these categories not only means that we do not have data on those occupations for hospital-based ESRD facilities, but it also makes it impossible to appropriately incorporate any data on occupations present in the hospital-based ESRD facility cost reports, since it would not be an appropriate comparison. We would have absolute numbers on the clinical staff of the hospital-based ESRD facility, which would be useful for other analyses, but without knowing the proportion of labor costs spent on the omitted hospital cost report categories, any attempt to incorporate the present data would rely on an assumption that the data reported for the categories not present in the cost report is comparable to that reported for those categories in freestanding ESRD facility cost reports. We did not believe that such an assumption was necessary as hospital-based ESRD facilities are a significant minority of the total population of ESRD facilities (about 5 percent), meaning their inclusion in the NEFOM would not have a substantial impact; furthermore, we believe freestanding ESRD facilities are a good proxy for the average national occupational mix for hospital-based ESRD facilities. Since the NEFOM only serves as weights for the mean wages for the occupations, we believe that the lack of hospital-based data would not unfairly disadvantage hospital-based ESRD facilities, or hospital-based pediatric ESRD facilities, since they would receive the same wage index as freestanding ESRD facilities in the same

[25] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.*

area. Furthermore, any shift to the NEFOM associated with the hypothetical inclusion of hospital-based ESRD facility cost report data, should it be possible, would not have any specific impact on hospital-based ESRD facilities compared to other ESRD facilities, as the NEFOM would be applied in the wage index calculation for all ESRD facilities in the same way. Additionally, we note that our analysis shows that hospital-based ESRD facilities would, on average, receive increased payments under this proposed new methodology.

We disagree with the claim that the IPPS wage index would be more appropriate for hospital-based ESRD facilities. Although hospital-based ESRD facilities' cost report data could not be incorporated into the NEFOM, we still believe that the freestanding ESRD facility cost report data is a reasonable proxy for hospital-based ESRD facilities. Furthermore, the new wage index methodology uses mean wage data from the BLS OEWS for occupations related to the furnishing of renal dialysis services, which we believe makes the new wage index methodology more appropriate for hospital-based ESRD facilities when compared to the IPPS wage index. While it is true that hospital-based ESRD facility data would be included in the IPPS wage index there are many other departments (including but not limited to the adults and pediatric unit, intensive care unit and surgical intensive care unit) included in the hospital cost reports which we would anticipate would be less similar to hospital-based ESRD facilities than freestanding ESRD facilities are. As we do not have comprehensive occupational mix data from hospital-based ESRD facilities, we cannot directly evaluate the claim about hospital-based ESRD facilities having more similar occupational mixes to hospitals overall than freestanding ESRD facilities, but we would not anticipate that this would be the case because of the unique types of labor required in furnishing renal dialysis services compared to other hospital services. Lastly, we would not anticipate the omission of hospital-based ESRD facilities from the NEFOM as having any geographic distributional implications, because the NEFOM only serves as a set of weights in the new wage index methodology, so any change to the NEFOM that could potentially arise from including hospital-based cost reports (if that were operationally feasible) would change the weights in the same way for all ESRD facilities.

Comment: One commenter suggested allowing pediatric hospital-based ESRD facilities to continue using the IPPS-based legacy wage index.

Response: We do not believe it would be appropriate for hospital-based pediatric ESRD facilities to be allowed to receive a different wage index value, as we believe that this new wage index methodology is the most appropriate for all ESRD facilities, including pediatric and hospital-based ESRD facilities, for the reasons discussed previously. We do not believe that the IPPS wage index is more applicable for hospital-based pediatric ESRD facilities. We believe these ESRD facilities are likely more similar to freestanding ESRD facilities than other divisions of hospitals because the provision of renal dialysis services likely dictates the occupational mix more than the location of the ESRD facility. That is, pediatric hospital-based ESRD facilities utilize the occupations for which we have utilized BLS OEWS data, as those are the occupations relevant in furnishing renal dialysis services. Furthermore, as the ESRD PPS wage index is intended to reflect the wages in the geographic area in which an ESRD facility is located, it generally would not be appropriate for two ESRD facilities in the same geographic areas to have different methodologies determine their wage index values, as they would generally draw from the same geographic labor market.

Comment: Several commenters expressed concerns with the BLS OEWS data used in the construction of the new ESRD PPS wage index methodology. An LDO and a coalition of dialysis organizations expressed concerns with the BLS OEWS data centered around the lack of data on employee benefits and limitations on traveling contract labor data. These comments emphasized both the importance of benefits in attracting staff and the necessity of using contract labor, which would include labor contracted across CBSAs. Another coalition of dialysis organizations suggested that we study these costs to ensure they are accounted for in this policy. One commenter noted that the BLS OEWS data was not based solely on ESRD facility wage costs and that BLS geographic area estimates do not stratify data by healthcare sector. One commenter noted that evidence shows that wages and benefits vary across labor markets. One commenter expressed a preference for a wage index derived only from ESRD facility wage data from ESRD facility cost reports.

Response: We appreciate these detailed evaluations of the potential limitations of the data sources used in the proposed methodology. In the proposed rule we acknowledged that a lack of information on employee benefits was a limitation of using the BLS OEWS data source. However, we note that the omission of benefits would only have a significant impact on the resulting wage index if the geographic variation in benefit costs is different from the geographic variation in wages. We note that this condition is different from the consideration one commenter raised that wages and benefits both vary geographically. While we cannot say for certain whether the geographic variation in wages is exactly the same as the geographic variation in benefits, we believe that ESRD facility wages are likely a fair proxy for the way ESRD facility benefits vary geographically, particularly when compared to the IPPS wage index, which is based on many factors unrelated to the furnishing of renal dialysis services. Our analysis of cost report data indicates that the percentage of labor costs associated with benefits does not vary substantially by geographic region, with all census regions' shares being between 22 and 24 percent. This is what we would expect to see if wages and benefits vary similarly across geographic regions. We agree with the commenter that benefits are an important tool in recruiting and retaining staff, but we note that wages are also an important tool, so we believe that generally ESRD facilities which need to expend additional money to attract more staff would likely use both increased wages and increased non-wage benefits. We note that employee benefits represent 9.5 percent of the cost weights in the 2020-based ESRDB (87 FR 67146) and, on average, represent approximately 23 percent of all compensation costs.

We note that contract labor is directly included in this policy in two ways, both as a part of the NEFOM and in the BLS OEWS data, although we note that self-employed contract workers are not captured by the OEWS. However, we understand the concern that the commenters raised regarding traveling contract laborers that may be included in the data for a different CBSA from where the ESRD facility is located. We anticipate that many contract laborers would be included in the BLS OEWS survey data for the CBSA in which the ESRD facility where they work is located. We note that the BLS OEWS data allows for the reporting of a worker's site of work; however, we wish to clarify that worksite reporting does not change the CBSA for which an employee would be counted. That is, a contract worker employed by an agency that is physically located in one CBSA but works in a different CBSA would be included in the wage estimates for the

CBSA in which their employing agency is located. We wish to reiterate that, as the wage index is relative, this would only have a significant impact on the wage index methodology if the way in which traveling contract labor is utilized varies geographically from other wages. We intend to continue to monitor and evaluate the performance of the new wage index methodology, including the extent to which contract labor is utilized and would consider making changes to the methodology in future rulemaking, if warranted. We believe the BLS OEWS wage data would better approximate the labor costs of ESRD facilities even if the omitted traveling contract labor differed greatly compared to the included wages, because contract labor hours are generally a small portion of total hours for ESRD facilities. Our data suggest that contract labor hours accounted for 1.3 percent and 1.1 percent of RN and Technician hours in 2022, respectively.

We recognize that the BLS OEWS data used in this methodology is not based solely on ESRD facility wage data; however, we note that this is also true for the IPPS wage index. We have decided on several occupations related to furnishing renal dialysis services for which to utilize BLS OEWS data. We believe it is appropriate to include data from other healthcare employers, as it is likely that ESRD facilities compete with other employers for labor. It is technically correct to say that BLS OEWS does not stratify their geographic area data by healthcare sector; however, we do not believe this is a flaw in the methodology, as the occupations we have chosen to utilize are, generally, healthcare specific. Table 1 in this final rule describes the full occupation titles for all of the occupations included in this wage index methodology. Many of these are inherently healthcare specific, such as nurses or health technologists and technicians. However, for those categories that may not be healthcare specific, such as administrative staff, we are using BLS data from the category that is healthcare specific (that is, Medical Secretaries and Administrative Assistants (SOC code 43–6013)). We believe that these categories are the most appropriate for the types of labor employed by ESRD facilities. Insofar as these categories do not separate data by type of healthcare facility, we believe this is appropriate, as different healthcare employers likely compete with each other for labor. Similarly, we do not believe a wage index based only on ESRD facility cost report data would be appropriate, because ESRD facilities compete against other healthcare employers and, furthermore, in certain CBSAs the number of ESRD facilities could be very small, leading to the ESRD facilities present having a very large impact on the cost report data and, therefore, the wage data for that CBSA.

Comment: Some commenters expressed an opinion that the data sources used in the proposed methodology were appropriate despite some of the limitations we discussed in the proposed rule. Several commenters stated that the omission of hospital-based ESRD facility cost report data from the NEFOM was reasonable and did not jeopardize the methodology as a whole. Other commenters stated that the OEWS data provided a better estimation of geographic wages even if it did not include benefit data and certain contract labor wages. Some commenters supported the occupations we have chosen and stated they were appropriate for the ESRD PPS. Some commenters, including MedPAC, suggested that we continue to monitor the validity of data sources and the resulting wage indices.

Response: We thank commenters for their support and agree that the data sources used in the new wage index methodology are generally appropriate for such a methodology. We intend to continue to monitor both the data sources and the ESRD PPS wage index to ensure they remain appropriate for use in the ESRD PPS.

Comment: Several commenters, including MedPAC and a coalition of dialysis organizations noted that several adjustments used in the ESRD PPS, such as the case-mix adjustments, are derived from a model which might be influenced by a change in the ESRD PPS wage index. MedPAC and one LDO requested that we conduct analysis in future years to determine whether some of the adjustment factors should be changed.

Response: We appreciate the commenters' thoughts on the interconnected relationship between the ESRD PPS wage index and the other adjustments used within the ESRD PPS. We note that we have not routinely updated the case-mix or facility-level adjustment factors when we have made updates to the ESRD PPS wage index in the past. However, we acknowledge that the new wage index methodology would result in more significant facility-level changes than past routine updates to the ESRD PPS wage index. We did not propose any changes to the ESRD PPS case-mix adjustments or facility-level adjustments for CY 2025. One reason for this was because the proposed new wage index methodology would represent a substantial change to the ESRD PPS, and we believe it is appropriate to avoid making multiple significant methodological changes to the wage index and other adjustment factors concurrently as payments to ESRD facilities could change substantially in multiple different ways. We generally believe it is most appropriate to update all of the case-mix and facility-level adjustment factors concurrently because of the interconnected nature of the factors. By this we mean that the case-mix and facility-level adjustment factors are originally derived from a cost-regression from the CY 2011 ESRD PPS final rule, and updated in the CY 2016 ESRD PPS final rule, which includes all such adjustments. By including multiple variables in the regression as adjustment factors we can derive the appropriate adjustment factor for each of the facility-level and case-mix adjustment, as the regression isolates the marginal impact of that facility-level or case-mix characteristic on the cost variable. This does not mean that it is inappropriate to update only one of these adjustment factors, but when we do so we generally intend to be cautious as not to change the adjustment factor in a way that would lead to duplicative payment from other adjustment factors, which could theoretically happen if there were two independent variables which are highly correlated. This is part of the reason why we proposed to update the LVPA adjustment factors in a manner which was budget neutral within the LVPA, rather than reduce the ESRD PPS base rate. We are considering how to update the case-mix and facility-level adjustment factors in a way which would best align relative payments with resource use and cost. We did not propose to update the case-mix and facility-level adjustment factors in the CY 2025 ESRD PPS proposed rule because we did not believe we had the proper data to make the most appropriate updates to the case-mix and facility-level adjustment factors at that time. As we explained in the CY 2024 ESRD PPS final rule, additional data would serve to provide moredata to better inform CMS's pursuit of equitable payment policies in the future by helping us evaluate and monitor the accuracy of our patient-level adjustment factors (88 FR 76397). Specifically, we do not yet have the data from either the updated reporting requirement effective January 1, 2025, for time on machine or the updates to the cost reports to better capture data on the costs for pediatric patients. We believe it is most appropriate to wait until we have these additional data sources and update the

case-mix and facility-level adjustment factors at that time as these additional data sources may allow us to better allocate resource use. Although sometimes substantial changes are unavoidable, they can create challenges for ESRD facilities when planning for future payment years, so we believe it is most prudent to make such a substantial change when we have the most appropriate data. We are not finalizing any changes to the case-mix or facility-level adjustment factors related to the new ESRD PPS wage index methodology, but we intend to consider whether such changes would be appropriate in future years.

Comment: Some commenters expressed concerns with the use of a single national occupational mix for all ESRD facilities. Several interested parties expressed concerns with the application of a wage index based on a national occupational mix to the U.S. Territories in the Pacific, stating that they believed a regional occupational mix would be more appropriate. One commenter suggested CMS allow some ESRD facilities to continue to receive the legacy wage index based on the IPPS wage index.

Response: The NEFOM's purpose in the wage index methodology is to weight the BLS OEWS mean wage data so that the resulting wage index would be more representative of the actual wage costs faced by ESRD facilities. We believe that a single national occupational mix achieves this goal in the most straightforward way. The new wage index methodology is the most appropriate estimation of wages for ESRD facilities. Although some types of ESRD facilities, such as ESRD facilities located in U.S. Territories, may have some other costs that are higher due to their location, if these costs are not directly related to wages it would not be appropriate for them to be reflected in the wage index methodology. As discussed earlier, we do not believe it would be appropriate for different ESRD facilities in a given CBSA to receive different wage index values, so we are not finalizing any exceptions to the new wage index methodology that would allow certain ESRD facilities or facility types to receive the legacy wage index.

Comment: One commenter stated that it would not be appropriate to apply a different wage index value to hospital-based ESRD facilities compared to other units of the hospital as they would have the same hiring practices.

Response: We recognize that hospital-based ESRD facilities likely share some practices with the hospital in which they are located. However, we do not agree with this assertion. We believe it is reasonable for a hospital-based ESRD facility to receive a different wage index from other units in the hospital, as the labor employed by ESRD facilities is different from the labor employed by other parts of a hospital. We note that under the current payment systems, hospitals functionally receive different payment rates for labor for different units, as the payment rates are based on more than the wage index, including the labor-related share and the base payment rate. Furthermore, we do not believe it would be appropriate for hospital-based ESRD facilities to receive different payment rates from similar ESRD facilities in the same CBSA, as we would generally expect ESRD facilities in the same CBSA to face similar labor costs both in mean hourly wage and in the types of labor employed.

Comment: One commenter stated a concern that the NEFOM had a large portion of dialysis technicians which, according to the commenter, would hurt independent ESRD facilities.

Response: We believe the commenter is saying that independent ESRD facilities utilize dialysis technicians at a lower rate than LDOs, and therefore would likely utilize more nurse labor. Our analysis of occupational mix data does not indicate that this statement is true. Our analysis showed that independent ESRD facilities had a slightly lower ratio of nurses to technicians compared to LDOs. The largest difference we found between independent ESRD facilities and LDOs was that independent ESRD facilities had higher rates of administrative staff and management, likely due to economies of scale for these occupations leading to larger organizations requiring relatively fewer of these staff compared to direct patient care staff. We would note that our analysis did find that regional dialysis organizations utilized significantly fewer technicians compared to both LDOs and independent facilities, instead hiring significantly more nurse aides (which are more similar in wages to technicians than RNs). Separate from this analysis, we acknowledge the commenter's stated belief that some ESRD facilities would have an occupational mix that differs from the NEFOM, but we disagree with the statement that this would ''hurt'' those ESRD facilities. The purpose of the ESRD PPS wage index is to best estimate the geographic variation in wages and, to that point, this new wage index better estimates how wages faced by ESRD facilities vary across different geographic areas. In this methodology, the NEFOM serves to weight the BLS OEWS wage data in a way that is generally appropriate for ESRD facilities. While some ESRD facilities would certainly have occupational mixes that differ from the NEFOM, we do not believe it would be more appropriate to pay according to each ESRD facility's occupational mix. ESRD facilities make hiring decisions based on their local labor market and other relevant factors, which may result in occupational mixes that differ from the NEFOM. This is consistent with the philosophy behind a PPS where we provide payment to ESRD facilities, which they can allocate to costs in the most efficient and appropriate manner for them.

Comment: One commenter stated that CMS did not adequately demonstrate that the proposed new wage index methodology would more accurately reflect ESRD facilities' labor markets. This commenter believed that implementing the new wage index methodology would be detrimental for some ESRD facilities.

Response: We understand the commenter's apprehension regarding such a significant methodological change. We believe that we have adequately explained why the proposed new ESRD PPS wage index methodology better estimates the realities of the labor markets for ESRD facilities. With respect to the commenter's desire for CMS to ''demonstrate'' the accuracy of the wage index methodology, we note that by its nature the wage index reflects an estimate of the general economic conditions in a labor market, and there is no more objective measure of those conditions against which its accuracy could be measured. We conducted an analysis of the cost versus payment ratio under the proposed new ESRD PPS wage index methodology and the legacy wage index methodology which found that, on average, ESRD facilities had a cost versus payment ratio of 0.997 under the proposed new methodology (without the application of the 5 percent cap) and 0.991 under the legacy methodology. Using this metric, the proposed new wage index methodology better aligns payment with resource use compared to the legacy methodology.

Comment: Several commenters expressed support for the 5 percent cap on wage index decreases. Some of these commenters stated that they believed the 5 percent cap would help smooth the transition between the legacy and proposed new methodologies. One LDO stated that they did not believe any other sort of transition would be necessary given the 5 percent cap. MedPAC reiterated support for a symmetrical cap on wage index increases. Another LDO suggested that a

symmetric cap on wage index increases could ameliorate some of the impact of this new wage index methodology on the ESRD PPS base rate resulting from budget neutrality.

Response: We appreciate the continued support for the cap on year-over-year wage index decreases. We agree that this 5 percent cap would help mitigate the negative impacts of this policy on certain ESRD facilities in certain years, allowing for a transition period for these ESRD facilities to adjust their business planning. We did not propose any changes to the 5 percent cap policy for CY 2025 and are not finalizing any changes. When we finalized the 5 percent cap in the CY 2023 ESRD PPS final rule (87 FR 67161), we explained why we did not believe a symmetrical cap on increases would be appropriate. We still believe that capping increases in wage index values would be inappropriate, as the new wage index value is the most appropriate for these ESRD facilities. The purpose of the cap is to increase the predictability of ESRD PPS payment for ESRD facilities and mitigate instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. In the CY 2023 ESRD PPS final rule we explained 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 to wage index increases (87 FR 67159). Although, we appreciate the suggestion for ameliorating the other commenters' budget neutrality concerns, as discussed, we do not believe that a cap on increases to wage index values would be appropriate, and we are not finalizing a cap on increases to wage index values.

Comment: One commenter raised concerns that the ESRD PPS wage index methodology did not include overtime wages. Specifically, the commenter emphasized that some geographic areas have laws which dictate rates for overtime, for example time-and-a-half, which would lead to higher relative costs compared to ESRD facilities in areas which did not have such legislation.

Response: We acknowledge that the BLS OEWS mean hourly wage data is not intended to capture overtime by its definition of wages. However, we do not believe that this is an issue with the methodology. Our goal in designing the new ESRD PPS wage index methodology was to better estimate geographic variation in wages, which this new methodology does. We interpret the commenter's main concern to be that because some geographic areas have legislation which dictates certain overtime rates, overtime costs would likely vary differently from non-overtime wages. Although the commenter is accurate in noting that regulations regarding overtime differ across the country, since overtime rates are generally based on non-overtime hourly wages, we believe it's reasonable to assume that on average places with higher non-overtime wages would generally have higher overtime wages. While non-overtime wages paid by ESRD facilities may not be a perfect proxy for overtime wages paid by ESRD facilities, we believe that they are a fairly good proxy and that use of the BLS OEWS data is nonetheless superior to using the IPPS wage index. In other words, we believe that most variation between geographic areas is captured by the variation in base wages utilized by the proposed new wage index methodology.

We appreciate the commenter raising this concern, and we have considered how we could incorporate overtime labor costs into this methodology. There are some technical limitations to the inclusion of overtime labor costs into this methodology, as overtime is not included in the BLS OEWS data source, and the source of the increased cost resulting from overtime could derive from either different overtime payment rates or different overtime utilization amounts. We did not propose to include overtime in the mean wage data used in the proposed new wage index methodology, and we are not finalizing any such changes in this final rule. We will consider proposing changes to account for overtime wages, if appropriate and feasible, in future rulemaking years.

Comment: One commenter expressed concern that we did not present the uncapped wage index value for each ESRD facility.

Response: The uncapped wage index value for each ESRD facility was available in Addendum A to the CY 2025 ESRD PPS proposed rule, as the uncapped wage index value for an ESRD facility is simply the wage index value for the CBSA in which the ESRD facility is located. We did not include that value in Addendum B, as that could have caused confusion, since the wage index after the application of the 5 percent cap would apply for CY 2025.

Comment: One commenter expressed support for the 0.6000 wage index floor. Several commenters requested CMS perform further analysis on the wage index floor and expressed a belief that such analysis would support an increase in the wage index floor. Commenters specifically suggested that a wage index floor of 0.7000 would be appropriate. These commenters specifically highlighted Puerto Rico and enumerated certain labor costs which they stated contributed to the cost of care in Puerto Rico.

Response: We thank commenters for the continued support of the wage index floor. We did not propose to change the wage index floor for CY 2025 and are not finalizing any changes in this final rule. We will continue to monitor the appropriateness of the current wage index floor, as well as the extent to which ESRD facilities in U.S. Territories may face certain higher costs and will consider any further changes through notice-and-comment rulemaking in future years.

Comment: MedPAC reiterated concerns that a wage index floor is not appropriate, as it distorts area wage indices.

Response: We appreciate the continued evaluation of the impact of the wage index floor. We did not propose, and are not finalizing, any changes to the wage index floor. We will take these concerns into consideration when determining whether further changes to the wage index floor are needed in future rulemaking.

Comment: Several commenters, including one letter from several interested parties concerning the U.S. Pacific Territories, expressed concerns over the impact of the proposed wage index methodology on the U.S. Pacific Territories. This letter from the interested parties stated that they believed that this new wage index methodology was a ''one-size fit all'' approach that would have negative impacts on marginalized communities. This letter expressed some support for the alternative state-level occupational mix which we discussed in the proposed rule, which would result in higher payments to for ESRD facilities in the Pacific Census region and expressed criticism for our choice to propose the simpler methodology using a national occupation mix. One ESRD facility located in the Northern Marianas Island noted that ESRD facilities in these regions face higher costs due to the nature of the isolated regions requiring importation of goods, including medication. This commenter requested that we develop a new methodology that would better account for actual wages rather than state-level wages.

Response: We thank the commenters for their insight on the impact of the proposed wage index policy on ESRD facilities in the U.S. Pacific Territories. We note that the purpose of the wage

index is to reflect the geographic variation in wages faced by ESRD facilities. We believe that this new wage index methodology achieves this goal, especially when compared to the legacy methodology based on the IPPS wage index. We recognize that this new policy will lead to a decrease in payment to ESRD facilities in the U.S. Pacific Territories. However, we note that the BLS OEWS data indicates that this is appropriate, as the new ESRD PPS wage index methodology represents the most recently available BLS OEWS mean wage estimates for the U.S. Pacific Territories. We do not agree with the characterization of this policy as a ''one size fits all'' approach, as this methodology uses BLS OEWS data which is CBSA specific.

We considered as an alternative state-level or regional occupational mixes rather than the proposed NEFOM reflecting the national occupational mix. Our concern with the state-level occupational mix policy was that it was a significantly more complicated alternative to a policy that already represented a significant increase in complexity to the legacy methodology. In addition, the use of a state-level occupational mix for weighting the mean hourly wage data would allow it to be possible that an area could have lower average hourly wages for all occupations but receive a higher wage index when compared to another area. It is accurate that the state-level occupational mix alternative would lead to higher payments to ESRD facilities in the U.S. Pacific Territories compared to the proposed methodology, but we wish to clarify that payments to these ESRD facilities would decrease under either methodology, because the main driver of the decrease in wage index values is the OEWS mean hourly wage data. The difference between payments for ESRD facilities in the U.S. Pacific Territories using state-level occupational mix data and the proposed national occupational mix was less than one percent.

We acknowledge that for the U.S. Pacific Territories the CBSA-level OEWS data serves functionally as a territory-level wage measure due to each of these territories containing exactly one CBSA; however we believe that this is appropriate. We note that the current IPPS wage index is also determined at the CBSA level and, therefore, combines the wages for the entire territory for each of Guam, American Samoa and the Northern Marianas Islands. Lastly, we appreciate the insight into additional costs paid by ESRD facilities in the U.S. Pacific Territories. We note that many of the additional costs listed were non-labor costs, and that the wage index serves to estimate the geographic difference in wages. We acknowledge that there is some evidence that non-labor costs may be relatively higher in regions which require importation of most goods, including the U.S. Pacific Territories; however, it would not be appropriate to address these higher costs through the wage index. We intend to carefully evaluate both the labor and non-labor costs for the U.S. Pacific Territories and other outlying regions of the United States and will consider whether any additional policies are warranted in future rulemaking.

Comment: One association commented that they commissioned an analysis of the impacts of the proposed new wage index methodology, which found that independent and small ESRD facilities would be worse off within industry segments under the new wage index methodology.

Response: Our analysis does not concur exactly with the conclusion the commenter drew about the new wage index methodology. As we presented in Table 6 of the proposed rule, our analysis showed that small ESRD facilities would receive higher payments under the new wage index methodology. Our analysis does show that independent ESRD facilities would receive lower payments. However, since the new wage index methodology is derived from the best available wage data, we believe this is appropriate, as the underlying BLS OEWS mean wage data indicates that the areas in which these independent ESRD facilities are located have lower relative mean wages compared to the legacy wage index.

Comment: One commenter expressed concerns that hospital cost report data was excluded from the calculation of the wage index budget neutrality factor.

Response: We wish to clarify that hospital cost reports were not included in the analysis for the NEFOM because of differences in the labor categories between the hospital-based and freestanding ESRD facility cost reports. Hospital-based ESRD facilities were included in the claims data that were used for determining the budget neutrality adjustment factor for the CY 2025 ESRD PPS wage index. We agree with the commenter that it is important to include hospital-based ESRD facilities in any impacts analysis, including the analysis used to determine average payments under the final CY 2025 ESRD PPS wage index, which was used to determine the wage index budget-neutrality factor. Omitting these hospital-based ESRD facilities would reduce the accuracy of the analysis without any good reason.

Comment: A few commenters recommended CMS allow ESRD facilities to reclassify their CBSA for the wage index, similar to the IPPS, which allows hospitals to reclassify.

Response: We appreciate this suggestion, and we recognize that many ESRD facilities stated that they would be better suited for an adjacent CBSA. However, our belief is that allowing reclassifications would not be appropriate for the ESRD PPS, as we believe the most appropriate wage index for an ESRD facility is for the CBSA in which it is located. We believe our new wage index methodology better estimates the actual wages paid by ESRD facilities in a given CBSA by utilizing data from the BLS OEWS. We did not propose to allow reclassifications under the proposed new wage index methodology, similar to how we did not allow reclassifications under the legacy methodology, and we are not finalizing any such changes in this final rule. We discuss our reasoning for not allowing reclassifications for the wage index for the ESRD PPS in further detail in the CY 2024 ESRD PPS final rule (88 FR 76360 through 76361).

Comment: One commenter, while discussing the proposed wage index budget-neutrality adjustment factor, stated an expectation that we would adjust the base rate down in future years according to this policy.

Response: We want to clarify that we do not anticipate significant repeated downward adjustments to the ESRD PPS base rate as a result of this proposal. The lower-than-typical wage index budget-neutrality adjustment factor is primarily a result of the application of the 5 percent cap on year-over-year wage index decreases, which is particularly impactful in CY 2025 due to the significant proposed change to the wage index methodology. We note that although this 5 percent cap could apply for multiple years in a row as a result of the adoption of the new wage index methodology, each year it is applied, the affected ESRD facilities' wage index values would become closer to the wage index values for their CBSAs, until their wage index values would be equal their CBSA's wage index value. In future years we anticipate the 5 percent cap would cause fewer ESRD facilities to receive wage index values higher than that of their CBSA, so the wage index budget-neutrality factor for CY 2026 would be higher than the wage index budget-neutrality factor for CY 2025. We note that the wage index budget-neutrality adjustment factor is multiplicative, so a ''higher'' value would lead to either a smaller decrease in the ESRD PPS base rate, should the

value still remain below 1, or to an increase to the ESRD PPS base rate, should the value rise above 1.

Comment: One commenter generally supported the idea of the proposal but noted the complexity of the proposal and requested additional time to review the new wage index methodology and impacts. One LDO suggested further analysis and potentially another TEP to continue to refine and test the methodology.

Response: We believe the 60-day timeframe provided a sufficient opportunity for interested parties to review the proposed rule and provide comments. To help interested parties understand the complexities and impacts of this proposal we included 3 addenda to the proposed rule. Addendum B included facility level impacts for all of our proposed policies, including the proposed change in the wage index methodology, as well as a side-by-side comparison of wage index values under the proposed new wage index and the legacy wage index based on IPPS data. Addendum C included a detailed methodological breakdown for this proposed new wage index methodology. We believe that this provided the public with ample information to thoroughly review the policy in the time available. In the proposed rule, we explained that we believe it would be beneficial to implement this proposed new wage index methodology alongside the more-routine updates to the CBSA delineations according to OMB 23–01. Additionally, we believe that this new wage index methodology is more appropriate for ESRD facilities and, therefore, should be implemented as soon as feasible. Similarly, we believe that we have sufficient information to determine that this policy is an improvement to the use of the IPPS wage index for the ESRD PPS and that holding another TEP would be an unnecessary delay for this policy. We are not finalizing any delay to the implementation date for this new wage index methodology, but we intend to carefully monitor the new ESRD PPS wage index, maintain a dialogue with interested parties, and consider further modifications to the methodology in future rulemaking.

Final Rule Action: After considering the comments received on this proposal, we are finalizing the use of the new ESRD PPS wage index methodology for CY 2025 without modification. Consistent with prior years, we are updating the CY 2025 proposed ESRD PPS wage index with the most recent available data. Most notably, this includes the release of the May 2023 BLS OEWS data as well as updated CY 2022 cost report data. We note that, contrary to our expectation, some CY 2022 cost report data was still not available at the time of the analysis conducted for this final rule, so we are finalizing to use CY 2021 cost report data where necessary. We believe that omitting these ESRD facilities without CY 2022 cost report data would be inappropriate, and CY 2021 cost report data is the most reasonable proxy for this missing data. Additionally, we are finalizing the proposed updates to 42 CFR 413.196(d)(2) and 413.231(a) to codify the new ESRD PPS wage index methodology with one change. To avoid confusion in connection with the use of the phrase ''most recent complete year of Medicare cost reports,'' as some CY 2022 freestanding ESRD facility cost reports are not available, we are finalizing to instead revise 413.196(d)(2) to read ''most recent full year of Medicare cost reports.'' This change clarifies our original intention to use the most recent completed cost-reporting CY, which is CY 2022 because CY 2023 cost reports beginning in November of 2023 (and ending November of 2024) would not be finished at the time of this final rule's publishing. This avoids confusion insofar as the word ''complete'' could refer either to the year (as intended) or the dataset of cost reports (which is not complete, as some CY 2022 cost reports were still not available at the time of this final rulemaking).

The final CY 2025 ESRD PPS wage index is set forth in Addendum A to this final rule 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 2024 wage index and the proposed CY 2025 wage index. Addendum B to this final rule 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*.

f. Implementation of New OMB Labor Market Delineations

(1) Background

As previously discussed in this final rule, the wage index used for the ESRD PPS was historically calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS and is assigned to an ESRD facility based on the labor market area in which the ESRD facility is geographically located. In the CY 2025 ESRD PPS proposed rule, we proposed a new wage index methodology that would similarly be based on the labor market in which an ESRD facility is located. ESRD facility labor market areas are delineated based on the CBSAs established by OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01 [26] issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13–01 established revised delineations for United States Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on the 2010 Census. OMB Bulletin No. 13–01 also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15–01,[27] which updated and superseded OMB Bulletin No. 13–01 issued on February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2012, and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01,[28] which updated and superseded OMB Bulletin No. 15–01 issued on July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2014, and July 1,

[26] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2013/b13-01.pdf.*

[27] *https://www.bls.gov/bls/omb-bulletin-15-01-revised-delineations-of-metropolitan-statistical-areas.pdf.*

[28] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf.*

2015. In OMB Bulletin No. 17–01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 [29] which updated and superseded OMB Bulletin No. 17–01 issued on August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18–04,[30] which updated and superseded OMB Bulletin No. 18–03 issued on April 10, 2018. OMB Bulletin Numbers 18–03 and 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2015, and July 1, 2016. In the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434), we finalized changes to the ESRD PPS wage index based on the most recent OMB delineations from OMB Bulletin No 18–04. This was the most recent time we have updated the labor market delineations used for the ESRD PPS and, therefore, reflects the labor market delineations we used for CY 2024 (88 FR 76360).

In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey, an ongoing survey conducted by the Census Bureau. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

In the CY 2025 ESRD PPS proposed rule, we explained that we believe it is important for the ESRD PPS to use, as soon as reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We believe that using the most current OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels, especially given the proposed new wage index methodology discussed previously. We carefully analyzed the impacts of adopting the new OMB delineations and found no compelling reason to delay implementation. Therefore, we proposed to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for CY 2025 under the ESRD PPS for use in determining both the wage index and the rural adjustment for ESRD facilities. We proposed that this would be implemented along with the new ESRD PPS wage index methodology, if finalized, or along with the alternative ESRD PPS legacy wage index based on IPPS data, should the proposed new wage index methodology not be finalized.

As previously discussed, we finalized a 5 percent cap on any decrease to a provider's wage index from its wage index in the prior year in the CY 2023 ESRD PPS final rule (87 FR 67161). We did not propose any additional transition policy for the CY 2025 wage index as we believe the 5 percent cap effectively mitigates the negative impact of large wage index decreases for an ESRD facility in a single year. In addition, we proposed to phase out the rural adjustment for ESRD facilities that are transitioning from rural to urban based on these CBSA revisions, as discussed in section II.B.2.f.(2) of this final rule. For a further discussion of changes to OMB's CBSA delineations, including a list of changes to specific CBSAs, see the FY 2025 IPPS proposed rule (89 FR 36139).

We invited public comment on our proposal to use the updated CBSA delineations. We received four comments regarding our proposal to use the updated CBSA delineations. The following is a summary of the public comments received on this proposal and our responses.

Comment: One commenter expressed specific support for our use of the updated CBSA delineations according to the most recent OMB delineations set forth in OMB Bulletin No. 23–01. Several other comments referenced our proposal to update the CBSA delineations; however, no other comment expressed a strong opinion on this policy. These comments that referenced the proposal generally included it alongside other proposals that appeared to be the focus of the comment, such as the new wage index methodology.

Response: We appreciate the commenters for reviewing the proposal to update CBSA delineations and appreciate the commenter for expressing support for the updated delineations.

Final Rule Action: After reviewing the comments received, we are finalizing our use of the most recent CBSA delineations from OMB Bulletin 23–01 for ESRD PPS wage index and rural adjustment for CY 2025 and beyond, consistent with prior updates to CBSA delineations.

(2) Proposal To Phase Out the Rural Facility Adjustment for Facilities Affected by Changes to CBSAs

In the CY 2016 ESRD PPS final rule (80 FR 69001), we established a policy to provide a 0.8 percent payment adjustment to the base rate for ESRD facilities located in a rural area. This adjustment was based on a regression analysis, which indicated that the per diem cost of providing renal dialysis services for rural facilities was 0.8 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 0.8 percent adjustment has been part of the ESRD PPS each year since it was finalized beginning for CY 2016, and its inclusion in the ESRD PPS is codified at § 413.233.

As previously discussed in this final rule, we proposed a change to the ESRD PPS wage index methodology as well as changes to the CBSA delineations. In the CY 2023 ESRD PPS final rule, we finalized a policy to cap year-to-year decreases in the wage index for any ESRD facility at 5 percent (87 FR 67161). The primary purpose of this change was to mitigate the negative effect associated with an ESRD facility being reclassified into a lower wage index CBSA as a result of changes in OMB's most recent CBSA delineations. We anticipated that the proposed change to the CBSA delineations and the changes to the wage index methodology, if finalized, would lead to numerous ESRD facilities having a significant decrease in wage index value in CY 2025 compared to CY 2024.

As previously discussed, we are finalizing the adoption of OMB Bulletin No. 23–01, which will determine whether an ESRD facility is classified as urban or rural for purposes of the rural facility adjustment in the ESRD PPS.

[29] *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*

[30] *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

Although the rural facility adjustment is not directly related to the wage index, the application of both is determined by the CBSA in which an ESRD facility is located and, therefore, is potentially subject to significant changes associated with the new CBSA delineations. It is reasonable to conclude that these proposed shifts in the CBSA delineations, in combination with the wage index methodological changes finalized in this final rule, could lead to a year-over-year decrease in payment greater than what a 5 percent decrease to the wage index would cause even if the decrease in the wage index value alone would be less than 5 percent. To mitigate the scope of changes that would impact ESRD facilities in any single year, we proposed to implement a 3-year phase out of the rural facility adjustment for ESRD facilities that are located in a CBSA that was categorized as rural in CY 2024 and is recategorized as urban in CY 2025, as a result of the updates to the CBSA delineations associated with the proposed adoption of OMB Bulletin No. 23–01.

We stated that overall, we believe implementing updated OMB delineations would result in the rural facility adjustment being applied where it is appropriate to adjust for higher costs incurred by ESRD facilities in rural locations. However, in the proposed rule we recognized that implementing these changes would have different effects among ESRD facilities and that the loss of the rural facility adjustment could lead to some hardship for ESRD facilities that had anticipated receiving the rural facility adjustment in CY 2025. Therefore, we stated it would be appropriate to consider whether a transition period should be used to implement these changes. For ESRD facilities located in a county that transitioned from rural to urban in OMB Bulletin 23–01, we considered whether it would be appropriate to phase out the rural facility adjustment for affected ESRD facilities. Adoption of the updated CBSAs in OMB Bulletin 23–01, which we are finalizing as proposed, will change the status of 44 ESRD facilities currently designated as ''rural'' to ''urban'' for CY 2025 and subsequent CYs. As such, these 44 newly urban ESRD facilities would no longer receive the 0.8 percent rural facility adjustment. Consistent with the rural transition policy proposed for IPFs and IRFs for FY 2025 (89 FR 23188, 89 FR 22267 through 22268) we proposed a 3-year, budget neutral phase-out of the rural facility adjustment for ESRD facilities located in the 54 rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these ESRD facilities. We believed that a phase-out of the rural facility adjustment transition period for these 44 ESRD facilities would be appropriate, because we expected these ESRD facilities would experience a steeper and more abrupt reduction in their payments compared to other ESRD facilities. We proposed to adopt these new CBSA delineations in a year in which we also proposed substantial methodological changes to our wage index. We noted that, while these proposed changes, would increase payment accuracy across the ESRD PPS, we also recognize that some ESRD facilities could lose the rural facility adjustment and receive a significantly lower wage index value in the same year. We stated that it would be appropriate for this transition policy to be budget-neutral compared to ending the rural adjustment for these facilities in CY 2025 because it is an extension of the rural facility adjustment, which was implemented budget-neutrally, and a result of the change in CBSA delineations, which was proposed to be implemented budget-neutrally alongside the wage index changes. The reasoning behind this proposal is similar to the reasoning behind the 5 percent cap on year-to-year decreases in wage index values, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67161), as it would ameliorate unexpected negative impacts to certain ESRD facilities. This rural phase-out in combination with the 5 percent cap policy would best reduce the negative effects on any single ESRD facility resulting from changes to the CBSA delineations. Therefore, we proposed to phase out the rural facility adjustment for these facilities to reduce the impact of the loss of the CY 2024 rural facility adjustment of 0.8 percent over CYs 2025, 2026, and 2027, consistent with the similar IPF and IRF proposals previously discussed. This policy would allow ESRD facilities that are classified as rural in CY 2024 and would be classified as urban in CY 2025 to receive two-thirds of the rural facility adjustment for CY 2025, or a 0.53 percent adjustment. For CY 2026, these ESRD facilities would receive one-third of the rural facility adjustment, or a 0.27 percent adjustment. For CY 2027, these ESRD facilities would not receive a rural facility adjustment. We believed, and continue to believe, that a 3-year budget-neutral phase-out of the rural facility adjustment for ESRD facilities that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural facility adjustment for existing CY 2024 rural ESRD facilities. The purpose of the gradual phase-out of the rural facility adjustment for these ESRD facilities is to mitigate payment reductions and promote stability and predictability in payments for existing rural ESRD facilities that may need time to adjust to the loss of their CY 2024 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. This policy would be specifically for the 44 ESRD facilities that are rural in CY 2024 that become urban in CY 2025. We did not propose a transition policy for urban ESRD facilities that become rural in CY 2025 because these ESRD facilities will receive the full rural facility adjustment of 0.8 percent beginning January 1, 2025, so they would not experience the same adverse effects as an ESRD facility that unexpectedly loses the rural facility payment adjustment. We noted that we understand that compared to rural payment adjustments in other Medicare payment systems, the ESRD PPS rural facility adjustment is not large in magnitude (for example, the rural adjustments for IPFs and IRFs are 17 percent and 14.9 percent, respectively), but we stated that it is important for ESRD facilities to be able to reasonably predict what their payments from the ESRD PPS would be in the next year.

We invited public comment on our proposal for a rural transition policy. One interested party commented on this proposal. The following is a summary of the public comment received on this proposal and our response.

Comment: One commenter expressed support for the rural transition policy and stated that this policy would avoid disruption of patient care.

Response: We thank the commenter and agree that this policy would help to stabilize payments for ESRD facilities in CBSAs which are losing their rural status for CY 2025.

Final Rule Action: After reviewing the comments on this proposal, we are finalizing the rural transition phase-out policy as proposed. For ESRD facilities that were in CBSAs designated as rural for CY 2024, but that would be designated as urban for CY 2025, claims for renal dialysis services provided to all adult ESRD patients would receive 2/3rds of the rural adjustment, or a 0.53 percent adjustment factor, for CY 2025 and 1/3rd of the rural adjustment, or a 0.27 percent adjustment factor, for CY 2026. Similarly, this transition would be applied for the current rural facility adjustment factor of 0.978 used for the

MAP calculation to determine the outlier payment made under § 413.237 for any eligible adult ESRD patient. This 0.978 adjustment factor represents a 2.2 percent reduction to the predicted MAP amount, so we will apply 2/3rds of the adjustment factor for CY 2025 and 1/3rd of the adjustment factor for CY 2026. For CY 2025 the rural transition adjustment factor applied to the outlier MAP calculation will be 0.9853 and for CY 2026 the rural facility transition adjustment factor applied to the outlier MAP calculation will be 0.9927.

3. CY 2025 Update to the Outlier Policy

a. 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 erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high-cost care, 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.[31]

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 ESRD 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.[32] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 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. In past years, the MAP amount has reflected 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 per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD 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 ESRD PPS base rate to account for the proportion of the estimated total Medicare 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.

Lastly, in the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these

[31] 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.

[32] 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.*

concerns, beginning with CY 2023, we began calculating 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 stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY 2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

For CY 2025, we proposed several methodological and policy changes to the ESRD PPS outlier policy to address a number of concerns that interested parties have raised in recent years. We noted that although the 1.0 percent outlier target was achieved in CY 2023, it was not achieved in the majority of the years since the establishment of the ESRD PPS in 2011. We stated that we expect each of these proposed changes would support the ability of the ESRD PPS to continue targeting outlier payments at 1.0 percent in CY 2025 and subsequent years. We discuss each of these proposed changes in detail in the following sections.

b. Expansion of ESRD Outlier Services

(1) Background and Current Issues

In the CY 2011 ESRD PPS final rule we finalized a policy that only renal dialysis services that were or would have been separately billable prior to the inception of the ESRD PPS would be eligible for the outlier payment. In the CY 2011 ESRD PPS proposed rule we explained that we believed that any unusual variation in the cost of the renal dialysis services comprising the base rate under the ESRD PPS would likely to be due to variation in the items and services that were, at that time, separately billable under Part B or renal dialysis service drugs and biological products that were then covered under Part D (74 FR 49988). We received some comments at that time that requested CMS consider alternative ways to determine outlier eligibility, including expanding eligibility to all renal dialysis services. However, we noted that we did not have adequate data at that time to include all Composite Rate Services (that is, renal dialysis services included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act, as defined in regulation at § 413.171) in the outlier calculation (74 FR 49989, 75 FR 49135).

In the CY 2019 ESRD PPS proposed rule we issued a comment solicitation on the potential expansion of outlier payments to composite rate supplies, drugs, and biological products (83 FR 34332). In this RFI, we detailed that such a change could promote appropriate payment for composite rate drugs once the TDAPA period has ended. Commenters' responses to this comment solicitation were mixed (83 FR 56969 through 56970). One commenter expressed that such a change would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations. Some commenters responded specifically regarding the TDAPA that extending availability of outlier payments would be particularly important when no additional money is being added to the base rate for the drug, as is the case with most drugs and biological products receiving the TDAPA. However, some commenters, including MedPAC, did not agree that such an expansion of the outlier eligible services would improve care, generally indicating that expanding the list of ESRD outlier services would hamper the outlier payment's functionality. One commenter stated that the purpose of the outlier adjustment was to pay for unusually costly patients, not new drugs and biological products, which the commenter noted the outlier payment was unable to do adequately. MedPAC commented that an outlier policy should act as a stop-loss insurance for medically necessary care, and outlier payments are needed when the ESRD PPS' payment adjustments do not capture all of the factors affecting providers' costs of delivering care. To that end, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. MedPAC further cautioned that should CMS expand the list of eligible ESRD outlier services, we should be clear as to what would qualify for the outlier payment.

In subsequent years, we took steps to expand the outlier policy to include certain potentially costly renal dialysis services that would have been included in the composite rate prior to the ESRD PPS. In the CY 2020 ESRD PPS final rule we finalized that any new and innovative renal dialysis equipment or supply would be eligible for the outlier adjustment after the end of the TPNIES period, regardless of whether it would have been separately billable prior to 2011 (84 FR 60697). In that rule, we explained that we believed allowing these items to be outlier eligible after the end of the TPNIES period would allow for these new and innovative supplies to be competitive with the other equipment and supplies also accounted for in the ESRD PPS base rate by establishing a level playing field where products could gain market share by offering the best practicable combination of price and quality (84 FR 60693). In the CY 2021 ESRD PPS final rule, we finalized that capital-related assets that are home dialysis machines will not become ESRD outlier services at the end of the TPNIES payment period (85 FR 71399). We explained that as assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. Unlike assets, these latter items are generally accounted for on a per patient basis and therefore, when used in excess of the average, constitute outlier use, which makes them eligible for outlier payments (85 FR 71424).

The definition of ESRD outlier services is codified at § 413.237(1)(a). Currently, drugs and biological products that were or would have been paid under the composite rate are not considered ESRD outlier services, and costs for these drugs are not included in the calculation for outlier payments on ESRD PPS claims. Current regulations at § 413.171 define Composite Rate Services as: ''Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.'' Under our longstanding policy, drugs and biological products that are substitutes for composite rate drugs and biological products are considered to be included in the composite rate portion of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49048), we cited existing guidance in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, which explicitly stated, ''drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate.'' This guidance remains in effect and was subsequently re-designated to section 20.3.F of the same chapter.

In the CY 2024 ESRD PPS final rule (88 FR 76391), we finalized a policy to

pay, beginning for CY 2024, a post-TDAPA add-on payment adjustment for any new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate that has previously been paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment generally will be applied for a period of 3 years following the end of the TDAPA period for those products. We finalized that the post-TDAPA add-on payment adjustment amount will be calculated based on the most recent available 12 months of claims data and the latest available full calendar quarter of average sales price (ASP) data (88 FR 76396). We explained that we divide the total expenditure of the new renal dialysis drug or biological product by the total number of ESRD PPS treatments furnished during the same 12-month period. In addition, we finalized that we adjust the post-TDAPA add-on payment adjustment amount paid on claims by the patient-level case-mix adjustment factors; accordingly, we apply a reduction factor to the post-TDAPA add-on payment adjustment amount to account for the application of the patient-level case-mix adjustment factors. We codified these policies by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that describe the post-TDAPA add-on payment adjustment and the calculation we use to determine the post-TDAPA add-on payment adjustment amount. In addition, we amended § 413.230 by adding reference to the post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

In the same CY 2024 ESRD PPS final rule, we summarized comments regarding the outlier policy as it pertains to the post-TDAPA add-on payment adjustment (88 FR 76396). One commenter pointed out that the CY 2024 ESRD PPS proposed rule did not indicate whether the ESRD PPS outlier adjustment would apply to products for which a post-TDAPA add-on payment adjustment is calculated. In response, CMS stated that under current policy, after the end of the TDAPA period, a drug or biological product is considered an eligible outlier service only if it meets the requirements of § 413.237(a)(1). We clarified that any renal dialysis drug or biological product included in the calculation of the post-TDAPA add-on payment adjustment would be considered an eligible ESRD outlier service only if it meets the requirements of § 413.237(a)(1). However, we further clarified that under current policy, Korsuva®, the only renal dialysis drug with a TDAPA period ending in CY 2024, would not be considered an eligible ESRD outlier service after the end of its TDAPA period, because it is a substitute for diphenhydramine hydrochloride, which was included in the composite rate prior to 2011, and therefore does not meet the requirements of § 413.237(a)(1) (that is, it would not have been, prior to January 1, 2011, separately billable under Medicare Part B).

Most recently, we have heard concerns from interested parties that excluding drugs and biological products that are substitutes for—or are used to achieve the same effect as—composite rate drugs and biological products from the definition of ESRD outlier services could limit the ability of the ESRD PPS outlier adjustment to appropriately recognize the drivers of cost for renal dialysis services. We considered these concerns, as well as the comments we received in response to prior rulemaking, to develop proposed changes to the definition of ESRD outlier services.

(2) Definition of ESRD Outlier Services

Effective for CY 2025, we proposed to change the definition of ESRD outlier services at § 413.237(a)(1) to include drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. We noted that this proposal would expand outlier eligibility to longstanding drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment. As discussed in section II.B.3.c of this final rule, we proposed and are finalizing technical changes to the calculation of outlier payments that will appropriately account for the post-TDAPA add-on payment adjustment for ESRD outlier services that are drugs and biological products.

In the CY 2025 ESRD PPS proposed rule, we stated that we considered the original intent behind the policy to limit outlier payments to drugs that were or would have been separately billable prior to 2011, which was that these drugs were likely the main drivers of the variation in the costs of treatment (74 FR 49988). We explained that we continue to believe an important aspect of the outlier adjustment should be its ability to target ESRD cases that are unusually costly. We noted that if the outlier adjustment methodology failed to recognize the main drivers of variation in the costs of ESRD treatment, then it could result in cases that are not unusually costly qualifying for the outlier adjustment, which would mean the impact of the outlier adjustment would be diluted. We also noted that many of the responses to the comment solicitation in the CY 2019 ESRD PPS proposed rule expressed concerns that expanding the scope of ESRD outlier services would potentially dilute the impact of the outlier adjustment. We explained that for CY 2025 we considered the potential impact of expanding the definition of ESRD outlier services to include additional drugs and biological products not currently included. We stated that we agree with the commenters who noted that the purpose of the outlier payment is not to pay for new drugs and biological products (83 FR 56969). We further stated that in the CY 2011 ESRD PPS final rule (75 FR 49134), CMS established the current outlier policy, including the 1.0 percent outlier target, because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We noted that under our current policy, new renal dialysis drugs and biological products that are paid for using the TDAPA are not considered ESRD outlier services. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69023), this is because during the TDAPA period we make a payment adjustment for the specific drug in addition to the base rate, whereas outlier services have been incorporated into the base rate. In contrast, we noted that the post-TDAPA add-on payment adjustment is paid on all claims, and drugs that are included in the post-TDAPA add-on payment adjustment amount are considered included in the ESRD PPS base rate. We explained that as a result, the amount paid under the post-TDAPA add-on payment adjustment does not correspond to the amount of a drug or biological product used on a claim, which would not be accounted for in any existing payment adjustment other than the outlier adjustment. For example, we stated that our analysis shows that patients using Korsuva® have costs of approximately $150 per treatment; however, because this drug is not recognized as an ESRD outlier service, these costs are not accounted for in determining the payment amount for the claim. Beginning April 1, 2024, the CY 2024 post-TDAPA add-on payment adjustment for Korsuva®

increases the payment amount per treatment by approximately $0.25, which is adjusted by the patient-level case-mix adjusters applicable to the claim. In aggregate, the post-TDAPA add-on payment adjustment accounts for 65 percent of the cost of furnishing Korsuva®; however, this payment is spread across all ESRD PPS treatments.

In the proposed rule, we explained that we did not propose to expand outlier eligibility to drugs and biological products that are paid for using the TDAPA during the TDAPA period, as the TDAPA amount is based on the full price (100 percent of ASP) for the amount of such drugs that is utilized and billed on the claim.

We further explained that we considered only expanding the definition of ESRD outlier services to include drugs and biological products that were previously paid for using the TDAPA. We noted the suggestion of past commenters that new renal dialysis drugs and biological products are likely to be drivers of cost, because these drugs are typically more expensive. We explained that we recognized the importance of supporting access to new renal dialysis drugs and biological products under the ESRD PPS through the establishment of the post-TDAPA add-on payment adjustment beginning in CY 2024 (88 FR 76391). We further noted that in the CY 2024 ESRD PPS final rule we agreed with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs (88 FR 76388). We noted that several commenters stated that the outlier adjustment and the ESRDB market basket updates cannot adequately account for these costs, and several organizations noted that if additional renal dialysis drugs and biological products with significant costs were incorporated into the outlier payment calculation, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. We described comments which expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We recognized that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA period, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries.

We stated that we believe it would be appropriate for the definition of ESRD outlier services to include all drugs and biological products that previously were paid for using the TDAPA. We explained that the inclusion of these drugs and biological products would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them. In the CY 2011 ESRD PPS proposed rule, we explained that significant variations in formerly separately billable items and services could impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs (74 FR 49988). We stated in the CY 2025 ESRD PPS proposed rule that we believe ESRD facilities may face similar disincentives for furnishing drugs and biological products that previously received payment under the TDAPA. We further stated that we believe this change would also align with the statutory authority for the outlier adjustment under section 1881(b)(14)(D)(ii) of the Act by protecting patients' access to medically necessary care through a payment adjustment that more fully recognizes unusual variations in the type or amount of such care. Specifically, we explained that we believe this change would encourage ESRD facilities to take on ESRD patients who would potentially require expensive new drugs and biological products, promoting health equity for these patients who require costlier care. Additionally, we noted that the technical changes we proposed, and which we are finalizing in section II.B.3.c of this final rule, would limit the impact of such drugs and biological products on the outlier threshold calculation, thereby enabling the ESRD PPS outlier adjustment to continue to protect access for beneficiaries whose care is unusually costly.

We stated that in light of the past comments that we described in the proposed rule, we further considered whether expanding eligibility to all renal dialysis drugs and biological products that are Composite Rate Services, as defined at § 413.171, would be appropriate. We reiterated that the purpose of the outlier adjustment is to protect access for beneficiaries whose care is unusually costly. We stated that although we continue to expect that the main drivers of cost would be drugs and biological products that were previously separately billable under Part B or Part D, or were previously paid for using the TDAPA, we nevertheless recognize that some patients could require higher utilization of composite rate drugs and biological products, which may result in the overall cost of their renal dialysis care being unusually high. For example, as we noted in section II.B.3.e of the proposed rule, our analysis identified that certain composite rate drugs are significant drivers of cost for pediatric patients, and therefore the proposed inclusion of those drugs as ESRD outlier services would improve the ability of the ESRD PPS outlier adjustment to target payment for pediatric patients whose care is exceptionally costly. We stated that including composite rate drugs and biological products in the calculation of the outlier adjustment could appropriately support care for such ESRD patients, because payments under the outlier adjustment would better align with resource use.

We explained that we also considered the comments from MedPAC in response to the CY 2019 ESRD PPS proposed rule. Specifically, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. As we stated in the CY 2024 ESRD PPS final rule, interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services (88 FR 76399). We noted that we finalized the collection of time on machine data, beginning for CY 2025, which we stated would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters, including age and comorbidities (88 FR 76400). We stated that we believe expanding the definition of ESRD outlier services could further support our understanding of the costs of Composite Rate Services, because it would encourage more comprehensive reporting of renal dialysis drugs and biological products that were formerly included in the composite rate for the purposes of calculating outlier payments. We further stated that this increased reporting would in turn support future revisions to patient-level adjustment factors that consider more complete information about costs at the patient level.

We stated that we do not agree that the proposed inclusion of composite rate drugs and biological products would dilute the impact of the outlier

adjustment, as some commenters in response to the CY 2019 ESRD PPS proposed rule suggested. Rather, we explained that our analysis indicates the inclusion of these drugs and biological products would appropriately recognize the situations when the provision of these services is unusually costly, which we estimate would increase the amount of outlier payment per outlier-eligible claim, thereby more effectively protecting access for beneficiaries whose care is exceptionally costly. We stated that if we made no changes to our outlier methodology or the definition of ESRD outlier services for CY 2025, the average outlier payment for outlier-eligible cases among pediatric patients would be $25.02, and the average outlier payment for adult patients would be $53.45. We noted that under the proposed changes to outlier eligibility, the average outlier payment for pediatric and adult patients would increase to $73.24 and $57.16, respectively. Furthermore, we explained that the inclusion of composite rate drugs and biological products would increase the pediatric MAP amount by a large amount, reflecting the utilization of certain high-cost composite rate drugs. We explained that although the proposed CY 2025 adult MAP amount was lower than the final CY 2024 adult MAP amount, the proposed adult MAP amount for CY 2025 was approximately $0.79 higher than it would have been absent the proposed policy changes in this rule, which we stated demonstrates that the inclusion of composite rate drugs and biological products would result in a higher MAP amount for adults.

In summary, we stated that the inclusion of composite rate drugs and biological products as ESRD outlier services would include more costs in the calculation of the ESRD PPS outlier adjustment for each case. We explained that as a result, fewer claims would qualify for outlier payments, but the amount of outlier payment per claim would be higher. Therefore, we stated that rather than diluting the impact of the outlier adjustment, these proposed changes would increase the impact of the outlier adjustment.

We proposed to amend the language at 42 CFR 413.237 by adding a new paragraph (a)(1)(vii), which would add to the list of renal dialysis services defined as ESRD outlier services the following: ''Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.''

We invited public comment on our proposal to include renal dialysis drugs and biological products that are composite rate services in the definition of ESRD outlier services. Approximately 13 commenters commented on this proposal. These commenters included LDOs, drug manufacturers, a nonprofit dialysis organization, a nonprofit kidney care alliance, a professional organization of nephrologists, a coalition of dialysis organizations, and MedPAC. The following is a summary of the public comments received on this proposal and our responses.

Comment: Several commenters expressed support for the proposed definition of ESRD outlier services. One LDO stated its belief that new drugs regardless of their status as a former composite rate service should be eligible for outlier payment. Similarly, a professional organization of nephrologists stated that if the proposed definition of ESRD outlier services is finalized, it would educate its members about this change and the importance of pediatric dialysis units appropriately billing for use of alteplase and other qualifying drugs to collect the outlier payment when appropriate. This commenter requested that CMS highlight any specific requirements for billing.

MedPAC likewise expressed support for expanding ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to the ESRD PPS. MedPAC reiterated its position that CMS should develop an outlier policy that addresses variation in the total cost of providing the entire ESRD PPS payment bundle, thereby avoiding the potential for misidentifying outliers (for example, a patient with very high costs for outlier-eligible services may have offsetting, lower costs for outlier-ineligible services). MedPAC further explained that considering the cost of the full ESRD PPS payment bundle would be more patient-centric and would align the ESRD PPS outlier policy with the policies that Medicare uses for other PPSs. One commenter expressed that CMS's continued reliance upon a distinction between ''composite rate'' and other products continues to confound the goals of moving the ESRD PPS toward a modern standard of care.

Response: We appreciate the comments in support of the proposed change to the definition of ESRD outlier services. We agree with commenters that the proposed definition would more broadly recognize ESRD PPS patients whose care is costlier. Regarding the commenter's statement that the distinction between renal dialysis drugs and biological products that were formerly separately billable and those that were or would have been historically paid under the composite rate does not best serve the goals of the ESRD PPS, we note that this distinction derives from the statutory definition of renal dialysis services in section 1881(b)(14)(B)(iii) of the Act. However, we recognize that providing payment under the ESRD PPS outlier adjustment for former composite rate and non-composite rate services would better serve CMS's goals, specifically CMS's longstanding efforts to develop a comprehensive patient cost model for the purposes of considering future refinements to the ESRD PPS adjustment factors.

In response to the request for specific billing guidance, we direct readers to the Medicare Claims Processing Manual (CPM), Chapter 8. ESRD facilities are instructed to report all renal dialysis drugs and biological products on the claim. Specific information about revenue codes and other billing requirements are found in section 50.2 of Chapter 8 of the CPM.

Comment: Several commenters, including LDOs, drug manufacturers, a nonprofit dialysis organization, a coalition of dialysis organizations, and a professional organization of nephrologists expressed that the proposed change to the definition of ESRD outlier services does not address what commenters stated is an underlying lack of payment adequacy for new drugs that are renal dialysis services. One LDO acknowledged that access to outlier funds is a small step in the right direction but stated that CMS policy for incorporating such drugs into the PPS is insufficient to adequately compensate dialysis providers. This commenter further stated that new drugs that represent a substantial clinical improvement should be incorporated into the bundled payment with new money regardless of their placement in a functional category. As an example of how the commenter believes the current policy is flawed, this commenter noted that lack of adequate payment has artificially depressed access to Korsuva® treatment and that nephrologists are reluctant to prescribe a therapy that does not have adequate long-term funding. Several commenters stated that approximately 16 percent of the ESRD patient population has severe pruritus for which Korsuva® is indicated. These commenters noted that if all of these patients were to receive Korsuva®, the total outlier payment for that one drug would be $350 million for CY 2025, more than three times the current outlier pool. Another commenter stated that changes still need to be made to fix the base rate and support innovation in

new drugs, biological products, and devices for pediatric kidney patients.

Several commenters stated that CMS should not finalize the proposed definition of ESRD outlier services but should instead advance funding mechanisms that would appropriately safeguard patient access to new drugs and biological products after the two-year TDAPA period expires.

Response: We appreciate the commenters' concerns regarding payment for new renal dialysis drugs and biological products under the ESRD PPS. As the commenters pointed out, and as we have previously stated, the purpose of the ESRD PPS outlier adjustment is not to pay for new drugs and biological products. Rather, the purpose of the ESRD PPS outlier adjustment is to protect access to care for beneficiaries whose care is exceptionally costly. In the proposed rule, we stated that including new renal dialysis drugs that previously received payment using the TDAPA would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them.

We disagree with commenters who stated that lack of adequate payment has artificially depressed access to Korsuva® treatment and that nephrologists are reluctant to prescribe a therapy that the commenters stated does not have adequate long-term funding. Nephrologists and ESRD patients make decisions about which drugs and biological products best serve the patients' needs, and these decisions depend on a number of factors including but not limited to considerations about the efficacy for the individual patient, side effects and interactions with other drugs and biological products the patient may be taking, and considerations related to affordability for the patient. As we explained in the CY 2019 ESRD PPS final rule, the purpose of providing the TDAPA for drugs that fall into an existing functional category is to help ESRD facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories (83 FR 56935). A new renal dialysis drug or biological product must demonstrate to patients and nephrologists that it presents value relative to existing treatment options, and the TDAPA further allows new products to become competitive by providing payment at 100 percent of ASP for the new drug or biological product. We expect that nephrologists and patients would consider all relevant factors and all available treatment options, and make the most appropriate decision for each patient. We do not believe we can infer that utilization of Korsuva® was depressed due to lack of adequate payment during the TDAPA period, because payment under the TDAPA for Korsuva® was based on 100 percent of ASP. Furthermore, in the CY 2024 ESRD PPS final rule, we finalized a policy to pay a post-TDAPA add-on payment adjustment for a period of 3 years following the payment of TDAPA. We stated that one goal of the post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period (88 FR 76393). Therefore, we believe that ESRD PPS policy provides appropriate and adequate payment in the short term during the 2-year TDAPA period, in the medium term during the 3 years of payment under the post-TDAPA add-on payment adjustment following the payment of TDAPA, and during the long term when such new renal dialysis drugs and biological products are paid for under the ESRD PPS base rate with no adjustment and are expected to compete with other drugs and biological products in the ESRD PPS.

We also cannot assume that utilization of Korsuva® should be higher than it was during the TDAPA period or that it would increase in response to the proposed outlier policy changes. We note that utilization of Korsuva® during the TDAPA period was significantly lower than the 16 percent figure cited by the commenters. We anticipate that the utilization of Korsuva® in CY 2025 would align with the levels of utilization observed during the TDAPA period, as these levels best reflect the actual prescribing patterns of nephrologists for that drug. Nevertheless, if utilization for Korsuva® were to increase significantly in CY 2025, then under our longstanding outlier methodology we would take such changes in utilization into consideration when establishing the FDL and MAP amounts prospectively in future years. As we have stated, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates would effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries.

Lastly, we do not believe that the current definition of ESRD outlier services better supports payment for new renal dialysis drugs and biological products than the proposed definition, because it excludes new renal dialysis drugs and biological products that are substitutes for drugs and biological products that were included in the composite rate. That is, the current definition of ESRD outlier services excludes certain new renal dialysis drugs and biological products that may be significant drivers of cost, and therefore we do not believe it would be more appropriate to maintain the existing definition of ESRD outlier services. We believe our proposed definition of ESRD outlier services would be more appropriate, because it would recognize all renal dialysis drugs and biological products that are significant drivers of cost for ESRD patients. Therefore, as discussed later in this final rule, we are finalizing our proposed revision to the definition of ESRD outlier services. We refer readers to section II.B.4 of this CY 2025 ESRD PPS final rule for a discussion about payment for innovation and the ESRD PPS base rate.

Comment: MedPAC reiterated its prior concerns from the CY 2019 ESRD PPS proposed rule about how CMS estimates the ESRD PPS's case-mix adjustments, including patient-level adjustments, and the accuracy of the adjustments' coefficients. MedPAC stated that these coefficients are used to calculate the Medicare allowable payment amount, which when combined with the fixed dollar loss amount, determines which treatments will receive an outlier payment. Therefore, MedPAC stated that to ensure the ability of the outlier policy to account for beneficiaries with high costs, the agency must improve the accuracy of the ESRD PPS's patient- and facility-level payment adjustments.

Response: We agree with MedPAC's assessment of the importance of accurate ESRD PPS case-mix adjustments for the ESRD PPS outlier adjustment. As we noted in the proposed rule, we believe expanding the definition of ESRD outlier services could further support our understanding of the costs of Composite Rate Services, because it would encourage more comprehensive reporting of renal dialysis drugs and biological products that were formerly included in the composite rate for the purposes of calculating outlier payments. In addition, we anticipate that this increased reporting would support future revisions to patient-level adjustment factors that consider more

complete information about the cost of furnishing renal dialysis services to a patient.

Comment: One commenter stated that a smaller outlier percentage on the order of 0.5 percent would be preferable to maintaining the existing 1.0 percent outlier percentage. This commenter encouraged CMS to consider exercising its discretion to set a lower outlier percentage.

Response: While we agree that section 1881(b)(14)(D)(ii) of the Act provides the Secretary with discretion to set an appropriate outlier percentage under the ESRD PPS, we note that we continue to believe the 1.0 percent target is more appropriate than a lower outlier percentage. 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 costliest, most resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We continue to believe the 1.0 percent target strikes the appropriate balance, and as we further noted in the CY 2023 ESRD PPS final rule (87 FR 67171), 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. We did not propose to reduce the outlier percentage for CY 2025, and we are not finalizing any such reduction in this rule.

Comment: Several commenters expressed concern about the burden of reporting renal dialysis drugs and biological products that were or would have been paid under the composite rate before the establishment of the ESRD PPS, and about the reliability of such reported data. One commenter stated that these drugs would not make any difference in a facility getting an outlier payment because of the relatively inexpensive cost of such drugs compared to new high-cost drugs on the market now or in the future. Other commenters acknowledged that the reporting of information on composite rate drugs is not as comprehensive as other data elements but stated that this is because ESRD facilities have never been required to report information about composite rate drugs and biological products because such information does not serve any ESRD PPS-related purpose. Several commenters stated that the observed disparity in alteplase utilization described in the CY 2025 ESRD PPS proposed rule is a difference in reporting and not a meaningful clinical or operational difference. An LDO and a coalition of dialysis organizations expressed concerns about CMS's ability to calculate MAP and FDL amounts for CY 2025 given the lack of complete information about utilization of composite rate drugs and biological products.

Response: We appreciate the concerns that commenters raised about the completeness of data on the utilization of composite rate drugs and the perceived burden associated with reporting these drugs on ESRD PPS claims. We disagree with the commenters who stated that composite rate drugs and biological products would not make any difference in a facility receiving payment under the outlier adjustment. As we explained in the proposed rule, we found that certain composite rate drugs such as alteplase were significant drivers of cost for pediatric patients. Although we acknowledge that some composite rate drugs and biological products are relatively low-cost, our analysis has found that this is not generally true of all composite rate drugs. We believe it would be most appropriate to make payment under the outlier adjustment for any renal dialysis drugs and biological products that do cause a patient's ESRD treatment to be exceptionally costly.

We further disagree with the commenters who stated that the proposed definition of ESRD outlier services would expand reporting burden for ESRD facilities. Section 60.2 of Chapter 8 of the CPM states that effective January 1, 2011, section 153b of the MIPPA requires that all drugs and biologicals used in the treatment of ESRD are included in the ESRD PPS payment amount and must be billed by the ESRD facility. Although we acknowledge that many ESRD facilities have not historically included composite rate drugs and biological products on ESRD PPS claims, we remind readers that ESRD facilities have long been encouraged to report all renal dialysis drugs and biological products on ESRD PPS claims, including composite rate drugs. In the CY 2016 ESRD PPS final rule (80 FR 69033), we clarified that ESRD facilities should begin reporting on their monthly claims those composite rate drugs that are on the consolidated billing list. Therefore, the proposal to change the definition of ESRD outlier services would not change the requirements for ESRD facilities to report composite rate drugs on ESRD PPS claims. In fact, we observe in our analysis of ESRD PPS claims data that hospital-based ESRD facilities are already more consistently reporting composite rate items and services, which in part explains the outsized impact of composite rate drugs and biological products on the FDL and MAP amounts for pediatric patients, who more frequently receive renal dialysis services from hospital-based ESRD facilities. In addition to reporting differences, we believe the differential rates of alteplase utilization between pediatric patients and adult patients could be related to higher rates of catheter use among pediatric patients.

Lastly, we do not agree with the concerns that commenters articulated about CMS's ability to calculate MAP and FDL amounts for CY 2025 given the lack of complete information about utilization of composite rate drugs and biological products. Our longstanding methodology for prospectively setting the MAP and FDL amounts uses the best available year of ESRD PPS claims, which is generally the most recent available year, to simulate claims for the upcoming CY. Additionally, we use the three most recent years to calculate the FDL amount which would have achieved the 1 percent outlier target. In any given year, changes in utilization of ESRD outlier services from the historical claims data to the upcoming CY can result in over- or under-estimates of the outlier percentage. CMS relies on the information reported by ESRD facilities for accurate modeling of ESRD PPS outlier payments. To the extent that the proposed change to the definition of ESRD outlier services further encourages ESRD facilities to report when composite rate drugs and biological products are used, we believe this would result in future claims data that is more complete and better fit for not only estimating future outlier payments, but also for analyzing comprehensive patient-level cost information to potentially inform future revisions to ESRD PPS adjustment factors.

Comment: Several commenters, including LDOs, drug manufacturers, a nonprofit dialysis organization, and a coalition of dialysis organizations, expressed concern that the proposed change to the definition of ESRD outlier services could result in outlier payments that exceed the 1.0 percent outlier percentage. Some commenters stated that since the 1.0 percent outlier percentage was achieved in CY 2023, CMS should use caution before making

further changes to the outlier policy. One commenter suggested that CMS might be required to reduce the ESRD PPS base rate if the 1.0 percent outlier percentage is exceeded in future years.

Response: We are reiterating that our longstanding methodology establishes FDL and MAP amounts 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. If our analysis indicates that the FDL and MAP amounts would result in outlier payments that are below 1.0 percent, we would reduce the FDL and MAP amounts accordingly in the subsequent year. Alternatively, if our analysis indicates that the FDL and MAP amounts would result in outlier payments that are above 1.0 percent, we would increase the FDL and MAP amounts accordingly in the subsequent year. In this methodology, we do not make modifications to the base rate in response to either exceeding or falling short of the 1.0 percent outlier percentage target.

Final Rule Action: After consideration of the comments, we are finalizing our proposal to amend the language at 42 CFR 413.237 by adding a new paragraph (a)(1)(vii), which adds the following to the list of renal dialysis services defined as ESRD outlier services: ''Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.'' The final CY 2025 FDL and MAP amounts are discussed in section II.B.3.e of this final rule.

c. Changes to Predicted MAP Calculation for Outlier Eligibility

As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67169), a claim is eligible for outlier payment when its imputed MAP amount exceeds the sum of the predicted MAP amount and the fixed dollar loss threshold. The predicted MAP amount for a claim is based on the national average MAP amount, adjusted by the case-mix adjustment factors that apply for that claim's patient-level and facility-level characteristics. As a result, when a claim's adjustment factors increase the payment amount per treatment, the claim's predicted MAP is also increased. This is because we expect that more complex patients would require a higher amount of spending for outlier services. However, this higher expected cost is recognized through a higher per treatment payment amount. In other words, a more complex patient must have even higher costs than are already accounted for in the adjustment factors compared to a less complex patient to be considered unusually costly. By increasing the predicted MAP based on the case-mix adjustment factors, the ESRD PPS outlier policy ensures that only cases that are unusually costly are considered for outlier payment.

As previously discussed in this final rule, we finalized a post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS final rule. The post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products is generally applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). The amount of this post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235, and this adjusted amount is added to the payment amount for each ESRD PPS treatment billed. We explained in the CY 2024 ESRD PPS final rule that during this 3-year post-TDAPA add-on payment period, a drug or biological product would be eligible for the outlier add-on payment if it met all of the other criteria for the outlier payment (88 FR 76396). The only drug or biological product which was set to end its TDAPA period in CY 2024 (and therefore would receive the post-TDAPA add-on payment adjustment that year) was Korsuva®, which is a substitute for a composite rate drug and, therefore, not outlier eligible under existing § 413.237(a)(1) (88 FR 76396). Accordingly, we did not propose any changes to the ESRD PPS outlier methodology to account for the post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS proposed rule as that would not have affected payments for CY 2024.

As discussed in section II.B.3.b of this final rule, we are finalizing our proposal to expand outlier eligibility to include renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171. This means that new drugs and biological products that are included in the calculation of the post-TDAPA add-on payment adjustment amount will become outlier eligible after the end of the TDAPA period, regardless of whether they are substitutes for composite rate drugs or biological products.

Accordingly, in the CY 2025 ESRD PPS proposed rule, we also proposed changes to the ESRD PPS outlier methodology to account for any future drugs and biological products which are outlier eligible during the post-TDAPA period. We proposed to add the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for a patient. We stated that this is appropriate because the post-TDAPA add-on payment adjustment amount represents average utilization of a drug or biological product, and is added to the payment amount, adjusted by the case-mix adjusters for the patient. We stated that this proposal would prevent duplicate payment for these drugs and biological products by accounting for the portion of the cost for these drugs or biological products which is included in the ESRD PPS bundled payment. We noted that this change would not affect the calculation of the imputed MAP for a claim, because a claim's imputed MAP would include the actual utilization of the drug or biological product that is included in the calculation of the post-TDAPA add-on payment adjustment, if that drug or biological product is billed on the claim.

We explained that we considered modifying the average MAP amount to account for outlier eligible drugs and biological products that are already included in the calculation of the post-TDAPA add-on payment adjustment amount, rather than proposing to modify the predicted MAP amount for each claim. However, we noted two main limitations with taking such an approach. First, the average MAP is set annually for an entire year and does not change from quarter to quarter; in contrast, the post-TDAPA add-on payment adjustment amount can change from quarter to quarter depending on when a drug or biological product's TDAPA period ends, and depending on the number of drugs and biological products included in the calculation. Second, our longstanding methodology for calculating the predicted MAP for outlier payments applies the outlier services multipliers to the average MAP. However, when we calculate the post-TDAPA add-on payment adjustment amount for a claim, we apply the ESRD PPS case-mix adjusters, which are different from the outlier services multipliers. We stated that we believe it would be most appropriate to continue to apply the ESRD PPS case-mix adjusters to the post-TDAPA add-on payment adjustment amount for the purposes of outlier calculation, so that the estimate of a claim's expected spending would align with the calculation used for the post-TDAPA add-on payment adjustment. For these reasons, we stated that we believe that it is more appropriate and more operationally feasible to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the

quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment, rather than publishing different average MAPs for different quarters of a single year.

For CY 2025, we explained that the impact of this technical modification would be a small increase to the pediatric and adult FDL amounts, due to the small post-TDAPA add-on payment adjustment amount calculated for each quarter of CY 2025, which is discussed in section II.B.6 of this final rule. We noted that without this proposed methodological change, the pediatric FDL amount would increase by $0.68. Likewise, we noted that the adult FDL amount would increase by $0.89. We stated that this proposed methodological change would avoid those increases, resulting in the proposed CY 2025 adult and pediatric MAP and FDL amounts shown in Table 7 of the proposed rule. We noted that although the effect would be small for CY 2025, the increase would be larger in potential future situations when utilization of a drug or biological product during the post-TDAPA period could be higher.

We invited public comment on our proposal to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment. Two commenters commented on this proposal. The following is a summary of the public comments received on these proposals and our responses.

Comment: MedPAC reiterated its concerns about how CMS estimates the ESRD PPS case-mix adjustments and recommended that CMS must improve the accuracy of the patient- and facility-level adjustments.

Response: We appreciate the recommendation, and as discussed earlier in this final rule, we believe that the proposed change to the definition of ESRD outlier services, combined with the collection of time on machine data beginning January 1, 2025, will contribute to CMS's ability to develop a patient cost model for the purposes of considering future refinements to the patient- and facility-level adjustments. We believe the application of the case-mix adjusted post-TDAPA add-on payment adjustment to the predicted MAP is the most technically appropriate methodology for calculating the predicted MAP in CY 2025 and future years. We would incorporate any relevant revisions to the patient-level case-mix adjustments into this calculation in future years, as appropriate.

Comment: One commenter stated that CMS should not include TDAPA or TPNIES values in outlier calculation for any future drugs or equipment and supplies that may be eligible for these adjustments as they are clearly not eligible for outlier services during the TDAPA or TPNIES period.

Response: We agree that under our longstanding policy, which CMS established in the CY 2016 ESRD PPS final rule (80 FR 69023), it would not be appropriate to include the payment amount for a new drug or biological product in the outlier calculation during the TDAPA period. Accordingly, we have excluded drugs that are receiving the TDAPA from the outlier calculation, and our calculations of the FDL and MAP amounts do not include TDAPA utilization as outlier-eligible utilization for drugs and biological products that will be paid under the TDAPA in the upcoming CY. However, we note that under § 413.220(b)(4), we established the outlier percentage is 1.0 percent of total payments (75 FR 49142 through 49143). By definition, total ESRD PPS expenditures for the non-outlier components include the base rate, TDAPA, TPNIES, post-TDAPA add-on payment adjustment, and other applicable adjustments. Additionally, since the TPNIES and TDAPA are components of the non-outlier portion of the total ESRD PPS spending, to remove them would shrink the base for which the total outlier target payment amount is calculated, and therefore increase the FDL and outlier threshold. In addition, as we finalized in the CY 2023 ESRD PPS final rule, we rely on historical TDAPA and TPNIES spending amounts to calculate the ''alternative'' retrospective FDL calculations for ESRD outlier services, which allows our projection of the FDL to appropriately account for increased utilization of ESRD outlier services in years when a new renal dialysis drug or biological product becomes an ESRD outlier service after the end if its TDAPA period (87 FR 67172 through 67175).

We are clarifying that we did not propose to include TDAPA or TPNIES values in the outlier calculation for CY 2025. Rather, the proposed incorporation of the post-TDAPA add-on payment adjustment to the predicted MAP would apply only for ESRD outlier services if the TDAPA period for such drugs or biological products has already ended, as they are excluded from the outlier calculation during the TDAPA period based on our longstanding policy, as discussed in the prior paragraph.

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment.

d. Technical Modifications to the Inflation Factors Used for the Outlier Calculations

(1) Background

In the CY 2011 ESRD PPS final rule we finalized our ESRD PPS outlier methodology, which included our methodology for updating data from past years to the CY for which CMS is establishing payment rates (75 FR 49134). In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177) by prospectively calculating 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. In that final rule we also clarified our longstanding methodology for updating data from prior years for the purposes of the outlier calculations (87 FR 67167). For drugs and biological products, we use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the CY for which CMS is establishing payment rates. For laboratory tests, we inflate prices to the CY for which CMS is establishing payment rates using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting Clinical Laboratory Fee Schedule (CLFS) rates.[33] For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

In the CY 2023 ESRD PPS final rule (87 FR 67173), we noted that MedPAC supported the proposed revisions to the FDL methodology, but also urged CMS to refine its approach for applying the pricing data that the agency uses to project future spending for outlier services, particularly for drugs. Specifically, MedPAC suggested CMS use a drug price inflation factor based on ASP values and noted that the ASP data that CMS uses to determine

[33] Since 2018, there has been no updated reporting for most clinical diagnostic laboratory tests; therefore, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0.

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.

For CY 2025, we stated that we have undertaken analysis of prices for ESRD outlier services and proposed several technical changes to the inflation factors, which are discussed in the following sections.

(2) Changes to the Inflation Factor for Outlier Eligible Drugs and Biological Products

As described earlier, we use a blended 4-quarter moving average of the ESRDB market basket price proxy for Pharmaceuticals to inflate drug prices to the upcoming CY for the purpose of estimating spending for outlier drugs and biological products in that CY. In the proposed rule, we explained that historically, this 4-quarter moving average is a positive factor, meaning that our longstanding methodology for modeling outlier spending amounts assumes that prices for ESRD outlier drugs and biological product will increase. For example, we noted that the projection of the CY 2025 price growth for ESRD outlier drugs and biological products, based on the ESRDB market basket price proxy for Pharmaceuticals for the CY 2025, was 1.9 percent, based on the IGI 1st quarter 2024 forecast with historical data through the 4th quarter of 2023.

We explained that to compare the actual changes in prices for ESRD outlier drugs and biological products against the assumed rate of change derived from the ESRDB market basket price proxies, we constructed an index of prices for ESRD outlier drugs and biological products. As we discussed in section II.B.3.b of the proposed rule, we proposed to expand the definition of ESRD outlier services to include renal dialysis drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. Accordingly, our constructed drug price index included these drugs and biological products as well as drugs and biological products that have historically been included in the definition of ESRD outlier services.

We stated that because the list of ESRD outlier drugs and biological products changes over time, we proposed to derive a chained Laspeyres price index of the drugs and biological products included in the definition of the ESRD outlier services. We explained that a chained Laspeyres price index does not require a fixed basket of drugs and biological products during the observation window. We explained that we constructed and then trended forward the year-over-year change in price index levels for this outlier drug index to calculate a projected inflation factor for ESRD outlier drugs and biological products for CY 2025, using the following steps:

Step 1: We obtained the annual list of ESRD outlier service drugs and biological products that appear in ESRD PPS claims during the CYs 2017 through 2023. These include both composite rate and formerly separately billable drugs and biological products.

Step 2: We obtained quarterly ASP for each drug and biological product during the same period 2017 through 2023, substituting annual ASP when quarterly information was not available.

Step 3: We obtained quarterly utilization data for each drug and biological product for the period 2017 through 2023.

Step 4: For each quarter, we established the base period as the prior quarter and held utilization fixed at the base period. We then constructed a Laspeyres price index based on all drugs and biological products that had price information in that quarter and the prior quarter.

Step 5: We chained together the quarterly indices starting from the 1st quarter 2017 through the 4th quarter 2023 to express price changes in the 4th quarter 2017 relative to the 1st quarter 2017. This step was repeated for all prior quarters, keeping the starting period fixed at the 1st quarter 2017.

Step 6: We calculated the percentage change between the current and prior 4th quarter chained price index for each year for CY 2021, 2022, and 2023, which we used as the annual drug price inflation factor for each year.

Step 7: Using the chained price indexes for the three most recent CYs (2021, 2022, and 2023), we used a linear regression to project forward these three historical inflation factors to determine the CY 2025 inflation factor.

Using this methodology, we calculated a projected inflation factor of -0.7 percent, meaning that prices for ESRD outlier drugs and biological products were projected to be 0.7 percent lower in CY 2025 relative to the prices of the ESRD outlier drugs and biological products in than in CY 2024. We noted that our analysis of year-over year changes in prices for ESRD outlier drugs and biological products shows a consistent, downward trend in prices, which stands in contrast to the positive inflation factors we have historically used to model outlier payments. As a result, we stated that our modeling of outlier spending in prior years has assumed that outlier prices will increase, when the ASP data shows that, overall, the prices have decreased.

Based on the results of our analysis, we stated that we believe applying an inflation factor based on the actual change in prices for ESRD outlier drugs and biological products would enable the ESRD PPS outlier adjustment to better target 1.0 percent of outlier payments in CY 2025, because such an inflation factor would better reflect the observed historical trend in spending and utilization for such drugs and biological products. We noted that although we have historically used the ESRDB market basket price proxy for Pharmaceuticals as the basis of our inflation assumptions for outlier modeling, and we believe that market basket price proxies would continue to be a reasonable and technically appropriate source for such assumptions, the market basket price proxies serve a distinctly different purpose than the inflation factors used in the outlier modeling. As we explained in the CY 2023 ESRD PPS final rule (87 FR 67147), we select the most appropriate wage and price proxies currently available to represent the rate of price change for each cost category in the ESRDB market basket. In contrast, we explained that the purpose of the inflation factors used in our outlier modeling is to represent the expected rate of change in price and utilization, so that we can prospectively set accurate FDL and MAP amounts that will result in outlier payments that equal 1.0 percent of total ESRD PPS payments. We stated that decreasing our estimates of future outlier spending, as we proposed to do, would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payments that would be paid on each claim. We stated that revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD outlier adjustment to pay for the costliest ESRD PPS claims. Therefore, we proposed to use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in prices and utilization for ESRD outlier drugs, as described in the previous paragraph.

(3) Changes to the Inflation Factors for Outlier Eligible Laboratory Tests and Supplies

In the proposed rule, we explained that CMS uses different methodologies for the inflation factors for laboratory

tests and supplies. We explained that we inflate laboratory test prices to the upcoming CY using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting CLFS rates; however, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0, because there has been no updated reporting for most clinical diagnostic laboratory tests since the CY 2018 CLFS. We further explained that for supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor. In the CY 2011 ESRD PPS proposed rule, we explained that we chose to use these factors so that the MAP would be based on pricing mechanisms currently in place for these services (74 FR 49991).

In the CY 2025 ESRD PPS proposed rule, we noted that the ESRDB market basket uses price proxies for goods and services included in furnishing renal dialysis services to determine the ESRDB market basket update. For example, we stated that the market basket price proxy for laboratory services is the PPI Industry for Medical and Diagnostic Laboratories (BLS series code #PCU621511621511) representing the change in the price of laboratory services conducted by medical and diagnostic laboratories reported on the ESRD facility cost reports. Similarly, we stated that the market basket price proxy for supplies is the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) representing the change in the price of medical supplies reported on the ESRD facility cost reports.

We stated that we considered whether these longstanding assumptions about price changes for laboratory tests and supplies would be appropriate for modeling changes in spending for outlier-eligible laboratory tests and supplies. Unlike with drugs and biological products, we explained that we do not have detailed historical pricing data for ESRD outlier laboratory tests and supplies to permit us to perform a similar analysis for these services as we did for drugs and biological products. However, we stated that we can compare the historical inflation factors we have used to the growth in the market basket price proxies for these categories of renal dialysis services. For supplies, we noted that we would typically assume a 0 percent update; however, we noted that the average 10-year historical growth in the PPI Commodity for Surgical and Medical Instruments is 0.9 percent. Likewise, we stated that in years when there is a CLFS data reporting period, we would typically use an inflation factor for laboratory tests based on a CPI projection, reduced by the productivity adjustment, through June of the year prior to the update year; however, we noted that the average 10-year historical annual growth for the PPI Industry for Medical and Diagnostic Laboratories was −0.4 percent.

Beginning for CY 2025, we proposed to use the ESRDB market basket price proxies for laboratory tests and supplies for the purpose of calculating the growth in estimated spending for these outlier services in the upcoming CY. We stated that these would replace the current inflation factors which are used for laboratory tests and supplies. Compared to the current inflation factors we use, we stated that we anticipate the market basket price proxies for laboratory tests and supplies would more appropriately reflect the change in prices of the laboratory tests and supply costs that are used by ESRD facilities. We stated that we believe using the market basket price proxies would better allow the ESRD PPS to estimate the changes in the prices of laboratory tests and supplies, which would improve the ability for CMS to target outlier payments at 1.0 percent of total ESRD PPS payments. We noted that decreasing our estimates of future outlier spending would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payment that would be paid on each claim. We further stated that revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD PPS outlier adjustment to pay for the costliest ESRD PPS claims.

We invited public comments on our proposed changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. Approximately 4 commenters including MedPAC, a non-profit kidney organization, a coalition of dialysis organizations, and one LDO commented on these proposed technical changes. The following is a summary of the public comments received on these proposals and our responses.

Comment: MedPAC expressed support for CMS's proposal to modify its method for calculating the increase in future spending for outlier drugs and biological products. MedPAC stated that this proposal is consistent with the Commission's comment letter on the CY 2024 proposed rule, in which the Commission urged CMS to use a drug price inflation factor based on ASP values to project future spending for outlier services. MedPAC further noted that the ASP data used by CMS to determine facilities' actual outlier payments might be a more accurate data source for drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

Response: We appreciate the support for the proposed technical changes to the inflation factors.

Comment: Some commenters stated that since the 1.0 percent outlier percentage was achieved in CY 2023, CMS should not finalize the proposed changes to the inflation factors. In particular, commenters expressed concern that the proposed inflation factor for drugs and biological products is negative as compared to the ESRDB price proxy that CMS has historically used. Commenters suggested that CMS might be required to reduce the ESRD PPS base rate if the 1.0 percent outlier percentage is exceeded in future years.

Response: We appreciate the concerns of commenters about these proposed technical modifications. CMS's analysis of year-over-year price changes for ESRD outlier drugs and biological products reveals a consistent downward trend. However, should prices for outlier drugs and biological products begin to increase as reflected in the ASP prices, such changes would be reflected in future updates to the chained Laspeyres drug price index.

We are reiterating that our longstanding methodology establishes FDL and MAP amounts 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. If our analysis indicates that the FDL and MAP amounts would result in outlier payments that are below 1.0 percent, we would reduce the FDL and MAP amounts accordingly in the subsequent year. Alternatively, if our analysis indicates that the FDL and MAP amounts would result in outlier payments that are above 1.0 percent, we would increase the FDL and MAP amounts accordingly in the subsequent year. In this methodology, we do not make modifications to the base rate in response to either exceeding or falling short of the 1.0 percent outlier percentage.

Final Rule Action: After consideration of the comments, we are finalizing our proposed changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological

products, we will use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in ASP prices and utilization for ESRD outlier drugs. For ESRD outlier laboratory tests and supplies, we will use the growth in the PPI Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments, respectively. In section II.B.3.e of this final rule, we present the final CY 2025 MAP and FDL amounts calculated using these inflation factors.

e. CY 2025 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2025, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2023 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2023 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). We stated that the latest available CY 2023 claims data showed outlier payments represented approximately 1.0 percent of total Medicare payments. We did not receive any comments on this proposal, and we are finalizing the CY 2025 FDL and MAP amounts based on the latest available data.

We are updating the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2023 claims data and updating the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). The latest available CY 2023 claims data shows that outlier payments represented approximately 1.0 percent of total Medicare payments.

The impact of this final update is shown in Table 7, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2024 with the updated estimates for this final rule for CY 2025. The estimates for the final CY 2025 MAP amounts, which are included in column II of Table 7, are inflation adjusted to reflect projected 2025 prices for ESRD outlier services, in accordance with the final changes to the inflation factors discussed in section II.B.3.d of this final rule.

TABLE 7: Outlier Policy: Impact of Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)*		**Column II Final outlier policy for CY 2025 (based on 2023 data, price inflated to 2025)****	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$22.30	$37.92	$58.30	$32.40
Adjustments				
Standardization for outlier services	1.0691	0.9763	1.0432	0.9768
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$23.36	$36.28	$59.60	$31.02
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$11.32	$71.76	$234.26	$45.41
Patient-month-facilities qualifying for outlier payment	20.86%	4.87%	6.09%	7.05%

*Column I was obtained from column II of Table 1 from the CY 2024 ESRD PPS final rule (88 FR 76363).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2021, 2022, and 2023.

As demonstrated in Table 7, the estimated FDL per treatment that determines the CY 2025 outlier threshold amount for adults (column II; $45.41) is lower than that used for the CY 2024 outlier policy (column I; $71.76). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $36.28 to $31.02. For pediatric patients, there is an increase in the FDL amount from $11.32 to $234.26. There is a corresponding increase in the adjusted average MAP for outlier services among pediatric patients, from $23.36 to $59.60. We note that this substantial increase in the outlier threshold for pediatric patients reflects the inclusion of certain composite rate drugs for outlier consideration, notably Healthcare Common Procedure Coding System (HCPCS) code J2997 (Injection, alteplase recombinant, 1 mg). As a result, we estimate that a smaller proportion of pediatric patients will receive outlier payments, but the

average outlier payment amounts will be significantly higher.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2025 will be 7.05 percent for adult patients and 6.09 percent for pediatric patients, based on the 2023 claims data and methodology changes in sections II.B.3.c and II.B.3.d of this final rule.

f. 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 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the CY 2023 claims, outlier payments represented approximately 1.0 percent of total payments, which has been our policy goal since the establishment of the ESRD PPS outlier adjustment. We believe the methodological changes to the outlier calculation and the change to the definition of ESRD outlier services, which we are finalizing for CY 2025, will continue to effectively set the outlier MAP and FDL amounts for CY 2025 and future years, enabling the ESRD PPS to continue targeting outlier payments at 1.0 percent of total payments. We also note that the recalibration of the FDL amounts will result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

4. Final Impacts to the CY 2025 ESRD PPS Base Rate

a. 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, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Annual Payment Rate Update for CY 2025

We are finalizing an ESRD PPS base rate for CY 2025 of $273.82. This will be a 1.0 percent increase from the CY 2024 ESRD PPS base rate of $271.02. This final 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 2025, 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 CY 2025 wage index budget-neutrality adjustment factor using treatment counts from the 2023 claims and facility-specific CY 2024 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2024. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2025. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2025 ESRD PPS wage index and proposed labor related share for CY 2025. As discussed in section II.B.2 of this final rule, the ESRD PPS wage index for CY 2025 includes the new wage index methodology based on BLS data, and the use of the most recent OMB delineations based on 2020-census data.[34] The total of these payments becomes the new CY 2025 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 2025 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2025 estimated payments, aggregate Medicare 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 the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The final CY 2025 wage index budget-neutrality adjustment factor is 0.988600. This final CY 2025 wage index budget-neutrality adjustment factor reflects the impact of all final wage index policy changes, including the CY 2025 ESRD PPS wage index using the new ESRD PPS wage index methodology based on BLS data, the 5 percent cap on year-to-year decreases in wage index values, the updated CBSA delineations, the 3 year rural phase-out for ESRD facilities in currently-rural CBSAs that will become urban under the new delineations, and the labor-related share (which we did not propose to change from CY 2024). We note that the application of the 5 percent cap on wage index decreases has a sizable impact on the budget-neutrality factor this year due to the new wage index methodology. That is, because a substantial number of ESRD facilities would have experienced a greater than 5 percent decrease in their wage index value as a result of the new wage index methodology, the budget-neutrality adjustment factor needed to offset the effect of limiting those decreases to 5 percent is larger than we expect it would be in a typical year. We note that the final CY 2025 wage index budget-neutrality factor does not include any impacts associated with the TPEAPA, as was the case with last year's combined wage index-TPEAPA budget-neutrality factor. This is consistent with how we have historically applied budget neutrality for case-mix adjusters, including pediatric case-mix adjusters. We do not routinely apply a budget-neutrality factor to account for changes in overall payment associated with changes in patient case-mix in years in which we do not propose any changes to the case-mix adjustment amount. Although the TPEAPA was established under the authority in section 1881(b)(14)(D)(iv) of the Act, which does not require budget neutrality, we stated in the CY 2024 ESRD PPS final rule that we were implementing the TPEAPA in a budget neutral manner because it was similar to the pediatric case-mix adjusters, and it accounts for costs which would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule (88

[34] *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

FR 76378). Because the adjustment to maintain budget neutrality associated with the TPEAPA was accounted for in the CY 2024 combined wage index and TPEAPA budget neutrality factor, it would not be appropriate to apply a budget-neutrality factor for the TPEAPA for CY 2025.

Market Basket Update: 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 an ESRD market basket percentage increase. As discussed in section II.B.1.b.(1) of this final rule, the latest CY 2025 projection of the ESRDB market basket percentage increase is 2.7 percent. In CY 2025, 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 previously discussed in section II.B.1.b.(2) of this final rule, the latest CY 2025 projection of the productivity adjustment is 0.5 percentage point, thus yielding a final CY 2025 productivity-adjusted ESRDB market basket update of 2.2 percent for CY 2025. Therefore, the final CY 2025 ESRD PPS base rate is $273.82 (($271.02 × 0.988600) × 1.022 = $273.82). In the CY 2025 ESRD PPS proposed rule (89 FR 55766), the productivity-adjusted ESRDB market basket update was 1.8 percent (reflecting a 2.3 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment). We 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 percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 ESRDB market basket update in the final rule.

We invited public comment on our proposed CY 2025 ESRD PPS base rate. Approximately 25 unique commenters including LDOs; SDOs, patient advocacy organizations; nonprofit dialysis associations; two coalitions of dialysis organizations; professional organizations; and MedPAC commented on the proposed payment rate. Many of these comments primarily focused on the proposed CY 2025 productivity-adjusted ESRDB market basket update, which we discuss and respond to in section II.B.1.b.(5) of this final rule. The following is a summary of the other public comments received on the proposed CY 2025 ESRD PPS base rate and our responses.

Comment: All commenters supported increasing the ESRD PPS base rate. Most commenters indicated a belief that the proposed CY 2025 ESRD PPS payment rates were too low. Commenters generally stated that the cause of these lower-than-appropriate payment rates was a combination of the proposed CY 2025 ESRDB market basket percentage increase and prior ESRDB market basket percentage increases being lower-than-appropriate. Only MedPAC stated a belief that the proposed CY 2025 ESRD PPS payment rate was appropriate.

Response: We appreciate the support for increasing payments under the ESRD PPS. We agree with MedPAC that payment rates under the ESRD PPS are generally appropriate. We concur with the commenters' general consensus that perceived inadequacies in the proposed CY 2025 ESRD PPS base rate are related to the perceived inadequacies of the ESRDB market basket. We have primarily addressed commenters' concerns related to the ESRDB market basket update in section II.B.1.b.(5) of this final rule. We wish to reiterate that the ESRD PPS base rate is calculated annually using the ESRDB market basket update and applying any applicable budget-neutrality factors, so the ESRD PPS base rate for a given year is constructed using several factors which are each derived from the best available data, as described in section II.B.1 and in section II.B.4. While we understand the concerns of commenters regarding the payment rates, we strongly believe that any change to this methodology should be data driven. We will take commenters' concerns into consideration for future rulemaking years to determine if any changes to the ESRD PPS base rate calculation or ESRDB market basket methodology are appropriate. Any changes to the ESRD market basket methodology or ESRD PPS base rate calculation would be made through notice and comment rulemaking.

Comment: Several commenters stated a belief that increasing the ESRD PPS base rate by 0.8 percent was not sufficient.

Response: We note that the proposed ESRDB productivity-adjusted market basket increase for CY 2025 was 1.8 percent (reflecting a proposed ESRDB market basket increase of 2.3 percent reduced by the statutorily-mandated proposed productivity adjustment estimated to be 0.5 percentage point). The proposed 0.8 percent increase to the ESRD PPS base rate was lower than the market basket increase as it also reflected the application of the proposed wage index budget-neutrality adjustment factor of 0.990228. Since the wage index budget neutrality factor is calculated to ensure that the changes between the CY 2024 and CY 2025 wage indices do not result in an increase or decrease of estimated aggregate payments, the application to the ESRD PPS base rate does not result in a decrease to total ESRD PPS payments.

Comment: One commenter noted that the proposed CY 2025 ESRD PPS base rate of $273.20 is only $43.57 more than the CY 2011 ESRD PPS base rate of $229.63. This commenter stated a belief that this has contributed to the ongoing net closures of ESRD facilities in recent years.

Response: We acknowledge that the ESRD PPS base rate has not increased as much as costs have for ESRD facilities; however, we note that the ESRD PPS base rate is not meant to be interpreted as an average or typical payment rate for renal dialysis services furnished to ESRD patients, because the ESRD PPS base rate is adjusted by several factors including the wage index and several case-mix and facility-level adjusters. Generally, these adjusters are implemented in a budget-neutral manner, which usually decreases the ESRD PPS base rate to account for the usually positive adjustment factor. For example, when we updated the case-mix adjustment factors in the CY 2016 ESRD PPS final rule, we applied a refinement budget-neutrality adjustment factor of 0.960319, which decreased the ESRD PPS base rate by approximately nine and a half dollars without reducing total estimated payments for CY 2016 (80 FR 69013). Thus, we do not believe it is appropriate to judge the payment adequacy of the ESRD PPS based on the base rate alone without accounting for the other adjustment factors, which heavily influence the actual payment amount received by ESRD facilities. The actual payment rate is generally higher than the unadjusted ESRD PPS base rate. The ESRD PPS base rate incorporates offsetting adjustments to maintain budget neutrality which, as discussed, have generally reduced the ESRD PPS base rate, so it should not be evaluated in isolation. As these adjustment factors have generally increased since the inception of the ESRD PPS in CY 2011, we believe that this increase in the ESRD PPS base rate from CY 2011 to CY 2025 is appropriate.

Comment: Many commenters who opined that the current payments under the ESRD PPS were too low included potential implications of a lower-than-appropriate payment rate. These implications included concerns related to quality of care, ability for ESRD facilities to remain open, ability for ESRD facilities to remain staffed, reduction of the hours of operation at ESRD facilities, and access concerns.

One commenter highlighted potential health equity concerns related to what they characterized as lower-than-appropriate payments. This commenter stated that dialysis patients are disproportionately African American/Black, live in medically underserved areas and are low income, so lower-than-appropriate payments would risk perpetuating health disparities.

Response: We appreciate the commenter's concerns regarding the wide range of potential implications of the proposed payment rate update. We note that we are statutorily required to increase the ESRD PPS base rate by a ESRDB market basket increase factor that reflects the forecasted change in prices of an appropriate mix of goods and services included in renal dialysis services. The final CY 2025 market basket update is 2.2 percent according to the latest available projection of the ESRDB market basket and productivity adjustment, which we note is 0.4 percentage point higher than the proposed ESRDB market basket update. We recognize that many commenters are concerned about payment adequacy, and we agree that it is important to ensure payments to ESRD facilities are adequate. We note that MedPAC's 2024 Report to Congress [35] projected a 2024 aggregate FFS Medicare margin for ESRD facilities of 0.0 percent. While we understand why interested parties may perceive these margins as being too low, we note that they indicate that in general ESRD facilities are being paid a reasonable amount given their costs.

We appreciate the thoughtful comments on the health equity implications of the ESRD PPS payment rate. We agree with the commenters that appropriate payments for renal dialysis services are important due to the potential vulnerability of many ESRD beneficiaries and the health disparities they may experience. We did not propose any changes to the ESRD PPS payment update methodology to further account for health equity, and we are statutorily required to update ESRD PPS payments based on the change in prices as measured by the ESRDB market basket. We intend to continue to consider a wide range of potential options for how we can address health equity concerns, for example, through refined case-mix and facility-level adjustment factors, in future rulemaking.

Comment: We received some comments which specifically discussed ESRD facilities in Puerto Rico and the appropriateness of the current ESRD PPS base rate there. One comment stated that relative rates between MA and FFS Medicare were larger than in the mainland United States. This commenter also mentioned several cost factors that were unique to Puerto Rico, including energy issues, laboratory costs, costs related to the importations of goods to areas outside the mainland United States, local legislation on administrative staff at ESRD facilities, and high property insurance rates.

Response: We appreciate the insight into the specific costs related to operating ESRD facilities in Puerto Rico. We believe that the ESRDB market basket appropriately accounts for all of the costs which the commenters described; however, we acknowledge that there could be geographic variation in these costs which would not be captured by the ESRDB market basket update. We understand that MA payment is critical for many ESRD facilities; however, MA payment rates are not the subject of this ESRD PPS rulemaking, and we are not substantively responding to any comments regarding MA payment rates in this final rule. We may consider how we could address the unique costs associated with the geographic isolation of U.S. Territories in the ESRD PPS in future policymaking.

Comment: Several commenters stated that the ESRD PPS does not adequately support innovation. These commenters generally expressed that payments under the ESRD PPS are not enough to incentivize new products, drugs, biological products, or other efficiencies to be developed for treatment of ESRD. Many of these comments were combined with more specific concerns regarding outlier payments for renal dialysis drugs that received the TDAPA after the end of the TDAPA period and the post-TDAPA add-on payment adjustment amounts, which we address in sections II.B.3 and II.B.6 respectively.

Response: Under section 1881(b)(14)(A)(ii) of the Act, the ESRD PPS is based on a fixed bundle of goods and services using data from 2007, 2008 or 2009, whichever had the lower per-patient utilization. Therefore, in the CY 2011 ESRD PPS final rule, we derived the ESRD PPS base rate from 2007 cost report data (75 FR 49152) which has been, and continues to be, annually updated based on the ESRDB market basket, reflecting the changes over time in the prices of an appropriate mix of the goods and services involved in furnishing renal dialysis services. Per this statutory scheme, the ESRD PPS is not designed to provide additional payment for new and innovative good or services through the ESRD PPS base rate. To promote innovation and achieve other objectives, we have finalized several policies using the statutory authority at section 1881(b)(14)(D)(iv) of the Act to provide temporarily increased payment to ESRD facilities that use certain new and innovative renal dialysis services. These include the TDAPA for certain new renal dialysis drugs and biological products (80 FR 69023), the TPNIES for certain new and innovative renal dialysis equipment and supplies (84 FR 60684), the TPNIES for certain capital related assets that are home dialysis machines when used in the home for a single patient (85 FR 71416) and, most recently, the post-TDAPA add-on payment adjustment for certain new drugs and biological products after the TDAPA period ends (88 FR 76388 through 76397). All of these add-on payment adjustments serve to provide increased payment compared to the ESRD PPS base rate, which we believe appropriately recognizes innovation through increased payment. As the statute specifically requires that the ESRD PPS be based on a fixed bundle of goods and services, we do not believe it would be appropriate to directly increase the ESRD PPS base rate for new goods and services which are broadly similar to goods and services within the ESRDB market basket, such as drugs and biological products in existing ESRD PPS functional categories.

Final Rule Action: We are not finalizing any changes to our methodology for calculating the ESRD PPS base rate. The final CY 2025 ESRD PPS base rate is $273.82, as described previously in this final rule.

5. 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

[35] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

rate. For purposes of this final rule, we 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 CYs.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2025, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2025. However, as required by § 413.236(f)(3)(v), we proposed to update the TPNIES offset amount annually according to the methodology described previously.

We are finalizing a CY 2025 TPNIES offset amount for capital-related assets that are home dialysis machines of $10.22, based on the final CY 2025 ESRDB productivity-adjusted market basket update of 2.2 percent (final 2.7 percent market basket percentage increase reduced by the final 0.5 percentage point productivity adjustment). Applying the final update factor of 1.022 to the CY 2024 offset amount resulted in the CY 2025 offset amount of $10.22 ($10.00 × 1.022 = $10.22). This is slightly higher than the proposed CY 2025 TPNIES offset amount for capital related assets that are home dialysis machines of $10.18. We did not receive any comments on our proposal to update the TPNIES offset for capital-related assets for CY 2025.

6. Post-TDAPA Add-On Payment Adjustment Updates

a. Updates to the Post-TDAPA Add-On Payment Adjustment Amounts for CY 2025

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjuster and is applied to every ESRD PPS claim. In that final rule we also clarified that for each year of the post-TDAPA period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. For CY 2024 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment. In the CY 2024 ESRD PPS final rule (88 FR 76397), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be $0.2493 and would begin on April 1, 2024.

For CY 2025, we will have two drugs included in the calculation of the post-TDAPA add-on payment adjustment. The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so, conditional upon the continued receipt of the latest full calendar quarter of ASP data as described in § 413.234(c)(3), Korsuva® will be included in the calculation for the post-TDAPA add-on payment adjustment for the entirety of CY 2025. The other drug, Jesduvroq (daprodustat), began its 2-year TDAPA period on October 1, 2023, so its post-TDAPA add-on payment adjustment period will begin on October 1, 2025, conditional upon the continued receipt of the latest full calendar quarter of ASP data.

In the CY 2025 ESRD PPS proposed rule we presented the proposed post-TDAPA add-on payment adjustment amounts for Korsuva® and Jesduvroq based on the most recently available utilization data at the time. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we proposed to update these calculations with the most recent available data in the final rule.

Based on the most recent utilization data, and following the calculation explained in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389) and § 413.234(g), the final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.4601 for all 4 quarters of CY 2025, an increase from the proposed post-TDAPA add-on payment adjustment amount of $0.4047. Under that same methodology, the current estimate of the post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0096 for only the last quarter of CY 2025, an increase from the proposed post-TDAPA add-on payment adjustment amount of $0.0019. We note that utilization data available for Jesduvroq available at the time the analysis was conducted for this final rule includes only data from October 2023 through June 2024. Table 8 shows the final post-TDAPA add-on payment adjustment amounts for each quarter of CY 2025.

TABLE 8: Final Post-TDAPA Add-on Payment Adjustment Amounts for CY 2025 by Quarter

Quarter	Final Add-on amount for Korsuva®	Add-on amount for Jesduvroq (Estimate)	Total post-TDAPA add-on payment adjustment amount
Q1 (January – March)	$0.4601	0	$0.4601
Q2 (April – June)	$0.4601	0	$0.4601
Q3 (July – September)	$0.4601	0	$0.4601
Q4 (October – December)	$0.4601	$0.0096	$0.4697

We invited public comment on our proposed CY 2025 post-TDAPA add-on payment adjustment amounts. Approximately 8 commenters including coalitions of dialysis organizations and several drug manufacturers commented on the proposed post-TDAPA add-on payment adjustment amounts. The following is a summary of the public comments received on these proposals and our responses.

Comment: We received several comments that reiterated concerns about the post-TDAPA add-on payment adjustment calculation that we addressed in the CY 2024 ESRD PPS final rule, in which we finalized the post-TDAPA add-on payment adjustment (88 FR 76388 through 76397). Commenters requested CMS calculate the post-TDAPA add-on payment adjustment amount based only on TDAPA claims that included the drug or biological product and then only apply the post-TDAPA add-on payment adjustment to claims with that drug or biological product. Commenters generally stated that this methodology would better support innovation and expressed access concerns for expensive drugs and biological products with low utilization after the TDAPA period. Some commenters included figures that they believed would be more appropriate amounts for the post-TDAPA add-on payment adjustment amount for Korsuva®, generally calculated using the suggested methodological changes.

Response: We did not propose a new methodology for the calculation of the post-TDAPA add-on payment adjustment for the same reasons we did not finalize the requested methodology in the CY 2024 ESRD PPS final rule (88 FR 76395). Specifically, calculating the post-TDAPA add-on payment adjustment amount by dividing the total payment for the drug or biological product across only those patients who utilize it would directly incentivize utilization of a particular drug or biological product, which can result in overutilization. We note that in future rulemaking we may propose changes to the case-mix adjustment factors, which could result in higher payments for treatments provided to some patients who utilize drugs or biological products that previously received the TDAPA, should the analysis show that treating these patients is more costly.

Final Rule Action: After reviewing the comments, we are finalizing a post-TDAPA addon payment adjustment amount of $0.4601 for Korsuva® that would be included in the calculation of the post-TDAPA add-on payment adjustment amount for all four quarters of CY 2025. Additionally, we are presenting an estimated post-TDAPA add-on payment adjustment amount of $0.0096 for Jesduvroq, which would be included in the calculation of the post-TDAPA add-on payment adjustment amount for the fourth quarter of CY 2025. As discussed later in this section of the final rule, this presented post-TDAPA add-on payment adjustment amount for Jesduvroq will be updated in a CR once we have a full year's worth of utilization data available for the analysis.

a. Proposal To Publish Post-TDAPA Add-On Payment Adjustment Amounts After the Final Rule in Certain Circumstances

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76393) and codified at 42 CFR 413.234(g), we have finalized a post-TDAPA add-on payment adjustment, which is based on the most recent year of utilization data and is calculated annually in each rulemaking cycle. Under § 413.234(g)(1), CMS bases the post-TDAPA add-on payment adjustment calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. However, when a drug or biological product begins its TDAPA period in the fourth quarter of a CY, and, therefore, would be included in the post-TDAPA add-on payment adjustment calculation beginning in the fourth quarter 2 CYs later, there would likely not be a full year's worth of utilization data available at the time of proposed or final rulemaking for that CY due to the time-lag associated with collecting and processing utilization data for the final rule. For example, at the time of rulemaking for last year's ESRD PPS final rule, we had data available through June 2023 when calculating the post-TDAPA add-on payment adjustment amount for Korsuva® (88 FR 73697). However, for a drug or biological product that began its TDAPA period in October of the prior year, data from October through June would only represent 9 months of data. We believe it is important to have a full year's utilization data when determining the post-TDAPA add-on payment adjustment amount so that the post-TDAPA add-on payment adjustment appropriately captures the utilization of the drug or biological product as required by § 413.234(g)(1).

We proposed that when there is insufficient data at the time of rulemaking, we will publish the post-TDAPA add-on payment adjustment amount via CR once we have a full 12 months of data. Specifically, we will publish the post-TDAPA add-on payment adjustment amount in a CR under the following circumstances: (1) a drug or biological product is ending its TDAPA period during the CY, and therefore under § 413.234(c)(1) will begin being included in the post-TDAPA add-on payment adjustment amount calculation during that CY; and (2) that drug or biological product does not have at least 12 full months of utilization data at the time the final rule is developed. Under this proposal, we would still include an estimated post-TDAPA add-on payment adjustment amount in the proposed rule and update that estimated amount in the final rule, but we would note that the estimated amount presented in the final rule is subject to change. We note that the final post-TDAPA add-on payment adjustment amount published after the final rule could be higher or lower than the estimated amount presented in the final rule. We do not anticipate having less than a full year's utilization data at the time of rulemaking for drugs and biological products that begin receiving TDAPA payments in quarters other than the fourth quarter of the year; however, should such an instance arise, we would similarly publish the post-TDAPA add-on payment adjustment amount in a CR once 12 months of utilization data are available. We would indicate the quarterly release CR in which we intend to publish the final post-TDAPA add-on payment adjustment amount.

For CY 2025, there is one TDAPA drug, Jesduvroq, which is ending its TDAPA period in CY 2025 and for which, at the time of proposed rulemaking, we did not anticipate having a full 12 months' worth of utilization data at the time of final rulemaking. As such, we stated that under this proposal we would indicate in the final rule that we intend to publish the post-TDAPA add-on payment adjustment amount for CY 2025 for Jesduvroq once we have a full year of utilization data. We generally intend to publish this updated post-TDAPA add-on payment adjustment amount two calendar quarters prior to the end of the TDAPA period, as this would allow for sufficient time to gather and analyze a year's worth of utilization data. We stated that for this drug, and for any drug or biological product that begins its TDAPA period in the fourth quarter of a CY, we would generally publish the post-TDAPA add-on payment adjustment amount at the beginning of the second quarter of the last CY of that drug or biological product's TDAPA period (that is, two

calendar quarters before the drug is included in the post-TDAPA add-on payment adjustment amount). However, should circumstances arise that prevent us from calculating a post-TDAPA add-on payment adjustment amount at that time, we would publish the final post-TDAPA add-on payment adjustment amount at a later time.

We noted that this approach to publishing the post-TDAPA add-on payment adjustment amount calculation would not impact any drug or biological product that has at least one full year's worth of utilization data at the time when the analysis for the final rule is developed, nor would it impact any drug or biological product that is already included in the post-TDAPA add-on payment adjustment calculation for a given CY. We do not intend to routinely update post-TDAPA add-on payment adjustment amounts quarterly, as we believe this will make it more difficult for ESRD facilities to estimate payments. However, for drugs or biological products that lack a full year's worth of utilization data at the time when the analysis for the final rule is developed, we believe it is appropriate to take this additional step to ensure that their post-TDAPA add-on payment adjustment is based on 12 months of utilization data as required by § 413.234(g)(1).

We invited public comment on our proposal to update post-TDAPA add-on payment adjustment amounts after the final rule is published in situations where 12 months of utilization data is not available at the time of the analysis calculated for the ESRD PPS final rule. We did not receive any comments on this proposal.

Final Rule Action: We are finalizing our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances, as we believe it is most consistent with § 413.234(g)(1), which requires that the post-TDAPA add-on payment adjustment amount be calculated using 12 months of utilization data.

7. Inclusion of Oral-Only Drugs Into the ESRD PPS Bundled Payment

a. 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 that section states that these services include other drugs and biologicals [36] that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of that 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 issued 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 drugs and biological products with only an oral form. We also finalized a policy to delay payment for oral-only drugs under the ESRD PPS until January 1, 2014. 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 ESRD PPS payment rates effective January 1, 2014, once we had collected and analyzed adequate pricing and utilization data. 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 for those beneficiaries with such coverage.

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.

Since then, the Congress has acted three times to further delay the inclusion of oral-only renal dialysis service drugs and biological products in the ESRD PPS. Specifically, as discussed in section II.A.1 of this final rule, ATRA in 2013, as amended by PAMA in 2014, and amended by ABLE in 2014, ultimately delayed the inclusion of oral-only drugs into the ESRD PPS until January 1, 2025.

Section 217(c)(1) of PAMA also required us to adopt a process for determining when oral-only drugs are no longer oral-only and to incorporate them into the ESRD PPS bundled payment. 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. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), we noted that when the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) were determined no longer to be oral-only drugs, we would pay for them using the TDAPA. We stated that this would 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.

In 2017, when an injectable calcimimetic became available, CMS issued a Change Request[37] to add all calcimimetics, including oral and injectable forms, to the ESRD PPS bundled payment beginning in CY 2018. CMS paid the TDAPA for calcimimetics for a period of 3 years (CY 2018 through CY 2020). When the TDAPA period ended, we went through rulemaking (85 FR 71410) to increase the ESRD PPS base rate beginning in CY 2021 to incorporate the cost of calcimimetics.

Most recently, in the CY 2023 ESRD PPS final rule (87 FR 67185 through 67186), we finalized a revision to the regulatory definition of an oral-only drug, effective January 1, 2025, to clarify our longstanding policy by specifying that an oral-only drug has no injectable functional equivalent. The effective date of this revised definition will coincide

[36] 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 final rule except where referencing specific language in the Act or regulations.

[37] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm10065.pdf* and *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2018downloads/r1999otn.pdf*.

with the January 1, 2025, incorporation of oral-only drugs into the ESRD PPS under § 413.174(f)(6). The revised definition of oral-only drugs reflects that drugs with similar end-action effects are treated as equivalent under the ESRD PPS, consistent with our approach to designating drugs into ESRD PPS functional categories.

b. Current Policy for Oral-Only Drugs in CY 2025

Existing regulations at § 413.174(f)(6) state that effective January 1, 2025, oral-only drugs will be paid for under the ESRD PPS. Although oral-only drugs are excluded from the ESRD PPS bundled payment until January 1, 2025, they are currently recognized as renal dialysis services as defined in regulation at § 413.171. Accordingly, CMS is planning to incorporate oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, using the TDAPA, as described in the CY 2016 ESRD PPS final rule (80 FR 69027) and subsequent rules.

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67180), 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 for outside the ESRD PPS. We stated that 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. We stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025. CMS discussed its process for incorporating calcimimetics in CMS Transmittal 1999, dated January 10, 2018, and in MLN Matters Number: MM10065.[38] [39] We stated that pricing for phosphate binders under the TDAPA would be based on pricing methodologies available under section 1847A of the Act. A new renal dialysis drug or biological product is paid for using the TDAPA, which is based on 100 percent of ASP. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. In such cases, CMS will undertake rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the cost and utilization of phosphate binders in the ESRD PPS bundled payment.

We note that on October 17, 2023, a new oral phosphate lowering agent received FDA marketing approval. According to the FDA-approved labeling for this drug, XPHOZAH® (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease who are on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. CMS has identified XPHOZAH® to be a renal dialysis service because it is used to treat or manage a condition associated with ESRD, per its approved indication. XPHOZAH® tablets are taken orally, usually twice a day with meals. CMS has also determined that XPHOZAH® meets the current regulatory definition of an oral-only drug as defined at § 413.234(a), and therefore, in accordance with § 413.174(f)(6), is not paid for under the ESRD PPS until January 1, 2025. Consistent with policies adopted in the CY 2016 and CY 2023 ESRD PPS final rules (see 80 FR 69025 and 87 FR 67183), XPHOZAH® will be included in the ESRD PPS effective January 1, 2025, using the drug designation process under § 413.234.

As set forth in § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form furnished to ESRD patients will be incorporated within the prospective payment system rates established by CMS in § 413.230, and separate payment will no longer be provided. As noted earlier in this section, we have recently published operational guidance, including information about the TDAPA amount, HCPCS codes, and ASP reporting requirements and timelines for phosphate binders at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf*. We note that we will use the same process that we used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025, and that we will not be following this process for any other oral drugs or biological products. Manufacturers would need to apply for a HCPCS code and the TDAPA for any other oral drugs or biological products to be eligible for the TDAPA.

Finally, we note that the TDAPA amount is not applied to claims for renal dialysis services provided to beneficiaries with acute kidney injury.[40] When ESRD facilities were paid the TDAPA for calcimimetics and the latter were incorporated into the ESRD PPS bundled payment for patients with ESRD, the TDAPA was not paid for claims for renal dialysis services provided to beneficiaries with acute kidney injury. Similarly, ESRD facilities will not be paid the TDAPA for phosphate binders for renal dialysis services provided to beneficiaries with acute kidney injury. This is discussed below in section III.E of this final rule.

We note that for any other oral-only drugs, such as XPHOZAH®, we will apply our drug designation process as we do for all new renal dialysis drugs and biological products, consistent with § 413.234 and the policy finalized in CY 2016 ESRD PPS final rule (80 FR 69027) and reiterated in the CY 2023 ESRD PPS final rule (87 FR 67180).

c. Operational Considerations Related to the Incorporation of Oral-Only Drugs

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. These advantages included 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.

In November 2023, in accordance with section 632(d) of ATRA, the Government Accountability Office (GAO) published a Report to Congressional Committees titled, ''End-Stage Renal Disease: CMS Plans for including Phosphate Binders in the Bundled Payment.'' (GAO–24–106288).[41] The report summarized the current status of payment for the phosphate binders as well as identifying areas of operational concerns. These include challenges related to hiring the staff needed for ESRD facilities to provide phosphate binders to patients, complexities relating to system updates needed to accommodate the volume and broad array of phosphate binders, and costs related to dispensing, storage, and

[38] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf.*

[39] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf.*

[40] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm102811.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1941OTN.pdf.*

[41] *https://www.gao.gov/assets/d24106288.pdf.*

transportation. The considerations identified in the GAO report generally align with the comments we have received on past ESRD PPS proposed rules. The GAO also interviewed dialysis organization representatives who stated that they are preparing to make the anticipated adjustments needed to dispense the phosphate binders.

With respect to considerations related to staffing, we note that the ESRD PPS includes payment for staffing related to the provision of renal dialysis services. We believe there are several strategies that ESRD facilities could employ to efficiently use available staff time to provide phosphate binders. There are parallels between the administration of phosphate binders and the administration of oral calcimimetics, which are also typically taken every day. First, we expect that patients with ESRD generally receive treatment for at least 3 hours per session, typically three times per week. We believe that during this treatment window there is generally staff availability to provide the patient with pre-packaged medication, which we note could include medication for multiple days. Second, ESRD facilities could maximize the efficiency of staff time by mailing the prescriptions, to the extent that doing so is consistent with state pharmacy laws. For example, the GAO report identified that one large dialysis organization only mails oral prescriptions to patients' homes, while others mail the medication to either the ESRD facility or the patient's home. Third, the GAO report identified that some ESRD facilities contract with outside pharmacies rather than operating their own pharmacy. By contracting with outside pharmacies, ESRD facilities could reduce or avoid the need to hire additional pharmacists and pharmacy staff to manage the volume of prescriptions.

Another challenge identified by the dialysis organizations was the complexity of dispensing phosphate binders because of the broad array of phosphate binders and the high volume of pills.[42] We acknowledge there are six common types of phosphate binders as compared to only one type of calcimimetics. The GAO report also noted that unlike calcimimetics, phosphate binders are typically taken with every meal and snack. We note that although Medicare will begin paying for phosphate binders under the ESRD PPS beginning January 1, 2025, we are not establishing any requirements regarding how or where patients take these medications. These decisions are made and will continue to be made by the patient, nephrologist, and care team.

We recognize that updates may be required to ESRD facilities' systems, including electronic medical records, billing systems, and inventory management systems to accommodate new procedures for dispensing phosphate binders. As we previously noted, we initially delayed the incorporation of oral-only drugs into the ESRD PPS in 2011, in part to allow ESRD facilities to make such operational changes and logistical arrangements. In addition, we have provided operational guidance on the CMS website at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf* that addresses HCPCS coding, billing, and price information. We expect that ESRD facilities will be able to make these system changes in advance of January 1, 2025.

As discussed in the CY 2025 ESRD PPS proposed rule, dialysis organizations have expressed concerns surrounding CMS using ASP to determine the TDAPA amount added to the ESRD PPS base rate for phosphate binders, which they believe does not adequately provide for dispensing cost.[43] Under current TDAPA policy, CMS intended to pay the TDAPA based on 100 percent of ASP for phosphate binders for at least 2 years. However, as noted in the CY 2025 ESRD PPS proposed rule (89 FR 55797), CMS recognized that updates may be required to ESRD facilities' systems, including electronic medical records, billing systems, and inventory management systems to accommodate new procedures for dispensing phosphate binders. In addition, we recognized the high percentage of ESRD beneficiaries that have at least one phosphate binder prescription and the large volume of phosphate binder prescriptions and stated that we were considering whether it may be appropriate to make additional payment to account for incremental operational costs in excess of 100 percent of ASP, such as dispensing fees, when paying the TDAPA for phosphate binders. Unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing functional categories, dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders. Therefore, in the CY 2025 ESRD PPS proposed rule, we also stated that we were considering whether a potential change in TDAPA amount policy for phosphate binders to account for such costs would be consistent with the TDAPA policy as finalized in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56948 and 84 FR 60673 through 60676). In the proposed rule, we noted one potential example we could consider would be paying 106 percent of ASP for 2 years as we did for calcimimetics. As discussed in the CY 2011 ESRD PPS final rule, the amounts added to the ESRD PPS base rate for oral drugs at that time were based on data from Part D, which included dispensing fees (75 FR 49043). We solicited comments on the extent to which 100 percent of ASP is an appropriate TDAPA amount for phosphate binders and whether there are any costs associated with the inclusion of phosphate binders into the ESRD PPS bundled payment that may not be accounted for by 100 percent of ASP. In the proposed rule we noted that CMS may finalize a change in the TDAPA amount for phosphate binders after considering comments on this topic.

As noted earlier, we have issued guidance[44] about the process we will use for paying the TDAPA for the phosphate binders and for their incorporation into the ESRD PPS bundled payment. This guidance addresses several key topics including billing information, information about the discarded drug policy, and information for manufacturers about reporting timelines for ASP data.

We invited public comment on the TDAPA payment methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. Approximately 162 commenters including LDOs; provider advocacy organizations; nonprofit dialysis associations; coalitions of dialysis organizations; a network of dialysis organizations; professional organizations; long-term care pharmacy association; ESRD facilities; ESRD beneficiaries, a trade association and pharmaceutical manufacturers, along with MedPAC, commented on the TDAPA payment methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. Of the 162 comments on oral-only drugs, we received 22 responses directly pertinent to the TDAPA methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. The remaining comments were out-of-scope, including 133 form letters, of which approximately 110 were from a unique

[42] Ibid.

[43] Ibid.

[44] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd* and *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf.*

submitter. The following is a summary of the public comments received on these proposals and our responses.

Comment: Multiple commenters expressed appreciation that CMS recognized the operational concerns and associated costs that were raised by ESRD facilities in the 2023 GAO report.[45] However, they expressed concern that CMS does not fully understand the costs and burdens associated specifically with staff time and dispensing of these drugs. Numerous commenters expressed concerns regarding the incremental operational costs and burden of incorporating phosphate binders into the ESRD PPS bundled payment. The commenters' concerns included, but were not limited to, distribution fees, mailing fees, storage fees, and increases in labor costs.

Response: CMS thanks the commenters for their appreciation and for sharing concerns regarding the costs and burden of incorporating phosphate binders into the ESRD PPS bundled payment. CMS has addressed these specific concerns in the responses to comments that follow in this rule. CMS recognizes that the introduction of oral-only medications into the ESRD PPS bundle can present some new logistic challenges. CMS is recognizing these costs through the modification to the TDAPA amount for phosphate binders in this final rule. In accordance with section 1881(b)(14)(B) of the Act, § 413.171 defines renal dialysis services to include oral-only renal dialysis services drug and biologicals. Oral-only renal dialysis service drugs and biological products were included in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044). At that time CMS finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014, to allow ESRD facilities to plan for the logistic challenges like those interested parties note in their comments. Legislation further delayed this date to January 1, 2025, and CMS ultimately updated the regulations at 42 CFR 413.174(f)(6) to finalize the date of the incorporation of oral-only drugs into the ESRD PPS bundled payment as January 1, 2025. CMS believes that the passage of over a decade since implementation of the ESRD PPS has provided sufficient time for interested parties to make the operational changes and logistical arrangements needed to furnish oral-only renal dialysis service drugs and biological products to their patients.

Comment: Numerous commenters stated that CMS should finalize the payment of a dispensing fee to account for such incremental operational costs when phosphate binders are added to the ESRD PPS bundled payment. They stated that the dispensing of oral medications to be taken daily will result in incremental operational costs and that these costs and dispensing fees are not included in the ESRD PPS base rate. An LDO and a coalition of dialysis organizations noted that every dialysis provider likely will implement a process that is most cost effective and efficient based on their footprint, organizational structure, patient population and other specific circumstances. Commenters stated that while the processes and procedures may vary by ESRD facility, every ESRD facility will incur distribution, storage, and staff expenses that are not accounted for in the ASP data, and this is an important distinction from the current processes related to calcimimetics. These other costs are discussed in the comments and responses that follow.

Response: In the CY 2025 ESRD PPS proposed rule, CMS recognized the high percentage of ESRD beneficiaries that have at least one phosphate binder prescription and the large volume of phosphate binder prescriptions and noted that we were considering whether it may be appropriate to make additional payment to account for incremental operational costs in excess of 100 percent of ASP, such as dispensing fees, when paying the TDAPA for phosphate binders. We stated that unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing ESRD PPS functional categories, dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders (89 FR 55797). CMS believes that payment for the incremental operational costs, such as distribution fees, mailing fees, storage fees, and increases in labor costs incurred by the ESRD facilities for the provision of phosphate binders should align with resource use; that is, ESRD facilities' outlay to provide the phosphate binders to the Medicare beneficiaries. In lieu of a dispensing fee, as discussed later in this section, we are finalizing a flat rate increase to the proposed 100 percent of ASP TDAPA amount for phosphate binders.

Comment: Coalitions of dialysis organizations commented that distribution costs, both dispensing fees and mailing fees, are not included in 100 percent of ASP. An LDO stated that CMS suggested that ESRD facilities can implement efficiencies by having phosphate binder prescriptions mailed to the patient's home to the extent possible under state pharmacy laws. They noted, however, that this still represents a new cost to ESRD facilities that is not accounted for in a drug's ASP. One commenter who is a pharmacy solutions company stated that the range of dispensing fees tends to be $5 to $30 for any given dispense, and incremental operational costs might include costs associated with call centers and pharmacists to receive prescriptions from ESRD facilities, as well as the internal processing costs associated with converting that into fillable medications. The commenter also stated that there is labor associated with the actual fulfillment of oral medications, which includes both quality control such as operational checks, and despite automation there is additional regulatory burden and oversight that is applied to mail order pharmacies. They stated that all these activities will result in incremental operational costs. The commenter stated that it is reasonable to expect that ESRD facilities, depending on their size and scale, might pay more than what would be incurred in mailing fees to dispense oral medications through a pharmacy. Commenters noted that these types of distribution costs exist regardless of whether the oral-only drugs are dispensed from a retail or mail or central pharmacy.

Multiple commenters stated that the ESRD facilities will be paying pharmacy charges to obtain the drugs through them. Commenters expressed concern that ESRD facilities will incur additional costs that should not be theirs to shoulder. A non-profit dialysis association noted that increased payment for these incremental operational costs is important, particularly now when according to the commenter ESRD facilities are at a financial breaking point. The commenter noted that the logistics involved with getting the phosphate binders to a patient can be more expensive than the drugs themselves. They stated that these costs are even greater when beneficiaries are based in rural communities, putting their ESRD facilities at an even greater disadvantage.

An organization of pediatric nephrologists supported the TDAPA amount based on 100 percent of ASP for oral phosphate binders. While the organization appreciated that adding

[45] ''End-Stage renal Disease: CMS Plans for Including Phosphate Binders in the Bundled Payment.'' (GAO–24–106288, Nov. 2023).

oral-only drugs to the bundled payment will improve patient access, they are concerned that these drugs are expensive, and pediatric centers will not be able to afford them. The organization stated that pediatric patients with kidney disease are mainly dialyzed in pediatric hospitals, which are not able to get bulk pricing deals for these drugs. By adding oral-only drugs to the ESRD PPS bundled payment without an appropriate increase in payment, the organization stated that there will be a huge cost to the pediatric hospitals that they cannot absorb. The commenter identified additional concerns about access, as these are not first-line drugs for pediatrics and there is often significant prior authorization involved in procuring these drugs for pediatric patients. They stated that the provision of phosphate binders for the pediatric ESRD population would include compounding charges and dispensary costs.

Several commenters noted that there will be mailing fees either in terms of obtaining drugs from pharmacies or sending the drugs directly to the patient's home, which is where they are taken. The pharmacy solutions company stated that the home delivery of medications is preferred by beneficiaries. The commenter predicted that most dialysis providers will rely on mail order or shipping from a central pharmacy to their clinics for distribution; others may rely on local retail pharmacies. The commenter stated that for home delivery, each prescription must be shipped to a patient's home through a carrier like the United States Postal Service, FedEx, UPS, etc. Thus, each dispense incurs an additional expense of $3 to $25 depending on weight and shipping method. The commenter also noted that given the number of types of phosphate binders used per patient, and the sheer volume of pills needed, there will be increased shipping costs previously unaccounted for in the ESRD PPS base rate for oral phosphate binders. A coalition of dialysis providers stated that shipping costs alone are expected to be significant, as pills must be packaged to ensure the medication is not damaged during transit, and shipping costs are likely to escalate year over year, as will the contract costs with mail-order pharmacies.

Drug manufacturers encouraged CMS to finalize a change in the TDAPA amount to 106 percent of ASP for phosphate binders. They stated that 100 percent of ASP does not consider the substantial cost for dispensing oral-only drugs particularly for the high volume of pills associated with phosphate binders, which a large majority of Medicare ESRD beneficiaries utilize. An LDO and a coalition of dialysis organizations commented on the distribution of phosphate binders to a subpopulation of patients with housing instability, for whom mailing medications to a home is not an option. Based on an assessment of the LDO's patient population, as well as internal and external assets and capabilities in efficiently ordering and distributing a large volume of oral drugs, they assessed that mailing medications to patient homes, arguably the least burdensome process for facility staff, is viable for only a subset of their population. Because many patients have unstable housing situations, the LDO stated that they cannot rely on mail order for every patient.

Multiple commenters noted that all these distribution options will incur new costs previously unaccounted for in the original underlying bundled payment and that are not covered by 100 percent of ASP, including additional staff time and facility infrastructure costs. Unlike the current process used for calcimimetics, staff will be required to accept and store individual prescriptions for each patient. An LDO stated phosphate binders currently flow through retail and mail order pharmacies, and that they will continue to flow through those channels when the payment changes from Part D to Part B. The LDO suggested that it would be appropriate for CMS to adjust the TDAPA payment amount to recognize Part B pharmacy supply fees paid for oral drugs paid as part of a physician's service, or in this case as part of the renal dialysis service.

Response: CMS thanks the commenters for sharing the challenges accompanying the complexity of dispensing phosphate binders because of the broad array of phosphate binders and the high volume of pills. We acknowledge there are six common types of phosphate binders as compared to only one calcimimetic. CMS also acknowledges the range of dispensing fees for the high volume of phosphate binders required to manage ESRD patients, along with the impact of potentially higher pharmacy supply fees on the rural community. We understand the concerns expressed by the commenters about ASP, and that small ESRD facilities may be unable to negotiate the lower drug prices attributed to volume, and inaccessibility to supply chain discounts. These unique challenges of the high volume of phosphate binders that ESRD facilities must provide to beneficiaries would be magnified by a higher cost-to-payment ratio for the smaller ESRD facilities. We recognize that unstable housing situations with some ESRD beneficiaries would affect the distribution of phosphate binders through mail order, which may be a preferred way for ESRD facilities to manage this process. In consideration of the incremental operational costs that will be incurred by the ESRD facilities, as noted later in this section, CMS has decided to finalize an increase to the current 100 percent of ASP calculation of the TDAPA amount paid to ESRD facilities for the inclusion of phosphate binders.

Comment: A coalition of dialysis organizations noted that ESRD facilities will need to update information technology systems to facilitate these changes. Changes are required to update electronic medical records, billing systems, and inventory management. The commenter also stated that e-prescribing is also a complex process that involves interactions with state regulatory authorities and that ESRD facilities will need to stand-up or expand their internal ability to engage with e-prescribing systems and contract with e-prescribing platforms to facilitate this policy change for phosphate binders. The coalition stated that all these changes represent both significant up-front costs and investments as well as ongoing administrative requirements to ensure operational connectivity and seamless delivery to the beneficiary. The commenter stated that ASP does not cover any of information technology costs for ESRD facilities to distribute phosphate binders to beneficiaries.

Response: CMS acknowledges that there will be changes needed in the IT systems for ESRD facilities to accommodate the updates and methodological changes accompanying the inclusion of the phosphate binders in the ESRD PPS. These changes and updates affect electronic medical records, billing systems, and inventory management systems. However, since publication of the CY 2016 ESRD PPS final rule, our existing regulations at § 413.174(f)(6) have stated that effective January 1, 2025, oral-only drugs, which includes phosphate binders, will be paid for under the ESRD PPS. As previously discussed, we initially delayed the incorporation of oral-only drugs into the ESRD PPS in 2011, in part to allow ESRD facilities to make such operational changes and logistical arrangements. In addition, we have provided detailed operational guidance on the implementation of the TDAPA policy as it pertains to phosphate binders to ensure that facilities have clear instructions on compliance and payment processes to facilitate a smooth

transition,[46] which addresses HCPCS coding, billing, and price information for phosphate binders. We expect that ESRD facilities will be able to make these system changes in advance of January 1, 2025. CMS will continue to issue operational guidance as necessary for the smooth implementation of the incorporation of phosphate binders into the ESRD PPS bundled payment. As discussed later in this section, CMS is finalizing an increase in the TDAPA amount for phosphate binders, which may help to offset the costs associated with the logistic steps that the commenter described.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists, a drug manufacturer and a health care system noted that supporting the provision of a significant volume of pills to patients along with the storage costs associated with maintaining the drugs at the ESRD facility if the decision is to distribute the drugs to patients during their dialysis treatment sessions is an additional cost to the ESRD facility. An LDO stated that the storage and distribution of oral calcimimetic medications are different from what they would be with phosphate binders. Commenters noted that because there is one oral calcimimetic medication, and half of their patient population on calcimimetic treatment (approximately 25 percent) receives this drug three times per week chairside, the storage and distribution processes are much simpler. They stated that ESRD facilities can maintain a supply of calcimimetics with relatively low burden compared to phosphate binders. The commenters stated that with more than 80 percent of ESRD patients being prescribed phosphate binders, and with more than six different types of oral phosphate binders and various dosages of each, phosphate binders represent a 225 percent relative increase over, and addition to, the percent of patients to whom the ESRD facilities are currently delivering calcimimetics. The coalition stated that the scale of operational requirements needed to deliver calcimimetics simply pales in comparison to what will be required to deliver phosphate binders to beneficiaries through the ESRD PPS.

The commenters also noted that because of the size of the pills and the quantity required for each prescription, most ESRD facilities are not equipped to store and dispense this volume of oral medication. They stated that phosphate binders represent an exponential increase in the volume of pills dialysis providers will need to acquire, distribute, store, and manage for their patients each month and year. The relative difference between managing 360 pills per year per patient for cinacalcet as compared with 3,240 pills per year per patient for calcium carbonate is 800 percent.

An LDO stated that the ESRD PPS bundled payment might have included storage administration fees for drugs that were previously separately billable (largely intravenous agents) when CMS established the bundled payment. However, they noted that the claims data CMS analyzed at that time omitted these oral medications. The LDO commented that it is incorrect to assume that the storage costs and dispensing fees for intravenous agents, which represent the vast majority of dialysis-provided drugs accounted for when the bundled payment was created, are equivalent to the administration and mailing costs associated with oral-only medications. A coalition of dialysis organizations stated that while their member ESRD facilities have increased their familiarity with dispensing oral drugs since the inception of the ESRD PPS, the difference between distributing several hundred pills to 25 percent of their patients each year and distributing thousands of large pills to 80 percent of the ESRD facilities' patients each year requires a significant expansion of their pharmaceutical distribution operations on a massive scale. The commenter stated that the ESRD facilities cannot simply repurpose existing systems to meet this goal—they must build, rebuild, and significantly expand the scale of their operations to accommodate a vastly larger number of patients taking exponentially more pills than they have ever provided before. The development, maintenance, and ongoing clinical management of these processes represent significant costs to ESRD facilities, which are not covered by setting the TDAPA for phosphate binders at 100 percent of ASP.

The LDO commented that intravenous agents and oral-only drugs differ in several respects. Most notably, intravenous agents are usually administered to patients while on dialysis. Thus, there is centralized shipping and administration of those products. In contrast, the commenter stated, under state and other pharmacy laws, a significant number of the oral-only drugs will be shipped and dispensed directly to the patient's home. This delivery model incurs fixed costs, such as shipping and administration fees, which differ from those associated with the previously separately billable intravenous drugs.

A coalition of dialysis organizations stated that ESRD facilities would also have to construct or install on-site storage with appropriate temperature controls and security measures compliant with state pharmacy laws and requirements. If the patient misses or changes their appointment, or if the delivery of their prescription is delayed by the shipping carrier, this process breaks down. The coalition stated that CMS's suggestion regarding labor allocation for in-center distribution of phosphate binders does not address the needs of patients using home dialysis, is not simple, and is not without costs. The commenter stated that having an ESRD facility staff member hand a patient their pre-packaged medication is the final step in a long, complex, and costly process. They stated that none of those costs will be supported if CMS sets the TDAPA amount for phosphate binders at 100 percent of ASP.

A non-profit treatment and research center stated that given the difficulties associated with dispensing these medications in the ESRD facility, these facilities may have to restrict the formulary of available medications, which may mean that some patients have difficulty accessing the optimal medication for them. A health care system stated that because of significant cost considerations, they are concerned that ESRD facilities may limit patient choice by offering fewer phosphate binders based on the cost to facilities.

In their comment, MedPAC refers to their comment in the CY 2019 proposed rule that stated that the ASP + 6 percent policy that is applied to many Part B drugs was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. MedPAC also stated that while the ASP payment policy never stated what cost the ''+6 percent'' was intended to cover, they noted that reimbursing dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC stated that they believe that rationale is diminished for dialysis facilities. MedPAC also stated that the TDAPA amount is in addition to the ESRD PPS base rate, which already includes payment for the cost of storage and administration of

[46] *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf.*

ESRD-related drugs. Therefore, if the intent of the ''+6 percent'' was to address storage and administration costs, MedPAC believes these costs are already addressed through the ESRD PPS bundled payment and do not contribute to the rationale for paying 106 percent of ASP for the TDAPA.

Response: We agree with MedPAC that the 106 percent of ASP percent policy was developed to pay physicians for the cost of drugs and that the TDAPA is an add-on payment adjustment to the ESRD PPS base rate, which already accounts for the cost of storage and administration of renal dialysis drugs. However, CMS recognizes the unique costs associated with the provision of phosphate binder drugs and believes it is appropriate to consider a potential change in the TDAPA payment policy for these drugs. CMS believes it is appropriate to make an incremental addition to the TDAPA amount to specifically account for incremental operational costs in excess of 100 percent of ASP for furnishing phosphate binders, such as distribution fees, mailing fees, excess storage fees, and increases in labor costs. Unlike other drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing ESRD PPS functional categories, these incremental operational costs, such as security of medications in storage, are not currently included in the ESRD PPS base rate for phosphate binders. We noted this in the analysis conducted to establish the base rate in the CY 2011 ESRD PPS final rule, and we did not include phosphate binders in that analysis due to a lack of data (75 FR 49043). CMS is making a provision for a fixed additional amount for each monthly claim that includes phosphate binders, which will increase the TDAPA amount to account for these unaddressed incremental operational costs in CY 2025 and CY 2026.

Regarding the concern about the difficulties associated with dispensing phosphate binders in the ESRD facility, and the risk that these facilities may have to restrict the formulary of available medications, which may mean that some patients have difficulty accessing the optimal medication for them, we believe that physicians and their patients should make the decision together on the appropriate form of the drug for treatment. It is not our intent to interfere with that decision making process. As the number of drugs within each ESRD PPS functional category increases and market share competition from the manufacturers is a factor, we anticipate easier access, more choices in care, and lower prices. We acknowledge that payment policies may have unintended consequences as identified by the commenters. However, it is our expectation that ESRD facilities will follow the physician's plan of care for the patient. Under the ESRD facility CfCs (for example, §§ 494.70(a)(12) and 494.90(a)(3)), if a physician determines that a particular phosphate binder is clinically best for a particular patient, the ESRD facility is obligated to make that drug available to the patient. In the CY 2011 ESRD PPS final rule, we specifically stated that we expect ESRD facilities to provide the appropriate medications, at the appropriate dosage, based upon individual patient needs. We expect the patient's nephrologist and the interdisciplinary team to identify medication needs in accordance with the individual patient's plan of care (75 FR 49038). CMS will be closely monitoring drug utilization at the beneficiary and facility level for these types of issues.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists and drug manufacturers commented that complying with state pharmacy laws for the distribution of phosphate binders is an additional cost. For example, these commenters noted that some states, like Alabama and Arkansas, do not allow ESRD facilities to distribute oral drugs directly to the patients, so there are additional contracting costs incurred. An LDO commented that ESRD facilities are limited by state rules in their ability to maintain a stock of medications that are dispensed to patients for consumption at home. They stated that CMS's recommendation that ESRD facilities could provide the patient with prepackaged medication when they are at the facility is not aligned with the reality of how ESRD facilities operate. They also stated that since they are not licensed to package medications, they will need to pay pharmacies to provide the medication so it can be distributed by registered nurses in their ESRD facilities to their patients. This fee is not included in the ASP, and the commenter stated that they will incur additional costs.

Another coalition of dialysis organizations commented that ESRD facilities are working diligently to stand up contracting and procurement agreements with manufacturers, distributors, mail-order pharmacies, and other entities to facilitate these changes to the payment system. The coalition notes that each provider must ensure compliance with federal rules as well as state pharmacy laws, which can vary significantly and prevent providers from having uniform policies and protocols across the country, creating inefficiencies that cannot be mitigated. Whether standing-up or significantly expanding these operations from their current, limited state to manage the phosphate binders, the coalition noted that ESRD facilities will need to invest in significant legal, administrative, and compliance staff resources to initiate and continuously maintain these operations going forward. The coalition also stated that some of their members noted that they will also need to help beneficiaries understand the limitations based on state pharmacy laws of what they can and cannot address with them about their prescription in the facility, as many state pharmacy laws require questions about prescriptions to be answered only by the pharmacist or prescribing clinician.

An organization of pediatric nephrologists stated that pediatric hospitals providing pediatric dialysis often do not have a license to dispense for Medicare.

A trade association stated that the dispensing flexibilities of pre-packaged mailed medications that extend to community-dwelling beneficiaries or contracting with external pharmacies to furnish the medications not dispensed during an in-center dialysis session, may not apply to those beneficiaries in long-term care facilities (LTCs), due to Federal or State nursing home regulations. In addition, this trade association stated that furnishing the oral-only phosphate binder medications to beneficiaries receiving home dialysis in a nursing facility will create excessive burdens on facility staff to establish ''work-around'' processes to intake, store, and dispense these oral-only dialysis medications in a manner different than their standard operating procedures for all other residents. The trade association wrote that such ''work-arounds'' increase the risk for missed medication administration and increase LTC provider operating costs, which may disincentivize providers from offering in-center dialysis room, akin to a ''den'' in a private home, or home dialysis services within the LTC facility, thereby limiting beneficiary care options.

A coalition of dialysis organizations stated that CMS should ensure that other providers, such as SNFs, are notified of forthcoming changes to the ESRD PPS regarding the provision of phosphate binders and work with those providers to ensure a smooth transition. Coalitions of dialysis organizations and a nephrology nurses association requested additional guidance from CMS regarding the complexity of

phosphate binder management for ESRD patients in the SNF setting. A trade association also requested that CMS address how ESRD and LTC facilities should address the unique operational considerations related to the incorporation of oral-only drugs into the ESRD PPS when the beneficiary's current home is a LTC facility. The association requested CMS to explain how the oral-only phosphate binder medications for Medicare dialysis patients should be made available to the LTC provider in a manner that complies with the Federal and State LTC provider regulations, whether it be from the ESRD facility, mail delivery or through an LTC pharmacy. The same commenters wanted to know if assurances will be provided that the costs of these medications directly related to the ESRD benefit and services will not be passed on to the SNF. Finally, the commenter questioned what, if any, are the documentation needs and requirements to be exchanged between the SNF and the ESRD facility.

Response: CMS expects that facilities should be prepared logistically for the inclusion of phosphate binders in the ESRD PPS bundled payment, given that the regulation establishing the current effective date was codified in 2016. This would include the logistics and contractual agreements for distributing the phosphate binders, whether in-center or for those patients receiving home dialysis, any need for increased storage due to the number of pills, and efficient use of ESRD facility labor. CMS is planning to hold at least two open door forums to inform interested parties about ESRD PPS policy and answer questions related to implementation of the incorporation of phosphate binders into the ESRD PPS bundled payment. In addition, CMS has a payment mailbox for incoming questions regarding the ESRD PPS payment policies. That mailbox address is: *ESRDPAYMENT@cms.hhs.gov*.

Regarding the commenter's concerns about pediatric hospitals' licensure to dispense phosphate binders, we believe the commenter is referring to regulations that prevent certain hospital pharmacies from providing drugs to patients to take home. We note that we expect ESRD facilities would contract with a pharmacy as necessary, and this would be the case for hospital-based ESRD facilities as well. Some hospitals may not have outpatient pharmacies, as would most freestanding ESRD facilities, but would be able to contract with a pharmacy to make phosphate binders available to patients. We note that the additional $36.41 increase to the TDAPA amount for phosphate binders would be intended cover incremental operational costs associated with such a contract.

CMS expects that LTC facilities will ensure that the current procedures they are using to supply oral drugs, such as calcimimetics, comply with the Federal and State LTC facility regulations. Accordingly, the same process should be followed for phosphate binders. In accordance with the statutory definition of renal dialysis services at section 1881(b)(14)(B)(iii) of the Act, § 413.171 defines phosphate binders as a renal dialysis service. Renal dialysis services have always been included within the scope of the Part A extended care benefit under section 1861(h)(7) of the Act that provides for coverage of those services (not specified elsewhere in section 1861(h)) that are generally furnished by, or under arrangements made by, SNFs. However, dialysis services described under section 1861(s)(2)(F) of the Act may be unbundled when furnished by an outside dialysis supplier. Given this, the SNF rarely bills separately for renal dialysis services. Rather, such services are billed for separately under the Medicare Part B dialysis benefit by the outside supplier. The incorporation of oral only drugs did not change the existing ESRD facility CfCs or associated guidance for providing home dialysis services in a LTC facility. Currently, CMS does not plan to update the QSO 18–24 guidance. As explained in QSO 18–24, collaborative care planning and delineated division of responsibilities is critical to the successful implementation of a patient's dialysis plan of care.[47] Listed below are the clinical areas that should be addressed in an agreement between an ESRD facility and LTC facility when home dialysis services are provided to residents of a LTC facility. This is not an exhaustive list, nor does it represent mandatory elements of a written agreement. This guidance is a resource for dialysis facilities to refer to prior to furnishing home dialysis care to nursing home residents. Guidance on clinical areas that should be addressed in an agreement include:

- Methods for enabling timely communication and collaboration between the ESRD facility and nursing home care team;
- Ensuring a safe and sanitary environment where the dialysis treatments occur;
- Ensuring active participation of the nursing home care team in the development and implementation of an individualized care plan;
- Delineation of patient monitoring responsibilities before, during, and after each treatment, ensuring any state scope-of-practice laws and limitations are adhered to when delineating responsibilities;
- Processes that ensure a review of the qualifications, training, competency verification, and monitoring of all personnel, patients, and caregivers (family members or friends) who administer dialysis treatments in the nursing home;
- Procedures for preparing nursing home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed; and
- Procedures to make sure that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.

Comment: A trade association questioned if CMS intends to update the QSO–18–24–ESRD guidance prior to implementation to assure that both the ESRD facility and the LTC provider clearly understand what may need to be updated in their agreements, policies and procedures, and training needs resulting from the revised payment methodologies and the potential shift in how these oral-only phosphate binder medications are made available to the LTC provider.

Response: The incorporation of oral-only drugs under the ESRD PPS will not change the existing ESRD facility CfCs or associated guidance for providing home dialysis services in a LTC facility. Currently, CMS does not plan to update the QSO 18–24 guidance. As explained in QSO 18–24, collaborative care planning and delineated division of responsibilities is critical to the successful implementation of a patient's dialysis plan of care.

Comment: A non-profit treatment and research center stated that there will be difficulty managing these medications for patients residing in nursing homes whether for short-term rehabilitation or as long-term residents. They stated that nursing homes have existing processes for obtaining medication for their patients which does not include obtaining it from ESRD facilities. The ESRD facilities will need to collaborate with any nursing facility in which their patients reside to arrange for the delivery of the medication. Further, the commenter stated that the nursing homes will ask for payment for the time their staff spend in providing the medication to the patient. They will need to have a pharmacist deliver the medication to the nurse caring for a

[47] *https://www.cms.gov/files/document/qso-18-24-esrd-revised.pdf.*

patient and then the nurse will have to provide the medication to the patient as prescribed.

Response: As noted previously, renal dialysis services have always been included within the scope of the Part A extended care benefit under section 1861(h)(7) of the Act that provides for coverage of those services (not specified elsewhere in section 1861(h)) that are generally furnished by, or under arrangements made by, SNFs. However, dialysis services described under section 1861(s)(2)(F) of the Act may be unbundled when furnished by an outside dialysis supplier. Therefore, LTCs can provide renal dialysis services, including provision of phosphate binders, to their residents in an ''under arrangement'' agreement with an ESRD facility.[48] Any payment arrangements, such as payment for the LTC staff time, with the ESRD facilities would involve contractual arrangements with the ESRD facility and the LTC facility. Alternatively, if the LTC is a Medicare-certified dialysis facility, it can provide renal dialysis services.

Comment: A coalition of dialysis organizations, a professional organization of nephrologists, a drug manufacturer, and a health care system all stated that adjusting drug supplies when a physician changes a patient's prescription to another product (which often occurs) is a cost not covered by 100 percent of ASP. In a comment from an LDO, they stated that their data suggests that relative to calcimimetics, phosphate binder prescriptions change frequently. They noted that approximately 23 percent of patients on a phosphate binder have a change in their prescription each month. The commenters stated that assuming mail delivery is used for appropriate patients, ESRD facilities will incur the cost of delivery, which in some cases may be more than once per month depending on the rate of prescription changes.

Response: CMS recognizes that there may be changes in the patient's prescription for phosphate binders to address the patient's side-effects from a current phosphate binder or to adjust following the results of laboratory testing. As a cost control measure, ESRD facilities could adjust the prescribed amounts to avoid additional mailing fees or could negotiate deeper discounted pricing from mail service pharmacies for long term, chronic therapies such as phosphate binder prescriptions. In the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We stated that ESRD facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. CMS notes that Medicare does not pay for drugs that are not in single-use packaging that have been dispensed and discarded. As noted in an October 2022 review article about mineral bone disorders in kidney disease patients, decisions about the use and dose of specific phosphate binders should be based on progressive or persistent hyperphosphatemia.[49] Additionally, changes in phosphate binder prescriptions most often occur in patients with ESRD who are new to dialysis [50] and may have higher costs. CMS provides an onset adjustment of 32.7 percent, which is a Medicare payment adjustment for patients with ESRD who are eligible for Medicare during their first 120 days of chronic renal dialysis. As noted in the CY 2011 ESRD PPS proposed rule (74 FR 49952) the higher costs of the new patients may be due to stabilization of the patient's condition, along with administrative and labor costs associated with the patients being new to dialysis.

Comment: A coalition of dialysis organizations and a health care system disagreed with the language in the proposed rule that suggested there would be no additional labor cost incurred when phosphate binders are added to the ESRD PPS bundled payment. The commenters stated that they anticipate that adding new duties associated with the distribution of phosphate binders will take significant time away from existing patient care activities. As a result, many ESRD facilities may find themselves having to hire additional health care professionals and other staff to maintain the same level of care provided today. The coalition and health care facility also stated that ESRD facilities continue to face significant labor costs and, while the tight labor market has abated somewhat, hiring additional staff remains a significant expense. An LDO noted that CMS suggested that ESRD facilities can efficiently use staff time by providing patients with pre-packaged medication that would include medications for multiple days. However, the LDO, along with a coalition of ESRD facilities commented that this represents a new cost to ESRD facilities that is not accounted for in a drug's ASP. They commented that what CMS presents as a simple solution is the end-result of a complex system that will require a significant up-front and ongoing investments of resources and staff time. To execute CMS's suggestion, the commenters noted that ESRD facilities need to contract with a pharmacy to dispense, fill, and ''pre-package'' the medication and arrange for delivery to the facility in advance of each patient's scheduled appointment. Facility staff would need to receive, inventory, store, and manage medication for all their patients on-site and then ensure that all pharmacy processes are coordinated with scheduled patient appointments. The LDO stated that under Part B, phosphate binders will continue to be distributed through pharmacies whether those prescriptions are mailed to the patient or to the facility. Regardless of where the patient receives the prescription (facility or home), the burden of managing oral phosphate binders through the facility affects every member of the staff. The LDO stated that the ESRD facility staff will need to manage medication orders, call in new prescriptions, conduct medication management, maintain delivery logs when prescriptions are delivered to the facility, review and maintain refill requests, educate patients on usage, and manage disposal of unused oral medications. Because many patients will lose the low-income subsidy and other beneficiary protections in Part D, the LDO noted, some facility staff time will now be dedicated to assisting patients who have trouble affording their medications.

A non-profit treatment and research center stated that not only are there costs incurred when their registered nurses dispense the medications to the patients, provide counseling about the medications and answer any questions patients may have, but the nurses will be taken away from their current patient care responsibilities to perform these functions, which the commenters noted will negatively impact the patients under their care. A health care system

[48] *https://www.cms.gov/Medicare/Medicare-Contracting/ContractorLearningResources/Downloads/ja0435.pdf.*

[49] *Int. J. Mol. Sci.* 2022, *23*(20), 12223; *https://doi.org/10.3390/ijms232012223*, Mineral Bone Disorders in Kidney Disease Patients: The Ever Current Topic.

[50] Expert Opinion on Drug Safety, 2022, 21(7); *https://doi.org/10.1080/14740338.2022.2044472*. An update on phosphate binders for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis: a review of safety profiles.

also stated that increasing the number of pharmacies will increase the administrative cost of providing services and the complexity of tracking the drugs for the ESRD facility.

The LDO stated that while approximately 25 percent of their patient population is on calcimimetic therapy, whereas approximately 70 to 80 percent of their population is on phosphate binder therapy, CMS cannot assume that because ESRD facilities are managing calcimimetics, the infrastructure is in place to manage phosphate binders. They stated that there will be a significant amount of staff time devoted to managing phosphate binders through the ESRD facility, which will almost certainly be required to hire additional staff to reduce the burden on clinical staff. The LDO stated that these areas represent the ongoing costs to providers and do not include startup costs of building storage capacity and upgrading IT systems to accommodate changed workflow and new business functions.

A coalition of dialysis organizations expressed the importance of medication management with ESRD patients, as they may have multiple co-morbidities and polypharmacy, and there is a potential for medication-related errors. This makes continuity of care and medication management systems important. They stated that CMS does not cover ESRD facilities' ongoing expenses to provide medication management for the phosphate binders.

Response: CMS has carefully considered the operational considerations and costs raised in the comments. With respect to considerations for ESRD facility staffing, CMS notes that the ESRD PPS includes payment for staffing related to the provision of most renal dialysis services. However, we acknowledge that there are some areas such as IT synchronization and the advancements in the delivery systems that had not been considered, when establishing both the ESRD PPS base rate and the current policy for TDAPA payments at 100 percent of ASP. These costs were considered in formulating the increased TDAPA payment which is intended to account for incremental operational costs associated with furnishing phosphate binders. CMS does believe there are several strategies that ESRD facilities could employ to efficiently use available staff time to provide phosphate binders. There are parallels between the administration of phosphate binders and the administration of oral calcimimetics, which are also typically taken every day. First, we expect that patients with ESRD generally receive treatment for at least 3 hours per session, typically three times per week. We believe that during this treatment window there is generally staff availability to provide the patient with pre-packaged multiple-day doses of their medication (should state law allow). Second, ESRD facilities could maximize the efficiency of staff time by mailing the prescriptions, to the extent that doing so is consistent with state pharmacy laws. For example, the GAO report identified that one large dialysis organization only mails oral prescriptions to patients' homes, while others mail the medication to either the ESRD facility or the patient's home. Third, the GAO report identified that some ESRD facilities outsource labor by contracting with outside pharmacies rather than operating their own pharmacy. By contracting with outside pharmacies, ESRD facilities could reduce or avoid the need to hire additional pharmacists and pharmacy staff to manage the volume of prescriptions. CMS acknowledges that these suggestions may not be fully applicable for LTC or SNF facilities. CMS will continue to engage and communicate with these facilities to ensure continuity of care and will continue to monitor patient outcomes under this policy change.

Comment: A coalition of dialysis organizations stated that while ESRD facilities and clinical teams, such as dietitians, are involved in the current management of bone and mineral metabolism and hyperphosphatemia, the process is currently managed under the auspices of the prescribing physician working within the formulary confines of the beneficiary's Part D plan or other source of drug coverage, which is managed largely outside of the ESRD facility. Migration of phosphate binders from Part D to Part B imposes new clinical administrative responsibility on ESRD facilities to develop clinical protocols and formularies, educate their clinician partners and clinical staff, and manage ongoing clinical evaluation and monitoring to ensure they are meeting the needs of our patients on an ongoing basis to manage a class of drugs for which they were previously not responsible. The coalition stated that the development, maintenance, and ongoing clinical management of these processes represent significant costs to ESRD facilities to hire and continuously employ clinical leaders across ESRD facilities and educate and train clinical staff on evolving educational protocols and educate beneficiaries on complex clinical issues. They noted that although ESRD facilities certainly already employ many clinicians, the expansion of the bundled payment to include phosphate binders represents an expansion of the duties their clinical teams need to undertake, which will result in an expansion of their clinical teams. They stated that ASP would not cover any of these clinical operations expenses required for ESRD facilities to take on the responsibility of managing the phosphate binders for ESRD patients.

Response: As discussed in the CY 2016 ESRD PPS final rule (80 FR 69010), we issued sub-regulatory guidance that instructs ESRD facilities to include all composite rate drugs and biological products furnished to the beneficiary on the monthly claim form (Change Request 8978, issued December 2, 2014). In CY 2015 ESRD PPS final rule (79 FR 66149 through 66150), we discussed the drug categories that we consider to be used for the treatment of ESRD with the expectation that all of those drugs and biological products would be reported on the claim. Along with capturing cost to align payment with resource use, we expected that ESRD facilities would be aware of all renal dialysis service drugs and biological products being taken by their dialysis patients in the event of a medical adverse event during dialysis. In addition, the ESRD QIP includes measures for coordination of care in the Care Coordination domain, which accounts for 30 percent of an ESRD facility's Total Performance Score. The QIP also includes a reporting measure for dialysis events. We have heard from interested parties that they are aware of and manage, with the patient's physician, the drugs and biological products taken by their ESRD patients. Therefore, CMS does not believe that the management of phosphate binders done in conjunction with the ESRD patient's physician, represents a new clinical administrative responsibility.

CMS will continue monitoring beneficiary utilization of phosphate binders, as well as beneficiary health outcomes that might be related to phosphate binder treatment, as it includes these drugs in the bundled payment. In addition, CMS is monitoring these metrics across beneficiary characteristics, including race or ethnicity and dual eligibility status, to ensure that vulnerable populations are not harmed by this change.

Comment: A coalition of dialysis organizations commented on the ESRD facilities' responsibility to educate ESRD beneficiaries on an ongoing basis. They stated that the migration of Medicare payment for phosphate binders from Part D to Part B would be a significant change for beneficiaries.

For some, this change would start with ensuring they understand that their phosphate binders will now be managed by their ESRD facility rather than through their local pharmacy. However, the commenter noted that some beneficiaries may experience a change in their recommended prescription related to the change from their prior drug coverage and will need clinical, dietary, and social work education in support of that change.

Response: Under the CfCs for ESRD facilities (73 FR 20480), the standard for patient education located at § 494.90(d) mandates that the plan of care include education and training for patients and family members or caregivers or both, in aspects of the dialysis experience and dialysis management, which includes medications they are taking. The plan of care would include a change in a patient's recommended prescription and would include the need for clinical, dietary, and social work education in support of that change. ESRD beneficiary education is a longstanding CfC requirement.

Comment: An LDO expressed appreciation of CMS's interest in exploring options for paying providers for costs in addition to the drug acquisition costs and acknowledgement that drug dispensing fees were included in the original bundling of oral drugs in 2011. An interested party requested that CMS consider the incremental operational costs involved when adding phosphate binders to the ESRD bundled payment, noting that the current proposal does not account for these costs, which could lead to increased financial strain on ESRD facilities. The commenter stated that a fair dispensing fee or a similar mechanism should be implemented to cover these additional expenses.

An LDO and a health care system requested CMS to consider that payment at 100 percent of ASP is inconsistent with Part B drug payment generally, where providers are typically paid at 106 percent of ASP percent or receive additional dispensing fees for certain drugs. Numerous commenters agreed that CMS should finalize the TDAPA payment for phosphate binders at 106 percent of ASP, rather than 100 percent of ASP, to account for additional facility incremental operational costs. One LDO stated that they strongly believe the savings CMS will obtain from including these drugs in the ESRD PPS bundled payment will cover the additional costs associated with appropriately recognizing dispensing and other incremental operational costs. The non-profit dialysis organization also recommended that beginning January 1, 2025, CMS should begin collecting and analyzing data to inform a mid-year correction to the TDAPA amount if data suggest that 106 percent of ASP is insufficient.

MedPAC commented that CMS should maintain its existing TDAPA policy to incorporate oral-only phosphate binders into the ESRD PPS. The commission wrote that in their comment in the CY 2019 ESRD PPS proposed rule, they stated that the 106 percent of ASP policy that is applied to many Part B drugs was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices.[51] MedPAC stated that while the ASP payment policy never stated what cost the ''+6 percent'' was intended to cover, they noted that payment to ESRD facilities is considerably different from payment to physicians. MedPAC stated that the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for ESRD facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC believed that rationale was diminished for ESRD facilities. In their comment letter, MedPAC referenced their comment on the CY 2019 ESRD PPS proposed rule, that setting the TDAPA at 100 percent of ASP appears to be a well-founded policy. Further, they stated that as CMS explained when the agency reduced the TDAPA amount for calcimimetics in CY 2020 from 106 percent of ASP to 100 percent of ASP, setting the payment level with the average sales price of the drug limits the financial burden on beneficiaries and taxpayers.

Response: As discussed previously, CMS agrees with MedPAC that the 106 percent of ASP policy was developed to reimburse physicians for the cost of drugs and that the TDAPA is an add-on payment adjustment to the ESRD PPS base rate, which already accounts for the cost of storage and administration of renal dialysis drugs and biological products. However, we also recognize that there are incremental operational costs with inclusion of phosphate binders into the ESRD PPS, that were not factored into the original payment policy. As described later in this section, CMS is making a provision for an increase in the calculation of the amount for the TDAPA for phosphate binders through a flat rate addition for two years to account for these unforeseen incremental operational costs.

Comment: A hospital association requested that CMS pay ESRD facilities for the costs associated not only with drug acquisition, but also with storing, managing and distributing oral drugs that are not consumed with the treatment. An LDO noted that in the proposed rule, CMS suggests that payment for phosphate binders at 106 percent of ASP may be appropriate for the 2-year TDAPA period. The LDO and a drug manufacturer agreed that this approach would be consistent with CMS policy for calcimimetics and would also be consistent with Part B drug payment policies generally. However, a non-profit treatment and research center stated that for some phosphate binder medications like sevelamer and calcium acetate, the 6 percent above ASP likely will not cover the costs they will have to pay to the pharmacy, much less the costs incurred when their registered nurses dispense the medications to the patients, provide counseling about the medications and answer any questions patients may have.

To maintain consistency with the treatment of calcimimetics during their first 2 years of TDAPA, to align with the way Medicare pays for drugs and biological products under the Hospital Outpatient PPS's pass-through payment policy, and to minimize administrative burden on CMS and ESRD facilities, multiple commenters recommend that CMS adopt the methodology outlined in section 1847A of the Act, which sets payment at the 106 percent of ASP; if ASP is not available, the payment is based on the Wholesale Acquisition Cost (WAC). Alternatively, an LDO urged CMS to use the flat rate part B supply fee for oral drugs under the Physician Fee Schedule as a precedent to provide the same payment adjustment for oral Part B renal dialysis drugs.

MedPAC opposed the TDAPA amount based on 106 percent of ASP for phosphate binders in their comment and noted that when CMS reduced the TDAPA amount for calcimimetics in CY 2020 from 106 percent of ASP to 100 percent of ASP, MedPAC stated that CMS explained that setting the payment amount at 100 percent of ASP of the drug limits the financial burden on beneficiaries and taxpayers.

Response: Consistent with our discussion in the CY 2020 ESRD PPS final rule (84 FR 60675), we continue to

[51] Medicare Payment Advisory Commission.2018. MedPAC comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2019. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.*

believe that 100 percent of ASP is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category, because there are already dollars in the per treatment base rate for the new drug's respective functional category. We further believe 100 percent of ASP is a reasonable basis for the TDAPA amount for new renal dialysis drugs and biological products that do not fall within an existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products. However, we note that the original analysis in the CY 2011 ESRD PPS final rule excluded phosphate binders, which are a longstanding renal dialysis service, and their associated costs, so a higher payment amount to capture these additional costs would be warranted. In addition, we believe the 106 percent of ASP payment could induce ESRD facilities to choose the higher priced phosphate binders for the higher payment rate. As detailed below, CMS is increasing the TDAPA amount for phosphate binders for two years in an amount similar to 106 percent of ASP to pay for the additional incremental operational costs of phosphate binder inclusion in the ESRD PPS while striking a balance between accessibility and efficiency and economy for the Medicare program.

Comment: Numerous commenters stated that CMS should adopt a dispensing fee using a rate of 106 percent of ASP for phosphate binders to align the ESRD PPS policies with those applied to other Medicare providers. They stated that both the Medicare Part D and Medicaid programs provide for dispensing fees. Under Part D, they noted that the dispensing fees are set through negotiations between the plan and pharmacy. Medicaid amounts are significantly higher and in the range of $9 to $12 per prescription, which the commenter noted would translate into a $0.69 to $0.92 per treatment amount in the context of the ESRD PPS, according to an analysis cited by the commenter. The commenters also noted that in accordance with section 1861(s) of the Act, Medicare Part B includes a $24 dispensing fee, which would be approximately $1.85 per treatment in the ESRD PPS context. Additionally, the commenters stated that according to the Medicare Claims Processing Manual, Chapter 17, § 90.4, CMS also provides a dispensing fee to hospital outpatient departments (HOPD) and ambulatory surgical centers (ASC), but relies upon 106 percent of ASP rather than a flat rate. The commenters stated that CMS decided to maintain the 106 percent of ASP policy in the HOPD and ASC settings after conducting a multi-year analysis of hospital cost reports. This analysis sought to determine the average overhead costs associated with providing drugs to patients, and CMS decided to adopt 106 percent of ASP as the payment amount. The commenters indicated that even though in the context of some HOPD/ASC products the add-on may result is higher payment amounts, CMS adopted this approach because of its administrative simplicity. Similarly, in these settings, the commenters stated that CMS also has adopted 106 percent of ASP as the basis for paying for separately payable non-pass-through drugs. One criterion a drug must meet to receive this separate payment is that the cost exceeds $135 per day.

The commenters stated that adopting a 106 percent of ASP policy as the basis of a dispensing fee rate would also align with the treatment of drugs in these other payment systems. They indicated that one analysis of phosphate binders demonstrates that the increase in per treatment payment for a 30-day supply of a phosphate binder could range from $1.46 to $8.03. The commenters stated that these amounts are not significantly different than those CMS finds acceptable in the HOPD/ASC setting or the other dispensing fee programs.[52]

The commenters requested that CMS adopt the 106 percent of ASP policy that it relies upon in other parts of the Medicare program, which the commenters described as straightforward and transparent.

Response: As CMS stated in the CY 2020 ESRD PPS final rule (84 FR 60676), we believe moving from pricing methodologies available under section 1847A of the Act, (106 percent of ASP) to 100 percent of ASP for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary co-insurance) and addressing stakeholder concerns discussed in section II.B.1.e of the CY 2019 ESRD PPS final rule (83 FR 56932). As an example of how the flat addition to the TDAPA amount would impact beneficiary copayment when compared to 106 percent of ASP, if a beneficiary's monthly utilization for a given phosphate binder totaled $1,000 (100 percent of ASP) + $36.41= $1,036.41, the beneficiary co-pay would be $207.28. However, if the same phosphate binder were to be paid a TDAPA amount derived from 106 percent of ASP ($1,000 * 1.06 = $1,060), then the beneficiary's copay would be $212 ($1,060 * 0.20 = $212). During the CY 2024 ESRD PPS rulemaking cycle, CMS indicated that it preferred to adopt policies that are less complex and more transparent. As noted later in this section of the preamble, we are finalizing the incorporation of a flat-rate add-on amount to the TDAPA, as allowed by section 1881(b)(14)(D)(iv) of the Act, for phosphate binders, which we believe reflects a similarly transparent and straightforward approach. We believe this fixed addition to the TDAPA amount for phosphate binders is relatively simple while being more predictable and more transparent than the requested 106 percent of ASP methodology, because ESRD facilities would not have their additional payment based on the ASP of the drug prescribed. Additionally, this fixed increase methodology would achieve many of the benefits described by commenters without incentivizing use of higher-cost phosphate binders.

Comment: Commenters generally agreed that payment of 100 percent of ASP would be insufficient to cover the incremental operational costs of including phosphate binders in the ESRD PPS bundled payment. In their comments letters, both MedPAC (citing their 2023 Report to Congress) [53] and LDOs have recognized the inherent incentives that a percentage-based payment policy creates in encouraging use of higher cost drugs when less expensive therapeutic alternatives are available.

A coalition for dialysis organizations recognized that utilizing 106 percent of ASP ties the value of the dispensing fee to ASP, which may present issues where ESRD facility incremental operational costs exceed 6 percent of ASP. They stated that they understand why some other payment systems have instead provided fixed dispensing fees that are intended to reimburse for incremental operational costs independent of ASP and arrive at the fixed dispensing fee through different mechanisms, including some that are set in statute.

Although MedPAC did not support setting the TDAPA amount at 106 percent of ASP to account for dispensing fees, which are intended to cover reasonable costs that are directly

[52] MedPAC. *Report to the Congress: Outpatient Dialysis Services* (Mar. 2024).

[53] Medicare Payment Advisory Commission.2023. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC:MedPAC.

related to providing the drug,[54] MedPAC did state in the comment that there is no consensus on the original intent of the percentage add-on to ASP. MedPAC stated that if CMS elects to include a dispensing fee in the TDAPA for phosphate binders, the agency should examine the dispensing fees for phosphate binders paid under Part D to assess if such data are appropriate to use under the ESRD PPS, noting that, in 2021, the median Part D dispensing fee was $0.50 per claim for the six common types of phosphate binders furnished to beneficiaries on dialysis. In their comment letter, the Commission indicated that it has also found that under Part D, dispensing fees for generic drugs are typically a fixed dollar amount (that is, not always related to the price of the product), and that similar to dispensing fees paid in the commercial sector, Part D plans typically pay dispensing fees of $1 per claim or less.[55] As an alternative to 106 percent of ASP, the LDOs, coalitions of dialysis organizations and the professional association of nephrologists would also support, and there is precedent for, a flat rate addition to the ASP. One LDO recommended a flat fee instead of a percentage of the cost of the medication. The LDO stated that dispensing expenses do not fluctuate based on the cost of the medication. The commenter estimated that dispensing fees would be roughly $11 and shipping fees would be approximately $15 per prescription. Other commenters stated that for certain conditions, Medicare Part B covers outpatient prescription drugs and biological products when they are part of a physician's service or used with covered durable medical equipment. For those drugs, Medicare Part B pays pharmacies a supply fee for each prescription. The commenters referred to 42 CFR 414.1001 and stated that pharmacies are paid $24 for the first 30-day period, and $16 for each subsequent 30-day period. On a per treatment basis, this would equate to approximately $1.23 to $1.85 when a patient receives 13 treatments in a month. Commenters suggested that CMS should recognize that under Part B, ESRD facilities will be required to pay for these pharmacy services.

Response: CMS has reviewed all of the comments regarding implementation of the inclusion of phosphate binders in the ESRD PPS bundled payment. In the CY 2016 ESRD PPS final rule, we stated that for at least 2 years we will pay for the existing oral-only drugs—phosphate binders and calcimimetics—using the TDAPA, which will be calculated based on the payment methodologies under section 1847A of the Act (80 FR 69027), which can include 106 percent of ASP. Following finalization of the CY 2016 ESRD PPS final rule, the regulation at § 413.234(c)(2) stated the TDAPA is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product is available, but not for less than two years. In the CY 2019 ESRD PPS final rule CMS stated that to balance the price controls inherent in any PPS we believe that we needed to take numerous issues into consideration to revise the basis for TDAPA payment. These issues included the use of the best available data, the avoidance of use of the highest price drugs for higher payment, and cost-sharing for beneficiaries. We noted that we are, and will continue to be, conscious of ESRD facility resource use and recognize the financial barriers that may be preventing uptake of innovative new drugs and biological products.

Therefore, we proposed to revise § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we would base the TDAPA payments on 100 percent of ASP instead of the pricing methodologies available under section 1847A of the Act (which includes 106 percent of ASP)(83 FR 56943–56944).

As we discussed previously, we believe that a flat increase to the TDAPA amount for phosphate binders would be most appropriate. We believe an increase in the payment adjustment amount that approximates 6 percent of ASP would provide the appropriate payment for incremental operational costs associated with ESRD facilities furnishing phosphate binders. We considered the differences in the availability of data for calculating the appropriate TDAPA amount for calcimimetics and phosphate binders. Prior to the TDAPA payment for calcimimetics in CY 2018, only those ESRD beneficiaries with Part D had access to the oral calcimimetic, Sensipar, but there was no utilization data for the injectable calcimimetic, Parsabiv, which would serve as a substitute for the oral calcimimetic. However, CMS was able to obtain data on phosphate binder utilization among ESRD PPS beneficiaries who had Part D coverage for phosphate binders to estimate expenditures, and there is no injectable phosphate binder for which we do not have utilization data. Therefore, with the knowledge of utilization of phosphate binders in Part D, coupled with the percentage of ESRD PPS beneficiaries who do not have Part D coverage, we believe we have adequate data to be able to calculate an appropriate amount to pay the TDAPA for phosphate binders for at least two years. Taking into account the estimates that were put forth by the commenters for the incremental operational costs to the ESRD facilities for supplying the phosphate binders to the ESRD facilities, along with our use of the Part D data, we have determined that a fixed amount derived from 6 percent of ASP of a monthly weighted average of the six most common phosphate binders based on past Part D utilization data best aligns payment with resource use and mitigates the incentive to use of the most expensive phosphate binders to obtain higher TDAPA payment and ultimately a higher dollar addition to the ESRD PPS base rate at the end of the TDAPA period. This aligns with the commenters' suggestions of using a flat rate adjustment instead of 106 percent of ASP. We are finalizing a flat rate increase to the TDAPA amount for phosphate binders, derived from 6 percent of the weighted average of Medicare expenditures for phosphate binders per month under Part D, for the first two years of TDAPA payment to ESRD facilities. The CY 2025 flat rate increase to the TDAPA amount will be $36.41. This payment adjustment is included for every monthly ESRD PPS claim that includes phosphate binders. We will consider changes to this amount through future rulemaking if appropriate; for example, this amount could be recalculated derived from the best available updated data for the second year of TDAPA payment for phosphate binders, potentially utilizing data from Part B.

Additionally, we are finalizing regulatory language at 413.234(c)(4), which states that we would pay an increased amount through the TDAPA for phosphate binders for two years. The increase to the TDAPA amount would be the equivalent of the monthly weighted average of 6 percent of ASP, calculated for each of the first two years of TDAPA payment for the phosphate binders.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists and a non-profit treatment and research center

[54] Under 42 CFR 423.100, dispensing fees are costs incurred at the point of sale in excess of the ingredient cost of a covered Part D drug. Dispensing fees include pharmacy costs such as checking insurance status, performing quality assurance, physical delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment.

[55] The Commission's calculation is based on Part D prescription drug event data from CMS. According to our stakeholder interviews, this amount is in line with most commercial insurance. *https://www.medpac.gov/wpcontent/uploads/2023/10/Generic-prices-Part-D-April-2024-SEC.pdf.*

stated that, due to the 2 percent reduction in Medicare FFS payments under sequestration, 100 percent of ASP equates to roughly ASP minus 1.6 percent, which the commenters stated does not cover the cost of acquiring phosphate binders. They commented that many medium and small ESRD facilities do not have the economies of scale and must purchase drugs at a significant percentage above the ASP. As a result, 100 percent of ASP is actually less than the acquisition cost of these drugs and will have a negative financial impact on these ESRD facilities. A non-profit treatment and research center noted that since the ASP is reduced by 1.6 percent because of the sequestration cuts, the gap between resource use and payment is even greater. A professional organization of dialysis providers and an LDO stated that Medicare only pays 80 percent of costs. For patients who are dual eligible receiving Medicaid, this remaining 20 percent goes unreimbursed, which, following sequestration, equates to 78.4 percent. Similar results would occur for patients without a secondary insurance if they are unable to pay the remaining 20 percent cost-sharing amount. An LDO asserted that for patients without secondary insurance, only 60 percent of the nonpayment is covered by bad debt.

Response: We appreciate the commenters' concerns about payment adequacy; however, we noted that these concerns generally fall outside the scope of ESRD PPS policy. Sequestration is a mandatory spending reduction that affects Medicare Part B payments broadly, including payments under the ESRD PPS.[56] Reductions in Medicare payments due to sequestration fall outside the scope of the ESRD PPS policy and are required under the Budget Control Act of 2011 (BCA; P.L. 112–25). In addition, the 20 percent beneficiary copayment amount is required by statute, and we did not propose any changes to this amount. Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent coinsurance after the deductible (and Medicare pays 80 percent). With respect to renal dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(A) of the Act, Medicare pays 80 percent of the total amount per treatment and the individual pays 20 percent (74 FR 50005). Some dual eligible beneficiaries could have their coinsurance reimbursed via Medicaid in some circumstances.[57]

Similarly, we did not propose any changes to the ESRD PPS bad debt policy, which is also dictated by statute. For instance, we have long interpreted Title I, section 153(b)(4) of MIPPA as providing that bad debt payments are available only for covered services under the composite rate.[58] In addition, section 1861(v)(1) of the Act, implemented at §§ 413.89 & 413.215(b), imposes certain reductions in the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts. Currently, general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and co-insurance are found in chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15–1) and cost reporting worksheets and instructions in the PRM Part 2 (CMS Pub. 15–2).

We acknowledge that some ESRD facilities may pay more or less than ASP for renal dialysis drugs and biological products that they purchase, since ASP represents an average, but we note that payment of the TDAPA based on ASP is consistent with the principles of prospective payment underlying the ESRD PPS more broadly. As stated earlier in this final rule, we are finalizing an increase to the TDAPA amount for phosphate binders to account for certain administrative costs not included in the ESRD PPS base rate, but this increase is not intended to account for sequestration costs, beneficiary copayment amounts, or bad debts.

Comment: Coalitions of dialysis organizations requested that CMS address what they consider to be a gap in the current Medicare guidance to support including phosphate binders into the ESRD PPS bundled payment. Specifically, regarding the reporting of oral drugs, the coalition notes that the current Medicare Benefit Policy Manual states that for oral or other forms of renal dialysis drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.[59] A non-profit treatment and research center stated that patients will be given all of their medications at one time, presumably a few days before the start of a new month. They noted that if a patient misplaces the medication, they will need to obtain a new supply from the ESRD facility. Since the ESRD facility is not paid for the lost medication, the lost medication will cost the ESRD facility significant money. The commenter also stated that the doses prescribed for these medications depend on blood tests which are performed monthly, typically during the mid-week dialysis treatment of the first week of the month. The results become available a few days later and are then reviewed by nephrologists who may prescribe dose changes in phosphate lowering medication or may prescribe a different phosphate lowering medication. In that case, the ESRD facility would have to provide the patient an additional supply of medication and would have to pay additional fees to the pharmacy. In the event the medication is changed, the facility would again not be paid for the unused medication. A professional organization of nephrologists stated that ESRD facilities absorb the costs of unused medications when patients are hospitalized, transfer to other facilities, die, or receive a kidney transplant. A coalition of dialysis providers provided additional illustrative examples of when the current payment policy does not work financially for ESRD facilities, including patient hospitalization or when the patient is on vacation over 30 days, patient death and changes in ESRD facility. To align the reporting and payment with similar provisions for hospitals and skilled nursing facilities (SNFs), coalitions of dialysis organizations referred to the Medicare Claims Processing Manual, Chapter 17, § 90.4 and requested that CMS require reporting on claims of one of the following:

- Both the quantity of the drug expected to be taken during the claim billing period and any unused quantity of drug that was prescribed under a prescription that was later revised.
- The total amount of the drug provided during the claim billing period.

The coalition of dialysis providers claimed that these changes would alleviate the financial losses to ESRD

[56] A general description of Medicare sequestration from the Congressional Research Service is available at *https://sgp.fas.org/crs/misc/R45106.pdf*.

[57] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/medicare_beneficiaries_dual_eligibles_at_a_glance.pdf*.

[58] See the November 17, 2004 Decision of the Administrator (*https://www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/Downloads-3/2004-D43.pdf*) and Medicare Benefit Policy Manual, Chapter 11, § 80 (*https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf*).

[59] Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease § 20.3.C.

facilities. The commenter stated that these changes do not need to be included in the CY 2025 final rule but can be done through guidance prior to the end of CY 2024 to apply to the forthcoming inclusion of phosphate binders in the ESRD PPS bundled payment to limit unnecessary losses for an already strained payment system. The commenter also stated that making these changes to the billing rules is also necessary for CMS to have accurate utilization data of the phosphate binders during the TDAPA period for the purpose of future rate setting exercises. The commenter believes that without these changes, not only will ESRD facilities experience real-time losses due to circumstances outside their control, but those losses will be baked into depressed utilization data used to update the base rate after the end of the TDAPA period for the phosphate binders, locking those losses into the ESRD PPS in perpetuity. In addition, the commenter noted that other providers, including hospitals, pharmacies and skilled nursing facilities, are all permitted by Medicare to submit claims for the full prescription dispensed in good faith to the beneficiary. They requested that CMS align the ESRD PPS billing policies with that of other health care providers rather than imposing what they characterized as unique and unnecessary burdens on a fragile payment system serving the most vulnerable patients.

Response: CMS thanks the commenters for their recommendations. Per the regulation at § 413.198(b)(5), each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. At § 413.198(b)(5)(ii), this includes information reported on ESRD PPS claims about the total number of billing units (or the expected number of billing units), for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217(b), which includes home dialysis services, support, and equipment as identified in § 410.52, to be included in the ESRD PPS effective January 1, 2011.

As we noted previously in this section, in the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We did not propose a change to the reporting requirements regarding the drugs expected to be taken during the claim billing period and any unused quantity of that drug that was prescribed under a prescription that was later revised, along with the total amount prescribed during the billing period. However, we thank the commenter for their suggestions and will take the commenter's suggestions into consideration in future rulemaking. Discarded drugs or biological products that are not in single use containers or single dose packaging are not billable under the ESRD PPS.[60] Similarly, we believe it would be most appropriate to make a future modification to the ESRD PPS base rate, if warranted, based on actual phosphate binder utilization and not discarded amounts. We expect that ESRD facilities will employ strategies to reduce discarded amounts of phosphate binders, which best serves the interest of efficient resource use and is consistent with the goals of the ESRD PPS.

Comment: A coalition of dialysis organizations recommended that CMS should amend the cost reports and update billing and payment policies in advance of the TDAPA period for phosphate binders. The current ESRD Facility Cost Report revision includes one line item for the TDAPA and one line item for the TPNIES. At the time this was implemented, there was only one drug receiving the TDAPA and one supply item receiving the TPNIES. At present and in the coming years, the commenter expects there will be multiple drugs and devices receiving the TDAPA and the TPNIES in the same year. The commenter stated that CMS and other policymakers would find it important and useful to be able to track costs associated with individual products receiving the TDAPA and TPNIES rather than have them reported in the aggregate. The commenter recommended that CMS add several line items for each of the TDAPA and TPNIES reporting sections and provide instructions that each product receiving the TDAPA or the TPNIES are to be reported separately on their distinct line-items. The commenter stated that CMS should also ensure that ESRD facilities have clear instructions for reporting the TDAPA for phosphate binders during the TDAPA period and that facilities have clear instructions for reporting the phosphate binders after they are bundled into the base rate after the end of the TDAPA period. The commenter stated that it is imperative that CMS amend the cost report and instructions in advance of the launch of the TDAPA period and end of the TDAPA period to ensure the integrity of dialysis facility cost reporting.

Further, the coalition requested CMS to make changes to billing procedures to make it easier for ESRD facilities to identify the correct TDAPA and TPNIES payments to report on the cost report. At present, they state that when CMS pays a claim that includes the TDAPA or TPINIES, ESRD facilities simply receive one payment for the adjusted base rate plus the TDAPA or TPNIES amount. The TDAPA or TPNIES is not indicated on a separate line item by CMS. The coalition stated that while the ESRD PPS is a bundled payment system with a standardized base rate, most claims are adjusted based on a dozen patient and facility characteristics. As a result, the commenter stated that to accurately report TDAPA and TPNIES payments on the Cost Report, ESRD facilities need to crosswalk each reimbursement to relevant patient claims or medical records to identify those for whom TDAPA or TPNIES payment was requested, then determine if and at what amount the TDAPA or TPNIES was paid, noting that the TDAPA and TPNIES payment amount fluctuates over the course of the year, and then report those figures on the cost report on an ESRD facility basis. For some ESRD facilities this is a manual, and not an automated exercise. The commenter requested that CMS amend billing and payment procedures to flag TDAPA and TPNIES payments separately on an itemized report so that ESRD facilities can more effectively and efficiently identify and flag these items for accurate reporting onto the Cost Report.

Response: CMS thanks the commenters for their suggestions regarding the cost reports. We are currently evaluating changes to the ESRD PPS cost reports and will take these suggestions into consideration for future cost report modifications.

Comment: A drug manufacturer questioned why the phosphate-lowering agent XPHOZAH® is receiving disparate treatment from phosphate binders with respect to the TDAPA. The drug manufacturer stated that they view CMS as treating XPHOZAH® similar to a phosphate binder for the purposes of inclusion in the ESRD PPS bundled payment, but different from a phosphate

[60] In the CY 24 ESRD PPS final rule, we finalized a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-dose container and single-use package renal dialysis drugs and biological products paid for under the ESRD PPS, effective January 1, 2025 (88 FR 76346, 76383–76386).

binder for the purposes of a potential increase to the ESRD PPS base rate after the end of the TDAPA period.

Response: Existing Medicare regulations state that effective January 1, 2025, oral-only drugs will be paid for under the ESRD Prospective Payment System (PPS). Although oral-only drugs are not included in the ESRD PPS bundled payment until January 1, 2025, they are currently recognized as renal dialysis services as defined in regulation. Accordingly, CMS is planning to incorporate oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, using the TDAPA, as described in the calendar year (CY) 2016 ESRD PPS final rule (80 FR 69027) and subsequent rules. In the CY 2022 ESRD PPS final rule (87 FR 67179) we stated that we finalized and issued 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 manufacturer's press release on October 17, 2023, they noted that XPHOZAH® is a phosphate-lowering therapy, and it is not a phosphate binder.[61]

As for the commenter's concern regarding CMS's treatment of XPHOZAH® with respect to a potential increase in the ESRD PPS base rate after the end of the TDAPA period, we note that we have been consistent in treating XPHOZAH® as an oral-only drug that is considered included in the ESRD PPS base rate because it falls within the bone and mineral metabolism ESRD PPS functional category. XPHOZAH® is a renal dialysis service under the definition at § 413.171 and is to be included in the ESRD PPS bundled payment effective January 1, 2025, according to § 413.174(f)(6). Any other oral renal dialysis drug or biological product without an injectable equivalent or other form of administration would also be included in the ESRD PPS bundled payment effective January 1, 2025. We note that XPHOZAH®, should it apply for the TDAPA, would receive the same consideration and treatment as other renal dialysis drugs and biological products in existing ESRD PPS functional categories which are considered included in the ESRD PPS base rate. In the CY 2016 ESRD PPS final rule we explained that we would modify the ESRD PPS base rate after the end of the TDAPA period only for calcimimetics and phosphate binders, but that we would not follow this process for any other potential future oral-only drugs in the bone and mineral functional category or any other functional category, as calcimimetics and phosphate binders were the only two drugs for which 2007 utilization data was available at the time the ESRD PPS base rate was first developed for which payment was delayed (80 FR 69025). In particular, the intention behind CMS's policy is that funds would be added to the base rate to account for phosphate binders because the costs associated with phosphate binders would have been included in the initial calculation of the base rate in CY 2011 if not for CMS's (and subsequently congress') decision to temporarily delay their inclusion. However, the delay was always with the intention that the costs would eventually be included in the ESRD PPS base rate. This is not true of other drugs or biological products that were not in use in the timeframe analyzed for the initial development of the ESRD PPS base rate, but that are considered included in the base rate because they fall within an existing functional category.

From a policy perspective, the ESRD PPS bundled rate is intended to encourage efficient resource use, and CMS therefore only would add funds, if appropriate, to the base rate for drugs that have a new function not accounted for when the initial base rate was developed or, in the case of calcimimetics and phosphate binders, that were intended to be included at the time the base rate was first developed but were temporarily excluded. As discussed previously, XPHOZAH® is not a phosphate binder (nor is it a calcimimetic), so under our established methodology it would be treated in the same way as all other new drugs (80 FR 69027). We note that any specific considerations regarding modification of the ESRD PPS base rate to account for phosphate binders, such as whether to incorporate data from drugs or biological products with a similar end-action effect that may be a substitute for phosphate binders, will be made through notice and comment rulemaking in the future. We will consider the commenter's suggestions related to how the ESRD PPS treats new renal dialysis drugs and biological products in existing functional categories which are considered included in the base rate for potential future rulemaking related to TDAPA and other payment policies under the ESRD PPS.

Comment: Some commenters expressed support for a delay for the inclusion of either oral-only drugs and biological products or phosphate binders, in the ESRD PPS bundled payment. We received 110 form letters from unique submitters that did not relate to policies proposed in the CY 2025 ESRD PPS proposed rule, but rather expressed support for -draft legislation that would delay the inclusion of certain oral-only drugs and biological products into the ESRD PPS bundled payment. One drug manufacturer requested CMS refrain from incorporating phosphate-lowering therapies into the ESRD PPS in January 2025. The drug manufacturer suggested that CMS should respond to stakeholder concerns regarding access issues and public health data on harms to patients.

Response: We did not propose any changes to § 413.174(f)(6) to modify the date of the incorporation of the oral-only drugs into the ESRD PPS. We note that in the CY 2011 ESRD PPS final rule we stated that the delay in incorporating oral-only drugs into the ESRD PPS bundled payment would allow additional time to address several issues including the following: the determination of oral-only drug pricing and utilization; adequate beneficiary education; assessment of potential problems which may arise in connection with the provision of oral drugs prior to the system's expansion to include oral-only drugs; analysis regarding the ability of ESRD facilities to provide oral-only ESRD drugs; and, evaluation of indicators applicable to the monitoring of certain patient conditions treated with oral-only drugs, such as bone loss and mineral metabolism associated with the provision of calcimimetics and

[61] *https://ir.ardelyx.com/news-releases/news-release-details/fda-approves-xphozahr-tenapanor-first-class-phosphate-absorption.*

phosphate binders, which could assist in determining the impact of the fully bundled ESRD PPS, and any unintentional consequences that might ensue, on quality of care (75 FR 49043 through 49044). CMS has actively been engaged in addressing the aforementioned issues since that rule was finalized 13 years ago in preparation for inclusion of the oral-only drugs into the ESRD PPS. Our data analysis has shown that because not all ESRD PPS beneficiaries have had Part D coverage some have lacked equal access to either calcimimetics or phosphate binders. Inclusion in the ESRD PPS bundled payment provides patients access to all the drugs and biological products in all the ESRD PPS functional categories, including those included in the bone and mineral metabolism functional category, averting potential harm to those Medicare beneficiaries currently lacking access to some of those drugs and biological products.

Comment: A coalition for dialysis organizations recommended that CMS should align MA and ESRD PPS policies in advance of the TDAPA period for phosphate binders and future inclusion of phosphate binders in the ESRD PPS base rate to ensure MA beneficiaries will receive necessary medication.

Response: With respect to MA, per section 1852(a)(1) of the Act and its implementation regulations (42 CFR 422.100 and 422.101(a)), Medicare Advantage organizations (MAOs) must cover items and services, including drugs, for which benefits are available under Parts A and B in the Traditional Medicare program, subject to limited exclusions. We note that phosphate binders are not subject to the limited exclusions at section 1852(a)(1) of the Act and, therefore, must be covered by MAOs. Specifically, in accordance with section 1852(a)(1) if the Act and 42 CFR 422.100 and 422.101(a), and as noted in [62] section 10.4 of chapter 4 of the Medicare Managed Care Manual,[63] MAOs must provide coverage of, by furnishing, arranging for, or making payment for, generally all services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees. In addition, with respect to coverage of Traditional Medicare benefits such as Part B drugs, MAOs must comply with applicable Medicare statutes, regulations, national coverage determinations (NCDs) and local coverage determinations (LCDs) of Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan (42 CFR 422.101(b)). In general, an MA plan that offers Part D benefits (MA–PD) must determine whether payment for the drug is allocated under Parts B or D, consistent with Traditional Medicare and Part D program drug coverage policies (see Appendix C, Attachment II, Question 5 of Chapter 6 [64] Medicare Prescription Drug Benefit Manual for additional detail). Concerning how Part D sponsors will determine whether a drug is covered under Part B, it is important to keep in mind that in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy. A Part D sponsor cannot deny payment for a particular drug on the basis that it is covered under Part B in some instances and Part D in others unless there is Part B coverage as the drug is prescribed and dispensed or administered in that particular instance. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug. Regarding new drugs, as decisions are made nationally or by individual A/B MAC contractors, this information will be available on the CMS and contractor websites. MA–PD coordinated care plans must coordinate all benefits administered by the plan with respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D (42 CFR 422.112(b)(7)). As a result of the rules and regulations described here, MAOs must cover oral-only ESRD drugs under their plans, as these are drugs under Part B and are not subject to the limited exclusions under section 1852(a)(1) of the Act.

Final Rule Action: After consideration of all the comments received, we agree with commenters that there are additional costs associated with ESRD facilities furnishing phosphate binders that are not currently included in the ESRD PPS base rate and that were not addressed when the ESRD PPS base rate was developed in CY 2011. This differentiates phosphate binders from other drugs and biological products in existing ESRD PPS functional categories, which justifies a change to the TDAPA policy, as phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule due to a lack of data available at the time of rulemaking. Consistent with past policies, we consider drugs and biological products in existing ESRD PPS functional categories to be included in the ESRD PPS base rate. The ESRD PPS base rate includes money for the costs, such as dispensing fees, associated with furnishing other drugs (in existing functional categories) paid for using the TDAPA. We are finalizing to pay the TDAPA for phosphate binders at 100 percent of ASP, increased by a fixed amount calculated at an amount that we believe most appropriately approximates 6 percent of ASP. For CY 2025, as utilization data and ASP reporting are currently unavailable, we are finalizing to use the weighted average of Medicare expenditures for phosphate binders per month under Part D for all phosphate binders used in a month, based on estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries. For CY 2025, this amount is $36.41, which will be added to any monthly claim for which there is a TDAPA payment for phosphate binders. For CY 2025 and 2026, the TDAPA amount for a phosphate binder is based on 100 percent of ASP plus an additional amount based on 6 percent of per-patient phosphate binder spending derived from utilization and cost data.

We are finalizing two changes to § 413.234(c) to codify this change in TDAPA policy for phosphate binders. First, we are amending paragraph (c) to note that we would not pay the TDAPA at 100 percent of ASP in this circumstance by adding in language which reads ''except as provided in paragraph (c)(4) of this section.'' Second, we are adding paragraph (c)(4) which reads: ''For calendar years 2025 and 2026, the transitional drug add-on payment adjustment amount for a phosphate binder is based on 100 percent of ASP plus an additional amount based on 6 percent of per-patient phosphate binder spending derived from utilization and cost data.'' As discussed previously, for calendar year 2025, the additional amount is estimated based on the weighted

[63] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/chapter4-final-may2012_0.pdf*

[64] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

average of Medicare expenditures for phosphate binders per month under Part D for all phosphate binders used in a month, derived from estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries. . We intend to reevaluate this amount in rulemaking next year; for example, for calendar year 2026, we may consider updating the additional amount quarterly derived from the actual phosphate binder utilization and ASP reported under Medicare Part B in the most recently available quarter, if appropriate.

d. Expected Impact of Incorporation of Oral-Only Drugs

We anticipate that the incorporation of oral-only drugs into the ESRD PPS will increase access to these drugs for beneficiaries. We estimate that there will be an increase in Medicare spending as a result of this increase in access. Specifically, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs; increases in expenditures 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, with significant positive health equity impacts. For example, based on the results of our ESRD PPS monitoring analyses, in December 2017, prior to incorporation of calcimimetics into the ESRD PPS bundled payment, utilization was at 28.97 percent for African American/Black beneficiaries but went up to 35.31 percent in January 2018 and eventually to 39.04 percent in at the end of the TDAPA period for calcimimetics in December 2021. This 10.07 percentage point increase in utilization reflects the significant access improvement for African American/Black beneficiaries of incorporating formerly oral-only drugs into the ESRD PPS.

Lastly, as part of the preparation for the inclusion of phosphate binders into the ESRD PPS, CMS has monitored Part D utilization of, and spending for, phosphate binders. We have developed budgetary estimates of the changes in Medicare Part B and Part D spending, which are discussed in section VII.C.1 of this final rule.

8. Changes to the Low-Volume Payment Adjustment (LVPA)

a. Background on the LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility.

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type or as specified in paragraph (g)(6)) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1 attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume facilities based on a treatment threshold. After consideration of public comments, we originally established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that these ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of low-volume facility claims from CYs 2012 and 2013 and cost report data indicated a multiplier of 1.239; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). This update was implemented budget neutrally alongside numerous other changes to the case-mix and facility-level adjusters. In CY 2022, 352 ESRD facilities received the LVPA. Using the most recent available data for CY 2023, the number of ESRD facilities receiving the LVPA was 330.

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID–19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we only considered total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. In the CY 2024 ESRD PPS final rule (88 FR 76344), we finalized changes to the LVPA regulation at § 413.232 that allow ESRD facilities affected by disasters and other emergencies to qualify for

exceptions to certain eligibility requirements for the LVPA. Facilities may close and reopen if they experience an emergency, or they may temporarily exceed the 4,000-treatment threshold if they take on additional patients displaced by an emergency and still qualify for the LVPA.

(1) Current Issues and Concerns

As discussed in the CY 2025 ESRD PPS proposed rule, interested parties, including MedPAC and the GAO,[65] have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[66] These groups and other interested parties have also expressed concern that the strict treatment count used to determine eligibility introduces a ''cliff-effect'' that may incentivize ESRD facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.[67]

We considered several changes to the LVPA eligibility criteria to address the concerns that interested parties, including the GAO and MedPAC, raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. Section 1881(b)(14)(D)(iii) of the Act requires that the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our analysis found that isolated low-volume facilities do not face higher costs than other low-volume facilities. Therefore, we stated in the CY 2025 ESRD PPS proposed rule that we do not believe that this requested change reconciles with the central statutory requirements and limitations for the LVPA, and we stated that we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act. We noted in the proposed rule that we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, and facilities in rural areas, as set forth in § 413.233. To avoid overlap with these existing facility-level adjustments, we stated that we are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

In addition, interested parties expressed that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Some also viewed the attestation process as burdensome to ESRD facilities and believed it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.[68] Given these concerns, we considered alternative approaches to the LVPA that would reduce burden, remove negative incentives that may result in gaming, and better target ESRD facilities that are critical for beneficiary access.

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.[69] During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.[70] One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural facility adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a recommendation for a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three large dialysis organizations (LDOs), a non-profit kidney organization, and a provider advocacy coalition commented that the rural facility adjustment should be eliminated and a LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the reliance of the census tract methodology used by the rural facility adjustment upon 'driving time' as a data measure, noting this presents legitimate equity issues. ESRD facilities that have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment.[71]

In the CY 2022 ESRD PPS proposed rule LVPA RFI, we sought input on alternative approaches to the LVPA methodology (86 FR 36398 through 36399).[72] Specifically, we requested input on—(1) whether a distinction other than census tract information should be considered; and (2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility. Additionally, we explored the LVI adjustment that MedPAC recommended in its June 2020 Report to Congress. Under the LVI methodology, a determination that a facility is low volume and isolated would be based on that facility's distance from the nearest facility and its total treatment volume. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In

[65] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.*

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

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

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

[69] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

[70] *https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.*

[71] The materials from the TEPs and summary reports can be found at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural facility adjustment should be maintained. As previously discussed, our most recent analysis of cost report data does not support the claim that isolated low-volume ESRD facilities face higher costs than non-isolated ESRD facilities; therefore, the LVI methodology would not adhere to the statutory requirement for the LVPA set forth at section 1881(b)(14)(D)(iii) of the Act.

(2) CY 2024 RFI on Potential Changes to the LVPA

In the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), we issued a RFI regarding several possible modifications to the current LVPA methodology.[73] We provided commenters the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function. We received 23 comments in response to the RFI, all of which had differing opinions. A coalition of dialysis organizations recommended a two-tiered approach, while MedPAC reiterated their support for a LVI adjustment. A common theme among a handful of comments was concern about administrative burden and transparency regarding the methodology that is chosen. Most commenters believed that the issue of payment cliffs is substantial, but many did not believe any of the options presented in the RFI could successfully eliminate gaming completely. CMS will continue to consider these comments to potentially inform future rulemaking.

(3) CY 2024 RFI on the Rural Facility Adjustment

We have considered several changes to the LVPA eligibility criteria to address the concerns that the GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. As previously discussed, we do not believe the suggestion to consider facilities' geographic isolation reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act.

The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. Interested parties, including MedPAC and the GAO, have recommended that CMS make refinements to the LVPA and rural adjusters to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas. The GAO and MedPAC, among others, have also raised concerns about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities to protect access to care.

In the CY 2024 ESRD PPS proposed rule's LVPA RFI (88 FR 42441 through 42445), we solicited comments on a potential new payment adjustment that accounts for isolation, rurality, and other geographical factors, including local dialysis need (LDN). The LDN methodology, as described in the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), would consider LDN instead of basing payment strictly upon a rural designation, as provided for by §§ 413.233 and 413.231(b)(2). In the CY 2024 ESRD PPS proposed rule's LVPA RFI, we suggested the utilization of census tracts to identify geographic areas with low demand, then calculating latent demand by multiplying the number of beneficiaries near (''near'' was defined by driving time to ESRD facilities) an ESRD facility by the average number of treatments for ESRD beneficiaries. The threshold to qualify for the LVPA could then be applied by determining the amount of adjusted latent demand. The ESRD facilities that fall below the threshold would be eligible. The statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, and preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. Because of this, the LDN methodology would be implemented under the authority in 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.

We received 23 comments in response to the LVPA RFI, all of which had differing opinions.[74] Some commenters supported eliminating the rural adjuster and reallocating its funds to either the LVPA or to a new adjustment that considers LDN. Others stated the rural facility adjustment should be removed, and those dollars be incorporated into one of the tiered LVPA methodologies. Many commenters noted that a LVPA, a rural facility adjustment, and a possible LDN-based adjustment would be redundant. A coalition of dialysis organizations stated that CMS's reliance on zip codes to identify rural facilities is no longer an adequate proxy for facilities in need, and cited data that many rural facilities enjoy a large patient count and positive profit margins. Other commenters supported the rural facility adjustment, explaining that it was especially appropriate in conjunction with a modified LVPA methodology, since under the options presented by CMS in the RFI, many facilities would experience significant decreases in payment. They claimed that the additional funds provided by the rural facility adjustment would protect against the closure of rural facilities. Several commenters expressed concern about administrative burden and transparency in a general sense, no matter the methodology chosen.

Generally, commenters were opposed to a payment adjustment based on the LDN methodology, reiterating many of the concerns raised during the 2020 TEP. A coalition of dialysis organizations voiced the concern that the LDN methodology would take away providers' ability to make financial decisions about their operations, since they would not be able to predict their eligibility for the LDN payment adjustment nor the amount they would receive. They maintained that the LDN may not target the appropriate facilities and could provide opportunities for gaming. The coalition also claimed that the central issue faced by these facilities is low patient count, which they stated that the LDN methodology would not recognize, and thus the adjustment could be provided to facilities that are isolated, but have high patient counts, and are not in need of an additional payment adjustment. A coalition of dialysis organizations and a non-profit dialysis association both stated that the current LVPA provision to aggregate the treatments of facilities under common ownership that are not at least 5 miles apart is an important feature that discourages gaming, one that is not included in the LDN methodology. Furthermore, the coalition noted that the LDN methodology would lack stability, given that patient location varies over time. MedPAC suggested that if the LDN were adopted, CMS should ensure that the methodology is transparent; for example, making the

[74] *https://www.cms.gov/files/document/cy-2024-esrd-pps-lvpa-rfi-summary-comments.pdf.*

specifications and results for the regression equation available on CMS's website and in the **Federal Register**. In addition, MedPAC stated that CMS should note how often the model would be updated, discuss how census tract populations changing over time would affect the stability of the adjustment, and how the approach would address MedPAC's anticipated increase in home dialysis use.

In addition to the questions outlined in the CY 2024 ESRD PPS proposed rule LVPA RFI, as discussed in the CY 2025 ESRD PPS proposed rule, CMS has also considered incorporating isolation criteria into the rural facility adjustment, where payment of the adjustment could be limited to ESRD facilities that are isolated from other ESRD facilities, or a higher adjustment could be applied for isolated rural facilities than for non-isolated rural facilities. Alternatively, the current rural facility adjustment could be replaced by an adjustment based solely on isolation. We noted that recent analysis has confirmed that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. This analysis aligns with suggestions from various commenters, including MedPAC, to refine or remove the rural facility adjustment to better target ESRD facilities that are critical to beneficiary access and are likely not being adequately targeted under the current methodology. However, we noted that many ESRD facilities which receive the rural facility adjustment are critical to patient access and that these ESRD facilities may be relying on the additional payment from the rural facility adjustment for the coming years. As discussed in section II.B.2.f.(2) of this final rule, we proposed to implement a phase-out policy for ESRD facilities that lose the rural facility adjustment as a result of being redesignated from a rural area to an urban area in the most recent CBSA delineations. We are not finalizing any other changes to the rural facility adjustment in this final rule.

b. Tiered LVPA Methodology

The goals of the ESRD PPS (including the LVPA) are to align resource use with payment, advance health equity, and protect access to renal dialysis services for vulnerable beneficiaries in underserved communities, including rural and isolated communities, by increasing payments to certain ESRD facilities in these areas to align with their higher costs. As noted in the CY 2016 ESRD PPS final rule (80 FR 68967 through 69077), we aim to target the benefit of the LVPA to facilities that serve the access needs of patients in remote locations. In the CY 2022 ESRD PPS final rule (86 FR 61874 through 62026), we detailed our commitment to achieving equity in health care outcomes for our beneficiaries using the definition of equity set forth in Executive Order 13985,[75] which places emphasis on individuals who belong to underserved communities. In the CY 2023 ESRD PPS proposed rule RFI (87 FR 38464 through 38586), we reiterated our commitment to achieving equity in health care and noted that we aim to align ESRD facility resource use with payment. Recent feedback from interested parties indicates that the current LVPA payment structure may lead some ESRD facilities to treat fewer patients to avoid a payment cliff. Proposing a revised methodology that would reduce the incentive for gaming, as the GAO described, would help advance health equity by removing the incentive for some ESRD facilities to limit access to renal dialysis services. We would expand access through payments that incrementally align resource use with payment to ESRD facilities that furnish different volumes of treatment.

In the CY 2025 ESRD PPS proposed rule, we proposed to refine the LVPA methodology to include two tiers based on treatment volume with different payment adjustments for each tier. This methodology would be similar to the methodology described in the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), but with methodological changes to improve consistency in an ESRD facility's tier assignment from year to year.

We analyzed cost report data from ESRD facilities to develop the tiered thresholds and adjustment amounts for the proposed LVPA. This analysis used a logarithmic regression model that controls for various geographical and facility level characteristics, including facility type and region, to estimate cost differences based on treatment volume. We also simulated attestation patterns by excluding a stratified random sample of ESRD facilities who are eligible for LVPA payment but do not submit LVPA attestations. This step allowed us to account for the fact that a portion of ESRD facilities that were within the treatment volume threshold routinely did not attest to meeting the LVPA requirements for other reasons. We analyzed numerous different potential tiered payment structures based on this analysis, where the estimated cost for the tier uses the upper bound of the treatment count for that tier. Based on the results of this analysis, we proposed a two-tiered approach; we believe the two-tiered approach is appropriate because it strikes a balance between simplicity for ESRD facilities, sufficiently large tiers to allow for treatment volume variation from one year to the next, and payment adequacy for current low-volume facilities, particularly those with the lowest volume.

Table 9 presents our proposed two-tiered LVPA methodology, which is based on data from ESRD facility cost reports such that the reporting periods include some part of the period between January 1, 2020, to December 31, 2022 (that is, beginning or ending during these 3 CYs). We noted that we have required budget neutrality for any change to the LVPA methodology, so any proposed changes to the LVPA cannot increase or decrease total estimated ESRD PPS payments; therefore, the two sets of potential adjustment factors in Table 9 would be implemented budget-neutrally. The second column presents the unscaled adjusters, which if implemented, would cause the ESRD PPS base rate to be reduced by a factor of 0.999262, or approximately $0.20, to achieve budget neutrality. The third column presents the adjusters scaled down by a factor of 0.815 to maintain the LVPA payment amount under the existing methodology of $26.7 million based on the expected CY 2025 LVPA payments. Using the scaled adjusters would maintain budget neutrality without lowering the ESRD PPS base rate.

[75] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

TABLE 9: Proposed LVPA Methodology with Two Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CMS Certification Numbers (CCNs)
Tier 1 (less than 3,000)	34.9%	28.4%	202
Tier 2 (3,000 – 3,999)	22.2%	18.1%	128

The adjustment factors in the second column are derived from the regression explained previously. These results indicate that facilities which furnish less than 3,000 treatments have costs that are 34.9 percent higher than non-low-volume facilities, and facilities that furnish between 3,000 and 3,999 treatments have costs that are 22.2 percent higher. The adjustment factors in the third column, which are scaled down, reflect the same relationship between the two tiers of low-volume facilities and non-low-volume facilities.

We explained that we believe a two-tier scaled approach is appropriate because it would increase payments to facilities with the lowest volume while keeping payment changes contained within the LVPA. In CY 2016 ESRD PPS final rule (80 FR 68972 through 69004) when we last updated the LVPA adjustment factor, we also updated most of the facility-level and case-mix adjusters. At that time, it was appropriate to apply a budget-neutrality factor that represented all of the changes to the facility-level and case-mix adjusters. However, we only proposed changes to the LVPA in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843) and believed it would be most appropriate to contain the changes within the current LVPA by applying a scaling factor to the LVPA adjusters.

We also analyzed a three-tiered option that would include a tier for ESRD facilities furnishing between 4,000 and 5,000 treatments, which is presented in Table 10. As noted previously, we considered both scaled and unscaled adjustment factors, with both maintaining budget neutrality. Our analysis showed that the scaled, three-tiered option would reduce payments for facilities furnishing less than 3,000 treatments as compared to both the current LVPA methodology and the proposed two-tiered scaled methodology. Because payments for facilities furnishing between 4,000 and 5,000 treatments would increase, payments for the lowest-volume facilities would need to decrease to maintain budget neutrality, which we did not believe would align with the goals of the LVPA outlined previously. We explained that if we were to propose a three-tiered option, we believe budget neutralizing the base rate rather than scaling the adjustment factors would better align with these goals. Our analysis shows that an unscaled three-tiered adjustment would result in a $0.99 reduction to the base rate. We sought comment on our proposed scaled, two-tier proposal and on the alternative three-tier LVPA structure. We noted that, should this alternative be finalized, we would make changes to § 413.232(b)(1) to reflect the increased LVPA threshold of 5,000. As discussed further in the next subsection, we also proposed to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. Therefore, expanding LVPA eligibility to ESRD facilities that furnished fewer than 5,000 treatments in each of the past three cost-reporting years would also increase the number of ESRD facilities that would qualify for tier 1 and tier 2, since ESRD facilities which furnished between 4,000 and 4,999 treatments in one of the past 3 years and fewer than 4,000 (or 3,000 for tier 1) in the other 2 years could qualify in these tiers.

TABLE 10: Alternative LVPA Methodology with Three Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CCNs
Tier 1 (less than 3,000)	34.9%	16.2%	257
Tier 2 (3,000 – 3,999)	22.2%	10.3%	224
Tier 3 (4,000 – 4,999)	14.2%	6.6%	166

c. Final Changes to the LVPA for CY 2025

We proposed a two-tiered LVPA using the scaled adjusters presented in the second column of Table 9. ESRD facilities that fall into the first tier (those that furnish fewer than 3,000 treatments) would receive a payment adjustment of 28.4 percent. Those that fall in the second tier (those that furnish 3,000 or more treatments but fewer than 4,000 treatments) would receive a payment adjustment of 18.1 percent. Outside of the change to the LVPA amount, this change would not impact how the LVPA is applied to ESRD PPS payments.

We stated that one potential complication with a tiered approach to the LVPA is that there would still be payment cliffs present between the tiers. This may discourage ESRD facilities from increasing their treatment volume in a given year, especially if it is uncertain whether the ESRD facility's treatment volume in future years will stay at the increased level. To address this, we proposed to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. This methodology would smooth payments over years, increasing stability and predictability in payments to low-volume facilities. We also proposed that, should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years would be used to make the facility's tier determination. We note that the median of two numbers is the average of those numbers, and the median of one number is that number. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, we would assign the facility to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met.

We stated that we believe that the proposed median treatment approach would promote stability, especially for facilities whose treatment counts are on the margins of a tier. We also believe that the proposed smoothing methodology for determining the treatment volume tier for which an ESRD facility qualifies is better than the alternative of using the highest tier (in terms of treatment volume) for which an ESRD facility has qualified in each of the past years. For example, if we used the highest tier of the last 3 years and a facility furnishes 3,500 treatments in one of the past 3 years, it would be categorized as tier 2 even if it furnished fewer than 3,000 treatments in the other 2 years. We believe that the proposed smoothing would mitigate the introduction of a cliff-effect within the tiers.

By contrast, under the proposed smoothing methodology, if the cost-reporting data indicated that the facility furnished 2,500, 2,999, and 3,500 treatments in the 3 years preceding the payment year, the median tier would be identified (tier 1 in this case), and the facility would (in the proposed two-tier system with scaling) receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year. We expect that any higher or lower payments from year to year under this policy would balance out over time without putting additional burden on the MACs. The structure of the proposed scaled, two-tier LVPA methodology is presented in Table 9, and the structure of the alternative three-tier unscaled LVPA methodology is presented in Table 10. For the purposes of comparison, we have included the scaled and unscaled version of both of the potential LVPA structures.

We noted that we did not propose any changes to the methodology for determining eligibility for the LVPA under § 413.232(b)(1), as the purpose of this change is to better allocate payments within the LVPA, not to expand the LVPA to facilities that have furnished more than 4,000 treatments in one of the past three cost-reporting years. We would continue to determine eligibility for the LVPA based on a facility's treatment count in each of the three cost-reporting years preceding the payment year as set forth in § 413.232(b)(1) and would not consider the median treatment count over that period for purposes of determining eligibility. Likewise, we did not propose any changes to § 413.232(g)(5), which allows for an exception to the requirement at § 413.232(b)(1) in the case of a disaster or other emergency. In the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214), we stated that we believe a 3-year waiting period serves as a safeguard against facilities that have the opportunity to take a financial loss in establishing facilities that are purposefully small. In response to the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), several interested parties commented that they believe CMS should maintain the 3-year attestation to determine eligibility for the LVPA, as it is an important safeguard against gaming. In addition, if we were to use the median tier methodology to determine LVPA eligibility, we estimate that the adjustment factors would decrease, because the scaling factor used to maintain budget neutrality within the LVPA would be smaller to account for a larger amount of ESRD facilities qualifying for the LVPA.

We stated that, if finalized, the proposed median treatment count methodology for determining an eligible ESRD facility's LVPA tier would improve the stability and predictability of the LVPA by basing tier determination on the median treatment count of the last 3 years as opposed to the treatment count for each of the last 3 years, where facilities could be disqualified from a higher adjustment based on marginal changes. The proposed tiered smoothing methodology would also better align payment with resource use by minimizing the impact of the payment cliff between the LVPA tiers in a transparent and reproducible fashion. We solicited comments on each aspect of our proposal: (1) the tiered structure of the LVPA; (2) using the median treatment count volume to determine the LVPA payment tier for ESRD facilities that are eligible for the adjustment; and (3) the scaling of the adjusters to maintain LVPA payments at the same level. As previously discussed, we also considered an alternative three-tiered structure, which would have the effect of reducing the base rate by $0.99. We solicited comments on whether this alternative methodology could be more appropriate than the proposed methodology.

We invited public comment on our proposal to change the LVPA methodology to include two tiers, use the median treatment count volume to determine the LVPA payment tier for eligible facilities, and to scale the adjusters to maintain budget neutrality without lowering the ESRD PPS base rate. Approximately 12 commenters including a non-profit dialysis organization, a non-profit kidney organization, multiple large dialysis organizations, a provider advocacy organization, a non-profit organization of ESRD networks, a non-profit kidney care alliance, a coalition of dialysis organizations, a small dialysis organization within a large non-profit health system, and MedPAC commented on the proposed changes to the LVPA methodology. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters supported CMS's proposed changes to the LVPA methodology, agreeing that introducing two tiers would help reduce

the burden of payment cliffs. Some of these commenters encouraged CMS to continue refining the LVPA as more data becomes available, and to continue evaluating the impact of creating additional tiers. Nearly all commenters expressed support for our proposal to use the median treatment count volume to determine the LVPA payment tier for eligible facilities.

Response: We thank commenters for their support and dedication to advancing health equity and protecting access to renal dialysis services for vulnerable beneficiaries. CMS will continue to monitor the ESRD PPS LVPA methodology to ensure that payments are appropriately aligned with resource use and adequately target low-volume facilities and make refinements, if appropriate, through rulemaking.

Comment: Some commenters cited analysis suggesting that CMS may have underestimated the number of facilities projected to furnish more than 3,000 treatments during CY 2025 in the CY 2025 impact file [76] and expressed concern that the adjuster amounts CMS calculated for both tier structures described in the CY 2025 ESRD PPS proposed rule may be inaccurate. Many of these commenters were also concerned that the two- and three-tiered structures presented in the proposed rule had the same adjusters despite a greater number of ESRD facilities qualifying for the LVPA under the three-tiered structure.

Response: The dialysis treatment counts reported in the impact tables in Addendum B represent Fee-For-Service (FFS) treatments furnished by each facility during 2023. LVPA tier assignment is based on facility size, which encompasses all treatments (Medicare FFS, MA, or non-Medicare) furnished during CYs 2020, 2021, and 2022, including treatments by ESRD facilities under common ownership and located within a 5-driving mile radius. The CY 2023 facility size information was considered separately from the FFS treatment during our analysis.

The two- and three-tier LVPA structures in the CY 2025 ESRD PPS proposed rule appear identical as both represent estimates of expected cost differentials derived from a common model that measures association between facility size and cost. The adjusters from the common model are stable because they are based on the overall relationship between cost and volume, not on the number of tiers into which facilities are divided. These estimates appear in the second columns of Tables 9 and 10 in this final rule. However, once facilities are assigned to a category and payment budget neutrality is applied, the adjusters for the two- and three-tier proposals diverge, as shown by the third columns in each respective table where the adjustment factors are scaled to maintain total LVPA payments at the same level.

Comment: Several interested parties expressed concern that the facilities in the second tier under the proposed two-tier LVPA methodology (furnishing between 3,000 and 3,999 treatments per year) would receive a lower adjustment compared to the current LVPA policy.

Response: We maintain our belief that a two-tier scaled approach is appropriate, as it replaces a one-size-fits all approach with one where payments more closely align with cost while keeping payment changes contained within the population of LVPA facilities. Maintaining budget neutrality in this manner when transitioning to a tiered structure necessitates payment adjustments that differ from the current adjuster at each tier. Therefore, it is unavoidable that the tier 2 LVPA facilities receive a lower LVPA adjustment factor under the tiered system while holding total LVPA payments at the same level.

We also maintain our belief that it is appropriate to implement a scaled approach as opposed to a budget neutrality factor applied to all ESRD PPS payments. We reiterate that when we last updated the LVPA adjustment factor in the CY 2016 ESRD PPS final rule (80 FR 68972 through 69004), we also updated most of the facility-level and case-mix adjusters and applied a budget neutrality factor that represented all of those changes. Since we only proposed changes to the LVPA in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we noted that it would be most appropriate to contain the changes within the current LVPA by applying a scaling factor to the LVPA adjusters.

Comment: MedPAC supported the proposal for a two-tier LVPA for existing ESRD facilities as well as maintaining budget neutrality with respect to the current LVPA policy but expressed multiple concerns about extending the LVPA to new ESRD facilities. MedPAC suggested that the two-tier proposal is an improvement over the current policy, but that they ultimately support a statutory change that would replace both the LVPA and the rural facility adjustment with a single payment adjustment that considers distance to the next nearest facility and treatment volume. MedPAC stated that such an adjustment would eliminate extra payments to low-volume facilities in close proximity to another facility and high-volume rural facilities.

Response: CMS appreciates the support expressed by MedPAC for the proposed changes to the LVPA methodology and its input on future refinements that could preserve access to renal dialysis services. CMS also shares MedPAC's concerns about extending the LVPA to new ESRD facilities, as this could result in decreased payment to the lowest-volume ESRD facilities. As we discussed in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), CMS aims to align resource use with payment, advance health equity and protect access to renal dialysis services for vulnerable beneficiaries in underserved communities, including rural and isolated communities, by increasing payments to certain ESRD facilities in these areas to align with their higher costs. We acknowledge MedPAC's continued support for an LVPA that incorporates geographic isolation but reiterate that such an adjustment would not be consistent with the statutory requirements for the LVPA unless geographic isolation is found to influence the extent to which low-volume ESRD facilities face higher costs, and we agree that such an adjustment would require a statutory change.

Comment: Multiple commenters once again called for the elimination of the rural facility adjustment and for its funds to be allocated to support a more robust LVPA, either within the current bounds of eligibility or to include ESRD facilities that furnish up to 6,000 treatments per year. Many of these commenters reiterated their support for MedPAC's LVI methodology and noted several concerns regarding the three-tier model presented by CMS in the CY 2025 ESRD PPS proposed rule. Some commenters stated that the three-tier model presented by CMS would cause substantial overlap between facilities receiving the LVPA and the rural facility adjustment, and that a large number of rural facilities are high-volume to an extent that may not warrant additional payment.

Response: In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), CMS noted that recent analysis has confirmed, in general, that low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. This analysis broadly aligns with suggestions from various commenters, including MedPAC, to refine or remove the rural

[76] The CY 2025 impact file can be found in Addendum B of the proposed rule.

facility adjustment to better target ESRD facilities that are critical to beneficiary access and are likely not being adequately targeted under the current methodology. However, CMS found that, on treatment weighted basis, over 65 percent of rural providers have no other providers in a 5-driving mile distance, and that this fraction increases to 83 percent for providers eligible for both the rural facility adjustment and the LVPA. These findings indicate that the overlapping payments for both the LVPA and rural facility adjustments are primarily going to small and isolated providers and align with our belief that many ESRD facilities which receive the rural facility adjustment are critical to patient access and may be relying on the additional payment from the rural facility adjustment for the coming years. We are not finalizing any changes to the rural facility adjustment at this time, but we are open to considering potential refinements to the definition of a rural ESRD facility in the future by considering alternate rural designations. Any future changes would consider the impact on rural ESRD facilities. Additionally, we note that the rural facility adjustment for the ESRD PPS is relatively small compared to other payment systems, at 0.8 percent, and that the suggested elimination of this adjustment would only account for about one third of the budget neutrality adjustment required for our alternative 3-tiered adjustment, which would expand the LVPA to ESRD facilities that furnish up to 5,000 treatments per year. Therefore, the funds currently associated with the rural facility adjustment would not be able to ''pay for'' expanding the LVPA to the commenter's suggested 6,000 treatment volume threshold without a significant budget neutrality reduction to the ESRD PPS base rate.

CMS also reiterates that because payments for facilities furnishing between 4,000 and 5,000 treatments would increase under the three-tier methodology presented in the proposed rule, payments for the lowest-volume facilities would need to decrease to maintain budget neutrality, and we do not believe this would align with the goals of the LVPA. We thank the commenters who presented analysis demonstrating why the three-tier methodology we presented may yield decreased payment to the lowest-volume facilities and how alternative methodologies, including MedPAC's LVI methodology, could potentially yield more equitable payment distribution to LVPA-eligible facilities. CMS intends to consider the provided analyses to inform future notice and comment rulemaking pertaining to the LVPA methodology.

Comment: A small dialysis organization within a large non-profit health system commented asking for additional clarification regarding the median tier calculation in the instance where a facility receives an exception for taking on additional patients due to a disaster or emergency.

Response: In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we proposed that, should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years would be used to make the facility's tier determination. We noted that the median of two numbers is the average of those numbers, and the median of one number is that number. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, we would assign the facility to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met. For example, if cost-reporting data indicated that an ESRD facility furnished 2,500, 2,999, and 4,500 treatments in the 3 years preceding the payment year, but received an exception under § 413.232(g)(5) during the year it furnished 4,500 treatments, the median treatment count from the two prior years (2,500 and 2,999) would be used determine the facility's LVPA tier, which would place the facility in tier 1 under the proposed two-tier methodology. The facility would then receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year.

Comment: Some interested parties commented that it is necessary to conduct analysis of the Pacific territories separately from the general Pacific census region to consider the unique costs that are exclusive to small island economies. The commenters cited air freight shipping costs, operational costs for utilities, limited availability of local healthcare professionals, and a lack of economies of scale as factors that may be raising the per-treatment costs across the Pacific territories. The interested parties acknowledged that CMS is barred from accounting for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, but claimed that CMS may have concluded that low-volume facilities that are rural, isolated, or located in low-demand areas generally did not have higher costs than low-volume ESRD facilities overall without adequately considering the unique situation of the Pacific territories. The commenters urged CMS to refine the LVPA to better target isolated ESRD facilities such as those in the Pacific islands and requested the Secretary to consider exercising the authority provided under section 1881(b)(14)(D)(iv) to establish other payment adjustments for the Pacific territories in the case that CMS is unable to better target these facilities due to statutory constraints.

Response: In the CY 2024 ESRD PPS proposed rule's LVPA RFI (88 FR 42441 through 42445), we solicited comments on a potential new payment adjustment that accounts for isolation, rurality, and other geographical factors, including local dialysis need (LDN). CMS stated that the statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, and preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. Because of this, we clarified that the LDN methodology could only be implemented under the authority in 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. Commenters were generally opposed to the LDN methodology for a variety of factors, and many supported MedPAC's LVI methodology in place of the existing LVPA and rural facility adjustments. The statute generally would not permit MedPAC's approach recommending payment directed at isolated facilities under the LVPA, and our preliminary analysis shows that the funds from the rural adjuster alone cannot support a third LVPA tier while maintaining budget neutrality and without decreasing payment to the lowest volume facilities. CMS is committed to achieving equity in healthcare outcomes for our beneficiaries, and we reiterate that the statutory requirement for the LVPA requires it reflect the extent to which low-volume ESRD facilities face higher costs. We intend to continue to evaluate whether geographic isolation is associated with higher costs for low-volume ESRD facilities and, should we find such evidence, we would be able to

consider alternative methodologies to the LVPA similar to MedPAC's LVI in potential future rulemaking. Should our future analysis show that isolated, low-volume ESRD facilities incur greater costs than other low-volume ESRD facilities, we would consider, if appropriate, making further refinements to the LVPA methodology through rulemaking. We recognize that the U.S. Pacific Territories are uniquely isolated compared to mainland ESRD facilities, so a different set of isolation criteria may apply distinctly to these ESRD facilities and, should they have higher costs than other LVPA facilities, support incorporating such isolation criteria into the LVPA under the current statute. However, we do not believe it would be appropriate to define isolation criteria based on predetermined ESRD facilities that we believe should be considered isolated. Additionally, as there are relatively few ESRD facilities in the U.S. Pacific Territories, any isolation criteria which would only identify these ESRD facilities would likely be very restrictive and not appropriate to be applied to the ESRD PPS overall. Therefore, we do not believe it would be most appropriate to address the higher costs that the commenter described through the LVPA. We intend to further consider the unique challenges and costs which are faced by ESRD facilities in the U.S Pacific Territories, and other similarly isolated places, and address these challenges and costs, if warranted, through an appropriate payment mechanism, such as an adjustment under section 1881(b)(14)(D)(iv), in potential future rulemaking.

CMS appreciates the unique challenges that ESRD facilities in the U.S. Pacific Territories face and the higher costs that might accompany them. However, we note that the LVPA is generally not constructed to account for factors outside of the costs that ESRD facilities incur as a result of furnishing a small number of treatments. CMS has also noted that there are ESRD facilities that may be eligible for the LVPA but have not submitted attestations to their MACs. CMS encourages these facilities to attest for purposes of the LVPA as we continue to consider appropriate ways to support Pacific Territory facilities that are critical to beneficiary access to renal dialysis services.

Final Rule Action: After considering the comments, we are finalizing as proposed the scaled two-tier LVPA methodology, where ESRD facilities that fall into the first tier will receive a payment adjustment of 28.9 percent and those that fall in the second tier will receive a payment adjustment of 18.3 percent. The structure of this methodology can be found in Table 11. We are also finalizing as proposed the tiered smoothing methodology, where an ESRD facility's LVPA tier will be determined based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count.

TABLE 11: Final LVPA Methodology with Two Tiers

Tier	LVPA Adjusters with Scaling	Number of Eligible CMS Certification Numbers (CCNs)
Tier 1 (less than 3,000)	28.9%	202
Tier 2 (3,000 – 3,999)	18.3%	128

We note that the final LVPA adjusters under the two-tier methodology are marginally different from those presented in the CY 2025 ESRD PPS proposed rule. The final LVPA adjusters presented in Table 11 reflect the use of more recent claims data in our analysis for this final rule, which results in changes to the scaling factor used to maintain total estimated LVPA payments at the same amount.

CMS reiterates that we did not propose and are not finalizing any changes to the methodology for determining eligibility for the LVPA under § 413.232(b)(1), as the purpose of the finalized changes is to better allocate payments within the LVPA, not to expand the LVPA to facilities that have furnished more than 4,000 treatments in one of the past three cost-reporting years. We will continue to determine eligibility for the LVPA based on a facility's treatment count in each of the three cost-reporting years preceding the payment year as set forth in § 413.232(b)(1) and would not consider the median treatment count over that period for purposes of determining eligibility. Likewise, we did not propose and are not finalizing any changes to § 413.232(g)(5), which allows for an exception to the requirement at § 413.232(b)(1) in the case of a disaster or other emergency.

d. Summary of RFI on Improving the LVPA for New ESRD Facilities

In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we sought comment on several approaches to modifying the LVPA methodology to ensure that payments are accurately aligned with resource use, adequately target low-volume facilities, and strive for healthcare equity for ESRD beneficiaries. We issued an RFI to seek feedback from the public on potential changes to the LVPA eligibility criteria, including the potential modification of the 3-year cost-reporting data requirement, and what commenters believe would be the best way for a new low-volume ESRD facility to demonstrate or attest that it expects to be low-volume. We also sought information regarding the potential implementation of a reconciliation process for ESRD facilities that fail to furnish a low enough treatment volume to qualify for the LVPA or their predicted tier. We also questioned commenters about the cost differences for providers of low-volume home dialysis and providers of low-volume in-center dialysis, and whether the

LVPA be an appropriate pathway to support the provision of home dialysis through increased payment. In particular, we sought input and responses to the following considerations, requests, and questions:

- Whether the LVPA or another adjustment, such as the LDN methodology discussed earlier, would be the most appropriate payment pathway to support access to renal dialysis services in areas that do not currently have sufficient capacity to furnish these services to all Medicare beneficiaries.
- What would be the most appropriate way or ways for a new ESRD facility to demonstrate or attest that it expects to be low-volume?
- The potential for future reconciliation process as an appropriate accommodation for new ESRD facilities.
- Whether a reconciliation process would be an effective tool for making appropriate payments to existing ESRD facilities that have three or more years of cost reporting data.
- Would a reconciliation process be operationally straightforward and understandable for an ESRD facility that has opened in the past 3 years?
- Would a reconciliation process make it more difficult for ESRD facilities to plan and budget for future payment years? Is this outweighed by the potential benefit of earlier access to the LVPA for these new facilities?
- Would it be useful or feasible to implement a reconciliation process for ESRD facilities that have not opened in the past 3 years but, for whatever reason, may have furnished a low enough treatment volume to qualify for the LVPA?
- Could the LVPA be changed in any way to better support ESRD facilities opening in underserved areas? Are there any costs specific to low-volume facilities for which the current LVPA does not account?
- How are the costs for providers of low-volume home dialysis different from the costs for providers of low-volume in-center dialysis? Could the LVPA be an appropriate pathway to support the provision of home dialysis through increased payment?

We did not receive any new feedback in response to our RFI regarding LVPA eligibility or the attestation process for new ESRD facilities. A handful of commenters reiterated their stance from the CY 2024 ESRD PPS RFI on the LVPA. Some commenters thanked CMS for our consideration of public comments as we continue to refine the LVPA methodology. We received one comment from an LDO in response to our RFI regarding the cost differences for low-volume home dialysis versus in-center dialysis providers. The comment explained that staffing dynamics make the 4,000-treatment LVPA threshold inapplicable for home dialysis programs but cautioned that a home dialysis-specific LVPA threshold may not address the challenges faced by low-volume home programs as the treatment aggregation mechanism within the LVPA disqualifies many of these programs due to their proximity to commonly owned in-center programs.

We thank the commenters for their detailed and thoughtful comments, including those who responded to the RFI. While we are not responding to these comments in this CY 2025 ESRD PPS final rule, we intend to take them into consideration for future rulemaking and future policy development.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Applications and Technical Changes for CY 2025

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we 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. For additional background on the TPNIES we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2025, no TPNIES application summaries, CMS analyses, or results have been included in this final rule.

2. Technical Changes to § 413.236(b)(4) and § 413.236(c)

As part of the TPNIES eligibility requirements in § 413.236(b)(4), a covered equipment or supply must have 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 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 particular CY. We have identified a minor error in § 413.236(b)(4). Specifically, we inadvertently transposed the words orthotics and prosthetics within the DMEPOS acronym. The acronym was intended to read durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) instead of durable medical equipment, orthotics, prosthetics and supplies (DMEPOS).

As described in the HCPCS Level II Coding Procedures, HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT® code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.

While the HCPCS level II Coding Procedures include DMEPOS as an example of items for which HCPCS Level II codes are established, we believe that the phrase non-drug and non-biological items more broadly reflects all items, supplies, and services for which HCPCS Level II codes are established and aligns with the HCPCS Level II coding procedures on the CMS website. Therefore, we proposed a technical change at § 413.236(b)(4) to remove the reference to the phrase durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) and replace it with the phrase non-drug and non-biological items. We are also adding the word supplies. These technical changes would better reflect the broader category of non-drug and non-biological item coding in the HCPCS Level II Coding Procedures available on the CMS website.[77]

We did not receive any comments on our proposed technical changes to § 413.236(b)(4). We are finalizing the technical changes as proposed at § 413.236(b)(4) and also finalizing the corresponding edit at § 413.236(c) for the same reasons that we identified for the proposed edit.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2025

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment

[77] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Available at: *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.* Accessed on January 16, 2024.

is continuing for CY 2025. As described in the CY 2024 ESRD PPS final rule, no new items were approved for the TPNIES for CY 2024 (88 FR 76431). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2025.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2025

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 July 2023, CMS approved Jesduvroq (daprodustat) for the TDAPA under the ESRD PPS, effective October 1, 2023. Implementation instructions are specified in CMS Transmittal 12157, dated July 27, 2023, and available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

In April 2024, CMS approved DefenCath® (taurolidine and heparin sodium) for the TDAPA under the ESRD PPS, effective July 1, 2024. Implementation instructions are specified in CMS Transmittal 12628, dated May 9, 2024, and available at: *https://www.cms.gov/files/document/r12628CP.pdf.*

Table 12 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2025: Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023 and DefenCath® (taurolidine and heparin sodium) that was approved for the TDAPA effective in CY 2024. Table 12 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and end dates.

TABLE 12: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	10/1/2023	9/30/2025
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	7/1/2024	6/30/2026

Comment: One commenter recommended that CMS monitor anemia outcomes with hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF–PHI) versus erythropoiesis stimulating agent (ESA) therapy.

Response: We thank the commenter for the recommendation and note that Jesduvroq (daprodustat) is a HIF–PHI.[78] CMS engages in ongoing monitoring and analysis of the ESRD PPS to identify trends in beneficiary health outcomes. An overview of the ESRD PPS claims-based monitoring program is provided on the CMS website.[79] CMS will continue the claims-based monitoring in CY 2025, inclusive of all drugs approved for the TDAPA. CMS intends to monitor anemia and cardiovascular outcomes among beneficiaries using Jesduvroq (daprodustat) and ESAs.

[78] Jesduvroq Prescribing Information. Accessed October 10, 2024. Available at: *https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jesdvroq/pdf/JESDUVROQ-PI-MG.PDF.*

[79] ESRD Prospective Payment System (ESRD PPS) Claims-Based Monitoring Program-Overview of 2010–2022 Claims-Based Monitoring Program. Accessed September 13, 2024. Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring.*

III. Final CY 2025 Payment for Renal Dialysis Services Furnished to Individuals With 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 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 1861(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. Public Comments and Responses on the Proposal To Allow Medicare Payment for Home Dialysis for Beneficiaries With AKI

1. Background

In the CY 2017 ESRD PPS final rule, we indicated that we did not expect beneficiaries with AKI to dialyze at

home; therefore, the home dialysis benefit was not extended to beneficiaries with AKI (81 FR 77870). There were commenters who advocated for beneficiaries to have the option to dialyze in a home setting, particularly those beneficiaries who started peritoneal dialysis (PD) in the hospital and desired to continue PD after discharge. However, other commenters indicated that beneficiaries with AKI needed close supervision during dialysis. Additionally, some commenters indicated that dialysis for AKI is a short-term treatment, and beneficiaries would not have time to learn to administer a home therapy. Therefore, we finalized the AKI payment policy in the CY 2017 ESRD PPS final rule as proposed without extending the AKI benefit to home dialysis beneficiaries. We indicated that we would gather data on the AKI beneficiary population and the extent of home training necessary to safely self-administer dialysis in the home, and that we would consider the use of home dialysis for beneficiaries with AKI in the future as we find that it may be beneficial for subsets of beneficiaries.

In past years we have received comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI, with the most recent comments received in response to the CY 2024 ESRD PPS proposed rule to update to the AKI dialysis payment rate (88 FR 76433). We have monitored data for beneficiaries with AKI and researched data in journal articles discussing the potential to expand dialysis for beneficiaries with AKI to a home setting, as noted in the CY 2017 ESRD PPS final rule (81 FR 77871).

In the CY 2017 ESRD PPS final rule, we clarified that the ESRD Facility CfCs apply to ESRD facilities, not to ESRD beneficiaries, and noted that the ESRD facility CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. We finalized a policy that our CfCs would not need to be revised to address the provision of dialysis treatment to beneficiaries with AKI (81 FR 77871 through 77872).

In December 2020, CMS's data contractor held a TEP that considered data related to utilization review and cost of AKI treatments since 2017. The TEP solicited input regarding how reported costs align with realized costs of treatment for beneficiaries with AKI. During the TEP, participants suggested that we extend Medicare payment for beneficiaries with AKI to allow them to dialyze in a home setting. Additionally, the TEP indicated that beneficiaries with AKI could benefit from different treatment regimens. The TEP noted that more frequent, gentler dialysis with a lower ultrafiltration rate would be a viable option for some beneficiaries. Members of the panel commented on the similar treatment frequencies observed for beneficiaries with AKI and ESRD, stating that the payment system is currently constructed to facilitate the standard treatment plan for beneficiaries with AKI. Panelists recommended that the ESRD PPS should be flexible in terms of number of treatments for beneficiaries with AKI, so that those who need more frequent treatments are not impeded from receiving them. Panelists related instances of hospitals starting a patient on PD, which can be done frequently in the home setting, only to convert the patient to a more standard treatment regimen such as three in-center hemodialysis treatments per week before discharging the patient to a dialysis facility. Panelists also advocated that we provide Medicare payment for beneficiaries with AKI to be treated at home.

We solicited comments regarding potentially modifying the site of renal dialysis services for beneficiaries with AKI and payment for AKI in the home setting as a RFI in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408). We received 16 comments from LDOs, patient advocacy groups, professional organizations, small dialysis organization within a large non-profit health system, and non-profit organizations. Most of the comments favored providing a payment option for beneficiaries with AKI to dialyze in a home setting; however, some commenters expressed concerns about doing so. A small dialysis organization within a large non-profit health system indicated that beneficiaries with AKI may have chronic kidney disease at a lesser stage, such as, Stage 3 or Stage 4 chronic kidney disease (CKD) rather than ESRD; however, the AKI makes dialysis necessary. This commenter noted that if the AKI were to cause the beneficiary's underlying Stage 3 or Stage 4 CKD to progress to ESRD in the future, training them to use a home modality during the AKI episode could prepare the patient for a home modality if they are diagnosed as having ESRD. One LDO indicated there is evidence that PD, which is typically used in the home setting, is associated with better preservation of residual kidney function compared to hemodialysis. A national organization of beneficiaries and kidney health care professionals advocated that PD may be learned quickly, reduces rapid hemodynamic changes that may potentiate kidney injury and impede recovery, and does not require a high-risk central venous catheter to provide treatment. We note that these comments are specific to PD as a treatment modality; however, when considering such a policy we would include payment for both PD and hemodialysis (HD) in the home setting for beneficiaries with AKI, consistent with our payment policy for home dialysis for patients with ESRD.

Most recently, as noted in the CY 2024 ESRD PPS final rule (88 FR 76433), we received 10 public comments on our proposal to update the payment rate for renal dialysis services furnished to individuals with AKI. Commenters included a coalition of dialysis organizations, a non-profit dialysis organization, a trade association, a renal product development company, and multiple large dialysis organizations. Most of the commenters requested that we allow payment for beneficiaries with AKI to select home dialysis modalities by changing the current policy, even though it was not proposed in the CY 2024 ESRD PPS proposed rule.

In the CY 2025 ESRD PPS proposed rule, we acknowledged there have been concerns in the past regarding the safety of beneficiaries with AKI dialyzing at home (89 FR 55806). However, we explained that we carefully reviewed the totality of the information and evidence presented to the agency and now recognize that current information regarding beneficiaries with AKI dialyzing in a home setting supports more frequent dialysis at a lower ultrafiltration rate. We stated that the ability to dialyze at a lower ultrafiltration rate supports a decrease in hemodynamic fluctuation and the complications associated with it, which in turn support recovery of kidney function.

2. Technical Analysis

In the CY 2025 ESRD PPS proposed rule, we noted that although there is only limited research regarding the use of home dialysis for the treatment of AKI, several studies support the use of home dialysis to generally improve access to dialysis and provide care that better meets patient needs (89 FR 55806 through 55807). We noted that many of the studies related to home dialysis in the AKI patient population use PD as the treatment modality, which we explained is consistent with comments received during the December 2020 TEP and comments received during rulemaking as noted previously. Additionally, we stated that data from the United States Renal Data System (USRDS) Annual Data Report (ADR),

indicated the percentage of incident dialysis patients performing home HD was only 0.4 percent in 2021, and a significant majority of dialysis patients performing home dialysis chose PD.[80] We stated that we believe the choice of a home modality would be comparable in the beneficiary population for those with AKI as those initiating chronic maintenance dialysis for ESRD. However, we affirmed that payment would be provided for either modality of home dialysis. For example, PD was used frequently for patients during the COVID–19 PHE due to challenging situations such as supply shortages, staffing shortages, and limited surgical availability for the placement of a venous access. In the proposed rule, we noted that a multicenter, retrospective, observational study of 94 patients who received acute PD in New York City in the spring of 2020 indicated that rapid deployment of acute PD was feasible. We stated that the rates of death and renal recovery were like those of patients with AKI requiring kidney replacement therapy (KRT) in other cohorts. Of those who were discharged on dialysis, four were discharged on PD, and one was discharged on HD.[81]

We further noted that the International Society for Peritoneal Dialysis (ISPD) reiterated in the 2020 guidelines, updated from the 2014 guidelines for PD in AKI, that PD should be considered a suitable modality for treatment of AKI in all settings. This was a strong recommendation from the ISPD based on evidence rated at the second highest level used by ISPD.[82] Researchers found little to no difference between PD and hemodialysis in all-cause mortality, recovery of kidney function, or infection as a complication.[83] We noted that this finding was augmented by an article that reviewed the resurgence of PD for the treatment of AKI since the COVID–19 PHE. The article listed cost effectiveness, low infrastructure requirements, ease of staff training, and more rapid recovery of renal function as benefits to the use of PD to treat AKI. We identified a survey of nephrologists from three international conferences which reported that 50.8 percent and 36.4 percent of respondents stated that PD was suitable for treating AKI in the wards and ICU, respectively. We found that PD is the predominant therapy used to treat pediatric patients with AKI, and until the mid to late 1990s was the predominant therapy to treat adults with AKI, but the use of this therapy has waned since the advent of pump driven continuous kidney replacement therapy.[84]

We noted that most studies regarding recovery of kidney function in patients with AKI were based around hospitalized patients. We further noted that there were very limited studies suggesting that self-care dialysis can yield faster recovery of kidney function; however, the results were not conclusive.[85] We identified that one study of hospitalized patients with AKI indicated that a median of 10 patients recovered kidney function more quickly utilizing PD.[86] We noticed another study of hospitalized patients with AKI that indicated that while the recovery of kidney function was similar in PD and HD (28 and 26 percent) there was a significantly shorter time to the recovery of kidney function for patients with AKI that utilized PD.[87]

We identified additional information from CMS AKI monitoring data, in which we found that current provision of AKI dialysis is very similar to the provision of ESRD dialysis. Data noted in the 2021 Quarter 4 public use file (PUF) [88] for AKI showed that hemoglobin for beneficiaries with ESRD averaged 10.6 gm/dL while the average hemoglobin for beneficiaries with AKI averaged 9 gm/dL. Although the data further suggested that beneficiaries with AKI were less likely to be prescribed an ESA than patients with ESRD, we identified research that indicated that patients using PD have a lower rate of anemia that those using HD. Additionally, patients receiving PD require lower doses of ESAs and iron than patients receiving HD.[89] We observed that this might indicate that dialyzing in a home environment could be effective to manage anemia in beneficiaries with AKI more appropriately, as the USRDS ADR indicated incident patients with ESRD typically choose PD as a home modality over home HD.[90] We stated that we believed that beneficiaries with AKI would make similar choices. Furthermore, the AKI PUF data showed that approximately 8 percent of beneficiaries with ESRD experienced incidences of fluid overload, while beneficiaries with AKI experienced episodes for which congestive heart failure was reported within 30, 60, and 90 days (which can be related to fluid overload) at rates of around 42 percent, 50 percent, and 53 percent, respectively.[91] This data was concerning because fluid overload in beneficiaries with AKI can be detrimental to recovering kidney function. Additionally, this data supported conclusions drawn from an article involving the review of 1754 patients with AKI requiring dialysis. The article indicated that treatment protocols for patients with AKI were like those of incident ESRD patients despite the underlying differences in treatment goals. The article further indicated that most patients with AKI who recovered had discontinued dialysis without ever having been weaned from their initial dialysis prescription, suggesting there may be substantial opportunity to wean dialysis sooner.[92] We continue to support the significant need to individualize the treatment of every kidney patient, but particularly beneficiaries with AKI, as this omission could result in a missed opportunity to recover kidney function.

We stated that we believed the proposal to provide payment for beneficiaries with AKI to dialyze in a home setting aligns closely with the CMS Strategic Pillars [93] of expanding access, engaging the ESRD community by being responsive to TEPs and RFIs, and driving innovation to promote patient centered care. We did not have utilization data for beneficiaries with AKI using a home modality available, but we used the USRDS ADR, which indicated that disparities currently exist for self-care dialysis in the home setting for the ESRD beneficiary population, with fewer African American/Black and Hispanic beneficiaries choosing a home dialysis modality. Additionally, fewer Medicare and Medicaid dual eligible

[80] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis*.

[81] *https://www.sciencedirect.com/science/article/pii/S0085253821004567*.

[82] *https://journals.sagepub.com/doi/10.1177/0896860820970834*.

[83] *https://pubmed.ncbi.nlm.nih.gov/29199769/*.

[84] *https://academic.oup.com/ckj/article/16/2/210/6696026*.

[85] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594060/*.

[86] *https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/1744-9987.12660*.

[87] *https://www.sciencedirect.com/science/article/pii/S0085253815528664*.

[88] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program*.

[89] *https://academic.oup.com/ckj/article/16/12/2493/7210548*.

[90] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis*.

[91] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program*.

[92] *https://journals.lww.com/jasn/abstract/2023/12000/initial_management_and_potential_opportunities_to.9.aspx*.

[93] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan*.

beneficiaries choose a home dialysis modality.[94] We noted that the ability for beneficiaries with AKI to choose self-care dialysis in a home setting would offer a pathway to reduce these current disparities (insofar as the AKI population mirrors the ESRD beneficiary population) by promoting access to treatment, as well as removing a disparity in care between AKI beneficiaries and ESRD beneficiaries. We continue to believe it is crucial that the policy revisions to payment for AKI renal dialysis consider health equity and the effects on underserved populations. We identified that the rate of AKI was about 81 percent higher among African American/Black beneficiaries than among White beneficiaries.[95] We noted that we had reviewed comments and concerns from interested parties and agreed that home dialysis could benefit beneficiaries with AKI. We noted that issues with fluid management could be managed with more frequent, gentler modalities, such as PD. We stated that we trusted that providing an avenue to expand treatment modalities would encourage individualized and patient-centered treatment plans for beneficiaries with AKI, for example, addressing anemia and ESA management. We will continue to monitor outcomes for beneficiaries with AKI with the expectation that AKI PUF are being reviewed in quality improvement efforts by ESRD facilities that provide services to beneficiaries with AKI.

3. Home Dialysis Benefit for Beneficiaries With AKI

As we explained in the CY 2025 ESRD PPS proposed rule (89 FR 55806), we did not extend the home dialysis benefit to beneficiaries with AKI when we initially implemented the benefit (81 FR 77870). However, as discussed in the proposed rule (89 FR 55806 and 55807), we reviewed AKI monitoring data that showed the outcomes for anemia, ESA use, and fluid management are not necessarily reflective of the specific, individualized care, and close supervision by qualified staff currently required during the in-center dialysis process. We further noted that research demonstrated the use of PD correlated with positive outcomes for fluid management and a lower rate of anemia with less utilization of ESAs and iron. In the proposed rule we indicated that research related to home dialysis in the AKI patient population has primarily discussed results using PD as the modality; however, we would provide payment for either PD or HD as a home modality. We noted our goal was for beneficiaries with AKI to receive the necessary care to improve their condition, recover kidney function, and be weaned from dialysis treatment. We also noted that the literature exhibits a high correlation between the use of PD treatment for beneficiaries with AKI and positive outcomes for fluid management, infection rates, mortality, and recovery of kidney function.[96] Additionally, we reviewed research that demonstrated that the use of PD to manage the care of beneficiaries with AKI as a result of COVID–19 was successful and that beneficiaries who had successfully begun a treatment regime that could transition from the hospital to a home modality should not have to change treatment to an in-center treatment modality.

We proposed, based on the current research we cited (89 FR 55806 through 55807), to extend the home dialysis benefit as defined at 42 CFR 410.52 to beneficiaries with AKI for either PD or HD. As discussed in section III.C.1 of this final rule, we proposed that the payment amount for home dialysis for AKI beneficiaries would be the same as the payment amount for in-center dialysis for AKI beneficiaries, consistent with payment parity within the ESRD PPS. This payment amount would be the ESRD PPS base rate, adjusted for geographic area, as described in section III.C.2 of this final rule. Additionally, as discussed in section III.C.3 of this final rule, we proposed to extend the training add-on payment adjustment for home and self-dialysis training in the same amount as for patients with ESRD, on a budget neutral basis. We proposed to revise § 413.373, which currently states ''The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act,'' by adding paragraph (a) before ''The payment rate'' that reads ''CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.'' We proposed to move the current language to paragraph (b) with a technical revision to add ''of the Act'' after ''section 1834(r)''. Furthermore, as discussed in section III.D of this final rule, we proposed changes to the ESRD facility CfCs that would accommodate the provision of home dialysis for beneficiaries with AKI and help ensure safe and high-quality care for Medicare beneficiaries in this setting.

We proposed to amend § 410.52 to provide Medicare payment for the treatment of patients with AKI in the home setting. We proposed to revise § 410.52 to read ''Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:'' by striking the words ''an ESRD patient'' after ''to'' and adding the words ''a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter'' after ''to''. We also proposed to revise § 413.374(a) to read: ''The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.''

We invited public comment on our proposal for extending the home dialysis benefit to beneficiaries with AKI. Approximately 27 commenters including LDOs; regional health systems; a home dialysis services provider; a coalition of dialysis organizations; a provider advocacy organization; a non-profit dialysis association; an advocacy group for people living with a serious illness; a non-profit organization of ESRD networks; a non-profit organization for environmental health and justice; a professional organization of pediatric nephrologists; a professional organization of nephrologists; a home dialysis stakeholder alliance; a national organization of patients and kidney health care professionals; a hospital association; a non-profit kidney care alliance; a non-profit kidney organization; device manufacturers; a patient-led dialysis organization; and ESRD patients commented on the proposed regulation. The following is a summary of the public comments received on these proposals and our responses.

Comment: Many commenters were overwhelmingly in favor of the proposal to extend the home dialysis benefit to beneficiaries with AKI. The commenters agreed that while evidence is limited, experience from the COVID–19 PHE supports modifying payment policy to ensure home modalities would be available for appropriate patients with AKI. A patient with ESRD spoke to the

[94] *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[95] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/chronic-kidney-disease/4-acute-kidney-injury.*

[96] *https://pubmed.ncbi.nlm.nih.gov/29199769/.*

importance the proposal would have in empowering beneficiaries, in reducing their travel burden, and in enhancing their general quality-of-life. A LDO expressed they were ''excited,'' and a home dialysis services provider expressed their ''enthusiastic support'' for the proposed policy change. Some commenters indicated that the proposal is an important step forward in mitigating health disparities. Additionally, some commenters expressed that providing patients with AKI access to home modalities, particularly PD, could support recovery of kidney function because of positive clinical outcomes. A few commenters spoke about the quality-of-life benefits and the positive move toward patient-centered care the proposal could generate. One commenter agreed that there are safety concerns surrounding home dialysis for beneficiaries with AKI, but that these can be mitigated with appropriate training. Finally, some commenters indicated that training beneficiaries with AKI for a home dialysis modality could be beneficial if the beneficiary did not recover kidney function and progressed to having ESRD.

Response: CMS appreciates the support from commenters for the proposal to extend the home dialysis benefit with appropriate training to beneficiaries with AKI. We agree with commenters that extending the home dialysis benefit with appropriate training to beneficiaries with AKI could advance positive outcomes for beneficiaries who choose a home dialysis modality.

Comment: A hospital association expressed confusion about the frequency of care received by chronic maintenance home dialysis patients and by extension the frequency of care a patient with AKI could receive in the home setting. Additionally, the same commenter indicated concern that the proposed rule does not include treatment of transplant patients with late graft recovery in the AKI definition.

Response: A beneficiary with AKI and their health care provider would still determine the best frequency of care. CMS would provide payment for home dialysis treatments furnished to AKI beneficiaries at the ESRD PPS base rate determined for the year under section 1881(b)(14) of the Act, as statutorily required at section 1834(r)(1) of the Act. In the CY 2011 ESRD PPS final rule CMS explained that home dialysis treatments are paid the same rate as in-center treatments (75 FR 49058). Additionally, CY 2011 ESRD final rule provided an explanation that a week of home dialysis is converted into three equivalent in-center HD treatments. In the CY 2017 ESRD PPS final rule we stated that there is no weekly limit on the number of dialysis treatments that will be paid for beneficiaries with AKI (81 FR 77867). AKI is defined statutorily at section 1834(r)(2) of the Act. CMS cannot change the definition of AKI to include beneficiaries who have had a kidney transplant that experience late graft recovery. Beneficiaries that have had a transplant are still covered under the ESRD benefit for three years post-transplant. Therefore, the beneficiary that had a transplant could dialyze in an outpatient ESRD facility under the ESRD benefit.

Comment: One commenter questioned how to use CPT codes such as 90945 (Dialysis procedure other than hemodialysis) and 90947 (Dialysis procedure other than hemodialysis requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revisions of dialysis prescription) when billing for home dialysis rather than in-center.

Response: We refer the commenter to the Medicare Claims Processing Manual Chapter 8 § 170, which indicates that codes 90935, 90937, 90945, or 90947 are only used if the place of service on the claim is an inpatient hospital. This is because all physicians' outpatient renal-related services are included in payment made under the monthly capitation payment.[97]

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to extend the home dialysis benefit to beneficiaries with AKI, as proposed. Accordingly, we are finalizing our proposal to revise § 410.52 to read: ''Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home.'' We are also finalizing our proposal to revise § 413.374(a) to read: ''The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.''

[97] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.*

C. Annual Payment Rate Update for CY 2025

1. CY 2025 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. As discussed in section II.B.4 of this final rule, the final ESRD PPS base rate is $273.82, which reflects the application of the CY 2025 wage index budget-neutrality adjustment factor of 0.988600 and the CY 2025 ESRDB market basket percentage increase of 2.7 percent reduced by the productivity adjustment of 0.5 percentage point, that is, 2.2 percent. Accordingly, we are finalizing a CY 2025 per treatment payment rate of $273.82 (($271.02 × 0. 988600) × 1.022 = $273.82) for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we have applied a $0.00 budget neutrality adjustment to the AKI per treatment base rate as discussed in section III.C.3 of this final rule to address the training add-on payment adjustment for home dialysis modalities in the AKI beneficiary population. We did not receive specific comments related to the CY 2025 AKI dialysis payment rate. We discuss general comments on the ESRD PPS base rate in section II.B.4 of this final rule, and we discuss comments related to the budget neutrality reduction to the AKI payment rate to account for the training add-on payment adjustment in section III.C.3 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 percentage increase 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. As discussed in section II.B.2.b of this final rule, we are finalizing a new ESRD PPS wage index methodology, which utilizes BLS OEWS

data and freestanding ESRD facility cost report data. We proposed to use this same methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice of using the ESRD PPS wage index for AKI dialysis payments. 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 ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. As stated previously, we are finalizing a CY 2025 AKI dialysis payment rate of $273.82, adjusted by the ESRD facility's wage index. We did not receive specific comments related to the CY 2025 AKI geographic adjustment factor. We discuss general comments related to the new ESRD PPS wage index methodology in section II.B.2 of this final rule.

3. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the previous section of this final rule, we proposed to extend AKI dialysis payment to home dialysis.

As we explained in the CY 2025 ESRD PPS proposed rule (89 FR 55807), we considered our existing payment policies for home dialysis for beneficiaries with ESRD in implementing payment for home dialysis in the AKI patient population. In the CY 2011 ESRD PPS final rule, we explained that although we included payments for providing training to beneficiaries in computing the ESRD PPS base rate, we agreed with commenters that we should pay for home dialysis training as a training add-on payment adjustment under the ESRD PPS to account for the cost of providing training to beneficiaries on the use of home dialysis modalities. Thus, we finalized the home dialysis training add-on payment adjustment of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either hemodialysis or peritoneal dialysis training and retraining (75 FR 49063). We clarified our policy on payment for home dialysis training again in the CY 2013 ESRD PPS final rule, in which we stated that training costs are included in the ESRD PPS base rate; however, we also provide a training add-on payment adjustment for each home and self-dialysis training treatment furnished by a Medicare-certified home dialysis training facility (77 FR 67468). We explained in the CY 2017 ESRD PPS final rule that it is not the intent of the training add-on payment adjustment to reimburse a facility for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility-level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone (81 FR 77854).

In the CY 2025 ESRD PPS proposed rule we considered making payment for home dialysis for beneficiaries with AKI under the ESRD PPS base rate without a training add-on payment adjustment for home modality training (89 FR 55807). As we noted in section III.A. of the final rule, the ESRD PPS base rate upon which the AKI dialysis payment rate is established contains monies for training related costs. However, we stated in the proposed rule (89 FR 55809) that we are concerned that not providing a home and self-dialysis training add-on payment adjustment for AKI dialysis may limit access to home dialysis care for the AKI beneficiary population. As previously noted, incorporation of an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act into AKI dialysis payments must be done on a budget neutral basis for payments under section 1834(r) of the Act. Therefore, we stated that establishing a training add-on payment adjustment for training for home and self-care dialysis could have an impact on the AKI base rate.

As discussed in the proposed rule, we reviewed options for applying budget neutrality to a home and self-dialysis training add-on payment adjustment for beneficiaries with AKI. We considered applying a budget neutrality adjustment factor by reducing the AKI dialysis payment rate amount (which is based on the ESRD PPS base rate and is then adjusted for wages according to § 413.372) for renal dialysis services provided to patients with AKI to account for the training add-on payment adjustment. We provided an example for a potential calculation based on ESRD PPS data in the proposed rule (89 FR 55809). Additionally, we noted our concern that a decrease in the AKI dialysis payment rate to account for the home dialysis training add-on payment adjustment might create a disincentive for ESRD facilities to treat beneficiaries with AKI. We welcomed comments regarding budget neutralizing the home dialysis training add-on payment adjustment and solicited comments on other venues where beneficiaries might receive training for a home dialysis modality (89 FR 55809).

We proposed, in accordance with section 1834(r)(1) of the Act and § 413.373, to extend the home and self-dialysis training add-on payment adjustment under § 413.235(c) to payments for renal dialysis services provided to beneficiaries with AKI using a home modality. We proposed to make payment for a home and self-dialysis training add-on payment adjustment at the same amount currently applicable under the ESRD PPS of $95.60 with a limit of 15 training treatments for PD and a limit of 25 training treatments for HD per patient excluding retraining sessions (75 FR 49063). Additional information regarding the maximum number of training treatments for which CMS provides payment under the ESRD PPS is located in the Medicare Claims Processing Manual.[98] We requested data, either actual or estimated, regarding the number of training sessions provided to beneficiaries with AKI and the number of beneficiaries with AKI using a home modality (89 FR 55809) to use this information to make a determination on a training add-on payment adjustment in the CY 2025 ESRD PPS final rule or in future rulemaking for subsequent years.

We invited public comment on our proposal for a payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting. Approximately 27 commenters including LDOs; a coalition of dialysis organizations; a regional health system; a provider advocacy organization; a non-profit dialysis association; and a

[98] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.*

home dialysis stakeholder alliance commented on the proposed payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters stated concerns regarding budget neutrality. The commenters indicated that they believe the home dialysis training add-on payment adjustment was previously budget neutralized in the ESRD PPS CY 2017 final rule. Additionally, they stated that they believe ESRD facilities that have provided services to beneficiaries with AKI have been underpaid since the budget neutralization in the CY 2017 ESRD PPS final rule. A few of the commenters indicated that beneficiaries with AKI that progressed to ESRD would already have received training for home dialysis and would not need to receive training as a beneficiary with ESRD. They believed this satisfied the budget neutrality requirement. Additionally, some commenters urged that CMS delay implementation of budget neutrality for these training add-on payment adjustments for AKI beneficiaries until sufficient data was collected on home utilization in the AKI beneficiary population.

Response: We appreciate the concerns of commenters that believe the training add-on payment adjustment was previously budget neutralized and therefore budget neutrality should not be a factor in this rule. We find that interpretation to be inconsistent with the statute because it would result in increased total AKI payments for CY 2025 relative to what they would be if CMS did not incorporate the training add-on payment adjustment. CMS rejected this premise in the ESRD PPS CY 2017 final rule where we indicated we interpret the payment rate for AKI to be the finalized base payment rate for ESRD, as the statute was clear that the payment rate for AKI dialysis must be the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act (81 FR 77867). CMS is compelled by section 1834(r)(1) of the Act to apply budget neutrality to the AKI payment to maintain total payments under section 1834(r) of the Act when incorporating an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

CMS appreciates the commenters that expressed that training beneficiaries with AKI for home dialysis would offset the training for the beneficiaries who progress to ESRD. However, the beneficiaries who progress to ESRD would be eligible for the onset add-on payment adjustment, since both the training add-on payment adjustment and onset add-on payment adjustment cannot be applied at the same time (75 FR 49063). Furthermore, we would not rule out that some beneficiaries with AKI might require retraining after their disease progresses to ESRD. We do not believe that training beneficiaries to perform self-dialysis would create budget neutrality if their disease should progress to ESRD. Additionally, we appreciate the commenter who suggested that budget neutrality be delayed until sufficient data was collected. However, this would not be consistent with our general interpretation of statutes requiring budget neutrality, such as section 1834(r)(1) of the Act, as payments would increase for CY 2025. Generally, when we implement policies within the ESRD PPS budget neutrally, we do so based on estimates for the rulemaking year rather than retrospectively, and we do not adjust such adjustment post-hoc. For example, when we implemented the LVPA in CY 2011 we applied a budget-neutrality adjustment factor to the CY 2011 ESRD PPS base rate which accounted for all budget-neutral payment adjustments, including the LVPA, by holding total estimated payments for CY 2011 constant (75 FR 49194). Because this downward adjustment to the CY 2011 ESRD PPS base rate carried forward into future years (in which the base rate is only increased by the applicable annual market basket increase), it continues to offset the spending associated with those budget-neutral payment adjustments in future years as well.

Comment: Several commenters expressed concern that CMS had over-estimated the utilization of home modalities in the AKI beneficiary population. These commenters believe that providers and patients would need time to receive education about beneficiaries with AKI receiving dialysis in a home setting and that growth would be slow. These commenters believe that because of the over-estimation of utilization there is the potential to disincentivize ESRD facilities from providing services to beneficiaries with AKI. Additionally, some of the commenters indicated that CMS had over-estimated the number of training sessions that would be required for beneficiaries with AKI to successfully manage a home modality. These commenters indicated that initial training for a home dialysis modality may be provided while the beneficiary is hospitalized. They indicated that beneficiaries with AKI would likely only require 5 to 6 training sessions to successfully manage a home dialysis modality.

Response: We appreciate the commenters that provided information regarding CMS's estimation of utilization in the CY 2025 ESRD PPS proposed rule (89 FR 55809). We agree with commenters that the majority of beneficiaries with AKI who choose a home dialysis modality likely will be those that transition from the hospital utilizing PD as their home treatment modality. Additionally, we agree that utilization of home modalities for beneficiaries with AKI will be dependent on education to providers and patients. We have reviewed the available data considering these comments and have made revisions to the calculation for budget neutrality. After considering the comments on the use of PD for AKI, we have determined that it would be more reasonable to estimate utilization for home AKI based on in-center PD utilization. We found that from 2017 through 2023, there were 10 beneficiaries with AKI that received PD in-center. For the calculation of budget neutrality, this is approximately 2 beneficiaries with AKI per year receiving PD. As we agree with commenters that beneficiaries with AKI likely will receive partial training in the hospital to manage the home dialysis modality, we will estimate 6 training treatments for beneficiaries with AKI transitioning to a home modality. Lastly, as the training add-on payment adjustment would be adjusted by the wage index for the ESRD facility furnishing the training, we will multiply the training add-on payment adjustment amount of $95.60 by the average wage index for AKI, which is 1.0204. Using this data, we could estimate a cost of training to be $1170.60 ($2 \times 6 \times \$95.60 \times 1.0204$) or $0.0042. ($1170.60/279,000) per AKI treatment. Since the per treatment budget neutrality estimate would round to $0.00, we believe that applying this amount of reduction to the AKI base payment will be negligible. While budget neutrality was applied to the AKI base rate for home training for beneficiaries with AKI, we note that the actual amount of the reduction to the AKI payment per treatment rounds to $0.00, and therefore the AKI CY 2025 base rate would be $273.82 ($273.82 − $0.00) using this estimate. We plan to monitor data related to AKI including the uptake of home dialysis. We may revisit the calculation for budget neutrality as appropriate in the future.

Comment: One commenter suggested that training within a nursing facility should be paid only if the patient was

transitioning to home dialysis outside of the nursing facility.

Response: We note the commenter addressed concerns regarding training of beneficiaries with AKI in nursing facilities. CMS addressed this in the ESRD PPS CY 2011 final rule. Nursing caregivers at nursing facilities are not paid through the ESRD PPS (75 FR 49057). Therefore, training provided by nursing caregivers at nursing facilities would not be paid through the ESRD PPS. A nursing home resident that is independently performing home dialysis treatments would be eligible for a training add-on adjustment if there is the expectation the beneficiary can successfully complete the training and perform self-dialysis.

Final Rule Action: We are finalizing our proposal to extend a payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting, beginning January 1, 2025. Specifically, we are finalizing our proposal to provide a payment for home dialysis training and home dialysis modalities for beneficiaries with AKI, with certain changes to the proposed methodology for calculating budget neutrality. As discussed previously, we are finalizing the requirement for a per-treatment budget neutrality reduction of $0.00 ($1146.84/279,000) which would be applied to the AKI base payment rate. We are codifying this requirement in regulation at § 413.373. As discussed in section III.C.3. of this final rule, we are finalizing the addition of a wage-adjusted training add-on payment adjustment per treatment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims. Furthermore, we are codifying in regulation at § 410.52, as discussed in section III.C.3. of this final rule, to provide Medicare payment for the treatment of patients with AKI in the home setting.

D. AKI and the ESRD Facility Conditions for Coverage

1. Statutory and Regulatory Background

ESRD is a kidney impairment that is irreversible and permanent. Dialysis is a process for cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. People with ESRD require either a regular course of dialysis or kidney transplantation to live. Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. Acute kidney injury (AKI) is different than ESRD; it is an acute decrease in kidney function due to kidney damage or kidney failure that may require dialysis. Unlike people with ESRD, most individuals with AKI who require dialysis are expected to regain kidney function within three months. People with either ESRD or AKI can receive outpatient dialysis services from Medicare-certified ESRD facilities, also called dialysis facilities.

The Medicare ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975, **Federal Register** (40 FR 27782), we published a proposed rule that proposed to revise sections of the ESRD requirements. On June 3, 1976, the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage or CfCs) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment. In addition, section 1881(c) of the Act establishes ESRD Network areas and Network organizations to assure that dialysis patients are provided appropriate care. The ESRD facility CfCs were first adopted in 1976 and comprehensively revised in 2008 (73 FR 20369). 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 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.

Medicare pays for routine maintenance dialysis provided by Medicare-certified ESRD facilities, also known as dialysis facilities. To gain certification, the State survey agency or CMS-approved accrediting organization performs an on-site survey of the facility to determine if it meets the ESRD facility CfCs at 42 CFR part 494. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, CMS then certifies the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. As of March 2024, there are approximately 7,700 Medicare-certified dialysis facilities in the United States,[99] providing dialysis services and specialized care to people with ESRD; 3,700 of which provide home dialysis services, including training and support.[100]

The ESRD facility CfCs found at 42 CFR part 494, consist of the health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients with kidney failure receive safe and appropriate care. In addition, the CfCs require patients to be informed about all treatment modalities (hemodialysis or peritoneal dialysis) and settings (home dialysis modalities or in-facility hemodialysis) (§ 494.70(a)(7)). A dialysis facility that is certified to provide services to home patients must ensure that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of § 494.100. The patient's interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10). Dialysis facilities monitor home dialysis by documenting adequate comprehension of the training; retrieving and reviewing complete self-monitoring data and other information at least every two months; and

[99] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

[100] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

maintaining this information in the patient's medical record.

In the CY 2017 ESRD PPS final rule (81 FR 77834), we clarified that ESRD facility CfCs apply to ESRD facilities, not to people with ESRD, and noted that the ESRD facility CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. While the language of the ESRD facility CfCs does not directly address treatment of beneficiaries with AKI, we believe that the current ESRD facility requirements are sufficient to ensure that such patients are dialyzed safely. For example, infection control protocols are the same for any individual receiving hemodialysis, regardless of the cause or likely trajectory of their kidney disfunction. For the areas in which care and care planning may differ, such as frequency of certain patient assessments, we note that the CfCs set baseline standards and do not limit additional or more frequent services that may be necessary for beneficiaries with AKI receiving temporary dialysis as they recover kidney function.

During the development of the CY 2017 ESRD PPS final rule, we did not anticipate that beneficiaries with AKI would be candidates for home dialysis due to the likely short-term duration of treatment and the unique needs of AKI. Therefore, we did not propose to extend the home dialysis benefit to beneficiaries with AKI at that time (81 FR 77870). The initial concerns about the appropriateness of dialysis at home for individuals with AKI have been allayed by the existing scientific evidence of the effectiveness of that modality in this population. By revising the CfCs to facilitate beneficiaries with AKI utilizing home dialysis, we would increase patient options for renal replacement treatment beyond in-center hemodialysis and better empower these patients to make decisions about their care. We encourage readers to refer to the CY 2025 ESRD PPS proposed rule for this detailed discussion (CMS–1805–P).

2. Provisions of the Proposed Regulations and Analysis and Response to Public Comments

In response to the proposed rule, we received 22 comments pertaining to the expansion of home dialysis for AKI patients, with 6 comments specifically mentioning the conforming changes to the CfCs. Commenters included patient care organizations, dialysis facilities, and individual patients. To support treatment location choices for individuals with AKI requiring dialysis and to align with the coverage changes, we proposed conforming changes throughout the ESRD facility CfCs at 42 CFR part 494. We noted that the phrase ''ESRD patients'' is exclusive of beneficiaries with AKI, while phrase ''kidney failure'' is inclusive of people whose kidney function is inadequate such that dialysis is necessary to maintain or prolong life. This can be a temporary (AKI) or permanent (ESRD) condition. Accordingly, we proposed to amend the definitions of home dialysis and self-dialysis at §§ 494.10, 494.70(c)(1)(i), and 494.130 introductory text by removing the descriptor ''ESRD.'' In addition, we proposed to amend the following requirements: §§ 494.70(a)(1) and (10) and 494.80 introductory texts by revising the phrase ''ESRD'' to say ''kidney failure;'' § 494.90(b)(4) by revising the phrase ''ESRD care'' to say ''dialysis care;'' § 494.100(a)(3)(i) by revising the phrase ''management of ESRD'' to say ''management of their kidney failure;'' § 494.120 introductory text by revising the phrase ''serve ESRD patients'' to say ''serve patients with kidney failure;'' and lastly § 494.170 introductory text by revising the phrase ''provider of ESRD services'' to say ''provider of dialysis services.''

Comment: All the comments expressed support for the expansion of coverage for home dialysis to beneficiaries with AKI, with a couple specifically agreeing with the conforming changes in the CFCs. Commenters cited many benefits including choosing hours that work best for the patient, reducing travel burden (especially for patients in rural areas), and saving on healthcare costs. In addition to increasing access to home dialysis for all AKI patients, commenters indicated that they believe this policy supports our goal to expand home dialysis services for those AKI patients that proceed to ESRD. Commenters stated that the provision would reduce health disparities associated with home dialysis services. Commenters agreed that ''patient'' and ''kidney failure'' are the appropriate terminology for the CfCs to encompass both ESRD & AKI patients.

One commenter shared concerns about the safety of getting dialysis at home for what will generally be a short or limited period. Another commenter requested clarification on application of this policy to residents of long-term care facilities.

Response: We thank commenters for their support and taking the time to respond. We believe that patients with AKI are medically complex, and the clinical decision regarding the next stage of treatment should be evaluated by a physician or other licensed advanced practitioner and agreed upon mutually among the patient, care partners, and physician. Importantly, the entire armamentarium of treatment options must be available to provide the most patient-centered care and allow for the best outcomes. This policy aligns with the broader goals of patient-centered care and individualized treatment plans. We believe the current CfCs for home dialysis services provide sufficient training, education, and safety standards for AKI patients to safely dialyze at home, regardless of the duration of the services. We view home therapies as supervised care that is of at least similar quality and intensity to in-center hemodialysis and highlight our commitment to ensuring the success of all patients with AKI, regardless of whether they are receiving dialysis in the home or in a hemodialysis facility. Additionally, the home dialysis CfCs are applicable to home dialysis suppliers who provide such services in long-term care settings, since these locations are considered to be a patient's home. The Quality, Safety and Oversight Group (QSOG) has published sub-regulatory guidance (QSO–18–24–ESRD) that addresses patients receiving home dialysis services in nursing homes. This guidance is applicable to AKI patients receiving home dialysis services in LTC facilities.

Final Rule Action: We are finalizing our proposal to amend the ESRD facility CfCs to be inclusive of patients with AKI, without modification. For the reasons discussed in section III.B. of this final rule, we are extending coverage of home dialysis services to beneficiaries with AKI, allowing them flexibility in choosing their preferred treatment modality (hemodialysis vs. peritoneal dialysis) and location (in-center vs. home). Since the ESRD facility CfCs apply to ESRD facilities as a whole, not to solely to their patients with ESRD, we are providing clarifying revisions to the CfCs to align with the final coverage changes.

3. Expected Impact

Beneficiaries with AKI requiring dialysis represent a small subset of individuals treated in outpatient dialysis facilities. Specifically, around 12,000 patients will be eligible for this optional service.[101] Expanding coverage to include beneficiaries with AKI will not present any changes in burden on ESRD facilities or establish new information collections subject to the Paperwork Reduction Act.

[101] USRDS Annual Data Report 2023.

E. Clarification About Medicare Payment for Phosphate Binders for Beneficiaries With AKI

In the CY 2025 ESRD PPS proposed rule, we did not propose any policies related to payment for phosphate binders for beneficiaries with AKI during the period beginning January 1, 2025, when these drugs will be incorporated into the ESRD PPS and paid for using the TDAPA. While we did not receive any public comments on this topic, we are taking the opportunity in this final rule to provide clarity on this issue.

Under our longstanding policy, we have not applied any ESRD PPS adjustments to the AKI payment amount, other than the wage index adjustment. When we established the AKI benefit in the CY 2017 ESRD PPS final rule, we adopted regulations at § 413.372, which specify that only the adjustment for wages as set forth in § 413.231 shall apply to the amount of payment for AKI dialysis services. We also finalized regulations at § 413.373, which state that any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act that may be applied to the payment for AKI dialysis services is applied on a budget neutral basis for payments under section 1834(r). We stated in the CY 2017 ESRD PPS final rule that we were not adjusting the payment amount by any other factors at that time but indicated that we would potentially do so in future years (81 FR 77868). In that same final rule, we further explained that we finalized a policy to pay separately for all items and services that are not part of the ESRD PPS base rate. We explained that once we have substantial data related to the AKI population and its associated utilization, we would determine the appropriate steps toward further developing the AKI payment rate (81 FR 77868).

In the CY 2018 ESRD PPS final rule, a commenter requested that we clarify whether the TDAPA applies to AKI renal dialysis services. In response, we stated that we would issue additional program guidance that would address the application of the TDAPA to AKI services and other billing guidance. We stated that if we determine that it is appropriate for the TDAPA to apply to AKI services, we would consider that to be a substantive payment policy, which would be established through notice and comment rulemaking (82 FR 50756). CMS subsequently issued guidance [102] [103] which clarified that ESRD facilities would not be responsible for furnishing calcimimetics to individuals with AKI while calcimimetics were being paid for under the TDAPA. We further explained that Sensipar (HCPCS code J0604) remained payable under Medicare Part D for AKI beneficiaries until the costs were rolled into the ESRD PPS bundled payment, at which point it would transition to the bundled payment amount. With regard to Parsabiv (HCPCS code J0606), we stated that this drug was not indicated for AKI and therefore no bills should be submitted for Parsabiv in the AKI population.

We believe that with respect to Medicare payment for phosphate binders for beneficiaries with AKI, it is appropriate to maintain the same policy which applied for calcimimetics during the period in which they were paid for using the TDAPA under the ESRD PPS. Section 1834(r) of the Act requires that any adjustments made to the AKI payment amount under 1881(b)(14)(D) of the Act, other than the applicable geographical adjustment factor applied under subparagraph (D)(iv)(II) of the Act, must be applied on a budget neutral basis for payments under section 1834(r) of the Act. Because the TDAPA is a non-budget neutral add-on payment adjustment under section 1881(b)(14)(D)(iv) of the Act, we do not believe that it is appropriate to apply the TDAPA to claims for AKI dialysis under section 1834(r) of the Act. More specifically, if we were to apply the TDAPA to AKI payments, we believe that section 1834(r) of the Act would require us to apply a budget neutrality adjustment factor, which would reduce the AKI dialysis payment rate and be contrary to the policy objective of the TDAPA to provide additional payment for certain new renal dialysis drugs and biological products.

We also believe that consistent with our policy for calcimimetics during CY 2018 through CY 2020, allowing phosphate binders to remain separately payable under Part D for beneficiaries with AKI that have a Part D medically-accepted indication meets the requirements under section 1834(r) of the Act and the requirements under § 413.374(a) to make payment under the AKI dialysis payment rate for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act. We have not interpreted these statutory and regulatory requirements to apply to renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate. Specifically, we note that oral-only drugs are renal dialysis services under subparagraph (B) of section 1881(b)(14) of the Act; however, we have not paid for these drugs as part of the AKI dialysis payment rate, because they were not included in the ESRD PPS base rate. If we had interpreted section 1834(r) of the Act and § 413.374(a) to require payment under the AKI dialysis payment rate for oral-only renal dialysis drugs and biological products, then we would have been required to include payment for these drugs in the AKI dialysis payment rate before payment was included under the ESRD PPS, which we believe would have conflicted with the statutory requirements of ATRA, as amended by PAMA, and amended by ABLE, which ultimately delayed the inclusion of oral-only drugs into the ESRD PPS until January 1, 2025. Rather, we have interpreted the requirements of section 1834(r) of the Act and § 413.374(a) to provide a single payment for those renal dialysis services that are considered included in the ESRD PPS base rate. Consistent with that interpretation, as discussed earlier in this final rule, we explained in sub-regulatory guidance that oral calcimimetics remained separately payable under part D for AKI beneficiaries until they were incorporated into the ESRD PPS base rate.

For this CY 2025 ESRD PPS final rule, we are clarifying that we are maintaining the same policy for phosphate binders provided to beneficiaries with AKI that we applied to calcimimetics. That is, we are clarifying that ESRD facilities will not be responsible for furnishing phosphate binders to individuals with AKI while phosphate binders are being paid for using the TDAPA under the ESRD PPS. As discussed in section II.B.7 of this final rule, CMS published guidance containing information about the HCPCS codes for phosphate binders at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf*. None of the drugs described by these HCPCS codes is indicated for patients with AKI, and therefore we do not expect these drugs will be provided for the treatment of AKI and billed for on AKI claims. To the extent that phosphate binders are provided to AKI beneficiaries other than for the treatment of their AKI, such as for preexisting chronic kidney disease, they will remain separately payable

[102] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017downloads/r1941otn.pdf*.

[103] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm102811.pdf*.

under Part D for beneficiaries with AKI that have a Part D medically-accepted indication until they are incorporated into the ESRD PPS base rate. We believe this policy will provide appropriate payment for phosphate binders furnished to beneficiaries with AKI.

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

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

In the proposed rule, we proposed to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a comprehensive measure on which facilities are scored for each payment year using one set of performance standards, with a Kt/V measure topic comprised of four individual Kt/V measures, beginning with PY 2027 (89 FR 55814 through 55815). We also proposed to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027 (89 FR 55815 through 55816). Table 12 of the proposed rule summarized the previously finalized and proposed updated measures that we would include in the PY 2027 ESRD QIP measure set (89 FR 55813). As discussed in IV.B.2 and IV.B.3 of this final rule, we are finalizing our updates to the PY 2027 ESRD QIP measure set as proposed. We describe the finalized PY 2027 ESRD QIP measure set in Table 13, which includes the previously finalized measures and the measures we are finalizing in this final rule. In the proposed rule, we stated that the technical specifications for current measures that would remain in the measure set for PY 2027 can be found in the CMS ESRD Measures Manual for the 2024 Performance Period (89 FR 55812).[104] We also noted that the proposed technical specifications for the measures in the proposed Kt/V measure topic can be viewed at *https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/technical-specifications-esrd-qip-measures*. Finally, we stated that if the Kt/V measure topic is finalized, these specifications will be included in the CMS ESRD Measures Manual for the 2025 Performance Period.

TABLE 13: Finalized PY 2027 ESRD QIP Measure Set

Consensus-Based Entity[105] (CBE) #	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 survey questions.
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 CBE #2979	Standardized Transfusion Ratio (STrR), a clinical 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.
Based on CBE #0323, #0321, #2706, and #1423*	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.
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 reporting 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 CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure

[104] *https://www.cms.gov/files/document/esrd-measures-manual-v91.pdf*.

[105] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

Consensus-Based Entity[105] (CBE) #	Measure Title and Description
	The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
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.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who are up to date on their COVID-19 vaccination.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.
N/A	Screening for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).
N/A	Screen Positive Rate for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety), and who screened positive for one or more of the HRSNs.

*We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule. We note that, although the Kt/V Dialysis Adequacy Measure Topic is not endorsed by the CBE, the four individual Kt/V measures that are included in the measure topic are CBE-endorsed.

**We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

2. Replacement of the Kt/V Dialysis Adequacy Comprehensive Clinical Measure With a Kt/V Dialysis Adequacy Measure Topic Beginning With the PY 2027 ESRD QIP

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of dialysis adequacy. Beginning with the PY 2027 ESRD QIP, we proposed to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a single comprehensive measure on which facility performance is calculated using one set of performance standards for each payment year, with a Kt/V Dialysis Adequacy Measure Topic, a measure topic comprising four individual Kt/V measures on which facility performance is calculated using performance standards for each individual Kt/V measure (89 FR 55814 through 55815).[106] In the CY 2025 ESRD PPS proposed rule, we proposed to remove the Kt/V Dialysis Adequacy Comprehensive clinical measure under § 413.178(c)(5)(i)(E), which is Measure Removal Factor 5 (a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available), and proposed to replace it with the proposed Kt/V Dialysis Adequacy Measure Topic, which consists of four individual Kt/V measures. Under this proposed update, we stated that the individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V (89 FR 55814).

By replacing the current Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures, we noted that we would be able to assess Kt/V performance more accurately based on whether the patient is an adult or child and what type of dialysis modality the patient is receiving. We also proposed to score the four measures as a Kt/V Dialysis Adequacy Measure Topic and to limit the total weight of that topic to 11 percent of the total performance score (TPS), which we stated is the weight of the current Kt/V Dialysis Adequacy Comprehensive clinical measure. We noted that these proposals would continue to maintain Kt/V measurement as an important part of the quality of care assessed by the ESRD QIP (89 FR 55814). Facilities are eligible to receive an individual Kt/V measure score if they treat at least 11 eligible patients using the modality addressed by that particular measure. For example, a facility treating at least 11 eligible pediatric HD patients during the applicable performance period would be scored on the Kt/V Pediatric HD measure. In the proposed rule, we stated that we would calculate a facility's measure topic score by first calculating the facility's performance on each of the Adult HD Kt/V, Adult PD Kt/V, Pediatric HD Kt/V, and Pediatric PD Kt/V measures, as applicable, using the applicable achievement threshold, benchmark, and improvement threshold for the payment year (89 FR 55814). Second, we would calculate the total number of eligible patients for weighting each of these measure scores to calculate a single measure topic score. We would calculate this total number by summing all eligible patients included in the denominator for each individual measure. Third, we would calculate the weighted score for each

[106] For further information related to the Kt/V Dialysis Adequacy Comprehensive clinical measure, we refer readers to 77 FR 67487 through 67490, 79 FR 66197 through 66198, and 80 FR 69053 through 69057.

measure within the measure topic by dividing the number of patients included in the denominator for each individual measure by the total number of eligible patients for all of the measures within the measure topic and multiplying by the respective measure score. Finally, we would add the weighted measure scores together and round them to the nearest integer. An example of how we would calculate the measure topic score for a facility that treats the minimum number of patients to be eligible for scoring on all four of the measures is provided below.

Measure	Measure Score	# Patients in denominator	Weighted Score
Kt/V Adult HD	8	60	8 * (60/125) = 3.84
Kt/V Adult PD	6	30	6 * (30/125) = 1.44
Kt/V Pediatric HD	9	15	9 * (15/125) = 1.08
Kt/V Pediatric PD	5	20	5 * (20/125) = 0.80

Kt/V Topic Score= 3.84+1.44+1.08+0.80 = 7.16, which rounds to **7**.

We noted in the proposed rule that a facility would not need to be eligible for scoring on all four individual measures to receive a measure topic score (89 FR 55814). For example, a facility that exclusively treats adult HD patients and, for that reason, is eligible to be scored on only the Kt/V Adult HD measure would receive a topic score that is the same score as its individual Kt/V measure score. We stated that the proposed measure topic scoring considers both a facility's individual ESRD patient population and the treatment modalities it offers, and then weights its performance on the topic proportionately to its overall ESRD patient population. As a result, we believe that a facility's measure topic score will be more reflective of its actual performance among its patient population and offered modalities than its current Kt/V Dialysis Adequacy Comprehensive clinical measure score, which is a composite assessment that blends the Kt/V measure data of all patients treated at that facility.

We noted that we previously adopted a Kt/V Dialysis Adequacy Measure Topic that included three of the four measures that we were now proposing to include in the topic (adult HD Kt/V, adult PD Kt/V, and pediatric HD Kt/V) in the CY 2013 ESRD PPS final rule (77 FR 67487 through 67490). In the CY 2015 ESRD PPS final rule (79 FR 66197 through 66198), we updated the Kt/V Dialysis Adequacy Measure Topic to include the pediatric PD Kt/V measure as well. In the CY 2016 ESRD PPS final rule (80 FR 69053 through 69057), we replaced the Kt/V Dialysis Measure Topic with the current Kt/V Dialysis Adequacy Comprehensive clinical measure, which assesses the percentage of all patient-months for both adult and pediatric patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the performance period. This change allowed more facilities to be eligible for measure scoring, which in turn allowed us to evaluate the care provided to a greater proportion of ESRD patients.

At the time we finalized the Kt/V Dialysis Adequacy Comprehensive clinical measure, three facilities were eligible for scoring on the pediatric HD Kt/V measure, six facilities were eligible for scoring on the pediatric PD Kt/V measure, 1,402 facilities were eligible for scoring on the adult PD Kt/V measure, and 6,117 facilities were eligible for scoring on the adult HD Kt/V measure. Given the relatively low numbers of facilities eligible for scoring on the pediatric HD Kt/V, pediatric PD KT/V, and adult PD Kt/V measures at that time, we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure to help ensure that data reflecting those patient populations contributed to facilities' total performance scores. Since the CY 2016 ESRD PPS final rule, however, we noted that Kt/V measure data (using the PY 2024/CY 2022 ESRD QIP eligible facility list, CY 2022 EQRS data, and CY 2022 claims data) indicates that more facilities are treating greater numbers of pediatric HD patients and pediatric PD patients, as well as greater numbers of adult PD patients, and therefore would be eligible to be scored on the individual measures based on an 11-patient case minimum (89 FR 55815). For example, there are now 21 pediatric HD facilities and 28 pediatric PD facilities with at least 11 qualifying patients. We stated that this shows a 600 percent increase in facilities eligible to be scored on the pediatric HD Kt/V measure, and a 366 percent increase in facilities eligible to be scored on the pediatric PD Kt/V measure, since the CY 2016 ESRD PPS final rule (89 FR 55815). Additionally, there are now 2,538 facilities eligible for scoring on the adult PD Kt/V measure, an 81 percent increase since the CY 2016 ESRD PPS final rule. By contrast, we noted that the number of facilities eligible for scoring on the adult HD Kt/V measure has increased by 14 percent during that same period of time.

In light of the increase in the proportions of pediatric HD patients, pediatric PD patients, and adult PD patients being treated at ESRD facilities since the time we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure, we have determined that it is appropriate and more reflective of facility performance to reintroduce the Kt/V Dialysis Adequacy Measure Topic in the ESRD QIP. In addition, we stated in the proposed rule that the proposed measure topic scoring methodology will more accurately capture facility performance with respect to dialysis adequacy because it assesses those facilities based on performance standards tailored according to Kt/V measurements that reflect ESRD patient age and treatment modality (89 FR 55815).

We noted that the proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also not affect a facility's measure data reporting requirements. A facility would continue to report the same Kt/V measure data into EQRS and Medicare claims as it would for the current Kt/V Dialysis Adequacy Comprehensive clinical measure. However, under the proposed Kt/V Dialysis Adequacy Measure Topic, the measure data would be used to score the facility on four individual Kt/V measures, as applicable based on their

ESRD patient population and treatment modalities.

In the proposed rule, we stated that the proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also advance the CMS National Quality Strategy Goals by scoring facilities on measure data that more accurately reflects the quality of care provided to different kinds of ESRD patients on different treatment modalities (89 FR 55815). We noted that the proposed Kt/V Dialysis Adequacy Measure Topic would allow us to evaluate dialysis adequacy in adult HD patients, adult PD patients, pediatric HD patients, and pediatric PD patients by scoring facilities in a way that accounts for differences in patient populations and treatment modalities. Therefore, this proposed update would ensure that a facility's performance on the measure topic more accurately reflects the quality of care provided by the facility.

We welcomed public comment on this proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, for the PY 2027 ESRD QIP and subsequent years. The comments we received, and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to remove the current Kt/V Dialysis Adequacy Comprehensive clinical measure and replace it with a Kt/V Dialysis Adequacy Measure Topic, noting that the measure topic will more accurately reflect a facility's performance based on different patient populations and treatment modalities. Several commenters expressed the belief that the proposed Kt/V Dialysis Adequacy Measure Topic will provide a more nuanced assessment of dialysis adequacy which will enhance the accuracy and relevance of quality assessments within the program. A few commenters also expressed support for the proposed Kt/V Dialysis Adequacy Measure Topic, noting that the current Kt/V Dialysis Adequacy Comprehensive clinical measure lacks transparency in terms of performance regarding patient population or dialysis modality, and also masks underlying social disparities in dialysis adequacy. A commenter expressed support for the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, noting that it does not change the current Kt/V data reporting requirements so there is minimal administrative burden associated with the proposed change.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the four individual Kt/V Dialysis Adequacy measures. A commenter expressed appreciation that the proposed update would align with other publicly reported data programs.

Response: We thank the commenters for their support.

Comment: A commenter expressed support for the inclusion of the pediatric HD Kt/V Dialysis Adequacy measure and the pediatric PD Kt/V Dialysis Adequacy measure, noting that including these measures in the Kt/V Dialysis Adequacy Measure Topic will help account for meaningful differences between pediatric and adult patient populations.

Response: We thank the commenter for their support.

Comment: A few commenters recommended that CMS adopt the original reporting requirements that assessed performance at the individual measure level, noting that reporting facility performance on the individual Kt/V measures would provide greater transparency to patients, caregivers, and health care providers. These commenters believed that such reporting requirements would be consistent with the legislative intent underlying the statutory authority of the ESRD QIP. A different commenter expressed concern that the measure data is not sufficiently transparent and that patients would not be able to assess a facility's performance relative to their specific treatment modality.

Response: We believe that the Kt/V Dialysis Adequacy Measure Topic, consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, strikes a balance between scoring a facility on its overall quality of care related to Kt/V dialysis adequacy while also reflecting its performance on Kt/V dialysis adequacy specific to different patient populations and treatment modalities. We note that information regarding a facility's performance on the individual measures, as well as the resulting measure topic score, is provided during the preview period and in final reports shared with the facility. We believe that this approach to measuring dialysis adequacy will further incentivize improvement on dialysis adequacy performance standards, consistent with section 1881(h) of the Act. We also note that data regarding facility performance on individual Kt/V dialysis adequacy measures is available through Dialysis Facility Compare, which reports the Kt/V dialysis adequacy measures individually on Care Compare. We will continue to monitor the Kt/V Dialysis Adequacy Measure Topic as it is implemented to ensure that it is sufficiently transparent in a way that is meaningful to patients, caregivers, and health care providers.

Comment: A commenter recommended that CMS ensure that the new individual measures do not impose new administrative or reporting burdens on care providers that may divert resources away from patient care.

Response: As we stated in the CY 2025 ESRD PPS proposed rule, the replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would not affect a facility's measure data reporting requirements, and therefore would not impose new administrative or reporting burdens on care providers (89 FR 55815). A facility would continue to report the same Kt/V measure data into EQRS and Medicare claims as it does for the current Kt/V Dialysis Adequacy Comprehensive clinical measure.

Comment: A commenter recommended including a measurement of residual kidney function (RKF) when appropriate in the determination of the HD Kt/V measure, noting the importance of taking RKF into account when assessing dialysis adequacy and the potential benefit to patient outcomes. Another commenter recommended that CMS adopt an alternate measure of dialysis adequacy for HD patients by looking at the percent of patients leaving dialysis at +/− 2 kg above/below their estimated dry weight.

Response: We thank the commenters for these recommendations and will take them into consideration for future updates. We consider the current HD Kt/V measure specifications to be sufficient for purposes of assessing dialysis adequacy among HD patients because these specifications reflect current clinical practices in dialysis adequacy measurement and assess measurable data that may incentivize improvement in quality of care provided to HD patients. However, we will continue to monitor the HD Kt/V dialysis adequacy measures and will also continue to monitor scientific advances in the field of ESRD care to assess appropriate alternative measures of dialysis adequacy for consideration in future rulemaking.

Comment: A commenter expressed concern regarding the use of Kt/V as a measure of dialysis adequacy for PD patients, noting that it may not be the most appropriate metric for patients who are new to dialysis or who have residual kidney function. This commenter recommended that CMS explore alternative measures of assessing dialysis adequacy for PD patients in future rulemaking.

Response: We thank the commenters for these recommendations and will take them into consideration for future updates. The current PD Kt/V measure considers residual kidney function as part of the measure calculation, and excludes patients who have been on ESRD treatment for less than 91 days as of the first day of the reporting month, which makes it an appropriate metric for all PD patients who have residual kidney function and have been on ESRD treatment long enough to be eligible for inclusion in the measure's calculations.[107] We consider the current PD Kt/V measure specifications to be sufficient for purposes of assessing dialysis adequacy among PD patients because these specifications reflect current clinical practices in dialysis adequacy measurement and assess measurable data that may incentivize improvement in quality of care provided to PD patients. However, we will continue to monitor the PD Kt/V dialysis adequacy measures for potential unintended consequences and will also continue to monitor scientific advances in the field of ESRD care to assess appropriate alternative measures of dialysis adequacy for PD patients for consideration in future rulemaking.

Comment: A few commenters expressed concern regarding the potential impact of the proposed Kt/V Dialysis Adequacy Measure Topic on home dialysis patients. A commenter expressed concern that the PD Kt/V measures could have unintentional consequences such as incentivizing in-center dialysis over home dialysis, which the commenter believed would result in diminished patient experience. A different commenter expressed concern that the proposed Kt/V Dialysis Adequacy Measure Topic will not sufficiently capture dialysis adequacy for home dialysis patients and recommended that CMS continue to explore ways to measure quality of care for home dialysis patients.

Response: For facilities offering both in-center dialysis and home dialysis treatment options, the Kt/V Dialysis Adequacy Measure Topic will more accurately reflect a facility's dialysis adequacy performance by differentiating between the Kt/V measure data of all patients treated at that facility and assessing facilities based on the Kt/V measurements according to ESRD patient age and treatment modality. Because of this differentiation, we expect that the Kt/V Dialysis Adequacy Measure Topic will better reflect the quality of care provided to patients on home dialysis, without incentivizing in-center hemodialysis over home dialysis. We expect that care providers will assess whether in-center hemodialysis or home dialysis would be more appropriate for a patient based on the patient's specific case and treatment plan. However, we will continue to monitor the Kt/V Dialysis Adequacy Measure Topic as it is implemented to assess the impact on the home dialysis patient population.

Comment: A few commenters did not support the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic. A commenter expressed concern that the Kt/V Dialysis Adequacy Comprehensive clinical measure is topped out. This commenter stated that replacing the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic comprised of individual Kt/V Dialysis Adequacy measures will not be effective because the commenter believed that those individual measures are also topped out, and therefore recommended changing the current Kt/V Dialysis Adequacy Comprehensive clinical measure to a reporting measure instead. Another commenter recommended that, instead of the proposed update to measure Kt/V data by different modalities and patient ages, CMS should measure dialysis adequacy based on patient differences.

Response: We disagree with the commenter's assertion that the individual Kt/V measures are topped out and therefore would make the Kt/V Dialysis Adequacy Measure Topic ineffective as a measure of a facility's dialysis adequacy performance. Quality measures that have been in use for several years may reach a stage where meaningful differences and improvement in performance are no longer achievable. These measures are referred to as ''topped-out'' and considered for removal from CMS quality improvement or value-based purchasing programs such as the ESRD QIP. When developing proposals for the CY 2025 ESRD PPS proposed rule, we assessed the ESRD QIP measure set to identify any measures that may be appropriate for removal due to their topped-out status. Based on our analysis, the NHSN Dialysis Event reporting measure was the only measure that achieved topped-out status. Furthermore, a facility's score on the Kt/V Dialysis Adequacy Measure Topic, consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, would be unique to each facility based on its own patient populations and their specific treatment modalities. This approach takes patient differences into account when measuring dialysis adequacy.

Final Rule Action: After considering public comments, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, for the PY 2027 ESRD QIP and subsequent years.

3. Removal of the NHSN Dialysis Event Reporting Measure From the ESRD QIP Measure Set Beginning With PY 2027

To ensure continued impact and effectiveness of our measure set on facility performance, we proposed to remove the NHSN Dialysis Event reporting measure beginning with PY 2027 (89 FR 55815). When we first adopted the NHSN Dialysis Event reporting measure in the CY 2012 ESRD PPS final rule (76 FR 70268 through 70269), we stated that reporting dialysis events to the NHSN by all facilities supports national goals for patient safety, including the reduction of Hospital Acquired Infections (HAIs). In the CY 2014 ESRD PPS final rule, we replaced the NHSN Dialysis Event reporting measure with the NHSN Bloodstream Infection (BSI) clinical measure (78 FR 72204 through 72207). We introduced the clinical version of the measure to hold facilities accountable for monitoring and preventing infections in the ESRD population, and to hold facilities accountable for their actual clinical performance on the measure. In the CY 2017 ESRD PPS final rule (81 FR 77879 through 77882), we reintroduced the NHSN Dialysis Event reporting measure to complement the NHSN BSI clinical measure as a way to incentivize facilities to report complete and accurate monthly dialysis event data in compliance with the NHSN Dialysis Event protocol.[108] In reintroducing the

[107] *https://www.cms.gov/files/document/esrd-measures-manual-v100.pdf.*

[108] For further information related to the NHSN Dialysis Event reporting measure, we refer readers

Continued

measure, we noted our concerns that facilities were not consistently reporting monthly dialysis event data, given the incentive to achieve high clinical performance scores on the NHSN BSI clinical measure. We stated that this may have been an unintended consequence of replacing the previous NHSN Dialysis Event reporting measure with the NHSN BSI clinical measure (81 FR 77879). Therefore, in the CY 2017 ESRD PPS final rule, we reintroduced the NHSN Dialysis Event reporting measure to be included in the ESRD QIP measure set along with the NHSN BSI Clinical Measure.

In the CY 2025 ESRD PPS proposed rule, we stated that, based on our analyses, facilities are consistently reporting monthly dialysis event data, and have been doing so for several years (89 FR 55815). In an assessment of ESRD QIP measure rate performance trends during PY 2020 through PY 2022, performance in the 5th percentile through the 100th percentile was 100 percent on the NHSN Dialysis Event reporting measure for all three performance years, meaning that most eligible facilities reported data on the measure for each of those years.[109] If most eligible facilities are reporting NHSN Dialysis Event measure data each year and measure performance levels at the 5th percentile and the 100th percentile are the same each year, then NHSN dialysis event data are now reported consistently and the measure is not likely to drive improvements in care.

We stated that our proposal to remove the NHSN Dialysis Event reporting measure is consistent with evolving the program to focus on a measure set of high-value, impactful measures that have been developed to drive care improvements for a broader set of ESRD patients (89 FR 55816). As such, we proposed to remove this measure from the ESRD QIP measure set under § 413.178(c)(5)(i)(A), which is Measure Removal Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made). Although we believe that removing this measure would enable facilities to focus on the remaining measures in the ESRD QIP measure set, we noted that facilities would still be required to fully comply with the NHSN Dialysis Event protocol and report all dialysis event data, including BSI, for the NHSN BSI Clinical Measure.

We welcomed public comment on our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. The comments we received, and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. A few commenters expressed support for the proposed removal because the measure is unlikely to drive improvements in care due to consistent reporting and high compliance. A few commenters expressed the belief that removing the measure from the ESRD QIP measure set will allow dialysis centers to focus on impactful measures and meaningful improvements in care. A few commenters recommended that CMS continue to reduce the number of measures in the ESRD QIP and focus on incentivizing improvements in critical and meaningful quality measures. A commenter expressed support for the proposed removal of the NHSN Dialysis Event reporting measure because facilities will still be required to comply with NHSN dialysis event protocol for the NHSN BSI clinical measure. A different commenter expressed support for the proposed removal because it would align the ESRD QIP with other publicly reported data programs. Another commenter expressed support for the proposal to remove the NHSN Dialysis Event reporting measure because the commenter believed the measure created incentives to decrease reported events that would potentially negatively impact patient care.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. A commenter recommended that CMS retain the NHSN Dialysis Event reporting measure, noting that facilities would still need to report the data to comply with Dialysis Event protocol as part of the NHSN BSI clinical measure and therefore removing the measure from the ESRD QIP would not alleviate facility burden. A different commenter expressed concern with the proposal to remove the NHSN Dialysis Event reporting measure, believing that the removal will lead to facilities underreporting adverse events and recommended retaining the measure to encourage and incentivize accurate reporting to NHSN.

Response: We thank the commenters for their feedback. Although we endeavor to minimize facility burden to the extent feasible, we proposed to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set because measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made. Additionally, removing the NHSN Dialysis Event reporting measure would enable facilities to focus on the remaining measures in the ESRD QIP measure set. We do not anticipate that removing the NHSN Dialysis Event reporting measure from the ESRD QIP measure set will lead to underreporting, as facilities would still be required to fully comply with the NHSN Dialysis Event protocol and report all dialysis event data (that is, BSI, IV antimicrobial starts, and pus, redness, and swelling) for the NHSN BSI Clinical Measure.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027.

4. Revisions to the Clinical Care and Reporting Measure Domains Beginning With the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS final rule (88 FR 76481 through 76482), we finalized revisions to the ESRD QIP measure domains beginning with PY 2027. The measure domains and weights we finalized in the CY 2024 ESRD PPS final rule were depicted in Table 13a of the CY 2025 ESRD PPS proposed rule (89 FR 55816) and are depicted in this final rule in Table 14a.

to 76 FR 70268 through 70269 and 78 FR 72204 through 72207.

[109] Partnership for Quality Measurement. 2023 Measure Set Review (MSR): End Stage Renal Disease Quality Incentive Program (ESRD–QIP). September 2023. Available at: *https://p4qm.org/sites/default/files/2023-09/MSR-Report-ESRD-QIP-20230911.pdf.*

TABLE 14a: Previously Finalized PY 2027 ESRD QIP Measure Domains and Weights

Measures by Domain	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	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Screening for Social Drivers of Health measure	1.43
Screen Positive Rate for Social Drivers of Health reporting measure	1.43
Facility Commitment to Health Equity reporting measure	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

In the proposed rule, we proposed to revise the Clinical Care Domain beginning with PY 2027 to reflect our proposal to replace the Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, and to revise the measure weights in the Reporting Measure Domain to reflect our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set (89 FR 55816). Under our proposal, we stated that the weight of the Kt/V Dialysis Adequacy Topic would continue to be the same as the current weight of the Kt/V Dialysis Adequacy Comprehensive Measure, but that weight would be applied to a facility's measure topic score, instead of being applied, as it is now, to a facility's score on the single Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure.

Given our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP beginning with PY 2027, we also proposed to update the individual measure weights in the Reporting Domain to accommodate the proposed new number of measures (89 FR 55816). Consistent with our approach in the CY 2023 ESRD PPS final rule, we proposed to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). Although we proposed to change the number of measures and the weights of the individual measures in the Reporting Measure Domain, we did not propose to change the weight of any of the five domains. The measures that would be included in each domain, along with the proposed new measure weights, for PY 2027 were depicted in Table 13b of the CY 2025 ESRD PPS proposed rule (89 FR 55817). These measure domains and weights, which we are finalizing as proposed, are depicted in this final rule in Table 14b.

TABLE 14b: ESRD QIP Measure Domains and Weights for PY 2027

Measures by Domain	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	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Measure Topic*	11.00
Adult Hemodialysis (HD) Kt/V	
Pediatric Hemodialysis (HD) Kt/V	
Adult Peritoneal Dialysis (PD) Kt/V	
Pediatric Peritoneal Dialysis (PD) Kt/V	
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain**	**10.00**
Screening for Social Drivers of Health measure	1.67
Screen Positive Rate for Social Drivers of Health reporting measure	1.67
Facility Commitment to Health Equity reporting measure	1.67
Hypercalcemia reporting measure	1.67
MedRec reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

*We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.
** We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

We welcomed public comment on these proposals to update the Clinical Care Measure Domain and Reporting Measure Domain. The comments we received, and our responses are set forth below.

Comment: A few commenters expressed support for the proposal to weight the Kt/V Dialysis Adequacy Measure Topic at 11 percent. A few commenters expressed appreciation that the weight appropriately reflects the statutorily required nature of the measure, while also allowing flexibility to assign more weight to other measures for which there is greater room for improvement. Another commenter expressed support for the proposed weight for the Kt/V Dialysis Adequacy Measure Topic because it is the same weight as the current Kt/V Dialysis Adequacy Comprehensive clinical measure.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern with the proposal to weight the Kt/V Dialysis Adequacy Measure Topic at 11 percent, believing that the proposed measure weight will disproportionately impact certain types of facilities. A commenter expressed concern that the proposed measure weight for the Kt/V Dialysis Adequacy Measure Topic disproportionately impacts home dialysis-only facilities, noting that they are not eligible for scoring on certain other measures. Another commenter recommended that CMS not limit the measure weight to 11 percent, and to only score pediatric facilities on pediatric-specific or cohort-neutral measures to ensure that the QIP is relevant to pediatric programs. This commenter expressed the belief that such steps are necessary to prevent unfair or inaccurate penalties based on ESRD QIP measures that are not relevant to the pediatric patient population.

Response: We thank the commenters for their feedback and appreciate their concerns. The Kt/V Dialysis Adequacy Measure Topic will more accurately reflect a facility's dialysis adequacy performance by differentiating between the Kt/V measure data of all patients treated at that facility and assessing facilities based on the Kt/V measurements according to ESRD patient age and treatment modality. Although facilities are only scored on measures they are eligible for based on their reported data, we acknowledge that home dialysis facilities and pediatric facilities may be

disproportionately impacted because they are not eligible to be scored on certain ESRD QIP measures due to their specific patient population. However, we have concluded that the importance of accurately measuring dialysis adequacy for home dialysis ESRD patients and pediatric ESRD patients to incentivize improvements in the quality of care provided to those patient populations outweighs possible concerns regarding potential disproportionate impacts. Because facilities are not scored on measures for which they are not eligible based on their reported data, their score reflects the quality of care provided to patients based on the measures for which they are eligible. We will continue to assess potential policies aimed at expanding measure eligibility for these facilities in future rulemaking.

Comment: A commenter requested that CMS limit the total weight of Kt/V measures to 11 percent because the commenter believed that the measure is topped out in many cases.

Response: In the CY 2025 ESRD PPS proposed rule, we proposed that the weight of the Kt/V Dialysis Adequacy Topic would be 11 percent, the same weight as the Kt/V Dialysis Adequacy Comprehensive Measure (89 FR 55816). Under our proposal, the total weight of the Kt/V measures would be 11 percent under the Kt/V Dialysis Adequacy Measure Topic.

Comment: A few commenters expressed concern that the weights of individual measures in the Reporting Measure Domain do not adequately reflect the burden associated with each measure's criteria and reporting requirements. A commenter recommended that the Reporting Measure Domain carry a higher weight to reflect the significance of the individual reporting measures, as well as the substantial burden associated with compliance.

Response: 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 (83 FR 56995 through 56996). We also consider (1) the number of measures and measure topics in a domain; (2) how much experience facilities have had with the measures and measure topics in a domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214). We assign weights to the measure domains based on the clinical value and meaningfulness of the measures to patients, and the burden of complying with individual measure requirements. We believe that the Reporting Measure Domain weights are appropriate to incentivize the provision of high-quality health care for all ESRD QIP measures.

Comment: A few commenters expressed the belief that the ESRD QIP's focus on meaningful measures should be reflected in the weights assigned to measure domains and individual measures. To ensure that the ESRD QIP takes a clinically driven approach to incentivizing improvement, a few commenters recommended that CMS work with organizations and care providers in the ESRD community to identify potential modifications to the individual measure weights. A few commenters expressed concern regarding the weighting distribution of individual measures relative to the growing number of measures in the ESRD QIP measure set. These commenters expressed the belief that there are too many individual measures within the ESRD QIP measure set, and that scoring facilities based on nearly 20 individual measures means that a facility's performance on each individual measure has little impact on the facility's overall score. A few commenters recommended that CMS reduce the ESRD QIP measure set by moving certain measures to Dialysis Facility Compare or by removing certain measures altogether where appropriate.

Response: We agree with commenters that the weights should reflect clinical value and meaningfulness to patients, which we took into account in developing our measure domains and individual measure weights. We expect that the measure domains and weights provide facilities with meaningful incentives to improve performance on measures that align with clinical value and importance to patients. 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. 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 measure removal factors codified at § 413.178(c)(5)(i).

Final Rule Action: After considering public comments, we are finalizing our proposals to update the Clinical Care Measure Domain and Reporting Measure Domain, beginning with PY 2027 as proposed, and therefore, are finalizing the ESRD QIP measure domains and measure weights provided in Table 14b in this section of the final rule.

5. Performance Standards for the PY 2027 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 determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

In the CY 2024 ESRD PPS final rule (88 FR 76480 through 76481), we set the performance period for the PY 2027 ESRD QIP as CY 2025 and the baseline period as CY 2023. In the proposed rule, we estimated the performance standards for the PY 2027 clinical measures in Table 14 using data from CY 2022, which was the most recent data available (89 FR 55818). We are updating these performance standards for all measures, using CY 2023 data, in this final rule, in Table 15.

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TABLE 15: Updated Performance Standards for the ESRD QIP Clinical Measures for PY 2027

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%*	11.04%*	4.69%*
Kt/V Dialysis Adequacy Measure Topic**			
Adult Hemodialysis (HD) Kt/V	95.79%	98.34%	99.68%
Pediatric Hemodialysis (HD) Kt/V	81.25%	92.37%	100.00%
Adult Peritoneal Dialysis (PD) Kt/V	87.34%	94.85%	99.04%
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%	82.06%	95.18%
Standardized Readmission Ratio[a]	34.27*	26.50*	16.18
NHSN BSI	0.642	0.215	0
Standardized Hospitalization Ratio[b]	166.60*	129.14*	87.98*
Standardized Transfusion Ratio[b]	48.29*	26.19*	8.46
PPPW	8.12%*	16.73%*	33.90%*
Clinical Depression	88.21%	94.34%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%*	67.90%*	79.15%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	55.68%	63.83%	74.22%
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	51.78%	65.18%	79.68%
ICH CAHPS: Overall Rating of the Dialysis Facility	55.76%	69.69%	84.10%

*Values are the same final performance standards for those measures for PY 2026. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2027 because they are higher standards than the PY 2027 numerical values for those measures.
**We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measure: 2023 EQRS; SRR, SHR, STrR: 2023 Medicare claims; Kt/V: 2023 EQRS and 2023 Medicare claims; NHSN: 2023 CDC; ICH CAHPS: CMS 2023; PPPW: 2023 EQRS and 2023 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2023 EQRS.

In addition, we summarize in Table 16 our requirements for successful reporting on our previously finalized reporting measures for the PY 2027 ESRD QIP.

TABLE 16: Requirements for Successful Reporting of ESRD QIP Reporting Measures for PY 2027

Measure	Reporting Frequency	Data Elements
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
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 are up to date on their COVID-19 vaccination.
Facility Commitment to Health Equity	Annually	Domains to which facility must attest affirmatively: • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement
Screening for Social Drivers of Health	Annually	Number of eligible patients who were screened for all five HRSNs: • Food insecurity, • Housing instability, • Transportation needs, • Utility difficulties, or • Interpersonal safety.
Screen Positive Rate for Social Drivers of Health	Annually	Number of eligible patients with 'Yes' or 'No' (non-missing) screening responses for each of the five HRSNs.

6. Eligibility Requirements for the PY 2027 ESRD QIP

In the proposed rule, we proposed to update eligibility requirements as part of our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027 (89 FR 55819). Our previously finalized and proposed new minimum eligibility requirements are described in Table 16 of the CY 2025 ESRD PPS proposed rule (89 FR 55820) and provided in Table 17 of this final rule.

TABLE 17: Previously Finalized and Proposed New Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2027

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (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
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	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
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 (Clinical)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of 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)	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Screening for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

Screen Positive Rate for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

* We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.
** We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

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We welcomed public comment on these proposals to update the minimum eligibility requirements to reflect the proposed Kt/V Dialysis Adequacy Measure Topic. We did not receive any comments on our proposals to update the minimum eligibility requirements to reflect the Kt/V Dialysis Adequacy Measure Topic.

Final Rule Action: We are finalizing our proposals to update the minimum eligibility requirements to reflect the Kt/V Dialysis Adequacy Measure Topic, beginning with PY 2027 as proposed, and therefore, are finalizing the ESRD QIP eligibility requirements provided in Table 17 in this section of the final rule.

7. Payment Reduction Scale for the PY 2027 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 § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. In the proposed rule, we stated that for PY 2027, we estimated using available data that a facility must meet or exceed an mTPS of 51 to avoid a payment reduction (89 FR 55821). We noted that the mTPS estimated in the proposed rule was based on data from CY 2022 instead of the PY 2027 baseline period (CY 2023) because CY 2023 data were not yet available. We presented the estimated payment reduction scale in Table 17 of the CY 2025 ESRD PPS proposed rule (89 FR 55821). We stated our intention to update and finalize the mTPS and associated payment reduction ranges for PY 2027, using CY 2023 data, in this CY 2025 ESRD PPS final rule. We have now finalized the payment reductions that will apply to the PY 2027 ESRD QIP using updated CY 2023 data. The mTPS for PY 2027 will be 51, and the finalized payment reduction scale is shown in Table 18.

TABLE 18: Updated Payment Reduction Scale for PY 2027 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-51	0%
50-41	0.5%
40-31	1.0%
30-21	1.5%
20-0	2.0%

C. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

As discussed in the following sections, in the CY 2025 ESRD PPS proposed rule we requested information on two topics to inform future revisions to the ESRD QIP. First, we requested information regarding potential future modifications to the existing ESRD QIP scoring methodology to reward facilities based on their performance and the proportion of their patients who are dually eligible for Medicare and Medicaid (89 FR 55822). Second, we requested information regarding potential updates to the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data (89 FR 55822 through 55823).

In the CY 2025 ESRD PPS proposed rule, we noted that each of these sections in the proposed rule is a RFI only (89 FR 55821). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We stated that respondents are encouraged to provide complete but concise responses (89 FR 55821). These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the United States Government to contract for any supplies or services or make a grant award. Further, we noted that we were not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders were advised that the United States Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to this request. We noted that we will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. We stated that information obtained as a result of these RFIs may be used by the United States Government for program planning on a non-attribution basis (89 FR 55822). Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. Finally, we noted that CMS may publicly post the comments received, or a summary thereof.

1. Request for Public Comment on Future Change to the Scoring Methodology To Add a New Adjustment That Rewards Facilities Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

Achieving health equity, addressing health disparities, and closing the performance gap in the quality of care provided to disadvantaged, marginalized, or underserved populations continue to be priorities for CMS as outlined in the CMS National Quality Strategy.[110] CMS defines ''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, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[111] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that reduce avoidable differences in health outcomes.

The ESRD QIP adopted three new health-equity focused quality measures in the CY 2024 ESRD PPS final rule (88 FR 76437 through 76446; 76466 through 76480). Although commenters were generally supportive of the new measures, a few commenters recommended that the ESRD QIP take additional action to support facilities that treat patient populations with higher proportions of health-related social needs (HRSNs) (88 FR 76473). In the CY 2025 ESRD PPS proposed rule, we stated that we are considering updating our scoring methodology in future rulemaking to add Health Equity Adjustment bonus points to a facility's TPS that would be calculated using a methodology that incorporates a facility's performance across all five domains for the payment year and its proportion of patients with dual eligibility status (DES), meaning those who are eligible for both Medicare and Medicaid coverage (89 FR 55822).

In the 2016 Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) reported that beneficiaries with social risk factors had worse outcomes and were more likely to receive a lower quality of care.[112] Patients with DES experience significant disparities are also likely to be more medically complex and remain one of the most vulnerable populations.[113] [114] [115] DES remains the strongest predictor of negative health outcomes.[116]

We recently finalized a Health Equity Adjustment scoring policy for the Hospital Value-Based Purchasing (VBP) Program (88 FR 59092 through 59106) and the Skilled Nursing Facility (SNF) VBP Program (88 FR 53304 through 53316). These policies provide Health Equity Adjustment bonus points to top tier performing hospitals and SNFs with a high proportion of patients with DES, and each program's policy is tailored to meet the needs of the specific program. For example, in the Hospital VBP Program, the Health Equity Adjustment bonus is calculated based on a hospital's performance on each of the four measure domains and its proportion of patients with DES (88 FR 59095 through 59096). In the SNF VBP Program, the Health Equity Adjustment bonus is calculated based on a facility's performance on each measure and its proportion of patients with DES (88 FR 53309 through 53311).

Our policy for scoring performance on the ESRD QIP is codified at § 413.178(e). In the proposed rule, we requested public comment on potential future modifications to the existing scoring methodology to reward excellent care to underserved populations (89 FR 55822). We also noted that any Health Equity Adjustment bonus for the ESRD QIP would need to align with the Program's statutory requirements under section 1881(h) of the Act. We welcomed public comment on the following:

- Would a Health Equity Adjustment be valuable to the ESRD QIP?

++ If a Health Equity Adjustment would be valuable to the ESRD QIP, how should it be structured?

[110] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[111] Health Equity Strategic Pillar. Centers for Medicare & Medicaid Services. *https://www.cms.gov/pillar/health-equity*.

[112] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf*.

[113] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[114] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, and Functional Risk Factors in Medicare Spending for Dual and Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[115] Wadhera, R.K., Wang, Y., Figueroa, J.F., Dominici, F., Yeh, R.W., & Joynt Maddox, K.E. (2020). Mortality and Hospitalizations for Dually Enrolled and Nondually Enrolled Medicare Beneficiaries Aged 65 Years or Older, 2004 to 2017. *JAMA, 323*(10), 961–969. *https://doi.org/10.1001/jama.2020.1021*.

[116] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs*.

++ If a Health Equity Adjustment would not be valuable to the ESRD QIP, why not?

• Are there other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity?

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters provided feedback on a Health Equity Adjustment. Several commenters expressed support for a Health Equity Adjustment, believing that it would be valuable to the ESRD QIP. Several commenters noted that ESRD is more prevalent among patient populations with higher social risk factors or from lower socioeconomic status or communities of color and observed that a Health Equity Adjustment could help promote more equitable care by rewarding excellent performance to underserved populations. Several commenters expressed support for a Health Equity Adjustment specific to the ESRD QIP, believing that it will help to reduce disparities among facilities that treat a greater proportion of DES patients. A few of these commenters observed that a Health Equity Adjustment may help to mitigate the impact of payment reductions that may disproportionately impact facilities that care for a greater proportion of low-income patients. A few other commenters noted that many facilities require more resources and specific care expertise to meet the care needs relevant to this patient population, and that a Health Equity Adjustment may further incentivize parity among care providers by providing them with resources necessary to provide high quality care to a complex patient population. A commenter expressed support for adopting a bonus scoring methodology for a Health Equity Adjustment in the ESRD QIP, noting that such a framework would align with current Health Equity Adjustments implemented in IPPS, SNF VBP, and ETC Model.

A few commenters agreed that a Health Equity Adjustment would be valuable to the care providers and patients. These commenters recommended that CMS engage with organizations and care providers in the ESRD community to discuss potential Health Equity Adjustment options and related policies for inclusion in future rulemaking, which commenters believed would be helpful to ensure that a future Health Equity Adjustment is developed and implemented in a meaningful way.

Several commenters expressed support for structuring the Health Equity Adjustment as a bonus that is applied to a facility's TPS. A few commenters recommended adding a Health Equity Adjustment bonus to a facility's TPS based on its performance in each of the five measure domains included in the TPS, adjusted for the facility's proportion of socioeconomically disadvantaged patients. A few commenters recommended that a Health Equity Adjustment be calculated based on a facility's performance across select measure domains, rather than all 5 measure domains. A commenter noted that fewer dialysis facilities are eligible for scoring on ICH CAHPS due to measure eligibility requirements, and therefore recommended that CMS exclude the Patient & Family Engagement domain from the measure performance calculation for purposes of calculating the Health Equity Adjustment. Another commenter recommended that a facility's performance within each measure domain should be assessed independently, such that a facility may be eligible for Health Equity Adjustment bonus points based on its performance in each domain. This commenter recommended that facility performance is grouped into three tiers for each domain, and that eligibility for HEA points be calculated based on the facility's performance within a given domain's tertile. A different commenter recommended that CMS calculate potential Health Equity Adjustment bonus points based on a facility's performance in Coordination, Clinical Care, and Safety measure domains relative to the quintile of that domain score.

Several commenters offered recommendations regarding Health Equity Adjustment bonus application. A commenter recommended that a future Health Equity Adjustment policy be designed to award bonus points to facilities that serve greater proportions of underserved patient populations and have higher quality performance. A commenter recommended that CMS consider structuring the Health Equity Adjustment as a positive payment adjustment tied to improved health outcomes for DES patients, citing the health equity incentives in the ETC and IOTA models. Another commenter suggested that Health Equity Adjustment bonus points be awarded based on the percentage of patients from underserved populations treated at the facility. This commenter believed that this approach would help to ensure that facilities caring for patients in underserved communities have adequate resources, observing that such facilities are more likely to be impacted by payment penalties which may result in decreased ability to provide care to such patient populations.

A few commenters recommended that CMS apply a Health Equity Adjustment bonus to a facility's TPS in a way that would allow facilities to move to a lesser payment reduction tier or a zero-payment reduction tier, believing that such a methodology would support facilities serving greater proportions of DES patients. A commenter recommended that Health Equity Adjustment bonus points should be limited to a maximum of 10 points to appropriately reward facilities for delivering excellent performance to underserved populations while also not skewing the TPS or creating unintended incentives.

A commenter requested that any Health Equity Adjustment policy not require changes to the current process for calculating a facility's TPS or to the payment reduction scales. This commenter suggested the potential equity points be combined as a weighted average that uses the same weights as the TPS. The commenter recommended a methodology that included: (1) multiplying the measure performance scalar by a logistic exchange function representing the facility in the percent of DES patient-months, which would provide the pre-scaled Health Equity Adjustment bonus; (2) multiplying the pre-scaled Health Equity Adjustment bonus by 10 to scale the Health Equity Adjustment bonus for incorporation into the TPS; and (3) adding the Health Equity Adjustment points to the existing TPS for a maximum value of 100 points. Pursuant to this commenter's recommended framework, although facilities would be assessed against a modified TPS, the payment reduction scale would be set based on unmodified TPS ranges.

A few commenters recommended that a Health Equity Adjustment should be structured so that it is not budget neutral, and therefore would not negatively impact facilities that don't qualify for the Health Equity Adjustment bonus. A few commenters observed that potential unintended consequences may result from a Health Equity Adjustment in the ESRD QIP, due to the unique nature of the program. These few commenters observed that a Health Equity Adjustment within the ESRD QIP would likely result in a decrease in the number and size of payment reductions imposed and recommended that CMS should not seek to increase overall payment reductions through other policy changes.

A few commenters offered recommendations regarding potential grouping methodology for calculating eligibility for a Health Equity Adjustment. A commenter recommended that CMS group facilities into quartiles or quintiles to calculate eligibility for a Health Equity Adjustment bonus. This commenter noted that there are a greater number of eligible facilities in the ESRD QIP, as compared to other CMS programs that apply a Health Equity Adjustment. A different commenter recommended that CMS structure a ESRD QIP Health Equity Adjustment by grouping facility performance into three tiers for each Measure Domain, and that eligibility for Health Equity Adjustment bonus points be calculated based on the facility's performance within a given domain's tertile.

Several commenters provided recommendations regarding the applicable patient population used to determine a facility's eligibility for Health Equity Adjustment consideration. A few commenters recommended that a Health Equity Adjustment account for both Medicare fee-for-service patients as well as Medicare Advantage patients to accurately represent the proportion of the targeted patient population. A commenter recommended that, in addition to DES patients, CMS include Medicaid-only and uninsured patients in its definition of underserved patient population. Another commenter recommended that CMS expand the applicability of Health Equity Adjustment eligibility to include low-income subsidy recipients, noting potential different impacts for facilities in states that did not expand their Medicaid programs. A different commenter recommended that CMS award Health Equity Adjustment bonus points based on the percentage of DES patients as well as low-income subsidy patients treated at the facility, noting that this approach would be consistent with the ETC Model. Another commenter recommended that CMS set a minimum threshold of 20 percent DES patient population for Health Equity Adjustment eligibility, noting that such a threshold would be consistent with the SNF VBP scoring policy.

A few commenters expressed concern regarding potential unintended consequences that may result from a Health Equity Adjustment in the ESRD QIP. A few commenters expressed concern that a Health Equity Adjustment may create confusion by inflating or otherwise impacting a facility's TPS. A commenter noted that an adjustment to a facility's TPS based on a Health Equity Adjustment would create further confusion for patients seeking to understand the significance of a facility's publicly available TPS. A commenter observed that a Health Equity Adjustment may suggest that facilities with higher proportions of DES patients are held to a lower standard or that those patients are allowed to have poorer health outcomes. Another commenter noted that a Health Equity Adjustment may not be valuable to all ESRD facilities and recommended that CMS consider the potential impact on facilities in certain areas that may have limited resources. A different commenter expressed concern that a Health Equity Adjustment may result in unintended financial incentives and requested that CMS ensure that any Health Equity Adjustment policy continues to focus on advancing health equity. A commenter requested that CMS clarify how it anticipates measuring for health equity success.

A few commenters expressed concern that a Health Equity Adjustment may not be valuable to the ESRD QIP. A commenter observed that a Health Equity Adjustment may not be sufficient or appropriate for the ESRD QIP as a means to address health disparities. Another commenter expressed concern that a Health Equity Adjustment would not be valuable because the ESRD QIP is a penalty-only program that does not award bonuses.

A commenter recommended that the ESRD QIP adopt a peer grouping methodology, similar to the methodology used in the Hospital Readmissions Reduction Program (HRRP). This commenter expressed the belief that stratification into quintiles would promote competition among facilities within the same quintile and provide a more accurate comparison of facility performance that takes patient population into account.

Several commenters recommended other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity. A few commenters recommended that the ESRD QIP adopt efforts that are more directly aimed at addressing health disparities. A commenter recommended that services aimed at navigating care coordination and HRSN-related needs be included as part of the quality care provided by ESRD facilities. This commenter noted that a facility that has staff trained in identifying and addressing such needs may help to mitigate the increased risk of poor outcomes for ESRD patients tied to unmet HRSNs. A different commenter expressed support for the three health equity measures recently added to the ESRD QIP, but expressed concern that the measures do little to directly address systemic health disparities and that facilities do not have the resources necessary to identify and facilitate solutions to address HRSNs. This commenter noted that, although collecting such data is essential, health disparities will persist in the absence of additional funding necessary to address these issues. Another commenter recommended that CMS explore policy approaches outside the ESRD QIP to reduce health disparities in the ESRD patient population, urging CMS to invest in structural and systemic capabilities that facilities require to comprehensively support the care needs of a complex patient population.

A commenter recommended that CMS consider restructuring the ESRD QIP to incorporate both negative and positive payment adjustments to incentivize high quality care and provide access to additional resources and support. This commenter expressed the belief that financial penalties do not necessarily facilitate improvement in quality of care, noting that such penalties also potentially reduce resources available to facilities that would benefit from them the most. Another commenter recommended that CMS continue to engage with the ESRD community to explore effective approaches to address health disparities and improve the quality of care provided to underserved populations.

A commenter recommended that CMS consider whether within-facility analysis is appropriate for addressing health disparities in the ESRD patient population, noting that the diversity of patient populations among different dialysis facilities often reflect the diversity of the population of the area which the facility is located. A different commenter recommended that CMS consider the role of patient autonomy and agency in developing future health equity measures, noting that individual patients may differ in their level of interest and engagement.

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 effectively address healthcare disparities and advance health equity. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity-related efforts.

2. Request for Public Comment on Updating the Data Validation Policy for the ESRD QIP

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP includes two types of data validation for this purpose: The EQRS data validation (OMB Control Number 0938–1289) and the NHSN validation (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb (now EQRS) data validation as a permanent feature of the Program (83 FR 57003). In the CY 2020 ESRD PPS final rule, we adopted the NHSN data validation as a permanent feature of the Program (84 FR 60727). Under both data validation policies, we validate EQRS and NHSN data from a sample of facilities randomly selected for validation. If a facility is randomly selected for validation but does not submit the requested records, 10 points are deducted from the facility's TPS.

In the proposed rule, we requested public comment on ways to update the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data (89 FR 55823). We have reviewed data validation policies in other quality reporting programs such as the Hospital Inpatient Quality Reporting (IQR) Program (81 FR 57180) and the Hospital Outpatient Quality Reporting (OQR) Program (76 FR 74486). These programs have adopted data validation policies that require a hospital selected for data validation to achieve a 75 percent reliability or accuracy threshold to receive full credit for data validation reporting.

We welcomed comments on potential future policy proposals that would encourage accurate, comprehensive reporting for data validation purposes, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold, introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on data validation reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

We received comments in response to this request for information and have summarized them here.

Comment: A few commenters offered feedback on ways to reduce administrative burden associated with participating in data validation. A few commenters recommended that CMS focus on improving the data validation system because they believe that the current framework is too burdensome for facilities. A few commenters recommended that CMS prioritize enhancing the functionality of EQRS and NHSN systems to facilitate easier data submission and correction, which commenters believe will support more accurate and comprehensive reporting. A commenter suggested that CMS adopt advanced technologies such as artificial intelligence (AI) and machine learning algorithms to reduce burden associated with traditional reporting mechanisms. A few commenters noted that the current data validation system is burdensome on facilities due to compliance requirements and timeframes, which commenters observed may detract from the facility's ability to focus resources on providing quality care. A few commenters expressed concern that smaller facilities faced a disproportionately greater administrative burden to comply with the data validation process, and therefore recommended that CMS look into mitigating that burden. A commenter recommended that CMS mitigate the burden on smaller facilities by ensuring that the data validation policy reflect variability across facility types. A few commenters recommended that CMS extend the submission window because the 60-day compliance timeframe is often challenging due to staffing constraints, absences, and competing priorities. A few commenters recommended that, to reduce administrative burden and encourage comprehensive and accurate reporting, CMS establish and distribute a schedule outlining which facilities will be included in the validation study and when, to provide facilities with adequate notice. A commenter recommended that CMS also provide a more predictable schedule for survey requests. A few commenters recommended that CMS reduce survey frequency, noting that completing surveys twice a year is time-consuming and further constrains already limited staff resources. A few commenters observed that previous validation study results suggest a level of stability that reduces the need for annual re-measurement. A commenter recommended that CMS reduce the frequency of data validation surveys to every five years or reasonable intervals. A commenter noted that CMS has reported consistently high accuracy rates of data reporting by participating facilities, which the commenter believes is an indication that the current data validation policy is generating accurate, comprehensive reporting of QIP data. A commenter noted that reducing the frequency of validation studies would provide facilities additional time to understand data collection requirements and ensure the accuracy of submissions.

A few commenters suggested that CMS consider providing a bonus for facilities that perform above an established reporting or data accuracy threshold, but only if the funding for such bonus were not obtained by reducing payments to ESRD facilities. A commenter recommended that participation in data validation be voluntary and that participating facilities receive bonus points awarded to their TPS, rather than penalties for non-participation.

A few commenters requested that CMS share the results of previous data validation studies to inform their recommendations regarding the establishment of a reporting or data accuracy threshold. A commenter expressed concern with updating the data validation policy, noting that insufficient data validation information was publicly available to provide comment on future updates to the data validation policy at this time. A few commenters recommended greater transparency with regard to the results of the data validations surveys. A few commenters noted that such transparency will help facilities understand their results and support targeted education efforts, which will lead to more accurate ESRD QIP data submitted for validation. Although a commenter expressed support for targeted education, this commenter opposed mandatory re-selection of facilities that do not meet an established reporting or data accuracy threshold because commenter believes that selected facilities need to be chosen at random.

A few commenters recommended that any updates to the data validation system include robust due process protections that are similar to those provided through other audit programs operated by CMS. A commenter expressed the belief that due process policies will help to ensure the accuracy of data submitted by ensuring that there is opportunity to address potential issues with data submission and interpretation to ensure that facilities are not unfairly penalized.

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 encourage accurate, comprehensive reporting for data validation purposes. We will continue to take all concerns, comments, and

suggestions into account for future development and expansion of these efforts.

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 Children's Health Insurance Program (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 ESRD 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.[117] CMS excludes all United States 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 Performance Payment Adjustment (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 would 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.

CMS has modified the ETC Model several times. In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We adjusted 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 LDT Beneficiaries (86 FR 61950 through 61951). We changed 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). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth MY of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280) and finalized our intent to publish participant-level model performance information to the public (87 FR 67280). In the CY 2024 ESRD PPS final rule (88 FR 76344) we finalized a policy whereby an ETC Participant may seek administrative review of a targeted review determination provided by CMS.

B. Provisions of the Proposed Rule

We proposed a modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model. As finalized in the Specialty Care Models final rule and codified at § 512.360, CMS retrospectively, that is, following a MY, attributes ESRD Beneficiaries and Pre-emptive Living Donor Transplant (LDT) Beneficiaries to an ETC Participant for each month during a MY. An ESRD Beneficiary may be attributed to an ETC Participant if the beneficiary has already had a kidney transplant and has a non-AKI dialysis or MCP claim less than 12 months after the beneficiary's transplant date and has a kidney transplant failure ICD–10 diagnosis code documented on any Medicare claim. Based on feedback from model participants, we became aware that the use of the ICD–10 code T86.12 to identify transplant failures may be incorrectly identifying beneficiaries for attribution to the ETC Model because a claim that is only coded with T86.12 may signify delayed graft function rather than a true transplant failure. To ensure that we are correctly identifying ESRD beneficiaries for the purposes of ETC Model ESRD Beneficiary attribution, we proposed to modify our definition of an ESRD Beneficiary at § 512.310. Our regulations currently define an ESRD Beneficiary as a beneficiary that meets either of the following criteria: (1) is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant, or (2) has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12-months after the beneficiary's latest transplant date; or less than 12-months after the beneficiary's latest transplant date and

[117] ZIP code™ is a trademark of the United States Postal Service.

has a kidney transplant failure diagnosis code documented on any Medicare claim. We proposed to modify the second criterion to specify that the beneficiary's latest transplant date must be identified by at least one of the following: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR). We proposed that if a beneficiary meets more than one of these criteria, that CMS will consider that beneficiary an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded. In our analysis of the proposed methodology for identifying transplant failures, we found that the use of all three criterion correctly identified more true transplant failures than did the use of T86.12 alone.

We considered a proposal to modify the language at 42 CFR 512.310 that an ESRD Beneficiary is a beneficiary that has already received a kidney transplant and has a non-AKI or MCP dialysis claim less than 12 months after the beneficiary's latest transplant date with kidney transplant failure diagnosis code documented on any Medicare claim. We considered removing the last clause; in other words, removing the specification that that the beneficiary must have a kidney transplant failure diagnosis code documented on any Medicare claim. We did not propose this modification to the definition of an ESRD Beneficiary because doing so would preclude the possibility for a beneficiary to be attributed to the ETC Model for 12-months after a transplant, regardless of if the transplant failed. We were concerned that this scenario would reduce the number of attributed beneficiary-months that would be available for us to use to calculate the home dialysis and transplant rate for ETC Participants. We solicited comment on our proposal to modify the definition of an ESRD Beneficiary to more accurately identify beneficiaries that may be attributed to the ETC Model due to receiving a kidney transplant that fails within 12-months of its receipt.

Comment: We received four comments on this proposed policy and the alternative policy put forth for consideration, all expressing collective agreement on the methodology modification. Two Patient Advocacy Organizations agreed with our plan to modify these definitions as described and specifically agreed that if a beneficiary meets more than one of the amended criteria, then they should be considered an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded. One commenter agreed with our decision to forgo the alternative policy to remove the specification that that the beneficiary must have a kidney transplant failure diagnosis code documented on any Medicare claim. One dialysis organization stated that they commend CMS' dedication to correctly identifying ESRD beneficiaries for attribution to the ETC Model. They believe the proposed clarification will help prevent beneficiaries with delayed graft function who have a claim coded with T86.12 from being incorrectly attributed to the ETC Model. The organization further encourages CMS to make needed refinements for the ETC Model's remaining duration and utilize its regulatory authority to mitigate penalties to physicians and dialysis providers.

Response: We appreciate the commenters' dedicated engagement with the design of the ETC Model and the methodology by which we assess transplant beneficiary attributions. However, we uncovered an inconsistency in the rule text between Paragraph 3 and Paragraph 4 of the proposed definition of an ESRD beneficiary. Paragraph 3 suggests that a kidney transplant failure would be identified from a beneficiary who has ''at least'' one of the following three criteria, whereas Paragraph 4 in the proposed rule states that if a beneficiary meets ''more than one'' of the criteria described in paragraphs (3)(i) through (iii) that they would then be considered an ESRD beneficiary. Given the specific comment from one interested party that expressed support for a beneficiary meeting more than one of the following criteria to be considered an ESRD Beneficiary for the purposes of ETC model attribution: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR), we plan to update the definition in paragraph three to resolve the inconsistency and delete the phrase ''at least one of the following''.

Final Decision: In consideration of the comments received, we are finalizing our proposed modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model with one modification. We will delete the phrase ''at least one of the following'' from the definition of kidney transplant failure in paragraph 3 so it reads, ''Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by''. Per paragraph 4 of the definition then, a beneficiary must meet more than one of the criteria laid out in paragraph 3 to qualify as having a kidney transplant failure.

C. Request for Information

1. Request for Information

In the Specialty Care Models final rule, we referenced a report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis that describes barriers to increased adoption of home dialysis including educational barriers, the need for home care partner support, the monthly visit requirement for the Monthly Capitation Payment (MCP) under the Physician Fee Schedule, variations in dialysis business practices in staffing allocation, lack of home clinic independence, and other restrictions resulting in the inefficient distribution of home dialysis supplies (85 FR 61265).[118] The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) controversies conference report, ''Overcoming Barriers for Uptake and Continued Use of Home Dialysis: An NKF–KDOQI Conference Report,'' describes clinical, operational, policy, and societal barriers to increased prescribing of and retention on home modalities. For example, lack of clinical confidence in prescribing home dialysis, lack of infrastructure, financial costs to patients associated with home modifications, the need for space to store home dialysis supplies, lack of housing, lack of appropriate education, care partner burnout, and patient fear of self-cannulation.[119]

[118] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879–885.doi:10.1053/j.ajkd.2011.06.028.

[119] Chan, C.T., Collins, K., Ditschman, E.P., Koester-Wiedemann, L., Saffer, T.L., Wallace, E., & Rocco, M.V. (2020). Overcoming barriers for uptake and continued use of home dialysis: An NKF-Kdoqi Conference Report. American Journal of Kidney

Continued

Since the Specialty Care Models final rule was published, interested parties have spoken to us about challenges associated with increasing access to home dialysis, particularly among beneficiaries with lower socioeconomic status, who have lower rates of home dialysis and kidney transplantation than people with higher socioeconomic status. The ETC Model was designed to address these barriers; for example, CMS applied the Home Dialysis Payment Adjustment (HDPA) to assist dialysis organizations with overcoming market realities that impose substantial barriers to opening and sustaining home dialysis programs. The upside and downside risk associated with the Performance Payment Adjustment (PPA) are designed to be strong incentives for behavioral change towards increasing beneficiary access to home dialysis. In the CY 2022 ESRD PPS final rule, we finalized a policy whereby we stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dual eligible for both Medicare and Medicaid or who receive the Low-Income Subsidy (LIS) (86 FR 61968). We also finalized the Health Equity Incentive (HEI), which rewards ETC Participant aggregation groups that demonstrate greater than 2.5 percentage points improvement on the home dialysis and transplant rate among dual eligible and LIS recipient beneficiaries from the Benchmark Year (BY) to the MY with a .5 increase in their improvement score (86 FR 61971).

Performance accountability in the ETC Model is scheduled to end on June 30, 2026. We are concerned that the end of performance accountability may reduce incentives for dialysis organizations to invest in access to home dialysis and address the challenges of the type we describe previously in this section. We were interested in hearing from interested parties regarding policies that the Innovation Center may consider specifically incorporating into any successor model to the ETC Model or that CMS may consider generally. Given the growth in ESRD beneficiaries choosing Medicare Advantage plans,[120] we were particularly interested in approaches CMS could take to improve beneficiary access to home dialysis modalities in Medicare Advantage.

We sought input on the following topics that may improve our understanding of other policy interventions that may increase access to high quality home dialysis within the context of Innovation Center models and across CMS.

1. How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?

2. What barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)? We request that commenters be as specific as possible.

3. What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?

4. How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?

We received comments in response to this request for information and have summarized them here.

Comment: Inclusion of the Kidney Disease Education (KDE) Benefit. Several commenters expressed their belief in the usefulness of KDE as a tool for individuals with kidney failure to learn about their disease state and options for treatment. The commenters mentioned it is also well known that patients who receive early and accurate modality education, such as what is provided through KDE, are more likely to choose a home modality should their disease progress to ESRD. Commenters urge CMS to maintain the ETC's changes to the KDE program in any future models related to increasing home dialysis and waiving the 20 percent coinsurance.

Consideration of Pediatric Patients in Future Models. A professional society for pediatric nephrologists expressed appreciation for the exclusion of children under 18 from participation in the ETC Model. The commenter reiterated their belief of current model goals and further highlighted that young adults who continue to be treated by pediatric nephrologists once they turn 18 years old are a particularly complex group of patients. Of note, the commenter urged CMS to consider collaboration with representatives of the pediatric nephrology community on future models to incentivize home dialysis and transplantation.

Increased Access to New and Innovative Drugs. A non-provider industry-associated interested party noted that within various CMS hospital inpatient and outpatient models advanced by the Innovation Center, add-on payments for innovative new technologies and therapies are purposely excluded from episode expenditures to ensure that Medicare beneficiaries have consistent access to innovations that improve their care. The interested party encourages the Innovation Center to apply the same reasoning and approach under future kidney models.

Data and Quality Metrics. A dialysis organization encouraged CMS to reconsider the concept of comparing geographic areas in potential successor models. Additionally, the commenter and several patient advocacy organizations encouraged the inclusion of home dialysis measures with greater specificity, such as a home retention metric or optimal starts, and the development of a home dialysis patient satisfaction and experience measure. Similarly, for transplant, CMS was encouraged to consider removing metrics that run counter to beneficiaries' waitlisting, such as waitlist mortality, and consider adding metrics, such as referral to waitlist percentage and time from referral to waitlist. A commenter further highlighted future models with more efficient data sharing capabilities to access performance data would be a strength.

Increased Efforts Towards Transplantation. Several commenters provided recommendations on ways to effectively increase transplantation, such as the creation of a patient navigator program to improve patient experience of care in seeking transplants.

Social Drivers of Health. Several commenters expressed support of future models that test how additional resources and/or direct patient incentives aimed at addressing social drivers of health would impact the uptake of home modalities and ultimately whether quality of life is improved. Commenters reiterated previous recommendations that CMS work with HHS and the states to revise federal, state, and local fraud and abuse laws to support dialysis facilities and physicians in their efforts to help individuals with kidney failure address socio-economic barriers to home dialysis. A commenter also suggested some barriers contributing to the lower uptake of home dialysis in communities of color and underserved communities could be addressed by encouraging Medicare Advantage (MA) plans to apply the Special Supplemental Benefits for the Chronically Ill (SSBCI). The commenter suggested these benefits could be used to reduce barriers to

Diseases, 75(6), 926–934. *https://doi.org/10.1053/j.ajkd.2019.11.007*.

[120] Nguyen, K.H., Oh, E.G., Meyers, D.J., Kim, D., Mehrotra, R., & Trivedi, A.N. (2023). Medicare advantage enrollment among beneficiaries with end-stage renal disease in the first year of the 21st Century Cures Act. *JAMA, 329*(10), 810. *https://doi.org/10.1001/jama.2023.1426*.

home dialysis, such as copay assistance programs for necessary dialysis related medications, stipends for utility costs and necessary home modifications, assistance for care partners or respite when needed, and assistance in installing and paying for broadband internet.

Model Structure. Several commenters expressed their support for future models being voluntary and including more flexibilities for smaller providers, like the Comprehensive ESRD Choices (CEC) model. Additionally, stakeholders believe future models should have a financial structure based on anticipated savings to increase incentives and should include Medicare Advantage (MA) beneficiaries. Other commenters recommend a model that tests the impact of additional Medicare payments for a package of comprehensive care services to aid in investments in infrastructure and care management capabilities for dialysis providers.

Recurring Barriers Elevated by Patients and Caregivers. Commenters elevated recurring barriers shared by patients and caregivers that dialysis providers noted being limited in their capacity to address, such as the fear of abandonment and/or lack of real time support in the home, inadequate space in the home for equipment and supplies, and the lack of available in-home support staff. A commenter suggested the development of a Technical Expert Panel (TEP) to evaluate evidence from the IM–HOME1 framework for resolving the barriers that exist for home dialysis.

Incentivizing Peritoneal Dialysis (PD) Catheter Placement. Commenters elevated several barriers impacting timely PD catheter placement previously identified by CMS: (1) challenges scheduling operating room time in the hospital setting for PD catheter placement, (2) the need for additional training on PD catheter placement for both surgeons and interventional nephrologists, and (3) the lack of dedicated PD catheter insertion teams in the hospital setting who can immediately place catheters for patients who ''crash'' into dialysis and would benefit from urgent start PD. Commenters encourage CMS to develop a demonstration to test the impact of policy changes for equal reimbursement rates between PD catheter placement procedures and vascular access placement procedures. A patient advocacy organization recommended a bonus incentive payment for vascular surgeons, hospitals, and surgical centers, that would increase reimbursement for PD catheter placements and become equal with the reimbursements provided for Arteriovenous (AV) Fistula reimbursement.

Fraud and Abuse Laws. Two commenters recommended we remove certain barriers that they believe are created by the physician self-referral law, Anti-Kickback Statute (AKS), and beneficiary inducement laws. The commenters described various arrangements they believe may be prohibited by such laws but would be beneficial to care coordination, management of patient care and disease progression, and patient education.

Increased Data Transparency. Commenters strongly suggested that publicly accessible data is needed to ensure that beneficiaries with kidney failure who elect an MA plan maintain access to the care they need. CMS is encouraged to update MA data collection and reporting efforts to match other Medicare programs and better align incentives across the health care continuum.

Time and Distance Standards and Network Adequacy. Commenters urge CMS to reconsider requiring time and distance standards in MA, as described in regulations at 42 CFR 422.116, for dialysis facilities that were removed in 2020. Interested parties across the kidney community have noticed unintended consequences on patients-including home dialysis patients-as a result of this amended policy. Patients and interested parties report that some plans have such narrow networks that patients have difficulty accessing vascular access surgeons, nephrologists, or even a dialysis facility near their homes. Commenters further note other patients have been listed as inactive on transplant waitlists because MA plans have removed their center from the network.

Expanded Staff Training Requirements. A commenter noted that a big obstacle to home dialysis is the current training requirements that limit training to one patient at a time, and for that trainer be a Registered Nurse (RN). This leads to significant backlogs for training and deters potential patients. The national shortage of RNs limits the availability of trainers, and a core curriculum could be developed to train other professionals who could provide home dialysis training. CMS is further encouraged to create incentives to support new technologies that support mobile dialysis such that patients living in rural or remote parts of our country may have access to same standard of care as those that reside in a large urban area.

Medicare Advantage (MA) Benchmarks and Plan Finder Tools. Commenters note that CMS should ensure that corresponding adjustments in MA benchmarks for ESRD are made to reflect any adjustments in FFS ESRD payments. Additionally, commenters stated that CMS should reinforce statutory requirements that MA patients maintain access to the same services as Medicare FFS patients, including home dialysis. Despite statutory requirements, commenters reported that many MA organizations (MAOs) limit beneficiary access to in-network home dialysis, a treatment modality to which all Medicare beneficiaries should maintain equitable access. Commenters further highlight that the Medicare.gov Plan Finder is a useful tool from CMS that helps people find MA and Medicare Part D plans available in their area and should include information regarding the availability of home dialysis programs by MA plan. In doing so, CMS can shift the responsibility away from patients and onto MAOs to ensure they are communicating clearly their plans' offerings and whether enrollees will have access to a home dialysis program. Commenters also believe MA plans would be incentivized to prioritize home dialysis uptake if home dialysis penetration was included as a new quality marker, in addition to established standards that measure their performance against a set of quality measures determined by CMS.

Changes to Physician Payments for Referrals and Training. Interested parties believe that upstream incentive payments could serve as a benefit for those physicians doing particular work with patients in later CKD stages. CMS is also urged to consider providing a one-time incentive payment for referral to home dialysis—either PD or Home Hemodialysis (HHD). A complimentary policy change to the recommendations earlier, is the increased payment for HCPCS codes G0420 and G0421, which are used for individual face-to-face education services and group face-to-face education services related to CKD. Commenters note that the codes have not been meaningfully updated.

Commenters highlighted the payment system is currently underfunded by approximately 6.9 percent due to inadequate adjustments for inflation and may be insufficient to achieve the goal of 20 to 25 percent of patients receiving dialysis at home. Minor inflationary updates have not accounted for the increased demand for home training nurses and staffing intensive TCU programs. Technological advances, like remote patient monitoring and other digital tools could help to fill the gap. A commenter noted that a TEP convened in May 2020 concluded that

facilities spent between 7.5 and 8 hours training patients on home hemodialysis. CMS is encouraged to conduct an analysis to determine a more accurate number of hours per session needed for successful home dialysis training and subsequently revise the home dialysis training add-on payment amount to capture growing costs.

Interested parties have reported barriers to physician training in home dialysis modalities has led to a reluctance to prescribe these therapies in practice. Additionally, the home dialysis training service codes, CPT codes 90989 (for a completed course of home dialysis training) and 90993 (for a single training session when the course is not completed) have not been updated. These are unique service codes in that they do not have relative value units (RVUs) assigned to them but rather flat rates of $500 for 90989 and $20 per session for 90993. Stakeholders believe an adjustment of this fee to $1,500 to $2000 would be a step in the right direction for incentivizing the nephrologists to offer home modality to their patients. Additionally, stakeholders recommend that CMS issue a transmittal for Medicare Administrative Contractors (MACs) clarifying that home dialysis training via CPT codes 90989 and 90993 are covered services in the Medicare physician fee schedule.

Response: We appreciate all the comments on and interest in the topics. We note that several of the suggestions made by commenters are beyond the scope of CMS' rulemaking authority. Nonetheless, we highly value this input, as it is essential to deliberations on future model successors and ESRD policy development as we work to advance administration initiatives to expand access to home dialysis and increase transplantation efforts.

With respect to comments on fraud and abuse laws, thank you for the comments related to certain arrangements that facilitate value-based health care delivery and payment. We note that to the extent such arrangements create financial relationships for purposes of the physician self-referral law, we see no reason why the parties to the arrangements described by the commenters could not use existing exceptions to the physician self-referral law, including those for value-based arrangements, and why the financial relationships could not be structured to satisfy the requirements of an existing applicable exception. Also, CMS may determine that the AKS safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available to protect remuneration exchanged pursuant to certain financial arrangements or patient incentives permitted under future models. Such determination, if any, would be set forth in documentation separately issued by CMS.

Final Decision: We intend to use comments received in response to this RFI to inform future policy development. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

2. Exemption of the RFI From the Paperwork Reduction Act Implementing Regulations

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we did not seek proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

A. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding wage estimates and resulting information collection burden calculations used in this final rule (88 FR 76484 through 76485). To derive wage estimates in the CY 2025 ESRD PPS proposed rule, we used data from the United States Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for Medical Records

Specialists, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation (89 FR 55825). In the proposed rule, we noted that when this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was $22.69 per hour.[121] In this final rule, we are updating the median hourly wage to $23.45 per hour, which reflects the most recently available data from the United States Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates.[122] 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. Using these assumptions, in the proposed rule we estimated an hourly labor cost of $45.38 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP (89 FR 55825). In this final rule, we are updating our previously estimated hourly labor cost to $46.90 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2027. We provide the re-estimated information collection burden associated with the PY 2027 ESRD QIP in section VI.C of this final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2027 (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2027 (88 FR 76485 through 76486). In the CY 2024 ESRD PPS final rule, we estimated that the aggregate cost of the EQRS data validation for PY 2027 would be approximately $34,035 (750 hours × $45.38), or an annual total of approximately $113.45 ($34,035/300 facilities) per facility in the sample. In this final rule, we are updating the aggregate cost of EQRS data validation for PY 2027 to reflect updated wage estimates. Using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2027 would be approximately $35,175 (750 hours × $46.90), or an annual total of approximately $117.25 ($35,175/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289; Expiration date: November 30, 2025). In the CY 2024 ESRD PPS final rule and re-stated in the CY 2025 ESRD PPS proposed rule, we estimated that the aggregate cost of the NHSN data validation for PY 2027 would be approximately $68,070 (1,500 hours × $45.38), or a total of approximately $226.90 ($68,070/300 facilities) per facility in the sample (89 FR 55826). We are updating the aggregate cost of NHSN data validation to reflect updated wage estimates in this final rule. Based on the updated wage data, we estimate that the aggregate cost of the NHSN data validation for PY 2027 would be approximately $70,350 (1,500 hours × $46.90), or a total of approximately $234.50 ($70,350/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1340; Expiration date: November 30, 2025).

C. Estimated EQRS Reporting Requirements for PY 2027 (OMB Control Number 0938–1289)

To estimate 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 2024 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2027 ESRD QIP was approximately $130.5 million for approximately 2,877,743 total burden hours (88 FR 76486).

We are finalizing changes to the ESRD QIP measure set in this final rule, but do not anticipate that any of these policies would affect the burden we have previously estimated for EQRS reporting requirements for PY 2027. Beginning with PY 2027, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive measure with a Kt/V Dialysis Adequacy Measure Topic. However, we are not updating facility reporting requirements as part of that finalized policy. Additionally, although we are finalizing our proposal to remove one measure from the ESRD QIP measure set beginning with PY 2027, the measure removal would not impact EQRS reporting requirements on facilities. We provided the burden estimate for PY 2027 in the CY 2025 ESRD PPS proposed rule (89 FR 55826) and are updating the information collection burden to reflect updated wage estimates, along with updated facility and patient counts, in this final rule. In the CY 2025 ESRD PPS proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 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 136 data elements for 511,957 patients across 7,695 facilities, for a total of 69,626,152 elements (136 data elements × 511,957 patients). At 2.5 minutes per element, this would yield approximately 377.01 hours per facility. Therefore, the PY 2027 burden would be 2,901,090 hours (377.01 hours × 7,695 facilities). Using the updated wage estimate for a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately $136.1 million (2,901,090 hours × $46.90). The information collection request under the OMB Control Number: 0938–1289 will be revised and sent to OMB.

D. ESRD Treatment Choices Model

Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the ETC Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

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

[121] *https://www.bls.gov/oes/2022/may/oes292072.htm.*

[122] *https://www.bls.gov/oes/current/oes292072.htm.*

furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of 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 Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This final rule includes updates and policy changes to the ESRD PPS for CY 2025. These changes include a new wage index methodology which utilizes BLS data and reflects revised OMB CBSA delineations, a wage index budget-neutrality adjustment factor, an expansion to the ESRD PPS outlier list, methodological changes to the outlier calculation, updates to the TPNIES offset amount, updates to the post-TDAPA add-on payment adjustment amounts for Korsuva® and Jesduvroq, changes to the LVPA payment structure, and an increase to the calculation of the TDAPA for phosphate binders. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2025 for renal dialysis services furnished to ESRD beneficiaries.

This final rule also has several policy changes to improve payment stability and adequacy under the ESRD PPS. These include updates to the LVPA and payments for ESRD outlier services. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

2. AKI

This rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we are extending Medicare payment for home dialysis to beneficiaries with AKI. As discussed in section III.C of this final rule, we also are applying the updates to the ESRD PPS base rate, wage index, and training add-on payment adjustment for home dialysis to the AKI dialysis payment rate. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2025 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 CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule finalizes updates for the ESRD QIP, which would remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027 and replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027.

4. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the Act, which 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 such programs.

This final rule finalizes a change to the ETC Model, specifically to the methodology CMS uses to identify transplant failures for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. As described in detail in section V.B of this final rule, we believe it is necessary, for the purposes of accuracy, to adopt this change to the ETC Model.

B. Overall Impact Analysis

We have examined the impacts of this final 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), Executive Order 14094, entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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). Executive Order 14094 amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 $200 million or more in any 1 year, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this final rule, OIRA has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of the rulemaking to the best of our ability. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, OMB has reviewed this final regulation, and the Department has provided the following assessment of their impact.

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS would result in an increase of approximately $260 million in Medicare payments to ESRD facilities in CY 2025. This includes $220 million associated with the payment rate update, the updated post-TDAPA add-on payment adjustment amounts, and continuation of the approved TDAPA as identified in Table 19. This also includes approximately $40 million for the additional TDAPA payment for operational costs in excess of 100 percent of ASP for phosphate binders, which is derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data as discussed in section II.B.7.c. of this final rule. In addition, this amount includes, but is not impacted by, the following budget neutral changes to the ESRD PPS: updates to the outlier list, updates to the outlier methodology and thresholds, updates to the wage index methodology, updates to the OMB CBSA delineations, and changes to the LVPA.

Although the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this final rule, we estimate for reference that total ESRD PPS spending for phosphate binders will be approximately $870 million ($220 million in beneficiary coinsurance payments and $650 million in Medicare Part B spending) in CY 2025 for the original phosphate binder TDAPA payment at 100 percent of ASP; however we note that these drugs are currently being paid for under Medicare Part D, which we estimate will lead to a decrease in spending of approximately $690 million ($0 million in beneficiary premium offset and $690 million in Medicare Part D spending), for a net payment increase of approximately $180 million.

2. AKI

We estimate that the final updates to the AKI payment rate will result in an increase of approximately $2 million in Medicare payments to ESRD facilities in CY 2025.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are finalizing in this final rule, the updated ESRD QIP will result in $17.9 million in estimated payment reductions across all facilities for PY 2027.

4. ETC Model

The change we are finalizing is the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model. This policy change is not expected to change the model's projected economic impact.

5. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2025 is $260 million based on the estimates of the updated ESRD PPS and the AKI payment rates. We estimate the impacts of the ESRD QIP for PY 2027 to be $136.1 million in information collection burden and $17.9 million in estimated payment reductions across all facilities. Finally, we estimate that the final methodology change to the ETC Model will not affect the model's projected economic impact described in the Specialty Care Models final rule (85 FR 61114) and in the CY2022 ESRD PPS final rule (86 FR 61874).

C. 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 2025 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 Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished by ESRD facilities by 2.2 percent based on the final CY 2025 ESRDB market basket percentage increase of 2.7 percent reduced by the final CY 2025 productivity adjustment of 0.5 percentage point 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. We estimate that overall payments under the ESRD PPS will increase by 2.7 percent as a result of the finalized policies in this rule.

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

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the policies finalized in this final rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2027, we are updating the estimated 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.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rates will result in a total increase of approximately $220 million in Medicare payments to ESRD facilities in CY 2025, which includes the amount associated with final updates to the outlier thresholds, and final updates to the wage index. This estimate includes an increase of approximately $2 million in Medicare payments to ESRD facilities in CY 2025 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $180 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $40 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this final rule.

We also estimate that the updates to the TDAPA payment policy for phosphate binders will result in an increase of approximately $40 million in Medicare payments to ESRD facilities in CY 2025, which includes approximately $30 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $10 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS 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 ESRD PPS final rule, we assume that the total number of unique commenters on this year's ESRD PPS proposed rule, which was 191 for the CY 2025 ESRD PPS proposed rule, is equal to the number of individual reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2025 ESRD PPS proposed rule. For these reasons we determined that the number of past commenters would be a fair estimate of the number of reviewers of this final rule. We used a similar methodology for calculating the regulatory review costs in the CY 2025 ESRD PPS proposed rule; in that proposed rule we welcomed any comments on the approach in estimating the number of entities which would review that proposed rule and did not receive any direct responses.

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 this proposal. We sought comments on this assumption.

Using the May 2023 wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits [123] (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 260 minutes (4.33 hours) for the staff to review half of this final rule, which has a total of approximately 130,000 words. For each entity that reviews the rule, the estimated cost is $559.78 (4.33 hours × $129.28). Therefore, we estimate that the total cost of reviewing this regulation is $106,917.98 ($559.78 × 191).

[123] Calculated by multiplying the mean wage for medical and health service managers by 2 to account for overhead and fringe benefits.

5. Impact Statement and Table

a. CY 2025 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2024 to estimated payments in CY 2025. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of August 02, 2024, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2023 claims to 2024 and 2025 using various updates. The final updates to the ESRD PPS base rate are described in section II.B.4 of this final rule. Table 19 shows the impact of the estimated CY 2025 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2024.

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TABLE 19: Impacts of the Final Changes in Medicare Payments to ESRD Facilities for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Routine Changes to Outlier Policy (C)	LVPA Changes (D)	Changes to TDAPA and Post-TDAPA Payments[1] (E)	Addition of Composite Rate Drugs to Outlier Services (F)	Wage Index Methodology Changes and updates to the CBSA delineations (G)	Total Percent Change[2] (H)
All Facilities	7,718	27.4	0.4%	0.0%	0.1%	0.0%	0.0%	2.7%
Type								
Freestanding	7,367	26.3	0.4%	0.0%	0.1%	0.0%	0.0%	2.6%
Hospital-based	351	1.1	1.4%	0.0%	0.1%	0.3%	0.4%	4.5%
Ownership Type								
Large dialysis organization	5,961	21.3	0.4%	0.0%	0.1%	0.0%	0.2%	2.8%
Regional chain	912	3.3	0.5%	0.0%	0.0%	0.0%	-0.3%	2.4%
Independent	485	1.7	0.6%	0.0%	0.1%	-0.1%	-1.9%	0.8%
Hospital-based	351	1.1	1.4%	0.0%	0.1%	0.3%	0.4%	4.5%
Unknown	9	0.0	0.6%	0.0%	0.1%	-0.2%	-2.2%	0.4%
Geographic Location								
Rural	1,245	3.8	0.4%	0.0%	0.1%	0.0%	1.7%	4.4%
Urban	6,473	23.6	0.4%	0.0%	0.1%	0.0%	-0.2%	2.4%
Census Region								
East North Central	1,191	3.7	0.4%	0.0%	0.1%	0.0%	0.0%	2.6%
East South Central	603	1.7	0.3%	0.0%	0.1%	0.0%	2.5%	5.1%
Middle Atlantic	872	3.5	0.6%	0.0%	0.1%	0.0%	-1.2%	1.5%
Mountain	438	1.5	0.3%	0.0%	0.1%	0.0%	1.6%	4.3%
New England	199	1.0	0.4%	0.0%	0.1%	0.0%	1.9%	4.6%
Pacific[3]	986	4.9	0.4%	0.0%	0.1%	-0.1%	-2.4%	0.2%
Puerto Rico and Virgin Islands	54	0.1	0.3%	0.0%	0.1%	-0.1%	2.6%	5.2%
South Atlantic	1,802	5.9	0.5%	0.0%	0.1%	0.0%	1.1%	3.8%
West North Central	477	1.5	0.5%	0.0%	0.1%	0.1%	-0.5%	2.4%
West South Central	1,096	3.5	0.4%	0.0%	0.0%	0.0%	1.3%	4.0%
Facility Size								
Less than 3,000 treatments	673	0.5	0.4%	0.8%	0.1%	0.2%	0.6%	4.3%
3,000 to 3,999 treatments	474	0.7	0.4%	-0.5%	0.1%	0.0%	0.4%	2.7%
4,000 to 4,999 treatments	540	1.0	0.4%	0.0%	0.1%	0.0%	0.7%	3.4%
5,000 to 9,999 treatments	2,928	8.2	0.4%	0.0%	0.1%	0.0%	0.7%	3.3%
10,000 or more treatments	3,103	17.0	0.5%	0.0%	0.1%	0.0%	-0.4%	2.3%

Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients								
Less than 2%	7,621	27.2	0.4%	0.0%	0.1%	0.0%	0.0%	2.7%
Between 2% and 19%	34	0.2	0.5%	0.0%	0.1%	0.0%	1.3%	4.1%
Between 20% and 49%	7	0.0	0.1%	0.4%	0.1%	1.9%	0.1%	4.8%
More than 50%	56	0.0	-0.1%	0.0%	0.1%	0.6%	0.3%	3.0%

[1]This column includes the impact of the end of TDAPA payment for Jesduvroq and the final post-TDAPA add-on payment adjustment amount for Korsuva® and the presented post-TDAPA add-on payment adjustment amount for Jesduvroq (beginning October 1, 2025). This column does not include the TDAPA for phosphate binders.

[2] This column includes the impact of the final updates in columns (C) through (F) in Table 19, and of the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent, reduced by 0.5 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.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final routine updates to the outlier payment policy, including final changes to the inflation factors used for calculating MAP and FDL amounts described in section II.B.3 of this final rule, is shown in column C. For CY 2025, the impact on all ESRD facilities because of the final changes to the outlier payment policy would be an increase in estimated Medicare payments of approximately 0.4 percent.

Column D shows the effect of the final 2-tiered LVPA as described in section II.B.8 of this final rule. This adjustment is implemented in a budget neutral manner, so the total impact of this change will be 0.0 percent. However, there will be distributional impacts of this change, primarily increasing payments to facilities that furnish fewer than 3,000 treatments by 0.8 percent and lowering payments to ESRD facilities that furnish between 3,000 and 4,000 treatments by 0.5 percent. Because we are finalizing our proposal to use the scaled adjustment factors, the only impact of this policy is among ESRD facilities that are eligible for the LVPA.

Column E shows the effect of year-over-year payment changes related to the post-TDAPA add-on payment adjustment amounts as described in section II.B.6 of this final rule and current TDAPA payments. The post-TDAPA add-on payment adjustment will not be budget neutral, but the total impact on payment is 0.1 percent due to relatively low utilization of drugs for which we will pay this adjustment in CY 2025.

Column F reflects the impact of the expansion of outlier eligibility to formerly composite rate drugs. Overall, the changes to the outlier policy, including those reflected in column C of this table, are budget neutral insofar as we estimate that we will better hit the 1 percent target for outlier payments. These changes will increase payments for facilities that treat a higher proportion of exceptionally costly cases.

Column G reflects the effect of the finalized changes to the ESRD PPS wage index methodology, the adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the rural transition policy as described in section II.B.2 of this final rule. This update will be budget neutral, so the total impact of this policy change is 0.0 percent. However, there will be distributional impacts of this change. The largest increase will be to ESRD facilities in Puerto Rico and the Virgin Islands, which would receive 2.6 percent higher payments because of the updated ESRD PPS wage index. The largest decrease would be for ESRD facilities in the Pacific Census region, which will receive 2.4 percent lower payments because of the updated ESRD PPS wage index and methodological changes.

Column H reflects the overall impact, that is, the effects of the outlier policy changes, LVPA changes, the post-TDAPA add-on payment adjustment amounts, the new wage index methodology, the new CBSA delineations, the rural transition policy, and the payment rate update as described in section II.B.4 of this final rule. The final ESRD PPS payment rate update for CY 2025 is 2.2 percent, which reflects the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent and the productivity adjustment of 0.5 percentage point. We expect that overall ESRD facilities will experience a 2.7 percent increase in estimated Medicare payments in CY 2025. The categories of types of ESRD facilities in the impact table show impacts ranging from a 0.2 percent increase to a 5.2 percent increase in their CY 2025 estimated Medicare payments.

This table does not include the impact of the inclusion of oral-only drugs to the ESRD PPS as we are unable to calculate facility level estimates at this time, nor does it include the impacts of the increase to the TDAPA amount for phosphate binders as finalized in section II.B.7.c of this final rule. We cannot include the impact of this final change in Table 19 because we do not have the patient-level utilization data required to model facility-level uptake. As noted previously, the overall impact of this TDAPA increase is approximately $40 million. Furthermore, we note that the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS beginning in CY 2025 is provided for by existing regulations and is not impacted by this final rule, other than the change in the TDAPA amount for phosphate binders. For public awareness, we estimate an increase in Medicare Part B spending of approximately $870 million in CY 2025, and a corresponding decrease in Medicare Part D spending of approximately $690 million in CY 2025, associated with payment for phosphate binders under the ESRD PPS.

(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 2025, we estimate that the ESRD PPS would 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 2025 would be approximately $6.2 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 2.1 percent in CY 2025.

(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 2.7 percent overall increase in the CY 2025 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2025, which translates to approximately $40 million.

As we have previously noted, the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this final rule. For public awareness, we estimate an increase in beneficiary coinsurance payments of $230 million. As noted in section II.B.7 of this final rule, we anticipate that the inclusion of oral-only drugs in the ESRD PPS will increase access to these drugs for beneficiaries, particularly disadvantaged populations who currently do not have Part D coverage.

(5) Alternatives Considered

(a) Wage Index Changes

We considered, but did not finalize, a one-year delay to the implementation date for the new ESRD PPS wage index methodology. This delay would have allowed us further time to consider several potential methodological suggestions, including MedPAC's suggestions for smoothing across and variation within CBSAs. However, we have decided that such a delay is not appropriate, because we believe the new ESRD PPS wage index methodology is the best estimation available for the geographic variation in wages ESRD facilities face. We considered MedPAC's suggestions for the proposed rule and decided that they would introduce additional complexity and would involve parameters which could be seen as arbitrary for purposes of estimating wages for occupations related to furnishing renal dialysis services and involve lower-quality data sources. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

(b) Expansion of Outlier Eligibility

We considered only expanding outlier eligibility to drugs and biological products previously paid for under the TDAPA after the end of the TDAPA period. As discussed in section II.B.3.b of this final rule, we have instead decided to finalize to expand outlier eligibility to all drugs and biological products that were or would have been composite rate services prior to the inception of the ESRD PPS. We believe that this is appropriate because formerly composite rate drugs represent potentially significant costs which are not currently accounted for by the outlier adjustment. Furthermore, most of the commenters' concerns with the inclusion of composite rate drugs revolved around concerns that should we overestimate outliers in one year we would reduce the ESRD PPS base rate in future years, which is with a misinterpretation of our outlier policy. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

(c) TDAPA Amount for Phosphate Binders

We considered, but are not finalizing, paying the TDAPA for phosphate binders based on 106 percent of ASP, rather than the fixed addition to the TDAPA amount which we have finalized. Paying the TDAPA for phosphate binders at 106 percent of ASP for at least 2 years to mirror our TDAPA payment approach for the first 2 years for calcimimetics would have many of the same effects of the flat TDAPA increase we finalized, as we based the size of the flat increase off of 6 percent of TDAPA expenditures. However, as discussed in section II.B.7.c of this final rule, we believe that paying 106 percent of ASP could potentially incentivize ESRD facilities to prescribe higher-cost phosphate binders to receive additional payment. We note that our final policy, with respect to TDAPA payment for phosphate binders, would best support small entities, as discussed in section VII.E of this final rule, as we expect small entities would have less bargaining power than large entities in negotiating prices for phosphate binders.

(d) Changes to the LVPA

We considered, but did not finalize, a three tier LVPA which would be funded by eliminating the rural facility adjustment. This was a suggestion of several commenters who recommended the LVPA be expanded beyond the current 4,000 treatment volume threshold. However, our analysis found that the elimination of the rural facility adjustment would not provide nearly enough funds to establish a third LVPA tier, even if we were to lower the treatment volume threshold to 5,000 from the 6,000 suggested by commenters. As discussed in section II.B.8.c of this final rule, we are finalizing a two-tiered scaled LVPA in part because it would not lead to any budget neutrality reduction to the ESRD PPS base rate. In the proposed rule, we presented an alternative three-tiered LVPA which could be implemented by reducing the base rate, but commenters were generally not supportive of the idea. Although our proposal did not involve the elimination of the rural facility adjustment and the reallocation of those funds, we did not believe that commenters would support the proposal. Additionally, we believe that the rural facility adjustment is a useful tool which protects ESRD facilities in potentially vulnerable areas. The continued use of the rural facility adjustment likely benefits small entities, as discussed in section VII.E of this final rule, operating in rural areas. As discussed previously, eliminating the rural facility adjustment would not provide enough funds to fully cover the suggested approach, so such a policy would require budget neutrality reduction which would reduce payment to small entities that receive the LVPA.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2025

Two renal dialysis drugs for which the TDAPA was paid in CY 2024 will continue to be eligible for the TDAPA in CY 2025.

(1) Jesduvroq (Daprodustat)

On July 27, 2023, CMS Transmittal 12157 [124] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Jesduvroq (daprodustat). The TDAPA payment period began on October 1, 2023, and will continue through September 30, 2025. As stated previously, TDAPA

[124] CMS Transmittal 12157, dated July 27, 2023, is available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

In the proposed rule, we based our impact analysis on the most current 72x claims data from November 2023, when utilization first appeared on the claims, through February 2024. During that timeframe, the average monthly TDAPA payment amount for Jesduvroq (daprodustat) was $23,075. In applying that average to each of the 9 remaining months of the TDAPA payment period in CY 2025, we estimated $207,675 in spending ($23,075 * 9 = $207,675) of which, approximately $41,535 ($207,675 * 0.20 = $41,535) would have been attributed to beneficiary coinsurance amounts.

Several commenters indicated that GlaxoSmithKline (GSK), Jesduvroq's manufacturer, is removing the drug from the market. The FDA's Orange Book [125] identifies Jesduvroq's marketing status as discontinued. GSK indicated that the change in marketing status does not reflect a change in availability or in FDA's approval of the product. GSK could not state definitively that there will be no TDAPA claims in CY 2025. Because we have no way of estimating how the change in Jesduvroq's marketing status will affect utilization, we have carried the proposed rule estimates forward unchanged. That is, we estimate $207,675 in spending, of which, approximately $41,535 will be attributed to beneficiary coinsurance amounts.

[125] FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed September 26, 2024. Available at: *https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=216951.*

(2) DefenCath® (Taurolidine and Heparin Sodium)

On May 9, 2024, CMS Transmittal 12628 [126] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for DefenCath® (taurolidine and heparin sodium). The TDAPA payment period began on July 1, 2024, and will continue through June 30, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

As of the drafting of this final rule, DefenCath® was in the first few months of the TDAPA payment period. Complete claims data, upon which we could base CY 2025 Medicare impact estimates, was limited to the month of July 2024. Due to the limited timeframe of complete and available claims data, we believe that it would have been more appropriate to base Medicare impacts on cost and utilization volume estimates furnished by the manufacturer, recognizing that the manufacturer is most familiar with the market conditions affecting its products. We requested but did not receive utilization volume estimates from the manufacturer. Therefore, we based our impact analysis on the most current 72x claims data for the month of July 2024, when utilization first appeared on the claims. In July 2024, the average monthly TDAPA payment amount for DefenCath® was $2,118,827. In applying that average to each of the 12 months of the TDAPA payment period in CY 2025, we estimate $25,425,924 in spending ($2,118,827 * 12 = $25,425,924) of which, approximately $5,085,184 ($25,425,924 * 0.20 = $5,085,184) will be attributed to beneficiary coinsurance amounts.

[126] CMS Transmittal 12628, dated May 9, 2024, is available at: *https://www.cms.gov/files/document/r12628CP.pdf.*

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

(1) Effects on ESRD Facilities

To understand the impact of the finalized changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2024 to estimated Medicare payments in CY 2025. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of August 02, 2024, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2023 claims to 2024 and 2025 using various updates. The updates to the AKI payment amount are described in section III.C of this final rule. Table 20 shows the impact of the estimated CY 2025 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2024.

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TABLE 20: Impacts of the Final Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
All Facilities	5,082	282.6	0.1%	2.3%
Type				
Freestanding	4,974	277.8	0.1%	2.3%
Hospital-based	108	4.8	1.2%	3.4%
Ownership Type				
Large dialysis organization	4,216	233.7	0.2%	2.4%
Regional chain	568	30.4	0.0%	2.2%
Independent	189	13.6	-1.3%	0.8%
Hospital-based[2]	108	4.8	1.2%	3.4%
Unknown	1	0.1	4.3%	6.6%
Geographic Location				
Rural	826	44.7	1.7%	4.0%
Urban	4,256	237.9	-0.1%	2.1%
Census Region				
East North Central	835	44.4	0.2%	2.4%
East South Central	376	17.2	2.5%	4.8%
Middle Atlantic	575	31.9	-1.0%	1.2%
Mountain	314	20.9	0.4%	2.6%
New England	139	7.1	1.6%	3.8%
Pacific[3]	647	48.4	-2.1%	0.0%
Puerto Rico and Virgin Islands	4	0.1	-1.1%	1.0%
South Atlantic	1,197	67.6	1.5%	3.7%
West North Central	322	13.4	-0.4%	1.8%
West South Central	673	31.7	1.4%	3.7%
Facility Size				
Less than 3,000 treatments	204	6.6	0.2%	2.4%
3,000 to 3,999 treatments	247	9.7	0.4%	2.6%
4,000 to 4,999 treatments	320	13.1	0.8%	3.0%
5,000 to 9,999 treatments	2,032	104.4	0.8%	3.0%
10,000 or more treatments	2,279	148.8	-0.4%	1.8%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,068	282.1	0.1%	2.3%
Between 2% and 19%	12	0.5	0.8%	3.0%
Between 20% and 49%	1	0.0	0.6%	2.8%
More than 50%	1	0.0	0.5%	2.7%

[1] This column includes the impact of the updates in columns (C) as well as the impact of the wage index budget-neutrality adjustment factor in Table 20, and of the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent, reduced by 0.5 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the final CY 2025 wage index changes, including the changes to the ESRD PPS wage index methodology, the adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the rural transition policy as described in section II.B.2.f.(2) of this final rule. We note the rural adjustment does not apply to beneficiaries with AKI, so this column only incorporates the budget neutrality factor associated with that policy.

Column D shows the overall impact, that is, the effects of the final wage index budget-neutrality adjustment factor, wage index updates, and the payment rate update of 2.2 percent, which reflects the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent and the final productivity adjustment of 0.5 percentage point, as well as the training add-on budget neutrality reduction of $0.00. We expect that overall ESRD facilities will experience a 2.3 percent increase in estimated Medicare payments in CY 2025 for treatment of AKI beneficiaries. This table does not include any distributional impacts of payments to ESRD facilities associated with the extension of payment for AKI home dialysis or extension of the add-on payment adjustment for training for home and self-dialysis (outside of the budget-neutrality reduction, as discussed), as we are unable to estimate potential uptake at a facility level at this time. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.0 percent to an increase of 3.8 percent in their CY 2025 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are finalizing 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 would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $70 million would be paid to ESRD facilities in CY 2025 because of patients with AKI receiving renal dialysis services in an 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 coinsurance 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 coinsurance 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 adjustments 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.

As discussed in section III.B of this final rule, we are finalizing payment for AKI dialysis in the home setting, and as discussed in section III.C.3 of this final rule we will apply the home and self-dialysis training add-on payment adjustment for such services provided to AKI patients. We considered paying for AKI home dialysis without the training add-on adjustment; however, we were concerned that access to home dialysis for AKI beneficiaries could be negatively impacted in the absence of an add-on payment adjustment to support home dialysis training. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

d. ESRD QIP

(1) Effects of the PY 2027 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2027 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2027, consistent with our regulations at § 413.177.

For the PY 2027 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 36.9 percent or 2,750 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,750 facilities that would receive a payment reduction, approximately 63 percent or 1,730 facilities would receive the smallest payment reduction of 0.5 percent. We are updating the estimated impact of the PY 2027 ESRD QIP that we provided in the CY 2024 ESRD PPS final rule (88 FR 76495 through 76497). Based on the policies finalized in this rule, the total estimated payment reductions for all the 2,750 facilities expected to receive a payment reduction in PY 2027 would be approximately $17,887,355. Facilities that do not receive a TPS do not receive a payment reduction.

Table 21 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 21: Updated Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4712	63.2%
0.5%	1730	23.2%
1.0%	760	10.2%
1.5%	177	2.4%
2.0%	83	1.1%

*233 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2027, we scored each facility on achievement and improvement on several clinical measures 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 22) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 22.

TABLE 22: Data Used to Update the Estimated PY 2027 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 2022-Dec 2022	Jan 2023-Dec 2023
SRR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
SHR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
PPPW	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Pediatric HD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Adult PD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Pediatric PD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
VAT		
% Catheter	Jan 2022-Dec 2022	Jan 2023-Dec 2023
STrR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
NHSN BSI	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Clinical Depression	Jan 2022-Dec 2022	Jan 2023-Dec 2023

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible 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 clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the final policies outlined in section IV.B of this final rule. Facility reporting measure scores were estimated using available data from CY 2023. 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 2027 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 23 shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027. 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 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 23: Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	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	7,695	27.0	7,462	2,750	-0.27%
Facility Type:					
Freestanding	7,348	26.0	7,135	2,601	-0.26%
Hospital-based	347	1.0	327	149	-0.41%
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	1,934	-0.22%
Regional Chain	908	3.3	881	343	-0.30%
Independent	461	1.6	444	319	-0.79%
Hospital-based (non-chain)	347	1.0	327	149	-0.41%
Unknown	37	0.0	18	5	-0.30%
Facility Size:					
Large Entities	6,850	24.4	6,673	2,277	-0.23%
Small Entities[1]	808	2.6	771	468	-0.63%
Unknown	37	0.0	18	5	-0.30%
Rural Status:					
1) Yes	1,245	3.8	1,209	373	-0.22%
2) No	6,450	23.2	6,253	2,377	-0.28%
Census Region:					
Northeast	1,069	4.4	1,033	393	-0.30%
Midwest	1,663	5.1	1,620	593	-0.27%
South	3,490	11.1	3,374	1,309	-0.28%
West	1,408	6.3	1,371	414	-0.21%
US Territories[2]	65	0.2	64	41	-0.41%
Census Division:					
Unknown	11	0.1	11	7	-0.50%
East North Central	1,188	3.6	1,155	449	-0.29%
East South Central	602	1.7	582	188	-0.22%
Middle Atlantic	870	3.4	836	334	-0.32%
Mountain	438	1.5	425	135	-0.22%
New England	199	1.0	197	59	-0.20%
Pacific	970	4.7	946	279	-0.21%
South Atlantic	1,793	5.9	1,737	698	-0.31%
West North Central	475	1.5	465	144	-0.23%
West South Central	1,095	3.5	1,055	423	-0.28%
US Territories[2]	54	0.1	53	34	-0.39%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,207	1.5	1,071	362	-0.31%
4,000-9,999 treatments	3,461	9.2	3,377	1,083	-0.23%
Over 10,000 treatments	3,027	16.3	3,014	1,305	-0.30%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

TABLE 24: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	$17,887,355
PY 2026	$15,990,524 (88 FR 76500)
PY 2025	$32,457,693 (87 FR 67297)
PY 2024	$17,104,031 (86 FR 62011)
PY 2023	$5,548,653 (87 FR 67297)
PY 2022	$0[127] (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)

(3) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of 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 continue to monitor and evaluate trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(4) Alternatives Considered

In section IV.B.2 of this final rule, we are finalizing the replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027. We considered not adopting this change. However, we concluded that replacing this measure was appropriate to ensure that facilities are scored on Kt/V measure data according to the individual facility's ESRD patient population and treatment modalities.

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), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), and the CY 2024 ESRD PPS final rule (88 FR 76344) 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. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of 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).

Table 25 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 would 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). The minor methodological change to the definition of an ESRD Beneficiary is not expected to change this estimate.

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

TABLE 25: 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

In Table 25, 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 Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The change finalized in this rule is not expected to impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The change finalized in this rule is not expected to 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) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(6) Effects on Medicare Beneficiaries

Our decision to finalize changes to the definition of an ESRD Beneficiary for the purposes of attribution is not expected to impact the findings reported for the effects of ETC Model on Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 61874).

(7) Alternatives Considered

Throughout this final rule, we have identified finalized changes to our policy and alternatives considered and provided information as to the likely effects of these alternatives and rationale for our changed policy.

The Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), the CY 2024 ESRD PPS final rule (88 FR 76344), and the finalized policy herein address a model specific to ESRD. These rules provide descriptions of the requirements that we waive, identify 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 section V.B. and to the previous citations.

D. 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 26 showing the classification of the impact associated with the provisions of this final rule.

TABLE 26: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2025)	
Category	**Transfers**
Annualized Monetized Transfers	$210 million
Bearers of Transfer Gain	Medicare ESRD Facilities
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$50 million
Bearers of Transfer Gain	Medicare ESRD Facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	$17.9 million
Bearers of Transfer Gain	Federal Government
ETC Model for July 1, 2022, through June 30, 2027	
Category	Transfers
Net Monetized Transfers	$28 million
Bearers of Transfer Gain	Federal Government

E. Regulatory Flexibility Act (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, an ESRD facility is classified as a small business if it has total revenues of less than $47 million in any 1 year.[128] For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $6.5 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 FFS 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 485 ESRD facilities that are independent and 351 ESRD facilities that are hospital-based, as shown in the ownership category in Table 19, to be small businesses. These ESRD facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 792 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 369 nonprofit ESRD facilities that are also considered small businesses, there are 1,259 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

As its measure of significant economic impact on a substantial number of small entities, HHS's practice in interpreting the RFA is to consider effects economically ''significant'' on a ''substantial'' number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We did not receive any public comments on our regulatory impact analysis for small entities. As shown in Table 19, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.7 percent. For the ESRD PPS updates in this final rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 4.5 percent increase in Medicare FFS payments for CY 2025. An independent facility (as defined by ownership type) is likewise estimated to receive a 0.8 percent increase in Medicare FFS payments for CY 2025. Among hospital-based and independent ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 5.3 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 2.1 percent increase in Medicare FFS payments. Among nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 6.0 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 2.8 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this final rule. This analysis is based on the assumptions described earlier in this section of this final rule as well as the detailed impact analysis discussed in section VII.C of this final rule, which includes a discussion of data sources, general

[128] *http://www.sba.gov/content/small-business-size-standards.*

assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 2,750 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 468 are ESRD small entity facilities. We present these findings in Table 21 (''Updated Estimated Distribution of PY 2027 ESRD QIP Payment Reductions'') and Table 23 (''Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027''). Table 21 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP. Table 23 shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027, and also details the distribution of ESRD facilities by size, geography, and facility type.

For the ETC Model, we do not anticipate any impact on ESRD facilities from our decision to finalize a change to the definition of an ESRD Beneficiary for the purposes of beneficiary attribution in the model. As previously stated, we estimate that the Medicare program would save a net total of $43 million from the ETC 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.

Therefore, the Secretary has determined that this final rule will have a significant economic impact, reflecting a positive revenue increase, on a substantial number of small entities. This RFA section along with the RIA constitutes our final regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. 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 would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 108 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 108 rural hospital-based ESRD facilities would experience an estimated 5.9 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.

F. Unfunded Mandates Reform Act (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 2024, that threshold is approximately $183 million. 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. Therefore, this final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. 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 State, local, or Tribal government.

H. 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

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 CMS's website under the regulation number, CMS–1805–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 (LDS) 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 23, 2024.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 494

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, 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 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.52 is amended by revising paragraph (a) introductory text to read as follows:

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:

* * * * *

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

■ 3. 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), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Section 413.196 is amended by revising paragraph (d)(2) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(d) * * *

(2) The wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent full calendar year of Medicare cost reports submitted in accordance with § 413.198(b).

* * * * *

■ 5. Section 413.231 is amended by revising paragraph (a) to read as follows:

§ 413.231 Adjustment for wages.

(a) 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 (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.

* * * * *

■ 6. Section 413.234 is amended by revising paragraph (c) introductory text and adding paragraph (c)(4) to read as follows:

§ 413.234 Drug designation process.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP), except as provided in paragraph (c)(4) of this section. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(4) For calendar years 2025 and 2026, the transitional drug add-on payment adjustment amount for a phosphate binder is based on 100 percent of ASP plus an additional amount derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data.

* * * * *

■ 7. Section 413.236 is amended by revising paragraphs (b)(4) and (c) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

* * * * *

(c) Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications. CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

■ 8. Section 413.237 is amended by adding paragraph (a)(1)(vii) to read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(vii) Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

* * * * *

■ 9. Section 413.373 is revised to read as follows:

§ 413.373 Other adjustments to the AKI dialysis payment rate.

(a) CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.

(b) The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

■ 10. Section 413.374 is amended by revising paragraph (a) to read as follows:

§ 413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.

* * * * *

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 11. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. l302 and l395hh.

■ 12. Section 494.10 is amended by revising the definitions of ''Home dialysis'' and ''Self-dialysis'' to read as follows:

§ 494.10 Definitions.

* * * * *

Home dialysis means dialysis performed at home by a patient or caregiver who has completed an appropriate course of training as described in § 494.100(a).

Self-dialysis means dialysis performed with little or no professional assistance by a patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a).

* * * * *

■ 13. Section 494.70 is amended by revising paragraphs (a)(1) and (10) and (c)(1)(i) to read as follows:

§ 494.70 Condition: Patients' rights.

* * * * *

(a) * * *

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with kidney failure;

* * * * *

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for kidney failure of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

* * * * *

(c) * * *

(1) * * *

(i) How plans in the individual market will affect the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange).

* * * * *

■ 14. Section 494.80 is amended by revising the introductory text to read as follows:

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for kidney failure, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

* * * * *

■ 15. Section 494.90 is amended by revising paragraph (b)(4) to read as follows:

§ 494.90 Condition: Patient plan of care.

* * * * *

(b) * * *

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing dialysis care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

* * * * *

■ 16. Section 494.100 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 494.100 Condition: Care at home.

* * * * *

(a) * * *

(3) * * *

(i) The nature and management of their kidney failure.

* * * * *

■ 17. Section 494.120 is amended by revising the introductory text to read as follows:

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve patients with kidney failure while the patients are in a temporary residence) and facilities established to serve patients with kidney failure under emergency circumstances.

* * * * *

■ 18. Section 494.130 is revised to read as follows:

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

■ 19. Section 494.170 is amended by revising the introductory text to read as follows:

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of dialysis services and all other home dialysis patients whose care is under the supervision of the facility.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 20. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 21. Section 512.310 is amended by revising the definition of ''ESRD Beneficiary'' to read as follows:

§ 512.310 Definitions.

* * * * *

ESRD Beneficiary means a beneficiary who meets any of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date.

(3) Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by:

(i) Two or more MCP claims in the180 days following the date on which the kidney transplant was received;

(ii) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or,

(iii) Indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR) database.

(4) If a beneficiary meets more than one of criteria described in paragraphs (3)(i) through (iii) of this definition, the beneficiary will be considered an ESRD beneficiary starting with the earliest month in which transplant failure was recorded.

* * * * *

Xavier Becerra,

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