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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS-1782-F]

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

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

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2024. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this final rule updates requirements for the ESRD Quality Incentive Program and the ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2024.

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

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional 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:

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I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this rule finalizes 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. Our policy objectives include 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 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)

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

beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, African American, 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, and racial and ethnic minorities. 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] Specifically, in the CY 2024 ESRD PPS proposed rule (88 FR 42431), we requested information regarding a potential payment adjustment for geographically isolated and rural ESRD facilities, proposed additional payment for the subgroup of Pediatric ESRD Patients (as defined in 42 CFR 413.171), and proposed policies to further our efforts to determine if payment to ESRD facilities treating patients with co-morbidities such as sickle cell anemia is aligned with resource use by such ESRD facilities. As discussed in sections II.B.1.g and II.B.1.j of this final rule, we are now finalizing the proposed payment adjustment for Pediatric ESRD Patients and policies to improve the measurement of individual resource use. Additionally, we are adding three new measures to the ESRD QIP measure set that are aimed at promoting health equity for ESRD patients, including by enabling ESRD facilities to identify gaps experienced by their patient populations.

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

[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.

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 final rule updates the ESRD PPS for CY 2024.

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 2024.

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 final rule finalizes several updates for the ESRD QIP, including: (1) updates that will begin with Payment Year (PY) 2026, including one new quality measure, modifications to two current measures, and the removal of two measures; (2) the addition of two new measures beginning with PY 2027; (3) a revision to the regulatory definition of "minimum total performance score" that more accurately captures how we calculate the median of national ESRD facility

performance on reporting measures; and (4) the codification of our previously finalized measure selection, retention, and removal policies.

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

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center) and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled "Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures" (85 FR 61114), referred to herein as the "Specialty Care Models final rule." We revised and updated certain ETC Model policies in the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136). In this final rule, we are finalizing a modification to our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. This change will provide ETC Participants with information about the availability of administrative review if an ETC Participant wishes to seek additional review of its targeted review request.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2024: The final CY 2024 ESRD PPS base rate is $271.02, an increase from the CY 2023 ESRD PPS base rate of $265.57. This amount reflects the application of the combined wage index and transitional pediatric ESRD add-on payment adjustment (TPEAPA) budget-neutrality adjustment factor (0.999534) and a productivity-adjusted market basket percentage increase of 2.1 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $271.02 (($265.57 × 0.999534) × 1.021 = $271.02).

- Annual update to the wage index: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2024, we are updating the wage index values based on the latest available data.

- Annual update to the outlier policy: We are updating the outlier policy based on the most current data. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2024 using the latest available CY 2022 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2022 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022. For pediatric beneficiaries, the final FDL amount will decrease from $23.29 to $11.32, and the MAP amount will decrease from $25.59 to $23.36, as compared to CY 2023 values. For adult beneficiaries, the final FDL amount will decrease from $73.19 to $71.76, and the MAP amount will decrease from $39.62 to $36.28. The 1.0 percent target for outlier payments was not achieved in CY 2022. Outlier payments represented approximately 0.8 percent of total Medicare payments rather than 1.0 percent.

- Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2024: The final CY 2024 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.00. This offset amount reflects the application of the ESRD Bundled (ESRDB) productivity-adjusted market basket update of 2.1 percent ($9.79 × 1.021 = $10.00). There are no capital-related assets set to receive the TPNIES in CY 2024 for which this offset will apply.

- Clarifications to the TPNIES eligibility criteria: We are finalizing certain clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b).

- TPNIES application received for CY 2024: In this final rule, we announce our determination on the one TPNIES application under consideration for the TPNIES for CY 2024 payment.

- Modifications to the administrative process for the low-volume payment adjustment (LVPA): We are finalizing exceptions to the current LVPA attestation process for ESRD facilities that are affected by disasters and other emergencies. These exceptions will allow ESRD facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. Additionally, the exceptions will allow an ESRD facility to receive the LVPA even if it exceeds the LVPA treatment volume threshold if its treatment counts increase due to treating additional patients displaced by a disaster or emergency.

- Policy to measure patient-level utilization: We are finalizing a requirement for ESRD facilities to report the time on machine (that is, the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims, effective January 1, 2025. This will serve to provide more data to better inform CMS's pursuit of equitable payment policies in the future.

- Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA): We are finalizing the establishment of a new budget neutral add-on payment adjustment of 30 percent of the per treatment payment amount for renal dialysis services furnished to Pediatric ESRD Patients effective January 1, 2024, for CYs 2024, 2025, and 2026. This will serve to bring Medicare payments for renal dialysis services furnished to pediatric patients more in line with their estimated relative costs for the next 3 years until further collection and analysis of cost report data can be conducted.

- Add-on payment adjustment following the end of the transitional drug add-on payment adjustment (TDAPA) period: We are finalizing a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period, which we call the post-TDAPA add-on payment adjustment.

This payment adjustment will be case-mix adjusted and set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA add-on payment adjustment will be applied to all ESRD PPS payments and paid for 3 years.

- Reporting of discarded billing units of certain renal dialysis drugs and biological products paid for under the ESRD PPS: We are finalizing 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.

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

We are updating the AKI payment rate for CY 2024. The final CY 2024 payment rate is $271.02, which is the same as the base rate finalized for the ESRD PPS for CY 2024.

3. ESRD QIP

We are finalizing several updates for the ESRD QIP. Beginning with PY 2026, we are adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set, modifying the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure to align with updated measure specifications developed by the Centers for Disease Control and Prevention (CDC), removing the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, and updating the Clinical Depression Screening and Follow-Up measure's scoring methodology and converting that measure to a clinical measure. Beginning with PY 2027, we are adding the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set. In addition, we are revising the codified definition of "minimum total performance score" and codifying our previously finalized measure selection, retention, and removal policies.

4. ETC Model

We are finalizing a modification to our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests.

C. Summary of Costs and Benefits

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

1. Impacts of the Final ESRD PPS

The impact table in section VII.D.5.a of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2024 compared to estimated Medicare payments in CY 2023. The overall impact of the CY 2024 changes is projected to be a 2.1 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 3.1 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.0 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $190 million in CY 2024 compared to CY 2023. This reflects an increase of approximately $180 million from the payment rate update and the final post-TDAPA add-on payment adjustment and approximately $10 million in estimated TDAPA payment amounts for Korsuva® and Jesduvroq (daprodustat), as further described in the following paragraphs. Because of the projected 2.1 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.1 percent in CY 2024, 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, the TPNIES payment period for the Tablo® System ends on December 31, 2023. As discussed in section II.E of this final rule, the TDAPA payment period for Korsuva® (difelikefalin) will continue through March 31, 2024, and for Jesduvroq, will continue throughout 2024. As described in section VII.D.5 of this final rule, we estimate that the overall TDAPA payment amounts in CY 2024 will be approximately $13.3 million, of which, approximately $2.7 million will be attributed to beneficiary coinsurance amounts. We note that these expenditures are estimated in addition to the overall $180 million increase described in the preceding paragraphs and are not fully represented in the detailed impact analysis shown in Table 24.

Lastly as discussed in section II.B.1.i of this final rule, we are finalizing a non-budget-neutral payment adjustment for certain new renal dialysis drugs and biological products after the TDAPA period ends, starting in CY 2024. The structure of the post-TDAPA add-on payment adjustment for a new renal dialysis drug or biological product will be based on the case-mix adjusted average per-treatment expenditure for such drug or biological product. We will apply a 65 percent risk-sharing adjustment to the calculated payment amount for the post-TDAPA add-on payment adjustment. We are finalizing a 3-year period following TDAPA during which the drug or biological product would be included in the post-TDAPA add-on payment adjustment. During this period, the renal dialysis drug or biological product would be considered for outlier payments, if it meets the definition of an ESRD outlier service. The first drug that will meet these criteria in CY 2024 will be Korsuva®, which fits into the existing ESRD PPS functional category for antipruritic drugs and biological products. The post-TDAPA add-on payment adjustment calculated for Korsuva® will be $0.2493.

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

The impact table in section VII.D.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 2023. The overall impact of the CY 2024 changes is projected to be a 2.0 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.1 percent increase in Medicare payments compared with freestanding ESRD facilities that have an estimated 2.0 percent increase. The overall impact reflects the effects of the final Medicare payment rate update and final CY 2024 ESRD PPS wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2024 ESRD PPS base rate, will increase by $1 million in CY 2024 compared to CY 2023.

3. Impacts of the Final Changes to the ESRD QIP

We estimate that the overall economic impact of the PY 2026 ESRD QIP will be approximately $136.9 million. The $136.9 million estimate for PY 2026 includes $120.9 million in costs associated with the collection of information requirements and approximately $16 million in payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2027 ESRD QIP will be approximately $144.3 million. The $144.3 million estimate for PY 2027 includes $130.5 million in costs associated with the collection of information requirements and approximately $13.8 million in payment reductions across all facilities.

4. Impacts of the Final Changes to the ETC Model

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

savings for the ETC Model. As the ETC Model targeted review process has already been finalized in the Specialty Care Models final rule and ETC Participants are not required to seek administrative review of targeted review determinations, we expect there will be minimal additional burden associated with the administrative review policy we are finalizing.

II. Calendar Year (CY) 2024 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 (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket 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.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010, in the

Federal Register (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, we published a final rule, which appeared in the November 7, 2022, 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 2023 ESRD PPS final rule." In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2023. We also finalized changes that included rebasing and revising the ESRD Bundled (ESRDB) market basket to reflect a 2020 base year, refining the methodology for outlier calculations, implementing a wage index floor of 0.600, implementing a permanent 5 percent cap on year-over-year wage index decreases for ESRD facilities, and modifying the definition of "oral-only drug." For further detailed information regarding these updates, see 87 FR 67136.

B. Provisions of the Proposed Rule, Public Comments, and Response to the Comments on the CY 2024 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" (88 FR 42430 through 42544), referred to herein as the "CY 2024 ESRD PPS proposed rule," appeared in the **Federal Register** on June 30, 2023, with a comment period that ended on August 25, 2023. In that rule, we proposed to make a number of annual updates for CY 2024, including updates to the ESRD PPS base rate, wage index, outlier policy, and the offset amount for the TPNIES. We also proposed two new exceptions to the

LVPA eligibility requirements for ESRD facilities impacted by a disaster or other emergency, a new add-on payment adjustment for pediatric ESRD patients, a new add-on payment adjustment for certain new drugs and biological products after the TDAPA period ends, a new reporting requirement for discarded billing units of certain renal dialysis drugs or biological products, and a new reporting requirement for time on machine data for in-center hemodialysis treatments. We proposed clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b) and included a summary of the one CY 2024 TPNIES application that we received by the February 1, 2023 deadline with our preliminary analysis of the applicant's claims related to substantial clinical improvement and other eligibility criteria for the TPNIES. In addition, the proposed rule included a request for information regarding potential changes to the LVPA and a potential new payment adjustment for geographic isolation.

We received 344 public comments on our ESRD PPS 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 a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home renal dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a health care consultant; and the Medicare Payment Advisory Commission (MedPAC).

We received comments related to issues that we either did not discuss in the CY 2024 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes in the rule. These include, for example, concerns regarding staff training, education for kidney disease patients, access to innovation for Medicare Advantage beneficiaries, transportation for ESRD patients, nutrition for ESRD patients, and telehealth. We also received several comments on Medicare coverage for certain Humanitarian

Use Devices. We are not providing detailed responses to those comments in this final rule because they are out of the scope of the CY 2024 ESRD PPS proposed rule. We thank the commenters for their input and will consider the recommendations in potential future rulemaking.

We received numerous comments on the potential inclusion of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025. As noted in the CY 2023 ESRD PPS final rule (87 FR 67180), we expect that the only oral-only drugs and biological products that would be included in the ESRD bundled payment in CY 2025 are phosphate binders. Commenters expressed concerns on potential access and health equity issues, which could result from including oral-only drugs and biological products in the ESRD PPS bundled payment. Some commenters also expressed additional concerns associated with the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment, such as concerns about the following: the administrative burden of managing a patient's dosage and combination of phosphate lowering drugs; administration of the prescription insofar as patients think they must go to the ESRD facility to obtain the phosphate binders; confusion for patients, in that some patients think the phosphate lowering drugs would only be dispensed at the ESRD facility, and since the drugs must be taken with food, they would not be able to take the drugs because eating during dialysis is not allowed, or they must go to the ESRD facility to get the phosphate binders even when they do not have a dialysis treatment; innovation of new oral-only drugs and biological products, such as phosphate lowering therapies, would be unavailable because of the cost of the new drugs or biological products; and the definition of oral-only drugs and biological products for phosphate lowering agents until an intravenous or injectable equivalent of the drug is available. We thank the commenters for their insight regarding the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment beginning in CY 2025; however, we did not make any proposals related to the potential inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment in CY 2025 in the CY 2024

ESRD PPS proposed rule. We will take commenters' insight, concerns, and recommendations into consideration for future rulemaking on this topic.

Additionally, we received some comments from commenters including ESRD patients and caregivers which contained details of quality-of-care concerns or adverse quality events for which the commenters had first-hand experience. We address these comments as they concern the proposals in the CY 2024 ESRD PPS proposed rule, but we wish to note that any serious adverse quality events can be reported to the CMS ombudsman. Information on beneficiary rights and how to report quality events can be found at https://www.cms.gov/center/special-topic/ombudsman/medicare-beneficiary-ombudsman-home.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2024 ESRD PPS.

1. CY 2024 ESRD PPS Update

a. CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

(1) 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 ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. 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.

(2) CY 2024 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 proposed CY 2024 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 the CY 2024 ESRD PPS proposed rule (88 FR 42435 through 42436), we proposed to calculate the market basket update

for CY 2024 based on the proposed market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(a) CY 2024 Market Basket Percentage Increase

Based on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket, the proposed CY 2024 market basket percentage increase was 2.0 percent. We also proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS proposed rule and before the publication of the 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 2024 market basket percentage increase in this final rule.

(b) Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the 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 will not affect the

data or methodology.[5] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to https://www.bls.gov/productivity/ for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we will be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment for CY 2024 (the 10-year moving average of TFP for the period ending CY 2024) was 0.3 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS 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 2024 productivity adjustment in this final rule.

(c) CY 2024 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2024 market basket percentage increase on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for CY 2024 based on IGI's first quarter 2023 forecast. Therefore, the proposed CY 2024 ESRDB market basket update was equal to 1.7 percent (2.0 percent market basket percentage increase reduced by a 0.3 percentage point productivity

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

adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the CY 2024 ESRD PPS proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase and productivity adjustment in the final rule.

We invited public comment on our proposals for the CY 2024 ESRDB market basket update and productivity adjustment. Approximately 150 commenters, including large dialysis organizations (LDOs); provider advocacy organizations; nonprofit dialysis associations; a coalition of dialysis organizations; a network of dialysis organizations; professional organizations and several ESRD facilities, commented on the proposed CY 2024 ESRDB market basket 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 and/or productivity adjustment) to determine the final CY 2024 ESRD PPS update. MedPAC recommended that the ESRD PPS base rate increase for CY 2024 should be updated by the amount determined under current law, and commented that analysis reported in the March 2023 Report to the Congress: Medicare Payment Policy[6] 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). Many commenters expressed concern that the CY 2024 payment update does not adequately factor in the effects of many challenges faced by ESRD facilities, such as the impact of the COVID-19 public health emergency (PHE), inflationary pressure, higher patient acuity, Federal budget sequestration, increasing labor costs due to labor shortages, and other increased costs, such as personal protective equipment (PPE), drugs, and

[6] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_v2_SEC.pdf

supplies. Several commenters also asserted that during the last two ESRD PPS rulemaking cycles the ESRDB market basket updates have not kept pace with the market basket increases for other Medicare providers, such as hospitals and Skilled Nursing Facilities (SNFs). Commenters additionally noted that the proposed CY 2024 ESRDB market basket increase was lower than certain other estimates of overall inflation and healthcare-specific inflation. One commenter stated that since the ESRD PPS' inception, the annual updates in several years have fallen far below other measures, such as general inflation or health care inflation as measured by the Consumer Price Index (CPI).

Response: We are required to update ESRD PPS payments annually by the market basket update adjusted for productivity, as directed by section 1881(b)(14)(F)(i) of the Act. Specifically, section 1881(b)(14)(F)(i)(I) of the Act states that the increase factor shall be based on an ESRD market basket percentage increase for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe the increase in the 2020-based ESRDB market basket adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide ESRD medical services and is technically appropriate to use as the ESRD payment update factor. The ESRDB market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the ESRDB market basket update would reflect the prospective price pressures described by the commenters (such as wage growth or higher energy prices) but would not inherently reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract workers and staffed employees. We note that cost changes (that is, the product of price and quantities) would only be reflected when a market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141), and therefore, any change in the cost structure

for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. We will continue to monitor the cost share weights and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly. Any proposal to rebase the ESRDB market basket would occur through notice-and-comment rulemaking. The final CY 2024 ESRDB market basket update reflects the most recent available data regarding prices of labor used to provide renal dialysis services. As set forth later in section II.B.1.a.(2)(c) of this final rule, the final productivity-adjusted CY 2024 ESRDB market basket update is 2.1 percent, representing a ESRDB market basket increase of 2.4 percent reduced by a productivity adjustment of 0.3 percent. We note that the final CY 2024 ESRDB market basket update is 0.4 percentage points higher than the proposed CY 2024 ESRDB market basket update. We recognize that this 2.1 percent productivity-adjusted ESRDB market basket update may still be lower than some commenters believe is appropriate; however, it reflects the most recent available data regarding expected price inflation for inputs required to provide renal dialysis services based on CMS's longstanding methodology.

We acknowledge commenters' claims that the CY 2024 ESRD PPS proposed market basket increase is less than increases for other Medicare payment systems, including the Inpatient Prospective Payment System (IPPS) and the Hospital Outpatient Prospective Payment System (OPPS). In response to these concerns, we note that one cause of these differences is that the mix of inputs used to provide renal dialysis services is different from those used for other services captured by other CMS market baskets. For example, the ESRDB market basket labor cost weights (reflecting those cost weights that use an Employment Cost Index (ECI) as price proxy) are generally lower than the labor cost weights in other CMS PPS market baskets, and the pharmaceuticals and medical supply cost weights in the ESRDB market basket (which is based on the ESRD Medicare cost report (Form CMS-265-11)) are higher than the pharmaceuticals and

medical supply cost weights in other CMS PPS market baskets.[7] The weighting together of these different mixes of inputs can appropriately result in differential rates of increase for various market baskets. Additionally, we acknowledge that many measures of inflation are higher than both the proposed 1.7 percent and the final 2.1 percent productivity-adjusted ESRDB market basket update for CY 2024. We note that some of the measures of inflation that commenters referenced in their comments are either measures of past inflation or measures of current inflation. The ESRDB market basket update is based on a forecast for the changes in input prices as measured by the ESRDB market basket for CY 2024, and not a measure of inflation during CY 2023. Under section 1881(b)(14)(F)(i) of the Act, the annual market basket update reflects the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe that this is a more accurate estimate of the changes in input prices faced by ESRD facilities than less specific measures such as overall inflation or inflation across the entire healthcare sector. Additionally, concerns raised by commenters that the ESRDB market basket updates have been lower than general inflation or healthcare inflation measures are not relevant comparisons, because the law requires that the increase be based on an index that measures input price pressures for providing renal dialysis services. We acknowledge that many patients, ESRD facilities, and other health care providers believe that rising prices are a major concern in providing high quality care; however, we project that growth in input prices for renal dialysis services will slow in CY 2024 relative to CY 2023, which is reflected in the productivity-adjusted ESRDB market basket update of 2.1 percent.

Comment: Several commenters indicated a belief that the ESRDB market basket update would have an impact on quality of care provided by ESRD facilities. Other commenters indicated that they believe the current quality of care that ESRD PPS beneficiaries receive is too

[7] Public data can be found at https://www.bls.gov/eci/home.htm and https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports.

low, and used this belief as justification for either supporting or opposing the ESRDB market basket update.

Response: We appreciate commenters' insight into the quality of care which Medicare beneficiaries receive at ESRD facilities. Medicare beneficiaries have a right to safe, appropriate, and quality health services. For ESRD facilities, the Federal health and safety requirements are codified at 42 CFR Part 494. To determine if a facility meets ESRD conditions for coverage, the State survey agency (SA), or a CMS-approved national accrediting organization (AO), performs an on-site survey of the facility. After the initial approval, dialysis facilities have routine onsite surveys to monitor compliance with the Federal requirements. If a dialysis facility is found to be deficient in one or more of the standards in the conditions for coverage, it may participate in, or be covered under, the Medicare program only if the dialysis facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS. In the case of an immediate jeopardy situation (that is, a situation in which the facility's non-compliance with one or more Medicare conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient), we may require a shorter time period for achieving compliance.

When poor quality or unsafe health care is furnished by any type of Medicare-certified provider or supplier, a complaint may be filed by anyone, including patients, family members, or staff. Dialysis facility complaints relating to improper care, unsafe conditions, and quality of care may be filed with the State Health Department or the ESRD Network.[8]

CMS has an established complaint process to protect all patients from abuse, neglect, exploitation, and inadequate care and supervision. The goal of the complaints process is to establish a system that will assist in promoting and protecting the health and safety of all patients receiving health services in a Medicare-certified facility. The procedures for handling

[8] https://www.cms.gov/training-education/open-door-forums/end-stage-renal-disease-clinical-laboratories-esrd/network

complaints are outlined in Chapter 5 of the State Operations Manual,[9] and they are followed when complaints and reported incidents, including referrals from the public or other Federal entities, involve Medicare-certified providers/suppliers. The evaluation, investigation, and resolution of complaints are critical certification activities. CMS and the SAs, or AOs, are responsible for ensuring that participating providers/suppliers of healthcare services continually meet Federal requirements. This requires that the SA, or AO, promptly reviews complaints/incidents, conducts unannounced onsite investigations of reports alleged noncompliance, and informs the CMS locations any time a facility is found to be out of compliance with the applicable certification requirements. We believe the resources provided by the ESRD PPS are appropriate to enable ESRD facilities to comply with the requirements and procedures described above.

Comment: One ESRD patient stated that ESRD facilities were already being paid too much and that the quality of care provided by ESRD facilities was insufficient given the payment amount.

Response: We appreciate the comments on Medicare payment amounts to ESRD facilities. As stated previously, we are required to update ESRD PPS bundled payments by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. As such, we believe that the final CY 2024 ESRDB market basket update is appropriate. We note that MedPAC states that payment rates are adequate for the ESRD facilities. In addition, regarding the commenter's belief that ESRD facilities are being paid too much, and the concerns the commenter noted citing specific quality of care issues for ESRD patients, we note that, as described earlier in this section, CMS is

[9] https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/som107c05pdf.pdf

actively engaged in efforts to ensure Medicare ESRD beneficiaries receive quality care. Additionally, the ESRD QIP actively monitors and adjusts payments to facilities under the ESRD PPS based on their performance on several quality measures.

Comment: Several commenters, including a coalition of dialysis organizations, stated that ESRD facilities face relatively small profit margins when caring for Medicare beneficiaries and indicated that they believe the ESRDB market basket increase amount would lead to lower standards of care in CY 2024 and that to prevent this, CMS should consider increasing payments by a larger amount. One ESRD patient characterized the proposed CY 2024 ESRDB market basket update as being insufficient for the extent of the financial impact of recent inflationary events. Numerous commenters stated that a larger payment rate increase would allow ESRD facilities to hire more staff and increase the quality of care. Some commenters suggested that CMS reevaluate the proposed market basket update and instead increase ESRD PPS payments by a larger amount.

Response: We understand that commenters are concerned about the profit margins for ESRD facilities. As stated previously, we believe that the final CY 2024 ESRDB market basket update reflects the most recent available data regarding the input prices required to provide renal dialysis services. We did not propose any additional increases to the ESRD PPS base rate to improve ESRD facility margins or otherwise account for factors that commenters believe are not adequately represented in the market basket update methodology, and we are not finalizing any such increases. We will continue to monitor the adequacy of the ESRD PPS payment amount and will consider these comments in potential future rulemaking. In addition, as described earlier in this section, CMS is actively engaged in efforts to ensure Medicare ESRD beneficiaries receive quality care.

Comment: Several commenters, including a provider advocacy organization, noted that the ESRD PPS payment rate update would have implications for Medicare Advantage payment

rates. Many of these commenters expressed that the proposed ESRDB market basket update of 1.7 percent would lead to lower payments from Medicare Advantage.

Response: We understand that some commenters are concerned about the impact that the proposed CY 2024 ESRDB market basket update would have on rates for other payors, including Medicare Advantage. However, we are required to update the ESRD PPS bundled payment by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. This update is not intended to account for or direct the business practices of other payors. We note that the final productivity-adjusted CY 2024 ESRDB market basket update is 2.1 percent, which represents an increase to the proposed productivity-adjusted CY 2024 ESRDB market basket update of 1.7 percent, and we anticipate that the increase alleviates some of the commenters' concerns. We did not propose to make any additional methodological changes to the market basket update or ESRD PPS base rate to account for other payors and are not finalizing any additional methodological changes on this topic.

Comment: We received numerous other comments on potential implications of the proposed CY 2024 ESRDB market basket update. Several commenters claimed the proposed CY 2024 ESRD PPS base rate update would have a negative impact on other factors including, but not limited to, wait times for dialysis appointments, access to innovative treatments for ESRD patients, ESRD treatments for nursing home patients, ESRD treatments for the elderly, Medicare Part A payments, and hospitalizations for ESRD PPS patients.

Response: We recognize that commenters are concerned about the impact that the magnitude of the CY 2024 ESRDB market basket update has on ESRD facilities' ability to provide quality renal dialysis services. As stated previously, the final CY 2024 ESRDB market basket update reflects the most recent available data regarding prices for inputs used to provide

renal dialysis services. We recognize that payment policy within the ESRD PPS can affect the quality and accessibility of renal dialysis services; however, the CY 2024 ESRDB market basket update adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, so we do not agree with commenters' claims that the ESRDB market basket update would have a negative impact on these other factors. We did not propose any changes to the existing ESRDB market basket update methodology in the CY 2024 ESRD PPS proposed rule and are not finalizing any such methodological changes in this rule. We appreciate the insight of commenters into the implications of the ESRDB market basket update and will keep these implications in mind in future rulemaking.

Comment: Several commenters questioned CMS's longstanding market basket methodology. Commenters expressed concern over the accuracy of the forecast underlying the proposed market basket update for CY 2024, including that CMS's use of the IGI forecast for determining the market basket update does not capture the specialized nature of ESRD facility costs. A few commenters requested that CMS reexamine the forecasting approach or consider other methods and data sources to calculate the final rule market basket update that better reflect the rapidly increasing input prices and costs facing ESRD facilities. Other commenters indicated that they believed that it is inappropriate to continue to use the same mix of goods and services that were used at the inception of the ESRD PPS in the CY 2011 ESRD PPS final rule. One ESRD facility suggested that, because there has been significant variation between the forecasted and actual ESRDB market basket price growth, CMS should evaluate whether the market basket methodology is inherently flawed. Several commenters believed that a retrospective adjustment to the base rate to account for past differences between the ESRDB market basket update for a given year and what the ESRDB market basket update would have been for that year based on the actual changes in prices, known as a forecast error adjustment, could alleviate some of the perceived flaws in the market basket update methodology.

Response: We thank commenters for providing these comments on the ESRDB market basket update methodology. In response to the commenters' request that we reexamine the current forecasting approach for determining the ESRDB market basket update, we provide the following information. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies used in the market baskets. At the time of the CY 2024 ESRD PPS proposed rule, based on the IGI first quarter 2023 forecast with historical data through the fourth quarter of 2022, the 2020-based ESRDB market basket update was forecasted to be 2.0 percent for CY 2024, reflecting forecasted compensation price growth of 3.7 percent (by comparison, compensation price growth in the ESRDB market basket averaged 2.6 percent from 2013 to 2022). In the CY 2024 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 2024 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 2024. Based on IGI's third quarter 2023 forecast with historical data through the second quarter of 2023, we are projecting a CY 2024 ESRDB market basket update of 2.4 percent (reflecting forecasted compensation price growth of 4.1 percent) and a productivity adjustment of 0.3 percentage point. Therefore, for CY 2024 a final ESRDB productivity-adjusted market basket update of 2.1 percent (2.4 percent less 0.3 percentage point) will be applicable, compared to the 1.7 percent productivity-adjusted market basket update that was proposed. We note that section 1881(b)(14)(F)(i) of the Act states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe that the current market basket update methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162), and most recently updated in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157) to reflect a 2020 base year,

fulfills this statutory requirement. We support the continued use of the current mix of goods and services to provide continuity to the financial impacts of the ESRD PPS payment policy, and we note that the weighting for this mix of goods and services is updated periodically through rebasing. However, we will consider the commenter's suggestion regarding the use of different methods or other data sources for the ESRDB market basket for future rulemaking. We discuss the commenters' request for a forecast error adjustment below. We did not propose any methodological changes to the ESRDB market basket update methodology for CY 2024, and we are finalizing the continued use of the ESRDB market basket methodology as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157). We do not believe that the ESRDB market basket update is inherently flawed because the forecast errors for CYs 2021 and 2022 were higher-than-normal due to the high inflation during the COVID-19 PHE, which we discuss further in section II.B.1.a.(2)(d) of this final rule. We will continue to monitor the performance of the ESRDB market basket update, and we will keep these comments on the market basket methodology in mind for future rulemaking. We note that CMS engages with the public, including the dialysis industry and associations, routinely throughout the year in our continuing efforts to align payment with resource utilization. We welcome continuing dialogue on the topic of improving the market basket update methodology, and other topics pertinent to the ESRD PPS, toward the common goal of improving care for ESRD patients.

Comment: Some commenters provided information on additional rising costs faced by ESRD facilities that the commenters believed were not adequately captured in the proposed CY 2024 ESRDB market basket update. These additional costs included the following: costs associated with compliance with additional regulations regarding infection control; costs related to supply chain problems; rising costs for certain supplies; and cost related to changes in labor, such as additional pay for traveling nurses or contract nurses.

Response: We appreciate the insight into changing costs that ESRD facilities face. As stated previously, the final CY 2024 ESRDB market basket update reflects the most recent

available data regarding prices for inputs used to provide renal dialysis services. These costs which commenters listed are included in the ESRDB and so the change in their prices would be included in the CY 2024 ESRDB market basket update. If the rising costs the commenters' mentioned are due to an increase in quantity of the good purchased, rather than an increase in price, we note that such cost changes would only be reflected when a market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141); therefore, any change in the cost structure for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. We believe that it is technically appropriate to use the 2020-based ESRDB market basket for the CY 2024 ESRDB market basket update.

Comment: One commenter asserted that experience over the past few years has indicated that the ESRD PPS methodology is unable to reflect short-term and long-term impacts of an economic shock, such as the COVID-19 PHE. The commenter noted that although CMS offers detailed explanations of the market basket's construction and issues data through its website, the dialysis provider community still has little insight into the factors contributing to annual payment updates that the commenter believes consistently fail to reflect increases in the cost of care delivery. The commenter urged CMS to engage in a formal dialogue with the kidney care community outside of the annual rulemaking process to better identify the methodology's limitations and inform development of improvements. The commenter also requested that IGI have representation and participation in this dialogue.

Response: We appreciate the commenter's concerns regarding the market basket methodology. Our longstanding ESRDB market basket update methodology sets rates prospectively on an annual basis. We acknowledge that over the course of a year, short term changes in economic conditions can lead to uncertainty, which may be exacerbated by economic

shocks. Because the ESRD PPS base rate is updated annually, the purpose of the ESRDB market basket update is to account for the change in price of the ESRDB from year to year, not necessarily to capture the effect of shorter term fluctuations of prices. That short term fluctuations are not addressed by the ESRDB market basket update is a consequence of the annual nature of the update as required by section 1881(b)(14)(F) of the Act. We believe the ESRDB market basket update appropriately captures the change in the price of goods and services over time in the long term. Some commenters have suggested a forecast error adjustment as a way to mitigate the impact of these short-term uncertainties, which we discuss in further detail in section II.B.1.a.(2)(d) of this final rule. CMS will continue to engage with the public regarding ways to ensure the Medicare ESRD PPS payments are appropriate and that the market basket price proxies and base year weights are accurate.

Comment: We received several comments, including from a patient organization, stating that the proposed ESRDB market basket update would not sufficiently support innovation.

Response: We note that ESRD PPS policies to encourage the adaptation of new innovations, such as the TDAPA and TPNIES, are add-on payment adjustments to the base rate, and although there is only one ESRD PPS bundled payment, these adjustments are not a part of the ESRDB and therefore, are not included in the ESRD PPS base rate or the ESRDB market basket update. This is similarly true for the post-TDAPA add-on payment adjustment that we are finalizing in this rule, which is described in further detail in section II.B.1.i of this final rule. These add-on payment adjustments are actively supporting the adoption of certain new and innovative drugs, biological products, equipment and supplies by ESRD facilities, by providing additional payment to offset the additional cost of those drugs, biological products, equipment and supplies. We did not propose any changes to the ESRDB market basket update methodology to account for innovation within the ESRD PPS and are not finalizing any such changes in this final rule. We will consider these comments on supporting innovation and access to innovative products in potential future rulemaking.

Comment: We received approximately 90 comments related to the nature of labor costs at ESRD facilities, including comments from large dialysis organizations, advocacy organizations, ESRD facilities, providers, and a coalition of dialysis organizations. Commenters generally stated that labor costs at ESRD facilities are increasing, which is driving overall cost increases at ESRD facilities, and that the proposed ESRDB market basket update was insufficient to cover these increased labor costs. Many of the commenters cited that the growth in their labor costs has outpaced the ESRDB market basket updates or the growth of the market basket compensation cost category in the ESRDB market basket. Additionally, some commenters noted that labor costs were rising across the healthcare sector, which the commenters asserted was not appropriately reflected in the ESRDB market basket update. Commenters described other barriers to hiring and maintaining staff including, but not limited to, burnout, lack of resources, inability to match competitive pay, and long travel times for staff. A coalition of dialysis organizations commented that it was increasingly difficult for ESRD facilities to hire new staff while competing with other health care providers with more resources and non-healthcare employers. They stated that this was leading to some ESRD facilities having to turn away patients or being unable to continue operations. One LDO noted that staffing concerns are leading to ESRD facilities using a higher percentage of more-expensive contract labor and that contract labor wages and benefits make up 1.9 percent and 0.5 percent of the 2020-based ESRDB, respectively. Some commenters highlighted the COVID-19 PHE as a significant factor in the workforce shortage that ESRD facilities face; however, some commenters indicated that they believe this workforce shortage has been in progress for a long time.

Some ESRD facilities and LDOs included various additional information or data on the extent to which their labor costs have increased over the past few years. Several commenters, including an LDO and a non-profit dialysis organization, referenced an analysis that showed labor costs grew at a compound average growth rate of 6.96 percent from 2018 to 2022, whereas

the proxy for labor used in the ESRDB market basket update methodology grew at a compound average growth rate of 3.15 percent from 2018 to Q1 2022. One provider advocacy organization commented that its analysis found that direct patient care labor costs per dialysis treatment increased by 18.9 percent from 2017 to 2022.

Commenters also stated that the increasing labor costs were resulting in staffing concerns at ESRD facilities. Some of these comments highlighted access issues arising from fewer available dialysis sessions. Some comments referenced quality issues related to the burden placed on workers at ESRD facilities by low staffing and the limited training of staff at ESRD facilities due to high turnover. Many of these comments came from ESRD patients, caretakers and patient advocates and included the commenters' personal experience on the issues related to receiving care at ESRD facilities (for example, difficulty finding appointments, having to travel significant distances to get care, and how low staffing at ESRD facilities has impacted their care). Other commenters conveyed their concern about inadequate staffing and related many incidents of significant adverse events and sub-standard quality care, which they attributed to low staffing. A kidney disease patient organization included multiple testimonials from ESRD patients regarding their issues in trying to locate dialysis treatments.

Some commenters highlighted the impact that staffing shortages had on home dialysis. Several patients expressed a willingness and desire for self-dialysis training, but stated they were unable to receive self-dialysis dialysis training due to staff shortages at their clinics.

Response: We thank commenters for their insight into labor supply and labor costs at ESRD facilities, and we recognize that labor costs are a driving factor in cost increases at ESRD facilities. We acknowledge that CY 2022 price growth for the 2016-based ESRDB market basket was higher (5.1 percent) than was forecasted at the time of the CY 2022 ESRD PPS final rule (2.4 percent). We note that the lower projected CY 2024 ESRDB market basket percent increase (2.4 percent) relative to the observed CY 2022 historical increase, as well as the forecasted CY 2023 ESRDB market basket increase of 3.1 percent, reflect the expectation that

wage and price pressures will lessen in CY 2024 compared to recent years. As described previously, the ESRDB market basket measures price changes (including changes in the prices for wages and salaries and benefits) over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the market basket is rebased. An ESRD-specific compensation price index is unavailable; therefore, we use a composite wage and benefit index of various Employment Cost Indices (ECIs) reflecting the occupational mix of full-time equivalents (FTE) data from ESRD Medicare Cost reports and ECIs from BLS (87 FR 67147). Health-related occupations account for 79 percent of the 2020-based ESRDB compensation cost weight and are proxied by the ECI for All Civilian Workers in Hospitals, reflecting similar medical occupations used in ESRD facilities (particularly nurses) and their associated price growth. As discussed in the CY 2023 ESRD PPS final rule, we believe the composite weighted index for wages and salaries and benefits to be a reasonable proxy for the compensation component of the ESRDB market basket. We note that section 1881(b)(14)(F)(i) of the Act states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. While labor is included in the mix of goods and services in the ESRD PPS bundled payment, the annual market basket increase accounts for more than the price change for labor. As such, it is possible for the market basket increase to be less than the increase in the price of labor if the other goods and services included in the ESRDB do not experience as large of a price increase. Our analysis of the data used to determine the ESRDB market basket forecast indicates that this dynamic is reflected in the market basket increases for the past few years. For example, in 2021 the overall market basket forecast was an increase of 1.9 percent, but the labor portion of the ESRDB market basket was forecasted to increase by 2.5 percent. We recognize commenters' view that the proposed ESRDB market basket increase for CY 2024 was less than ESRD facilities' reported labor increases. However, if, as commenters have stated, labor is the driving factor for

the increase in costs for ESRD facilities, it would be expected that the labor percentage increase would be greater than the overall ESRDB market basket percentage increase. This is because the ESRDB market basket increase is a weighted average of the changes in prices for the ESRDB market basket. Labor is only one part of the ESRDB market basket, and commenters have indicated that other components of the ESRDB market basket have not experienced the same growth in price as labor. We believe the 2020-based ESRDB market basket increase adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, including labor, and is technically appropriate to use as the ESRD PPS payment update factor. The ESRDB market basket update will reflect the expected prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices) but inherently will not reflect other factors that might increase the level of costs, such as the quantity of labor used. Therefore, the final CY 2024 ESRDB market basket update reflects the most recent available data regarding both prices and the items and services used to provide renal dialysis services.

We thank commenters for including detailed information and data on the changes to labor costs that ESRD facilities face. We agree that during the COVID-19 PHE, labor costs increased more than normal. According to our analysis, the ESRDB market basket compensation price growth was forecasted to increase a cumulative 18.9 percent from CY 2017 to CY 2022. This is the same as the figure which one commenter described as being the change in direct labor costs over that time. We recognize that some comments indicated that ESRD facilities experienced larger or smaller changes in labor costs than this over that time. We note that the ESRDB market basket does not measure each individual ESRD facility's own experience, but instead the ESRDB market basket cost weights reflect the experience of the average ESRD facility. Therefore, if one area of the country experienced an increase in labor costs at a higher rate than other areas of the country, that would not be wholly captured in the annual update. Instead, the relative difference in labor cost growth should be captured in changes to the wage index for that

ESRD facility. However, we recognize that our wage index methodology uses historical data instead of a forecast and as such takes longer to update in response to periods of large change.

We appreciate comments from ESRD patients which highlighted their experiences at ESRD facilities. We are concerned by the comments which indicate access and quality concerns at ESRD facilities related to staffing issues. We note that § 494.180(b) requires that an ESRD facility have an adequate number of qualified and trained staff; however, the governing body of the facility has a measure of discretion when determining staffing. The ESRD PPS provides a bundled payment that encompasses all renal dialysis services, including labor. We recognize that staffing shortages can pose a difficulty to ESRD patients who desire training for self-dialysis. We note that the ESRD PPS includes an add-on payment adjustment for self-dialysis training (42 CFR 413.235(c); 81 FR 77851 to 77856). We appreciate the comments regarding these staffing issues and will consider them for potential future rulemaking.

Comment: One commenter encouraged CMS to explore other changes to the composition of the market basket to better capture evolving dynamics in the labor force. The commenter provided as an example that the ECI may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs.

Several commenters expressed concern that not all the ESRDB market basket price proxies, particularly the labor-related price proxies, accurately reflect ESRD facilities' faster than expected cost growth. One commenter noted that for healthcare providers across all sectors, the impact of the tight labor market (both in the healthcare sector and general economy overall) has forced ESRD facilities to rely more heavily on contracted labor. The commenter further pointed out that under the 2020-based ESRDB market basket, contract labor wages and benefits have 1.9 percent and 0.5 percent weights, respectively; however, the commenter expressed concern that these weights were derived by assuming that ESRD facilities use the same labor amount and mix as they did more than a decade ago, which does not reflect the current

environment in which dialysis providers deliver care. They stated that use of the U.S. Census Bureau's Services Annual Survey (SAS) data may not reflect staffing ratio or minimum wage requirements adopted by State and municipal governments since 2012, the recent years' shift in labor mix, unanticipated increase in compensation expenses, or the COVID-19 PHE's overall impact on the healthcare labor force.

A few commenters stated that certain market basket components rely, to some extent, on severely lagged data, which during times of unusual circumstances, could limit a forecast model's ability to capture economic shocks and the subsequent impact on health care providers' costs. The commenters stated, for example, the BLS's ECI price proxies generally hold the employment mix constant for several years. They stated that the ECI's weights reflected the 2012 occupational mix until recently (the December 2022 BLS release updated the data to reflect 2021 employment weights). The commenters noted that since ECI employment weights are held constant for a period this would introduce inaccuracies into the market basket updates. They stated that since the ECI 2012 weights were used for the price proxies in the ESRDB market basket through the CY 2022 rulemaking cycles it could have resulted in errors in the ESRDB market basket update.

Response: We appreciate the commenters' concerns about the composition of the ESRDB market basket and whether the price proxies used in the market basket are accurately capturing the price pressures experienced by ESRD facilities.

The commenters are correct that the ECI data are based on fixed occupational weights; however, we believe these indexes continue to be technically appropriate measures of pure compensation inflation to be used in the ESRDB market basket. Because the market baskets are intended to measure price changes over time, and not changes in costs that also reflect quantity and intensity changes, the fixed occupational distribution of the ECI is appropriate. BLS periodically updates these distributions (in the January 2023 release of December 2022 ECI data they introduced updated 2021 fixed employment weights, replacing the 2012 weights used

through September 2022). Additionally, the observed ECI for Wages and Salaries for All Civilian workers in Hospitals (which accounts for 29 percent of the 2020-based ESRDB market basket) data has reflected recent wage "price" pressures as growth in 2021 and 2022 accelerated relative to 2020. The projection of the ECI also considers anticipated wage pressures due to various economic and industry-specific factors; the hospital ECI is projected to grow faster in 2023 compared to the historical average growth in the series, particularly prior to 2021. We note that when developing its forecast for the ECI for All Civilian Workers in Hospitals, IGI considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital. We also acknowledge the commenters' concerns that the ECI only reflects employed labor costs; however, we note that the alternative publicly available average hourly earnings series also does not include contract labor costs. Additionally, we analyzed the FTE data reported on the Medicare cost reports and found that the share of contract labor FTEs is about 2 percent of all FTEs and has remained relatively constant in 2021 and 2022. We will continue to monitor the cost report data as it is received to ensure that the ECI series used to proxy ESRD labor categories continues to offer the most appropriate price proxies for measuring compensation price growth in ESRD facilities.

Lastly, we acknowledge commenters' concern that the contract labor cost weight in the ESRDB market basket relies on 2012 SAS data published by the United States Census Bureau inflated to 2020-dollar values as the basis for the contract labor cost weight. We proposed and finalized the methodology for deriving the compensation cost share weights in the CY 2023 ESRD PPS rulemaking cycle (87 FR 67141 through 67157). Because the Medicare cost report data does not capture the specific costs for contract labor, we therefore must rely on other data sources to estimate the share of contract labor costs that are reported within Administrative and General costs on the cost reports. We have not identified any other data source that provides specific contract labor costs for ESRD facilities.

Final Rule Action: After consideration of the comments received, we are finalizing a CY 2024 ESRDB productivity-adjusted market basket increase of 2.1 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2024 ESRD PPS final rule (that is, IGI's third quarter 2023 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2023), the CY 2024 ESRDB market basket update is 2.4 percent. Based on the more recent data available from IGI's third quarter 2023 forecast, the current estimate of the productivity adjustment for CY 2024 is 0.3 percentage point. Therefore, the current estimate of the CY 2024 ESRD productivity-adjusted market basket increase factor is equal to 2.1 percent (that is, the 2.4 percent market basket update reduced by the 0.3 percentage point productivity adjustment).

(d) Requests for a Forecast Error Payment Adjustment

In the CY 2024 ESRD PPS proposed rule (88 FR 42435), we discussed that in the CY 2023 ESRD PPS final rule (87 FR 67157), many commenters requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during the inflationary period occurring at that time, particularly accounting for what commenters stated was an error in the forecasted payment updates for CYs 2021 and 2022. In response to those comments, we reminded readers that ESRDB market basket updates are set prospectively, meaning 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. We explained that while there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.[10] We also explained that due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was -0.8 percentage point, while the CY 2021 ESRDB forecast

[10] FAQ—Market Basket Definitions and General Information. Available at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf.

error was +1.2 percentage points. At the time of the CY 2023 ESRD PPS final rule, CY 2022 historical data was not yet available to calculate a forecast error for CY 2022; however, based on the latest available historical data for CY 2022, we now calculate that the CY 2022 ESRDB forecast error was +2.7 percentage points.

We further noted that, in the CY 2023 ESRD PPS final rule (87 FR 67156), we recognized that recent higher inflationary trends impacted the outlook for price growth over the next several quarters. For that CY 2023 ESRD PPS final rule, we used an updated forecast of the price proxies underlying the market basket that incorporated more recent historical data and reflected a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We explained that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations, and that forecast errors are unpredictable (87 FR 67517). Prior to the COVID-19 PHE period, the positive differences between the actual and forecasted market basket increase in prior years have offset negative differences over time. Therefore, we stated in the CY 2024 ESRD PPS proposed rule that, in accordance with our longstanding ESRDB market basket update methodology, we would not propose to apply a forecast error adjustment to the ESRDB market basket update for CY 2024.

Comment: We received approximately 30 comments related to CMS's decision not to propose a forecast error adjustment for CY 2024. These commenters, including a coalition of dialysis providers, several LDOs, and numerous provider and patient advocacy organizations, requested that CMS reevaluate and implement a payment adjustment to account for past forecast errors. Many commenters requested that CMS apply a forecast error adjustment to the ESRD PPS payment update for CY 2024. Some specific suggestions for payment adjustments included: a CY 2024 adjustment of 10 to 20 percent per discharge; an adjustment for the "underpayment" of ESRD facilities since 2020; and/or the adoption a forecast error adjustment like the one used in the SNF PPS. Several commenters stated that absent a forecast error adjustment they may be

forced to close some of their ESRD facilities, particularly those facilities located in areas with vulnerable populations.

The commenters stated that the forecast error was driven mainly by unforeseen increased costs for labor (including a higher reliance on contract labor staff), equipment, and medical supplies (including PPE and pharmaceuticals), which resulted in increased costs to provide care to ESRD beneficiaries that were never properly reimbursed under the Medicare ESRD PPS payments. Commenters stated that while the growth in these costs has begun to stabilize somewhat in 2023, they continue to be substantially higher than pre-pandemic levels. Commenters also pointed out that while high wage inflation and labor shortages affect all health care providers, dialysis providers are particularly vulnerable because there is not variation in types of services performed or billed and due to the less variable payer mix that relies more on Medicare and Medicaid payment than other health care provider types.

One commenter noted that while other health care providers have experienced similar forecast errors in CY 2022 and CY 2023, the current cumulative underpayment error for the ESRD PPS exceeds the errors in other payment systems such as IPPS, home health, and long-term care hospitals.

Some commenters acknowledged that since the market basket updates are set prospectively, they are inherently imperfect, and forecast errors from year to year may occur in either a positive or negative direction. However, several commenters noted that in the case of the ESRDB market basket these differences have not offset one another over time. The commenters stated a belief that the magnitude of the errors in 2021 and 2022, which they state resulted from a flawed methodology that failed to accurately forecast higher than normal inflation, are highly unlikely to even out over time unless there is a similar, fast moving deflationary event resulting in the same magnitude in the forecast.

Many commenters requested CMS establish a payment adjustment modeled after the forecast error adjustment for payments to SNFs that was established in 2004 (68 FR 46057).

These commenters responded to CMS's view that historical negative forecast errors are offset by positive errors by noting that over the past few years the forecast errors have been predominantly positive, at 1.2 percent and 2.7 percent in CYs 2021 and 2022 respectively. As such, the ESRD PPS base rate is lower than it would have been if the forecasts had been accurate. Many of these commenters supported a forecast error adjustment methodology that would, like the SNF adjustment of 2004, only be applied if the error is larger than a certain threshold. Multiple commenters supported a threshold of 0.5 percentage point for this adjustment. Many commenters compared the state of SNF payment in 2004 and of the ESRD PPS today, emphasizing the similarities in the amount by which the recent market basket updates had been incorrect, the source of the error mainly attributable to unexpectedly large increases in the costs of labor, and certain similar statutory language describing the SNF PPS and the ESRD PPS. A coalition of dialysis organizations suggested that for the CY 2024 ESRD PPS final rule CMS should adjust the ESRD PPS base rate by the cumulative forecast error since 2019 but added that they would also approve of adjusting the ESRD PPS base rate by the cumulative forecast error since the inception of the ESRD PPS in 2011. Some commenters, including an LDO, suggested in lieu of a permanent forecast error adjustment policy for ESRDs, CMS could apply a one-time positive adjustment to the ESRD PPS base rate to account for the forecast error in recent years, with commenters suggesting it be applied to the ESRD PPS base rate in a non-budget neutral manner. Some commenters, including an LDO, recognized that CMS's view that the market basket errors could balance out over time could be true for small variations; however, the commenters stated that it would not hold true for periods of significant missed forecasts due to periods of rapid change, for example during the COVID-19 PHE. Generally, commenters stated that they agreed with CMS on the importance of predictability for payments but stated that payment accuracy was more important, so a forecast error payment adjustment would be useful as it would improve payment accuracy.

Some comments included additional information on what commenters stated could happen with or without a forecast error adjustment. One LDO commented that their analysis indicated that the under-forecast would lead to a total of $1.8 billion in underpayments between CY 2021 to 2027. One patient-led dialysis organization recommended an "Essential Worker Safety Catch" to revise past updates to ensure labor is adequately compensated. A provider advocacy organization questioned CMS's use of 2020-cost reports in determining payment for CY 2024, saying it was outdated and inaccurate. One ESRD facility commented that given the size of recent errors, they believed it was likely that errors would continue to increase and potentially become larger in the future.

Response: While the projected ESRDB market basket updates for CY 2021 and CY 2022 were under-forecast (that is, actual increases were greater than forecasted), as is the preliminary CY 2023 forecast error, this was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE. 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. We recognize that the COVID-19 PHE and high inflationary environment have had an adverse impact on costs for ESRD facilities. Due to ESRD payments being set prospectively, we rely on a projection of the ESRDB market basket that reflects both historical and forecasted trends. Due to the uncertainty regarding future price trends, the difference between the projected and actual market basket increases can be both positive and negative. We note that from CY 2012 to CY 2020, the only year in which the forecast error of the ESRDB market basket update exceeded the 0.5 percentage point threshold in absolute terms (which is applicable for the SNF PPS forecast error adjustment) was CY 2017. The forecasted CY 2017 ESRDB market basket update was 0.8 percentage point higher than the actual CY 2017 percentage increase of the 2012-based ESRDB market basket based on historical data. We also acknowledge that the ESRDB market basket forecast errors for CY 2021 (1.2 percentage points) and CY 2022 (2.7 percentage points) exceeded the 0.5 percentage point threshold where the

forecasted ESRDB market basket updates were lower than the actual percentage increases based on historical data. 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 rapidly accelerating inflationary environment. Rapid increase in costs during the COVID-19 PHE has led to a positive forecast error for every Medicare PPS.

The data on which the final CY 2024 ESRDB market basket update is based is the most recent available data. We note that the 2020 cost report data was used for rebasing the market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), and at the time of CY 2023 rulemaking the 2020 cost report data was the most recent year of complete cost report data available to develop the ESRDB market basket cost weights. The ESRDB market basket cost weights do not change from year to year since it is a fixed-weight Laspeyres index; therefore, for CY 2024, we use the most recent available forecast of the price proxies to estimate the growth in the input prices of this mix of goods and services for providing renal dialysis services for the coming year. The most recent forecast of the price proxies in the ESRDB market basket for this final rule is the IGI third quarter 2023 forecast with historical data through the second quarter of 2023. This is the established methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162). Therefore, while the weighting of the various goods and services that make up the ESRDB market basket did utilize 2020 data for rebasing, it is inaccurate to characterize the CY 2024 market basket increase as being based on 2020 data generally. We do not agree with the commenter that stated a belief that because forecast errors have been greater in recent years it is likely that forecast errors will be larger in the future. As we have indicated, the larger-than-normal forecast errors in CY 2021 and CY 2022 were largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE, which we do not anticipate will continue in CY 2024. Our preliminary estimates of the CY 2023 ESRD PPS forecast error indicate that it was smaller than the forecast errors in CY 2022 and CY 2021.

For these reasons, after evaluating the historical performance of the ESRDB market basket and the financial environment unique to ESRD facilities, we do not believe it is appropriate to include adjustments to the ESRDB market basket update for future years based on the difference between the actual and forecasted ESRDB market basket increase in prior years. However, we will continue to monitor the overall performance of the ESRDB market basket update, including analyzing the change in the price of labor inputs for ESRD facilities over time. We will take commenters' concerns into consideration for potential future rulemaking.

Comment: One LDO commented that they believe that CMS has a statutory obligation to implement a forecast error adjustment under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. The commenter acknowledged that forecasting prices is inherent in a PPS but indicated that they believe that the current methodology fails to annually capture the changes over time in the price of providing renal dialysis services. The commenter stated that correcting for prior and future forecast errors is a step CMS can easily implement to ensure the ESRD PPS payment, and future market basket update factors, reflect the prices of delivering renal dialysis services. The commenter noted that in 2004 when CMS implemented a forecast error adjustment in the payment system for SNFs it was based on very similar statutory language and was implemented under what the commenter stated were "virtually identical" circumstances to the ESRD PPS today.

Response: We thank the commenter for sharing their view on this issue; however, we do not agree that CMS's position regarding an ESRD PPS forecast error payment adjustment conflicts with any statutory requirements for the ESRD PPS. We appreciate the commenter's interpretation of the circumstances involved in the implementation of the forecast error adjustment for SNF payment; however, we disagree with the claim that the circumstance was

virtually identical to the ESRD PPS today. While the cumulative under-forecast of the SNF market basket increases in 2004 was based on a rapid increase in the price of labor, it was not due to a PHE as occurred with the ESRD PPS's under-forecast in recent years. Additionally, it was an issue which only SNFs were experiencing, unlike the current ESRD PPS environment where multiple Medicare payment systems have faced similar forecast errors. 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 do not agree 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.

Final Rule Action: After consideration of the comments we received, we are finalizing a CY 2024 ESRDB productivity-adjusted market basket increase of 2.1 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2024 ESRD PPS final rule (that is, IGI's third quarter 2023 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2023), the CY 2024 ESRDB market basket update is 2.4 percent. Based on the more recent data available from IGI's third quarter 2023 forecast, the current estimate of the productivity adjustment for CY 2024 is 0.3 percentage point. Therefore, the current estimate of the CY 2024 ESRD productivity-adjusted market basket increase factor is equal to 2.1 percent (2.4 percent market basket update reduced by 0.3 percentage point productivity adjustment). We are finalizing our proposal to determine the CY 2024 ESRDB market basket update for the final rule without an adjustment to account for past forecast errors. Additionally, we did not propose and are not finalizing any methodology for a forecast error payment adjustment. We will continue to monitor the performance of the ESRDB market basket forecasts and will consider the information provided by commenters for potential future rulemaking.

(e) 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 2024 ESRD PPS payment update, we proposed 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).

Comment: We received three comments which acknowledged our proposal to use the labor-related share of 55.2 percent as finalized in the CY 2023 ESRD PPS final rule. Additionally, one LDO commented on the weights attributed to contract labor and benefits in the 2020-based ESRDB market basket, indicating that they thought that these areas were under-represented in the 2020-based ESRDB market basket. This LDO recognized that CMS did not propose any changes to the labor-related share from CY 2023. One provider advocacy organization suggested CMS utilize a different labor-related share for ESRD facilities with low wage index values, noting that for facilities with low wage index values, labor likely relates to a smaller share of total costs.

Response: We thank commenters for reviewing the proposed labor-related share. We appreciate the comment on the weights of contract labor in the 2020-based ESRDB market basket. As stated in section II.B.1.a.(2)(c) of this final rule, changes in both the cost and quantity of an input are reflected when the ESRDB market basket is rebased, and the base year weights are updated to a more recent time period. We finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141), and, therefore, any change in the cost structure for ESRD facilities that occurred between 2016 and 2020 is now reflected in the cost weights for the 2020-based ESRDB market basket, which was the most recent fully complete cost data available at the time of rulemaking. Our monitoring indicates that the 2020-based ESRDB market basket is still appropriate for determining the cost weights for inputs for

providing renal dialysis services. Therefore, following the methodology finalized in the CY 2011 ESRD PPS final rule (75 FR 49116), we consider the labor related components of the ESRDB market basket to be an appropriate basis for the labor-related share for the CY 2024 ESRD PPS payments. We will continue to monitor the cost share weights and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly. We appreciate the suggestion to use a different labor-related share for low wage index ESRD facilities. We did not propose any methodological changes to the application of the labor-related share, such as using a different labor-related share for different ESRD facilities, but we will consider this comment in potential future rulemaking.

Comment: One commenter expressed appreciation that the labor-related share of the ESRD PPS increased from 52.3 percent to 55.2 percent in CY 2023 and stated that they believe this is a consistent trend with the ESRD PPS, for which CMS has increased the labor-related share of the market basket over the lifetime of the PPS. The commenter opined that increasing the labor-related share of the market basket, while positive, does not fully address the steep rising costs of labor needed to deliver care to Medicare beneficiaries with ESRD, since it only alters the percentage of ESRD PPS payments allocated to labor as compared with other inputs required for renal dialysis services but does not deliver more resources through the ESRD PPS to cover the rising costs of care associated with the increases in the cost of labor.

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 hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. We note that the historical increase to the labor-related share is based on the increase to the labor-related cost-weights in the ESRDB market basket.

As acknowledged by the commenter, the purpose of the labor-related share is to allocate ESRD payment between labor-related costs and non-labor costs. The labor-related share is not meant to increase payments overall for the rising cost of labor.

Final Rule Action: We are finalizing our proposal to use the labor-related share of 55.2 percent, as finalized in the CY 2023 ESRD PPS final rule, for CY 2024 ESRD PPS payments.

b. CY 2024 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the 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. 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 in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural

areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

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 in Puerto Rico and the U.S. 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 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 2024, as discussed in section II.B.1.a.(2)(e) of this final rule, the labor-related share to which the wage index will be applied is 55.2 percent.

(2) CY 2024 ESRD PPS Wage Index

For CY 2024, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We proposed to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2024, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020 (FY 2020 cost report data).

For CY 2024, we proposed to update the ESRD PPS wage index to use the most recent hospital wage data. We proposed that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the wage index), we would use such data, if appropriate, to determine the CY 2024 ESRD PPS wage index in the final rule.

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

Comment: We received several comments on CMS's proposal to use the most recent wage index data in the CY 2024 ESRD PPS final rule. Commenters were generally supportive of the use of more recent data. Additionally, several commenters reiterated support for the 5 percent cap on wage index decreases that we finalized in the CY 2023 ESRD PPS final rule (87 FR 67161).

Response: We thank the commenters for their support on the use of more recent data and for the policy to cap wage index decreases.

Comment: One ESRD facility expressed concerns that the ESRD PPS wage index does not reflect the realities that it faces and, specifically, does not accurately reflect the increase in its cost of labor over the past few years.

Response: We appreciate the concerns that the commenter raised; however, we did not propose to change the wage index methodology for CY 2024 and are not finalizing any changes to that methodology in this final rule. The wage data used to construct the ESRD PPS wage index are updated annually, based on the most current data available, and are based on OMB's CBSA delineations when applying the rural definitions and corresponding wage index values. As discussed in CY 2011 ESRD PPS final rule (75 FR 49200), the wage index reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Because the wage index is scaled relative to the national average, it does not reflect changes over time to the cost of labor. Rather, the market basket increase accounts for national trends, including inflation. As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42435), we proposed to increase the ESRD PPS base rate for CY 2024 by the market basket increase factor in accordance with section 1881(b)(14)(F)(i) of the Act, which provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services that reflect the costs of furnishing renal dialysis services. As discussed in section II.B.1.a.(2).(c) of this final rule, the final productivity-adjusted market basket update for CY 2024 is 2.1 percent based on the latest available data. We note that this final update is 0.4 percentage point higher than the proposed update and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2024 for ESRD facilities. We believe the final productivity-adjusted market basket update will address some of the commenter's concerns regarding rising wages due to inflation.

Comment: Several commenters, including MedPAC, a coalition of dialysis organizations and an LDO, suggested that CMS reevaluate the wage index methodology for the ESRD PPS. MedPAC recommended 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. Two ESRD facilities and a provider advocacy organization requested CMS use the floors and reclassifications that IPPS uses for their wage

index. Some of these commenters additionally indicated a belief that this change would help ESRD facilities compete with hospitals for labor.

Response: We appreciate the suggestions from commenters on how to improve the ESRD PPS wage index methodology. The use of hospital wage data for the ESRD PPS wage index is set forth in §§ 413.196(d)(2) and 413.231(a). As we previously discussed in the CY 2011 ESRD PPS proposed rule (74 FR 49968), the ESRD PPS wage index uses the same wage index values used in the basic case-mix adjusted composite payment system, which are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The application of the pre-floor, pre-reclassification hospital wage index for the ESRD case-mix adjusted composite payment system is further discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69726, 69758) and the CY 2007 PFS final rule (71 FR 69624, 69685). We did not propose changes to the ESRD PPS wage index methodology for CY 2024, and we are not finalizing any changes to that methodology in this final rule.

As discussed in the CY 2023 ESRD PPS final rule (87 FR 67160), the wage index is intended to be a relative measure of the value of labor in prescribed labor market areas. There is a variety of reasons why our longstanding ESRD PPS wage index policy has not applied the same floors or reclassifications as applied under the IPPS, which we note, are not applied to the ESRD PPS wage index by statute (sections 1881(b)(12)(D) & (b)(14)(D)(iv)(II) of the Act). For example, applying reclassifications to the ESRD PPS wage index would significantly increase administrative burden, both for ESRD facilities and for CMS, that would be associated with ESRD facilities reclassifying from one CBSA to another, and it would significantly increase the complexity of the methodology.

Furthermore, because floors and reclassifications would be applied budget-neutrally under the wage index, these policies would increase the wage index for some ESRD facilities while reducing ESRD PPS payments for all other ESRD facilities, which would upset the

long-settled expectations with which ESRD facilities across the country have been operating. For example, under the IPPS rural floor policy, section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Applying the IPPS rural floor to the ESRD PPS wage index would result in increasing the wage index for any ESRD facilities located in an urban area whose wage index is less than the rural wage index for that State. As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67164 through 67165) with respect to the increase to the ESRD PPS wage index floor in that year, a higher wage index floor will slightly decrease the ESRD PPS base rate for all ESRD facilities due to the application of the budget neutrality factor. Given that increasing the wage index floor results in a proportional decrease in the base rate for all ESRD facilities, we established a wage index floor value that strikes a balance between providing increased payment to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicates, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities.

For these reasons, we believe that the ESRD PPS wage index is the most appropriate data to use for estimating the variation in wage levels across the country. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: A non-profit health insurance organization commented that they believed a wage index floor of 0.7000 was justified and suggested CMS reevaluate the current wage index floor of 0.6000. The commenter indicated that CMS would find it appropriate to raise the wage index floor to 0.7000.

Response: We appreciate the suggestion and will consider it for potential future rulemaking. We did not propose any change to the current wage index floor of 0.6000 specified in § 413.231(d) and are not finalizing any changes to that floor in this final rule.

Final Rule Action: We are finalizing our proposal to update the ESRD PPS wage index for CY 2024 to use the most recent hospital wage data, as proposed. The final CY 2024 ESRD PPS wage index is set forth in Addendum A and is available on CMS's 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 2023 wage index and the CY 2024 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on CMS's website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.

c. CY 2024 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of 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.[11]

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.[12] 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 Medicare Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were

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[11] 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.

[12] 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.

or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the 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 for clarity, to 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. 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 finalized that we would continue to follow our established methodology for the calculation of the adult and pediatric MAP amounts, but we would prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.

(2) CY 2024 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2024, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2022 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2022 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). CY 2022 claims data showed outlier payments represented approximately 0.8 percent of total Medicare payments (88 FR 42432 and 42438).

The impact of this final update is shown in Table 1, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2023 with the updated estimates for this final rule. The estimates for the CY 2024 MAP amounts, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2024 prices for ESRD outlier services.

TABLE 1: Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023) *		**Column II Final outlier policy for CY 2024 (based on 2022 data, price inflated to 2024) ****	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$24.13	$41.36	$22.30	$37.92
Adjustments			.	.

Standardization for outlier services	1.0819	0.9774	1.0691	0.9763
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$25.59	$39.62	$23.36	$36.28
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$23.29	$73.19	$11.32	$71.76
Patient-month-facilities qualifying for outlier payment	12.90%	5.90%	20.86%	4.87%

*Column I was obtained from Column II of Table 11 from the CY 2023 ESRD PPS final rule (87 FR 67176).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2020, 2021, and 2022.

As demonstrated in Table 1, the estimated FDL per treatment that determines the CY 2024 outlier threshold amount for adults (Column II; $71.76) is lower than that used for the CY 2023 outlier policy (Column I; $73.19). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $39.62 to $36.28. For pediatric patients, there is a decrease in the FDL amount from $23.29 to $11.32. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $25.59 to $23.36.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2024 would be 4.87 percent for adult patients and 20.86 percent for pediatric patients, based on the 2022 claims data and methodology finalized in the CY 2023 ESRD PPS final rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(3) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1 percent target (87 FR 67170 through 67174). We stated in the CY 2024 ESRD PPS proposed rule that, based on the CY 2022 claims, outlier payments represented approximately

0.9 percent of total payments. Based on more complete CY 2022 claims data, this figure has been updated to 0.8 percent for this final rule, which is below the 1 percent target due to declines in the use of outlier services. However, this is significantly closer to the 1 percent target than the outlier payments based on CY 2021 claims, which represented approximately 0.5 percent of total payments. In the CY 2024 ESRD PPS proposed rule, we noted that we believe the update to the outlier MAP and FDL amounts for CY 2024 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us even closer to meeting our 1 percent outlier policy goal, because we would be using more current data for computing the MAP and FDL amounts, which is more reflective of current outlier services utilization rates. We also noted that the proposed recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

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

Comment: We received several comments on CMS's proposals to update the FDL and MAP amounts for CY 2024. Commenters were generally supportive of the use of more recent data to determine the CY 2024 ESRD PPS final MAP and FDL amounts. Several commenters stated that they appreciated that the methodological changes CMS made to the outlier policy in the CY 2023 ESRD PPS final rule resulted in the total percentage of payments for outliers being closer to the 1 percent target than ever before. However, some commenters noted that the ESRD PPS base rate is reduced on the assumption that 1 percent of total payments will be attributable to outlier payments, and if the actual percentage is less than 1 percent it means that total payments to ESRD facilities are less than they should be. Commenters suggested that CMS should implement a policy to recompense ESRD facilities for underpayment when total outlier payments are less than 1 percent of total ESRD PPS payments. One commenter recommended CMS reduce the outlier target to 0.5 percent of total payments.

Response: We appreciate the support for the proposed use of more recent data to update the MAP and FDL amounts for the outlier policy and the thoughtful suggestions provided by commenters. We acknowledge that, even with annually adjusting the MAP and FDL amounts to reflect the most recent utilization and costs of ESRD PPS eligible outlier services according to the updated outlier methodology finalized in the CY 2023 ESRD PPS final rule, total outlier payments have not yet reached the 1 percent target. However, the performance of the outlier payments has improved significantly due to the modification to the outlier methodology finalized in CY 2023 ESRD PPS final rule, as outlier payments represented 0.8 percent of the total payments in CY 2022. We appreciate the comments suggesting solutions for refining the outlier policy methodology, for example, reducing the outlier percentage, as defined at § 413.220(b)(4), to less than 1 percent or establishing a mechanism that pays back ESRD facilities those allocated outlier amounts that were not paid out in the projected year. We did not propose any modifications to the ESRD PPS outlier policy for CY 2024 codified at § 413.220, and we are not finalizing any changes to the methodology in this final rule. We will consider the commenters' suggestions regarding changes in methodology in potential future rulemaking.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2024 displayed in Column II of Table 1 of this final rule based on the most current data.

d. Impacts to the CY 2024 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in

accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2024

In the CY 2024 ESRD PPS proposed rule, we proposed an ESRD PPS base rate for CY 2024 of $269.99 (88 FR 42432). We are finalizing an ESRD PPS base rate for CY 2024 of $271.02. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2024, we did not propose and are not finalizing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2024 wage index budget-neutrality adjustment factor using treatment counts from the 2022 claims and facility-specific CY 2023 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2023. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2024. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final CY 2024 ESRD PPS wage index and final labor-related share for CY 2024. As discussed in section II.B.1.b of this final rule, the ESRD PPS wage index for CY 2024 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. The total of these payments becomes the new CY 2024 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 2024 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2024 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 wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The final CY 2024 wage index budget-neutrality adjustment factor is 1.000031. This CY 2024 wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the final CY 2024 ESRD PPS wage index and labor-related share.

TPEAPA Budget-Neutrality Adjustment Factor: As explained in section II.B.1.g.(7) of this final rule, we are finalizing a new, budget-neutral transitional add-on payment adjustment for pediatric ESRD renal dialysis services, which we call the TPEAPA. The final CY 2024 budget-neutrality adjustment factor for the TPEAPA is 0.999503. The budget-neutrality adjustment factor for the TPEAPA is discussed in section II.B.1.g of this final rule.

Combined Wage Index and TPEAPA Budget-Neutrality Adjustment Factor: For purposes of calculating the ESRD PPS base rate for CY 2024, we are using one combined budget-neutrality adjustment factor includes both the wage index budget-neutrality adjustment factor and the TPEAPA budget-neutrality adjustment factor. The CY 2024 combined wage index and TPEAPA budget neutrality factor is 0.999534 (1.000031 × 0.999503). This application would yield a CY 2024 ESRD PPS base rate of $265.48 prior to the application of the CY 2024 market basket update percentage ($265.57 × 0.999534 = $265.45).

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 previously in section II.B.1.a.(2)(a) of this final rule, the latest CY 2024 projection of the ESRDB market basket percentage increase is

2.4 percent. In CY 2024, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a.(2)(b) of this final rule, the latest CY 2024 projection of the productivity adjustment is 0.3 percentage point, thus yielding a CY 2024 productivity-adjusted ESRDB market basket update of 2.1 percent for CY 2024. Therefore, the final CY 2024 ESRD PPS base rate is $271.02 (($265.57 × 0.999534) × 1.021 = $271.02).

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

Comment: We received several comments which characterized the proposed CY 2024 ESRD PPS base rate as too low. Some of these commenters requested that CMS increase the base rate. The reasoning for this requested increase varied by commenter. Some commenters wanted an increase to account for recent under-forecasts, whereas other commenters wanted an increase to allow facilities to provide an increased quality of care.

Response: The CY 2024 ESRD PPS base rate is derived from the CY 2023 ESRD PPS base rate, the CY 2024 ESRDB market basket update, and the CY 2024 combined wage index-TPEAPA budget neutrality factor. In accordance with section 1881(b)(14)(F) of the Act, the primary factor in determining the ESRD PPS base rate increase from one year to the next is the ESRDB market basket update. We believe the final CY 2024 ESRDB market basket update reflects the most recent available data regarding the forecasted prices of labor used to provide renal dialysis services. We discuss the CY 2024 ESRDB market basket update in more detail in section II.B.1.a of this final rule, with detailed responses to comments on the magnitude of the productivity-adjusted ESRDB market basket increase in section II.B.1.a.(2)(c) of this final rule and detailed responses to comments on previous forecast errors for the ESRDB market basket update in section II.B.1.a.(2)(d) of this final rule. We appreciate the concerns of the commenters, but we did not propose any new payment adjustments to the base rate based on

those concerns. We will continue to monitor the adequacy of the ESRD PPS payment and will consider these commenters' insights for future rulemaking.

Final Rule Action: We are finalizing a CY 2024 ESRD PPS base rate of $271.02. This amount reflects the combined CY 2024 wage index-TPEAPA budget-neutrality adjustment factor of 0.999534, and the CY 2024 ESRD PPS productivity-adjusted market basket update of 2.1 percent.

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

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

As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42432), there are currently no capital-related assets that are home dialysis machines set to receive TPNIES for

CY2024, as the TPNIES payment period for the Tablo® System ends on December 31, 2023, and the only TPNIES application for CY 2024 is not for a home dialysis machine. 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 proposed a CY 2024 TPNIES offset amount for capital-related assets that are home dialysis machines of $9.96, based on the proposed CY 2024 ESRDB productivity-adjusted market basket update of 1.7 percent (2.0 percent market basket percentage increase reduced by 0.3 percentage point productivity adjustment). We explained in the CY 2024 ESRD PPS proposed rule that applying the proposed update factor of 1.017 to the CY 2023 offset amount resulted in the proposed CY 2024 offset amount of $9.96 ($9.79× 1.017 = $9.96). We proposed to update this calculation to use the most recent data available in the CY 2024 ESRD PPS final rule.

We received three comments on this proposal to update the TPNIES offset amount for capital related assets that are home dialysis machines, including comments from an LDO and a device manufacturer. The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: A device manufacturer requested that CMS remove the TPNIES offset for capital-related assets that are home dialysis machines. The commenter and two others indicated that they believe that the TPNIES offset, combined with the 65 percent reduction for risk sharing, are leading to capital-related assets that are home dialysis machines being undervalued. An LDO agreed that the TPNIES for capital-related assets that are home dialysis machines should be offset by an amount currently in the base rate.

Response: We appreciate the commenters' insight into the impacts of the TPNIES offset for capital-related assets that are home dialysis machines. We did not propose any methodological changes for this TPNIES offset amount set forth at § 413.236(f), and we are not

finalizing any changes. We will consider the commenters' concerns for potential future rulemaking.

Final Rule Action: We are finalizing our proposal to calculate the CY 2024 TPNIES offset amount using the most recent data available. The CY 2023 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.79. As discussed previously in section II.B.1.a.(2)(c) of this final rule, the final CY 2024 ESRDB productivity-adjusted market basket update is 2.1 percent (2.4 percent market basket percentage increase reduced by 0.3 percent productivity adjustment). Applying the update factor of 1.021 to the CY 2023 TPNIES offset amount results in a final CY 2024 TPNIES offset amount of $10.00 ($9.79 × 1.021).

f. Refinement of the Low-Volume Payment Adjustment (LVPA)

(1) Background

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. In this section of the final rule, we discuss the low volume-payment adjustment (LVPA) under the ESRD PPS.

The current amount of the LVPA is 23.9 percent. 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 and to determine the treatment threshold for those ESRD facilities identified. After consideration of public comments, we established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and

indicated that this increase to the ESRD PPS 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 CYs 2012 and 2013 low-volume facility claims and cost report data indicated a multiplier of 1.239 percent; 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). In CY 2021, 366 ESRD facilities received the LVPA. Using the most recent available data for CY 2022, the number of ESRD facilities receiving the LVPA was 353.

(a) Current LVPA Methodology

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 paragraph (g)(4)) 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) in the 3 cost-reporting years (based on as-filed or final settled 12-consectuive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with and 5 road miles or less from the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative

Contractor (MAC) confirming that it meets all the requirements 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 is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1st 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 1st 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 payment 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 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 PHE. Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. ESRD facilities that would not otherwise meet the number of treatments criterion because of the COVID-19 PHE may attest that their total dialysis treatments for those 6 months of their cost reporting period ending in 2020 are less than 2,000. The attestation must further include that although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID-19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2.

(b) Current Issues and Concerns from Interested Parties

Interested parties, including MedPAC and the Government Accountability Office (GAO),[13] 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.[14] These groups and other interested parties have also have expressed concern that the strict treatment count introduces a "cliff-effect" that may incentivize ESRD facilities to restrict their patient caseload to remain below 4,000 treatments per year to meet the LVPA threshold.[15]

(2) Requests for Information on Modification of LVPA Methodology and Development of a New Payment Adjustment Based on Geographic Isolation

In the CY 2024 ESRD PPS proposed rule (88 FR 42440 through 42441), we explained that we recognize the importance of revising the ESRD PPS LVPA adjustment methodology to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities, and to strive for healthcare equity for ESRD beneficiaries. 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. We noted several points of concern that interested parties have raised in the past, as well as certain statutory limitations that could apply to some of the methodological approaches suggested in the past. We solicited information from the public about potential approaches to refine the ESRD PPS methodology, which we would take into consideration for any potential changes to the LVPA in the future.

This section addresses several RFIs regarding the LVPA and a potential new adjustment for geographically isolated ESRD facilities.

(a) Comment Solicitation for Modifications to LVPA Methodology

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

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

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

In the CY 2024 ESRD PPS proposed rule, we solicited comments on potential changes to the LVPA methodology (88 FR 42441 through 42444), including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function. Any potential refinements to the LVPA methodology that may result from our consideration of these comments would be proposed through notice-and-comment rulemaking in the future. We requested that commenters keep in mind that section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services.

(i) Maintain a Single LVPA Threshold

As discussions about modifying the existing treatment threshold or payment adjustment percentage have been ongoing since the beginning of the multi-year LVPA reform efforts, we solicited comments on maintaining a single threshold for the LVPA. ESRD facilities that fall below the treatment threshold would continue to receive payment, and payments would not be adjusted for those ESRD facilities above the threshold. We stated that we were engaged in continuing monitoring efforts to align resource use with payment. As noted in the CY 2024 ESRD PPS proposed rule (88 FR 42442), if we were to re-compute the LVPA percentage amount using the latest available claims and cost report data and the methodology established in the CY 2011 and CY 2016 ESRD PPS final rules (75 FR 49118 through 49125 and 80 FR 69001), the current treatment threshold of 4,000 treatments per year would correspond to a 17.6 percent payment adjustment. The 4,000-treatment threshold could be maintained, or the treatment threshold could be recalibrated to maintain the 23.9 percent payment adjustment. Maintaining a single threshold would not address concerns regarding the potential for gaming or remove what commenters call the payment cliff. Potential approaches for a single LVPA threshold are outlined in Table 2.

TABLE 2: Potential Approaches for a Single LVPA Threshold

Option	Description

Status quo	4,000-treatment threshold with 23.9 percent payment adjuster
Maintain Treatment Threshold	4,000-treatment threshold with 17.6 percent payment adjuster
Maintain Payment Adjuster	Reduce treatment threshold to 3,750 treatments to maintain 23.9 percent payment adjuster

(ii) Establishment of Multiple LVPA Tiers

We solicited comments on creating a tiered payment adjustment that would include multiple thresholds, with separate payment adjustments calibrated so that ESRD facilities in tiers with the lowest treatment volume would receive the highest payment adjustment, and vice versa. MedPAC has previously recommended setting LVPA treatment thresholds at fewer than 4,000 treatments, between 4,000 and 4,999 treatments, and between 5,000 and 6,000 treatments, with payment adjustments calibrated so that ESRD facilities in tiers with the lowest volume would receive the highest payment adjustment, and vice versa.[16] Establishing multiple thresholds, with a separate payment adjustment for ESRD facilities under each threshold level, would reduce the potential for gaming through reduction of the magnitude of the payment cliff. Additionally, LVPA eligibility would be expanded to more ESRD facilities. We solicited comments regarding the establishment of multiple thresholds, including up to an eight-tiered structure for the LVPA. Tables 3 through 6 outline various methodological options. Tables 3 and 4 would establish larger adjustment factors on average than the current methodology but would require reductions to the ESRD PPS base rate to maintain budget neutrality. Tables 5 and 6 show adjustment factors which are scaled to maintain budget neutrality within the LVPA, keeping the LVPA's budget at the same amount that would occur under the current methodology without requiring reductions to the ESRD PPS base rate. As illustrated below, scaling the adjusters while maintaining budget neutrality within the LVPA results in lower LVPA adjusters.

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

For example, Tier 1 (less than 5,000 treatments) in the Four-Tiered Model varies based on the approach to maintaining budget neutrality, as the LVPA adjuster is 13.7 percent where budget neutrality is maintained within the ESRD PPS (Table 3) and 5.8 percent where budget neutrality is maintained within the LVPA (Table 5). For comparison, the Eight-Tiered Model shows that for Tier 1 (less than 1,000 treatments), ESRD facilities would receive a 123 percent LVPA adjuster where budget neutrality is maintained within the ESRD PPS (Table 4) and 40.5 percent LVPA adjuster where budget neutrality is maintained within the LVPA (Table 6).

TABLE 3: LVPA Adjustment with Four Tiers ($1.20 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 5,000)	13.7%
Tier 2 (5,000 – 5,999)	8.4%
Tier 3 (6,000 – 6,999)	4.7%
Tier 4 (7,000 – 7,999)	1.9%

TABLE 4: LVPA Adjustment with Eight Tiers ($1.80 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 1,000)	123.0%
Tier 2 (1,000- 1,999)	57.6%
Tier 3 (2,000-2,999)	33.9%
Tier 4 (3,000-3,999)	21.4%
Tier 5 (4,000 – 4,999)	13.7%
Tier 6 (5,000 – 5,999)	8.4%
Tier 7 (6,000 – 6,999)	4.7%
Tier 8 (7,000 – 7,999)	1.9%

TABLE 5: LVPA Adjustment with Four Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	**LVPA Adjuster**	**Est. Facilities Receiving Adjustment**
Tier 1 (less than 5,000)	5.8%	767

Tier 2 (5,000 – 5,999)	3.6%	331
Tier 3 (6,000 – 6,999)	2.0%	332
Tier 4 (7,000 – 7,999)	0.8%	318

TABLE 6: LVPA Adjustment with Eight Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	**LVPA Adjuster**	**Est. Facilities Receiving Adjustment**
Tier 1 (less than 1,000)	40.5%	22
Tier 2 (1,000- 1,999)	19.0%	69
Tier 3 (2,000-2,999)	11.2%	137
Tier 4 (3,000-3,999)	7.1%	250
Tier 5 (4,000 – 4,999)	4.5%	290
Tier 6 (5,000 – 5,999)	2.8%	331
Tier 7 (6,000 – 6,999)	1.5%	332
Tier 8 (7,000 – 7,999)	0.6%	318

(iii) Continuous Function

We also solicited comments on potentially establishing a continuous function to adjust LVPA payments. Under this approach, ESRD facilities with the lowest treatment volume would receive the highest payment adjustment, and the payment adjustment would decrease continuously as volume increases. This could include calibration of the point at which the payment adjustment becomes zero to correspond with the existing 4,000 treatment upper bound, or establishment of a new upper bound based on a regression analysis. Establishment of a continuous function has the potential to significantly reduce the potential for gaming by eliminating payment cliffs entirely. Additionally, this would increase payment for ESRD facilities with the lowest volume, therefore better aligning payment with resource use. Furthermore, a continuous function would potentially expand LVPA eligibility to the most ESRD facilities.

In the CY 2024 ESRD PPS proposed rule, we noted that we are considering several approaches to modifying the LVPA to address concerns about its incentive structure, treatment

threshold, and administrative burden, as expressed by interested parties (including the GAO, MedPAC, and industry representatives). We issued this RFI to seek feedback on the suggested changes to the LVPA, as described previously, and to solicit further input from interested parties to inform future modifications to the methodology used to determine the LVPA.

CMS welcomed input and responses to the following considerations, requests, and questions:

- Regarding concerns about a payment cliff in the existing LVPA, we are considering implementing payment tiers or a continuous adjustment, based on treatment volume, in place of the current single tiered adjustment.

++ Comment on which payment structure would be more appropriate: single threshold as currently employed, tiered structure, or continuous function, and provide the reasoning behind your recommendation.

++ Comment on which option would be most effective in removing gaming incentives and which option would bring greater congruency between cost of providing renal dialysis services and payment.

- Using the alternative methodology described previously, under a tiered or continuous payment adjustment, the treatment threshold for eligibility would be determined based on the median treatment count among all ESRD facilities (approximately eight thousand treatments per year). The resulting tiers and incremental payment adjustments between tiers could follow several different configurations.

++ What factors should be evaluated to best determine the treatment count threshold, as well as the tiering structure? Specifically, comment on the treatment volume beneath which per-treatment costs begin to increase.

++ Enumerate any concerns you might have should the implementation of a tiered or continuous adjustment result in an expanded set of eligible ESRD facilities, and payment redistribution.

● Interested parties have voiced concern regarding the administrative burden involved in the current LVPA attestation process. As such, we are considering potentially decreasing the number of years of attestation data needed to determine LVPA eligibility.

++ Comment on the extent to which this change would alleviate burden, and if there are other administrative changes that could be made to simplify this process.

++ Describe any anticipated effects of decreasing the amount of treatment volume data used to determine LVPA eligibility.

++ Describe the ways that simplifying the attestation process could help ESRD facilities with fewer resources to promote health equity by improving their ability to serve vulnerable and underserved communities.

(b) Comment Solicitation on the Development of a New Payment Adjustment Based on Geographic Isolation

CMS is striving to promote health equity by ensuring that ESRD facilities, including both rural and low-volume facilities, are being paid equitably for serving populations that are currently underserved. Therefore, in the CY 2024 ESRD PPS proposed rule (88 FR 42444 through 42445), we solicited comments on potentially assisting geographically isolated ESRD facilities and promoting access in these areas, including labor force hiring and retention. We stated that we considered establishing a new payment adjustment that accounts for isolation, rurality, and other geographical factors. We also requested information on geographic isolation to determine if ESRD facilities that are currently considered rural would benefit from a geographic isolation adjustment. The new geographically based payment adjustment may consider local dialysis need (LDN), as explained later in this section, instead of basing payment strictly upon a rural designation, as set forth in § 413.233 and 413.231(b)(2). We considered changes to the eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities that are necessary to protect access to care. As noted previously, under section 1881(b)(14)(D)(iii) of

the Act, 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. We explained that our 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. Therefore, certain changes that interested parties have suggested would not comport with the statutory requirements and limitations for the LVPA. We solicited comments on potential methodologies for creating a separate payment adjustment that could potentially address GAO and MedPAC's concerns, relying upon the authority under 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 solicited responses to the following questions.

++ What factors should be considered in formulating a payment adjustment for ESRD facilities in isolated geographical areas or areas for which there is a low need for renal dialysis services?

++ What are the best ways to incentivize renal dialysis service provision in isolated geographic areas?

++ Our analysis of the LDN methodology has shown that low LDN census tracts intersect with areas designated as Health Professional Shortage Areas. What impact would a payment adjustment based on geographic isolation have on the ability of ESRD facilities in isolated areas to recruit and retain health care professionals?

++ Comment on the appropriateness of maintaining the rural facility adjustment under § 413.233 if we were to establish an LDN payment adjustment in conjunction with a modified LVPA.

++ Comment on the relationship between geographic isolation and cost. Please provide any data that could further inform CMS's understanding of the relationship between geographic isolation and cost for low volume facilities.

++ Comment on the appropriateness of utilizing driving time between current beneficiary address and treatment location as the appropriate metric for travel time.

++ Are there ways in which the suggested methodology for this potential payment adjustment could fail in targeting isolated ESRD facilities, or ESRD facilities in areas with low LDN?

++ Are there ways in which the determination of LDN might be subject to gaming?

++ Would a payment adjustment for ESRD facilities in areas with low LDN improve health equity? Are there specific recommendations to change the LDN methodology described above to promote quality access to care for all ESRD beneficiaries?

++ Comment on the favorability of CMS's implementation of a new payment adjustment for ESRD facilities in areas with low LDN as described above.

++ Are there any other considerations we should keep in mind when considering proposing a new payment adjustment based on an LDN methodology?

(c) Summary of Request for Information on Potential Modification to LVPA Methodology and Information Received from Commenters

As discussed above, in the CY 2024 ESRD PPS proposed rule (88 FR 42430), we sought comment on several approaches to modifying the LVPA to address concerns about its incentive structure, treatment threshold, and administrative burden. We issued an RFI to seek feedback from the public on potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities. We also solicited comments on the establishment of an add-on payment adjustment for geographic isolation of ESRD facilities. We asked commenters whether a payment adjustment for

geographic isolation of ESRD facilities in areas with low local dialysis need would improve health equity.

We received 23 public comments in response to our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; and MedPAC. A high-level description of these comments is included in the following subsections of this CY 2024 ESRD PPS final rule.

We thank the commenters for their detailed and thoughtful comments. While we will not respond to these comments in this CY 2024 ESRD PPS final rule, we intend to take them into consideration for future rulemaking and future policy development. We will provide more detailed information about the commenters' recommendations in a future posting on CMS's website located at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

(i) Responses on Criteria for Receiving LVPA Status

We received a wide range of responses to the RFI. Many commenters supported MedPAC's proposal of implementing a two-tier low-volume and isolated (LVI) adjustment in place of the LVPA so that facilities can expand services to meet patient needs without substantial payment decreases while limiting administrative burden. Some commenters supported maintaining a single threshold with varying recommendations for adjusted treatment counts. Other commenters supported establishing varying numbers of tiers at varying treatment counts. Some commenters also supported establishing a continuous function as described in the CY 2024 ESRD PPS proposed rule. Many comments included general concerns regarding the administrative burden and transparency of the various methodologies described. While we are not providing a detailed response to these comments in this final rule, we thank the commenters for their input and will consider the recommendations in potential future rulemaking.

(ii) Responses on the Local Dialysis Need (LDN) Methodology

Commenters generally believed that the LDN methodology was overly complicated and lacked transparency. Several commenters expressed renewed support for incorporating geographic isolation directly into the LVPA formula, using a methodology such as the LVI adjustment that MedPAC suggested. While we are not providing a detailed response to these comments in this final rule, we thank the commenters for their input and will consider the recommendations in potential future rulemaking.

(3) Exception to the Current LVPA Attestation Process for Disasters and Other Emergencies

Under our current regulations at § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in § 413.232(g)(4)) 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) 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. When we first established these requirements in the CY 2011 ESRD PPS final rule, we explained that looking across data for three years provided us with sufficient information to view consistency in business operations (79 FR 49123). In the CY 2019 ESRD PPS final rule (83 FR 56949) and the CY 2021 ESRD PPS proposed rule (85 FR 42165), we acknowledged commenters' concerns that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility during disasters or other emergency situations like the COVID-19 PHE. Commenters have emphasized that low-volume facilities rely on the LVPA, and that loss of the payment adjustment could result in beneficiary access issues.

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42165), the COVID-19 PHE caused ESRD facilities to have to shift patients among ESRD facilities to provide uninterrupted care to their Medicare ESRD population. In some cases, this patient shifting

increased dialysis treatments at some low-volume ESRD facilities, putting the ESRD facility temporarily over the LVPA treatment threshold. This increase in dialysis treatments, resulting from the COVID-19 PHE, disqualified some ESRD facilities that would have otherwise received the LVPA of 23.9 percent per treatment. In the CY 2021 ESRD PPS final rule (85 FR 71485), we established a policy that ESRD facilities would be held harmless from increases in treatment counts due to temporary patient shifting because of the COVID-19 PHE. To be held harmless, ESRD facilities must follow the attestation process for the exception set forth in § 413.232(g)(4) and are expected to provide supporting documentation to the MACs upon request. Interested parties have expressed support for CMS's swift response to the COVID-19 PHE's impact on ESRD facilities, with an association of dialysis providers stating that holding harmless LVPA status for these ESRD facilities will better ensure that ESRD patients can continue to access the life-sustaining dialysis treatment they need, particularly in rural and underserved areas where low-volume facilities heavily depend on the LVPA to remain open and provide treatment for patients.

In the CY 2024 ESRD PPS proposed rule, we stated that we recognize there could be future circumstances, potentially like the circumstances of the COVID-19 PHE, in which it would be appropriate to provide flexibilities with respect to certain LVPA requirements (88 FR 42446). Commenters have previously expressed concerns about the strict attestation requirements for ESRD facilities to remain eligible for the LVPA, particularly when faced with a disaster or other emergency, such as a local or national emergency, natural disaster, catastrophic event, or public health emergency. We noted that during disasters or other emergencies, low-volume facilities could be forced to close, or could experience increases in their treatment counts if they treat patients who are displaced from a nearby ESRD facility that is impacted by such an event. For example, in August of 2021, an ESRD facility in Louisiana sustained significant damage because of Hurricane Ida, which required the ESRD facility to close for repairs and temporarily stop furnishing renal dialysis services. The ESRD facility served a rural community

and for over 10 years received the LVPA due to the low number of dialysis treatments it furnished each year. This ESRD facility sought recourse to maintain its eligibility for the LVPA when it resumed operations following the required repairs to the ESRD facility, however, recourse was unavailable due to the limitations set forth in § 413.232(b). We explained that when we established the LVPA in the CY 2011 ESRD PPS final rule, we stated that we believed the LVPA should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic (75 FR 49118). Given that these requirements for low-volume facilities were created to protect access to care for the vulnerable patient population that these ESRD facilities serve, we noted, adding certain flexibilities during disasters or other emergencies would promote our commitment to ensuring access to care for ESRD patients.

(a) Changes to the LVPA

We proposed to make two changes to the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. First, we proposed to create a new exception to the attestation process for disasters and other emergencies. Second, we proposed to establish a process that would allow low-volume facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. CMS would assess whether a particular situation is a disaster or other emergency based on the totality of the circumstances that could result in disruption of or inability to furnish renal dialysis services at one or more ESRD facilities, thus affecting the ESRD facility or facilities' ability to qualify for the LVPA. For purposes of the proposal, disasters or other emergencies would include, but not be limited to, the below examples:

- A public health emergency declared by the Secretary due to a significant outbreak of infectious disease or bioterrorist attacks.

- Natural disasters including winter storms, floods, tornados, hurricanes, wildfires, earthquakes, or any combination thereof.[17]

- Catastrophic events outside of an ESRD facility's control that disrupt operations and result in an ESRD facility's closure, for example, loss of operations or patient shifting due to a local emergency such as fire, floods, earthquakes, or tornadoes.

- Other disasters or emergency conditions under which a waiver could be granted pursuant to section 1135 of the Act.

We stated that these policy changes could help displaced ESRD patients maintain access to renal dialysis services by preventing ESRD facilities from permanently closing due to the loss of their LVPA. It is important that ESRD facilities that are receiving the LVPA can maintain LVPA eligibility despite the impacts caused by a disaster or other emergency. This policy could potentially protect other ESRD facilities that need to maintain the LVPA to remain open from potentially losing their LVPA by exceeding the treatment threshold because they accepted displaced patients. We noted that we do not want the fear of losing the LVPA due to increased treatments exceeding the threshold to disincentivize ESRD facilities from accepting patients from other ESRD facilities experiencing a disaster or other emergency. It is also important that ESRD facilities that are forced to close due to a disaster or other emergency can maintain their LVPA eligibility upon reopening to ensure continued access in areas that otherwise may lack sufficient ESRD facilities. This policy could also help those ESRD facilities affected by the disaster or other emergency potentially resume operations and avoid permanent closure if they would be allowed to receive the LVPA upon reopening despite the closure or disruption of operations.

(i) Exception to the LVPA Treatment Threshold for ESRD Facilities that Accept Patients from an ESRD Facility Affected by a Disaster or Other Emergency

[17] https://www.dhs.gov/natural-disasters.

We proposed in the CY 2024 ESRD PPS proposed rule to create an exception to the LVPA treatment threshold requirements set forth in § 413.232(b)(1) under a new provision in § 413.232(g)(5), which would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or other emergency. Qualification for the exception would require an ESRD facility to absorb those displaced patients from an outside or adjacent ESRD facility that experienced a temporary closure or operational disruption (such as a water shut off). If an ESRD facility accepts the patients of the ESRD facility affected by the disaster or other emergency, causing that ESRD facility to meet or exceed the 4,000-treatment count for all dialysis patients, it would attest to its MAC that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility due to a disaster or other emergency. We proposed to define temporary patient-shifting in the context of the LVPA in the ESRD PPS as providing renal dialysis services to one or more patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). The ESRD facility would be required to request this exception from CMS by writing to the ESRD Payment Mailbox (ESRDPAYMENT@cms.hhs.gov) no later than the annual attestation deadline of November 1st. CMS would review the exception request within 30 days to determine if the ESRD facility qualifies for the exception. If approved by CMS, the ESRD facility would be paid the LVPA for Medicare beneficiaries for up to the first 4,000 dialysis treatments in the payment year in which the temporary patient-shifting occurred. Under this exception, the ESRD facility would be held harmless for meeting or exceeding the 4,000-treatment threshold during one or more cost reporting years within the 3-year lookback for LVPA eligibility as long as their 4,000-treatment threshold was exceeded as a result of temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. If CMS does not approve the request, CMS would notify the ESRD facility and the

MAC, and the ESRD facility would be disqualified from receiving the LVPA until it meets all the LVPA criteria (including the 3-year lookback). The ESRD facility receiving this exception must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that previously treated those patients and closed or experienced an operational disruption due to a disaster or other emergency and must provide such documentation to CMS and the MAC upon request. The ESRD facility requesting this exception would have to repeat the process for requesting an exception for each cost reporting year in which its treatment volume meets or exceeds 4,000 due to temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. Additionally, the ESRD facility requesting this exception would have to follow the attestation process as described at § 413.232(e) for the two payment years following the last cost reporting year in which its treatment volume meets or exceeds 4,000 due to treating displaced patients from the ESRD facility that experienced the disaster or other emergency and attest that the ESRD facility meets the criteria established at § 413.232.

We provided the following example: if a disaster occurs on June 1, 2024, which results in ESRD facility X's closure or operational disruption resulting in ESRD facility Y (an existing low-volume facility) treating additional patients from ESRD facility X that puts ESRD facility Y's total renal dialysis treatments for cost reporting year 2024 over the 4,000 treatment threshold, ESRD facility Y would be required to request an exception to § 413.232(b)(1) from CMS by November 1, 2024 to continue receiving the LVPA. Since ESRD facility Y began treating the displaced patients in CY 2024, the window for temporary patient shifting would extend until December 31, 2025. To be approved for the exception under the proposed provision in § 413.232(g)(5), CMS would determine that ESRD facility Y furnished treatments equal to or more than 4,000 in the cost reporting year due to temporary patient-shifting because of the closure or operational disruption of ESRD facility X resulting from a disaster or other emergency. Should the exception be approved by CMS, ESRD facility Y would receive the

LVPA for up to the first 4,000 treatments it furnished in 2024. Additionally, ESRD facility Y would not be disqualified from receiving the LVPA for payment years (PYs) 2025 and 2026 due to exceeding the treatment volume threshold in cost reporting year 2024, assuming the temporary patient-shifting from ESRD facility X occurred only in cost reporting year 2024. For PY 2025 and PY 2026, ESRD facility Y would have to attest that it meets all the criteria for the LVPA because it furnished treatments equal to or more than 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency and received an exception for cost reporting year 2024. This would be the same attestation process as if ESRD facility Y did not furnish any excess treatments and was attesting that it continued to meet the criteria for the LVPA for those payment years. If the closure or operational disruption of ESRD facility X causes the treatment volume for ESRD facility Y to meet or exceed the 4,000-dialysis treatment threshold in cost reporting year 2025, ESRD facility Y would have to submit another request for an exception by November 1, 2025. Should this exception be approved, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in cost reporting year 2025 and would not be disqualified from receiving the LVPA for PYs 2026 and 2027 due to exceeding the treatment volume threshold in cost reporting year 2024 and cost reporting year 2025. If ESRD facility Y continued to treat displaced patients from ESRD facility X in cost reporting year CY 2026, it would only be considered temporary patient-shifting if ESRD facility Y treated those patients before January 1, 2026, and if patients treated after January 1, 2026 cause ESRD facility Y to exceed the 4,000-treatment volume threshold in cost reporting year 2026 then the ESRD facility would be disqualified from receiving the LVPA under § 413.232(b)(1). Under this example, ESRD facility Y would still have to meet the other eligibility requirements to receive the LVPA in any PY in which the ESRD facility would receive the LVPA.

(ii) Exception to the LVPA Closure Provision for ESRD Facilities Affected by a Disaster or Other Emergency

In addition to the proposed exception to the treatment threshold requirement under § 413.232(b)(1) and (g)(5), we proposed an exception under § 413.232(g)(6) that would allow an ESRD facility to still receive the LVPA if it temporarily closes. That is, if an ESRD facility temporarily ceases to operate and the patients must go to another ESRD facility to receive renal dialysis services due to a disaster or other emergency, and the ESRD facility subsequently reopens, we proposed to create an exception to the requirement in § 413.232(b)(2) that an ESRD facility "has not opened, closed, or received a new provider number" in the 3 cost reporting years preceding the payment year. If an ESRD facility is affected by a disaster or other emergency and the ESRD facility is forced to close and re-open later, the ESRD facility would need to request an exception from CMS in writing at the ESRD Payment Mailbox at ESRDPAYMENT@cms.hhs.gov within 60 days of the closure and inform the MAC of the request. CMS would review the request within 30 days of receipt and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and would inform both the ESRD facility and the MAC of its decision.

Under the proposal, upon reopening and providing renal dialysis services, the ESRD facility would be required notify CMS and the MAC in writing within 30 days of its reopening. CMS would acknowledge receipt of the written notification within 30 days. If the exception is approved and CMS is duly informed of the ESRD facility's reopening, the ESRD facility would remain eligible for the LVPA and the MAC would process payment accordingly. To continue receiving the LVPA the ESRD facility would still have to meet all the other eligibility requirements for the LVPA. The exception to § 413.232(b)(2) would be applicable for a period of 2 cost reporting years following the date of closure of the ESRD facility. After a period of 2-cost reporting years the ESRD facility would follow the normal attestation process for the LVPA specified in paragraphs (e) and (g) of § 413.232. The ESRD facility would be required to maintain documentation regarding its closure, and to provide such supporting documentation to CMS and/or the MAC upon request.

We provided the following example: If a disaster occurs on June 1, 2024, which results in an ESRD facility experiencing a closure, the ESRD facility would request an exception to § 413.232(b)(2) from CMS within 60 days of June 1, 2024 (that is, on or before July 31, 2024). CMS would review the request and notify the ESRD facility and the MAC within 30 days if the exception is approved or denied. If the ESRD facility then reopens on September 1, 2024, the ESRD facility would notify CMS and the MAC in writing within 30 days of reopening (that is, on or before October 1, 2024). CMS would notify the ESRD facility and the MAC of its receipt of the reopening notification within 30 days. If the exception was approved by CMS, the ESRD facility would remain eligible for the LVPA for the rest of payment year 2024 and for the entirety of payment year 2025 and payment year 2026, provided the ESRD facility continues to meet the other eligibility requirements for the LVPA.

We received 10 public comments on our proposals to modify the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. These comments came from three LDOs, a non-profit dialysis organization, a coalition of dialysis organizations, a non-profit advocacy organization, and a non-profit kidney organization. The comments on our proposals and our responses are set forth below.

Comment: All of the comments supported CMS's proposal to establish exceptions to the LVPA requirements for ESRD facilities impacted by a disaster or other emergency.

Response: We appreciate the support for our proposed exceptions to the LVPA requirements for ESRD facilities that are impacted by a disaster or other emergency.

Comment: One LDO requested that CMS reevaluate the attestation deadline for ESRD facilities that exceed the LVPA treatment volume threshold due to accepting displaced patients from an ESRD facility that closes or experiences an operational disruption due to a disaster or other emergency. This LDO noted that if the disaster were to occur late in the year, it might be difficult for an ESRD facility to meet the November 1st attestation deadline.

Response: We thank the commenter for the thoughtful suggestion on how to improve the proposed exception for ESRD facilities that exceed the 4,000-treatment volume threshold due to treating patients displaced by a disaster or other emergency. We note that § 413.232(e) currently states that "to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section," except as otherwise specified. We did not propose to change the attestation deadline for ESRD facilities impacted by a disaster or other emergency. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a yearly November 1st deadline for attestation submission, and noted that this timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria. It is important that all ESRD facilities have the same attestation deadline for the LVPA to allow adequate verification time for the MACs and so that those ESRD facilities eligible for LVPA are able to receive it timely. In the past when we have extended the LVPA attestation deadline, we have done so for all ESRD facilities (85 FR 71442). However, we believe that a November 1st deadline is necessary so that the LVPA attestations can be properly processed, and payments can begin on January 1st of the next CY. In response to the concern for ESRD facilities which are impacted by a disaster late in the year, we are modifying the proposed regulation language at § 413.232(g)(5) to allow an ESRD facility to request the exception to the 4,000-treatment volume threshold requirement up to 30 days after the end of the cost reporting year for which they are attesting. Although the ESRD facility would still have to submit an attestation by the November 1st deadline, this will allow additional flexibility for ESRD facilities that experience temporary patient shifting late in the year if their cost-reporting year ends within 30 days of the attestation deadline. We clarify that under this exception, an ESRD facility would have to submit the exception request by either the attestation deadline or 30 days after the end of the ESRD facility's cost reporting year, whichever is later, but would not be required to have received the exception by the attestation deadline. Then, in the event that the

ESRD facility does not receive approval for the exception from CMS, the MAC would follow the current process. Specifically, as noted in § 413.232(h)(2), if the MAC determines an ESRD facility does not meet the definition of a low-volume facility, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

Comment: A coalition of dialysis organizations requested that the exception to the attestation process for ESRD facilities that treat displaced patients be extended to ESRD facilities that treat displaced patients from ESRD facilities that closed for reasons not related to a disaster or other emergency. This commenter noted that between 2020 and 2023, 383 ESRD facilities closed, which impacted an estimated 21,000 patients.

Response: At this time, we do not agree that it is appropriate to allow ESRD facilities to exceed the LVPA treatment volume threshold due to treating displaced patients from ESRD facilities that close for reasons unrelated to disasters or other emergencies. If an ESRD facility closes due to a disaster or other emergency, the ESRD facility could re-open or another ESRD facility could open in its place, which would lead to the accepting ESRD facility returning to a lower treatment volume. However, if an ESRD facility closes for reasons unrelated to a disaster or other emergency, such as lack of demand or profitability, it is less likely that the ESRD facility would re-open or that a new ESRD facility would replace it. Additionally, implementing this commenter's suggestion could lead to perverse incentives. For example, an ESRD facility that does not receive the LVPA and closes temporarily has its patients receive treatment at another affiliated ESRD facility, which usually receives the LVPA (and therefore, a higher payment rate). If the commenter's suggestion were to be implemented, with the influx of new patients, the "accepting" ESRD facility could strategically surpass the 4,000-treatment level and still receive the LVPA.

Final Rule Action: We are finalizing our proposals to establish an exception process to allow a facility to close and reopen in response to a disaster or emergency and still receive the LVPA, and to allow a facility to receive the LVPA even if it exceeds the LVPA threshold if its

treatment counts increase due to treating additional patients displaced by a closure or operational disruption caused by a disaster or other emergency, as proposed, with two modifications. First, as noted above, we are finalizing one modification to § 413.232(g)(5)(ii) to change the deadline by which the ESRD facility must request the exception to § 413.232(b)(1) to be the later of the attestation deadline or 30 days after the end of the cost reporting year for which the ESRD facility is attesting. Specifically, we are finalizing § 413.232(g)(5) which states that if an ESRD facility exceeds the 4,000-treatment volume threshold due to temporary patient shifting from an ESRD facility that experiences a closure or operational disruption due to a disaster or other emergency, the accepting ESRD facility would be able to apply for an exception to the requirement at 413.232(b)(1) and, if the exception is approved, the ESRD facility would not be disqualified from receiving the LVPA on the basis of 413.232(b)(1) due to exceeding the 4,000-treatment volume threshold in that cost reporting year. The deadline for requesting this exception would be either the attestation deadline or 30 days after the end of the cost reporting year for which the ESRD facility is attesting, whichever is later. We are finalizing a definition of temporary patient shifting in the context of the ESRD PPS LVPA as providing renal dialysis services to one or more patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). We are finalizing a second modification of the proposed regulation text at § 413.232(g)(5)(iv) to indicate that we will not limit the LVPA payment to 4,000 treatments for the payment year in which the temporary patient-shifting occurred due to a disaster or other emergency. We proposed that if an exception is approved under § 413.232(g)(5), the ESRD facility would be paid the low-volume adjustment on claims for Medicare beneficiaries for up to the first 4,000 dialysis treatments during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. The intent of this proposed limit was to support stability of payments for ESRD facilities experiencing temporary patient-shifting due to an emergency at a level commensurate with their

historical treatment volumes, while protecting the Medicare program against the risk of paying the LVPA for a large number of treatments. After further consideration of the operational and payment implications of this policy, we are making this change to be consistent with our historical practice of not limiting payment of the LVPA in the year in which the LVPA threshold is exceeded. We are concerned that limiting LVPA payment to 4,000 treatments for facilities would create operational confusion for facilities and could limit the ability of these ESRD facilities to take on patients who are displaced by a disaster or emergency. Furthermore, we considered that low-volume ESRD facilities generally receive the LVPA on fewer than 4,000 treatments per year, since the 4,000 treatment threshold includes all treatments that the facility provides. We therefore do not believe it is necessary to apply the proposed limit, since ESRD facilities operating under an exception would be unlikely to exceed 4,000 treatments paid under the ESRD PPS. We intend to monitor the use of these new exceptions to ensure that they are being applied appropriately and do not create opportunities for gaming.

Additionally, we are finalizing § 413.232(g)(6), which states that if an ESRD facility has closed and reopened in response to a disaster or other emergency, it would be able to apply for an exception to the requirement at 413.232(b)(2) and, if the exception is approved, the ESRD facility would not be disqualified from receiving the LVPA on the basis of 413.232(b)(2) due to closing in that year. The deadline for requesting this exception is 60 days after ESRD facility's closure.

(4) Technical Correction to § 413.232(g)

We proposed a technical correction at § 413.232(g) to replace "their" with "its," to clarify the regulation language.

Final Rule Action: We did not receive comments regarding the technical correction to the regulations text for the LVPA, and we are finalizing this revision as proposed.

g. Transitional Pediatric ESRD Add-on Payment Adjustment for Pediatric Patients with ESRD Receiving Renal Dialysis Services

(1) Background

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, including a payment adjustment for pediatric providers of services and renal dialysis facilities. Determining such a payment adjustment has been historically difficult due to the consistent lack of data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population, representing approximately 0.14 percent of the total ESRD patient population in 2022. In the past, CMS has considered various payment adjustments for pediatric patients with ESRD, including different Medicare payments by sex or comorbidities (74 FR 49984 through 49986). However, many of these considered adjustments were not used as we were unable to get acceptable precision due to the small sample size of pediatric patients with ESRD.

Prior to the establishment of the ESRD PPS, payment for pediatric ESRD renal dialysis services was generally the same rate as adult ESRD renal dialysis services, unless the ESRD facility qualified for an exception to the composite rate. Section 1881(b)(7) of the Act stated that, subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA), the Secretary shall provide for exceptions as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). During this time, CMS received many comments and concerns regarding the payment rate for renal dialysis services furnished to pediatric patients with ESRD. Section 623(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) later amended section 422(a)(2) of BIPA to provide that any pediatric ESRD facility would be eligible for an exception to the composite rate, effective October 1, 2002. This statute defined pediatric ESRD facilities as facilities with at least 50 percent patients under the age of 18. This enabled pediatric ESRD

facilities to obtain payments that specifically recognized the higher cost associated with treating these patients (69 FR 47530).

We finalized a basic case-mix adjustment to the composite payment rate in the CY 2005 Physician Fee Schedule (PFS) final rule published on November 15, 2004 (69 FR 66327). This included a 62 percent pediatric payment increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility when furnishing outpatient renal dialysis services to pediatric patients with ESRD. This factor was derived from the average exception amounts for 20 ESRD facilities that had received exceptions for pediatric patients. This was intended to be a temporary measure, which would be eliminated once we developed the case-mix methodology that would apply for the ESRD PPS bundled payment. The use of this methodology allowed CMS to provide additional payment for the pediatric ESRD population under the composite rate in a data-driven manner to account for the higher costs pediatric patients faced (69 FR 66327).

Section 153(b) of MIPPA added section 1881(b)(14) of the Act, which required CMS to implement an ESRD bundled PPS beginning January 1, 2011, under which a single payment for renal dialysis services is made in lieu of any other payment. Renal dialysis services generally include items and services included in the composite rate for renal dialysis services as of December 31, 2010, and services furnished to individuals for treatment of ESRD, which were formerly separately billable, including drugs and biological products and laboratory tests. In the CY 2011 ESRD PPS proposed rule, we proposed a single composite rate modifier of 1.199 for all Pediatric ESRD Patients receiving dialysis (74 FR 49982 through 49983). A "Pediatric ESRD Patient" is defined as an individual less than 18 years of age who is receiving renal dialysis services (§ 413.171). We also proposed an eight-group system for separately billable renal dialysis services furnished to Pediatric ESRD Patients with two subdivisions for each of the following factors: age (under 13, 13 to 17), modality (hemodialysis, peritoneal dialysis) and number of comorbidities (none, one or more) (74 FR 49983 through 49987). The CY 2011

ESRD PPS proposed rule then calculated an "expanded bundle" modifier, which combined the composite rate and separately billable modifiers for each of the eight groups (74 FR 44987). These expanded bundle modifiers were the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. These modifiers were based on a regression of costs for all renal dialysis services furnished to Pediatric ESRD Patients. Comments on this proposed rule indicated that many interested parties believe the expanded bundle modifier was insufficient (75 FR 49128). In the CY 2011 ESRD PPS final rule, we responded to those comments by implementing the first iteration of the current four-group system for both the expanded bundle and the separately billable services. This methodology was data driven, but unlike the simple regression for composite rate costs, allowed for different Medicare payment amounts based on two sets of two characteristics: age of the patient (under 13 or 13 to 17) and modality of the treatment (hemodialysis or peritoneal dialysis). Additionally, this methodology used the same groups for the expanded bundle and separately billable modifiers (75 FR 49134).

We codified the Pediatric ESRD Patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality. These multipliers were updated in the CY 2016 ESRD PPS final rule using the same methodology (80 FR 69001 through 69002). The current expanded bundle case mix adjusters are presented in Table 7.

TABLE 7: Current Pediatric ESRDB Payment Modifiers

Current Pediatric ESRD Expanded Bundled Payment Modifiers by Age and Modality (Effective 1/1/2016)		
Age	**<13**	**13-17**
Hemodialysis	1.306	1.327
Peritoneal Dialysis	1.063	1.102

As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42449), despite these changes intended to improve payment accuracy for renal dialysis services furnished to Pediatric

ESRD Patients, we continue to receive comments and concerns from interested parties that the payment amounts for renal dialysis services furnished to Pediatric ESRD Patients are too low. In addition to comments received through the annual ESRD PPS rulemaking, we have also solicited comments from interested parties on several occasions. During the December 2020 TEP, we queried a panel of experts on how to improve payment for pediatric dialysis care under the ESRD PPS. Panelists[18] generally preferred creating more refined case-mix adjusters over creating an entirely new pediatric ESRD PPS, citing the costs of creating an entirely new system both on CMS and the ESRD facilities and the need for new legislation to be able to increase payment through a separate pediatric ESRD PPS. Panelists also pointed to labor costs as a major reason for higher costs among pediatric dialysis clinics because these patients need more nursing attention and specialized pediatric nutritionists.

We noted that, in the CY 2023 ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding health equity for pediatric patients with ESRD. Many commenters asserted that Medicare payments for Pediatric ESRD Patients are too low and that the ESRD PPS bundled payment does not target the unique issues facing ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

As we explained in the CY 2024 ESRD PPS proposed rule, we are committed to improving health equity for Pediatric ESRD Patients receiving renal dialysis services by improving payment equity through more efficient Medicare payments. Ensuring Medicare payments are appropriate and reflect costs for renal dialysis services furnished to Pediatric ESRD Patients would allow more ESRD facilities to provide quality care to this vulnerable population. The main barrier to payment equity is the lack of sufficient data to determine the relative costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. To improve payment rate accuracy for Pediatric ESRD Patients, CMS has issued changes to the cost reports

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

for both freestanding ESRD facilities and hospital-based ESRD facilities effective January 1, 2023.[19,20,21] These changes include separate categories for labor and supplies used in furnishing renal dialysis services to Pediatric ESRD Patients. These updates are intended to provide data for CMS to more comprehensively estimate the additional costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. However, we estimated it would take approximately 3 years to obtain and analyze the granular data provided by the stratified cost reports data from these changes that we need to consider proposing a more finely tuned payment adjustment.

(2) Alternative Methodology for Estimating Relative Costs for Furnishing Renal Dialysis Services to Pediatric ESRD Patients

As discussed in the CY 2024 ESRD PPS proposed rule, payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of Pediatric ESRD Patients receiving renal dialysis services paid for under the ESRD PPS. Pediatric ESRD dialysis treatments are also furnished differently from adult ESRD dialysis treatments in several crucial ways. For example, pediatric ESRD facilities are more likely to be hospital-based and, on average, have lower treatment volume and are in higher wage index areas. These systematic differences in treatment, when combined with the small sample size, make it very difficult to obtain low variance estimates of the differences in costs between pediatric and adult ESRD dialysis patients. Even if simple cost models show statistically significant estimates, it is possible that the systematic differences between pediatric and adult ESRD facilities can bias these estimates. Obtaining a reliable estimate of the additional costs that Pediatric ESRD Patients incur would allow us to create a payment adjustment to bring relative Medicare payments more in line with relative costs.

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[19] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242.
[20] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i.
[21] 87 FR 26760 (May 5, 2022). https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-activities-submission-for-omb-review-comment-request.

One can account for this bias by selecting a specific sample of ESRD facilities that have similar characteristics except for proportion of dialysis treatments furnished to Pediatric ESRD Patients. This would help to show the additional costs of furnishing dialysis to Pediatric ESRD Patients based on the variation in costs across the ESRD facilities. To achieve this, we would use propensity score matching (PSM).

PSM is a technique that uses regression analysis to account for systematic differences between two populations to isolate the effects of a single variable, in this case percentage of Pediatric ESRD Patients. The PSM regression includes a wide range of ESRD facility-level characteristics including facility type, size, geographic location, and the pediatric ESRD dialysis population nearby the ESRD facility to make a propensity score. This propensity score represents the probability that a given ESRD facility treats a high volume of Pediatric ESRD Patients given its facility-level characteristics.

Once the propensity score for each ESRD facility is determined, each ESRD facility with a significant percentage of Pediatric ESRD Patients (high-pediatric) is matched with the ESRD facility without a significant percentage of Pediatric ESRD Patients (low-pediatric) with the most similar propensity score. We can then compare the relative per-treatment costs of those ESRD facilities to estimate the additional costs an ESRD facility faces when it furnishes renal dialysis services to a higher proportion of Pediatric ESRD Patients, controlling for some important facility-level characteristics. The dependent variable of this regression is the log of the cost per treatment for the ESRD facility. The independent variables are the percent of dialysis treatments that are furnished to Pediatric ESRD Patients, the log of the facility size, the type of ESRD facility (hospital-based, children's hospital-based or freestanding), the log of the wage index for the ESRD facility and the year for the cost report data. The regression equation for cost per treatment given a certain percentage of dialysis treatments furnished to Pediatric ESRD Patients is:

$$\text{Log}\left(\frac{\text{Cost}}{\text{Treatment}}\right) = \text{Pediatric Share} + \log(\text{Facility Size}) + \text{Hospital Type} + \log(\text{wage Index}) + \text{Year Indicator}$$

This cost regression should be unbiased due to the use of PSM. However, PSM also requires a reduction in sample size, because there are relatively few ESRD facilities with a significant number of treatments furnished to Pediatric ESRD Patients that could be matched using PSM. This smaller sample size inherently results in an increase in margin of error. We stated that we believe this is a necessary tradeoff because a biased estimate cannot be relied upon, but we must be cautious while using high-error estimates. The result of this regression is that ESRD facilities that solely serve Pediatric ESRD Patients incur costs that are 40 percent higher per patient for furnishing renal dialysis services than similar ESRD facilities that serve no Pediatric ESRD Patients. The confidence interval of this estimate is 20 percent to 60 percent. Therefore, on average, furnishing renal dialysis services to a Pediatric ESRD Patient costs 40 percent more than furnishing renal dialysis services to an adult patient with ESRD.

(3) Current Medicare Payments for Renal Dialysis Services Furnished to Pediatric ESRD Patients

As discussed in the CY 2024 ESRD PPS proposed rule, the ESRD PPS already accounts for some of the higher costs that ESRD facilities incur while furnishing renal dialysis services to Pediatric ESRD Patients through the case-mix adjusters. Because the analysis described previously uses cost report data, it does not incorporate either the current case-mix adjusters or payment rates for Pediatric ESRD Patients receiving renal dialysis services. We noted that our most recent estimates showed that payments for dialysis treatments furnished to Pediatric ESRD Patients were approximately 10 percent higher than for adult patients with ESRD in CY 2022.

We explained that we are striving for payment accuracy, which is achieved when relative Medicare payments are proportional to relative costs. There are several ways we could adjust ESRD PPS payments to achieve payment accuracy, including calculating the unaccounted-for cost differential, which is the amount by which ESRD PPS payments for pediatric ESRD renal dialysis services must be increased to achieve payment accuracy. We could do this by reducing the cost differential estimate of 40 percent by a factor 1.1 to account for the current payment

differential of 10 percent. This would yield an unaccounted-for cost differential of approximately 30 percent (1.4 divided by 1.1 is 1.27 which we are rounding to 1.3). This is a reasonable estimate of the additional labor and supply costs, which are not accounted for by the current case-mix adjusters, incurred by ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

(4) Transitional Pediatric ESRD Add-on Payment Adjustment

As we stated in the CY 2024 ESRD PPS proposed rule, despite the high margin of error of the cost regression using PSM, we believe that 30 percent cost is the most reasonable estimate of the unaccounted-for costs incurred in treating Pediatric ESRD Patients compared to adult ESRD patients. Creating a new add-on payment adjustment using this figure would provide pediatric ESRD facilities with Medicare payments proportional to their estimated costs for a temporary period while we collect additional data. However, due to the high margin of error of the model, increasing Medicare payments to ESRD facilities such that payments are 40 percent higher for Pediatric ESRD Patients compared to all patients would risk making payments higher than appropriate. We noted that when we conduct the analysis with the more comprehensive cost report data provided by the cost report changes implemented for CY 2023, we might find that our analysis overestimated the cost of furnishing renal dialysis services to Pediatric ESRD Patients (that is, that the additional 30 percent payment adjustment was too large). We further stated that if we finalized the transitional add-on payment adjustment for Pediatric ESRD Patients as proposed, pediatric ESRD facilities should be prepared for the possibility that the payment rate for Pediatric ESRD Patients could decrease in the future, should that be indicated by future data analysis and finalized through notice-and-comment rulemaking. We discussed the alternative to propose a smaller, more cautious add-on payment adjustment based on the 20 percent lower bound of the confidence interval, leading to an additional 10 percent transitional add-on payment adjustment after accounting for the current payment rate. This option would still represent a significant increase in Medicare payments to ESRD facilities for

Pediatric ESRD Patients without much risk of making payments higher than appropriate. However, this alternative option may lead to underpayment to ESRD facilities serving Pediatric ESRD Patients, which is contrary to our goal of aligning resource use with payment. We invited comments on the most appropriate amount for the proposed transitional add-on payment adjustment.

We proposed in the CY 2024 ESRD PPS proposed rule a new transitional add-on payment adjustment of 30 percent (adjustment factor of 1.3) for dialysis treatments furnished to Pediatric ESRD Patients for 3 CYs, effective January 1, 2024. We stated that based on the time lag for cost report data, 3 years should allow for enough time for CMS to get more detailed data from the changes to the cost reports described previously. After that period, we would evaluate the more comprehensive cost report data from the first year of cost reporting periods beginning on or after January 1, 2023, to refine our methodology for determining the payment rate for pediatric ESRD dialysis. As proposed, this would be a separate, additional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230, which reflects the other patient and facility level adjustments. This adjustment would not be part of the case-mix adjusters. This payment adjustment would only apply to the ESRD bundled payment and not to any outlier adjustments. Due to the multiplicative nature of the case-mix adjusters it would function similarly to a 30 percent increase to the expanded bundle case-mix adjusters. For comparison, the effective case-mix adjusters are presented in Table 8.

TABLE 8: Pediatric ESRDB Effective Payment Modifiers

Pediatric ESRDB Effective Payment Modifiers by Age and Modality				
Age	**Modality**	**Current Case- Mix Adjuster (Effective 1/1/2016)**	**30% Increase Effective Case- Mix Adjusters**	**Alternative 10% Increase Effective Case-Mix Adjusters**
<13	PD	**1.063**	1.382	1.169
<13	HD	**1.306**	1.698	1.437
13-17	PD	**1.102**	1.433	1.212
13-17	HD	**1.327**	1.725	1.460

We noted that the exact magnitude of the increase in payment would vary based on the age of the patient and the wage index of a given area; we estimated approximately $80 for (hemodialysis-equivalent) peritoneal dialysis treatments and $100 for hemodialysis treatments. This would represent a substantial increase in payment for renal dialysis services furnished to Pediatric ESRD Patients and would account for the extra costs that this population incurs temporarily until additional cost data is available. This payment adjustment would apply for all dialysis treatments furnished to ESRD patients under the age of 18, not solely treatments furnished in pediatric ESRD facilities. This is warranted because many of the additional costs related to the treatment of Pediatric ESRD Patients are not specific to treatments furnished in pediatric ESRD facilities.

We proposed to call this the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) and make this adjustment budget neutral. We explained that, in general, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be budget neutral under the ESRD PPS, but we stated that we believed in this instance that budget neutrality is appropriate, due to the way this adjustment is derived. We noted that other non-budget neutral add-on payment adjustments that we have established under this authority generally account for costs that were not used for the construction of the ESRD PPS bundled payment, such as the TDAPA for calcimimetics (80 FR 69013 through 69027). We explained that we have also established certain non-budget neutral add-on payment adjustments for items or services that were not commonplace, and therefore not adequately represented in cost reports, such as home dialysis training (75 FR 49063). However, we noted that we have implemented other payment adjustments under this authority in a budget neutral manner; for example, the changes to the wage index in the CY 2023 ESRD PPS final rule were implemented in a budget neutral manner as they represented a shifting of cost allocations, rather than new costs not originally included in the ESRD PPS bundled payment (87 FR 67157). We stated that this TPEAPA is primarily for costs that 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. We explained that the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. Therefore, we explained, it would be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. Furthermore, we stated that any changes to the case-mix adjustments are required by section 1881(b)(14)(A)(ii) of the Act to be budget neutral, which means that any future modifications to the pediatric case-mix adjusters would be budget neutral. The proposed budget neutrality adjustment factor for the proposed TPEAPA consisting of 30 percent of the per treatment payment amount was 0.999532. We explained that applying this budget neutrality factor to the proposed ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated $0.12. We stated that under the alternative 10 percent TPEAPA discussed in the proposed rule (88 FR 42464), the budget neutrality factor adjustment would be 0.999847. We explained that applying this budget neutrality factor to the proposed ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated $0.04.

To establish this new TPEAPA, we proposed to amend § 413.235 by splitting current paragraph (b) into paragraphs (b)(1) and (2). Paragraph (b)(1) would set forth the established age and modality of treatment case mix adjustment methodology as currently stated in paragraph (b). Paragraph (b)(2) would state that beginning January 1, 2024, we will provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during CYs 2024, 2025, and 2026. We also proposed to revise the current language of § 413.235(b) to use the term "Pediatric ESRD Patients," which is defined at § 413.171, to improve clarity for this section.

(5) Costs and Benefits for a Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA)

As we explained in the CY 2024 ESRD PPS proposed rule, we believe CMS could better align the resource use of pediatric ESRD renal dialysis services with payment. Our analysis using the methodology outlined previously found that costs for Pediatric ESRD Patients receiving renal dialysis services are estimated to be 40 percent higher than for adult patients and that the current payment adjusters account for 10 percent higher costs. Implementing a transitional 30 percent add-on payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients would improve payment equity for these patients by increasing payments to align with the estimated costs of treatment more closely. A 30 percent increase in ESRD PPS payments for pediatric ESRD renal dialysis services would represent approximately $80 to $100 per pediatric ESRD dialysis treatment, although the exact magnitude of the increase would depend on age, modality, and the wage index of the area. This payment increase would have beneficial health equity impacts on this population by improving access to care and quality of care. Some ESRD facilities may not be able to absorb the additional expense of the Pediatric ESRD Patient population. Patients may need to travel to a limited number of primarily hospital-based ESRD facilities where pediatric ESRD dialysis is performed. As a result, this population may be underserved and disadvantaged with respect to access to ESRD care. We stated that additional payment to those ESRD facilities treating Pediatric ESRD Patients would thereby benefit this potentially underserved and disadvantaged population of Pediatric ESRD patients. Additionally, this would have a beneficial financial impact on the ESRD facilities, both pediatric and non-pediatric, that serve this pediatric population.

We proposed that this payment adjustment be budget neutral, which would lead to an estimated decrease of $0.12 to the ESRD PPS base rate, corresponding to a budget neutrality factor of 0.99954. This relatively small adjustment would represent less than a twentieth of a percent of the total ESRD PPS base rate. However, we recognized that any decrease in the ESRD PPS base rate would represent a monetary loss to ESRD facilities. As stated previously, our analysis indicated that this transfer would be reasonable given the likelihood that the

methodology used in the case-mix adjusters attributed some pediatric costs to the general population. However, we noted, should future analysis of the stratified pediatric cost data indicate that pediatric ESRD renal dialysis services costs are less than 40 percent higher than adult costs, this budget neutral decrease would mean that the treatments for adult patients with ESRD were slightly underpaid during this 3-year period. In either case there would be a risk of underpayment for one group of patients. We stated that we believe using the mean estimate of the analysis will provide us with the best approach for achieving payment accuracy while we collect additional data. Additionally, the health equity implications of potentially underpaying for Pediatric ESRD Patients receiving dialysis by 20 percent would be significantly higher than the implications of potentially underpaying for adult patients by less than 0.1 percent. We noted that in CY 2021 there were 116 ESRD facilities that furnished more than 2 percent of their dialysis treatments to Pediatric ESRD Patients, out of 7882 total ESRD facilities. These ESRD facilities are a relatively small group, but they are critical for the care of Pediatric ESRD Patients. For these reasons, we stated that we believe the expected benefits for the TPEAPA would outweigh the costs.

We explained that we believe providing this 30 percent TPEAPA for CYs 2024, 2025, and 2026 would be the best approach for improving payment accuracy until more precise data is available. However, we acknowledged that in any case there is a risk of making payments which are higher or lower than appropriate. Therefore, in the CY 2024 ESRD PPS proposed rule we requested comments on our proposal, including on (1) the alternative adjustment amount; and (2) the budget neutrality of the proposal.

We received 30 comments in response to our proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) for pediatric ESRD patients receiving renal dialysis services. Respondents included large and small dialysis organizations, non-profit organizations, an advocacy organization, a coalition of dialysis organizations, a large non-profit health system, and individual providers. The comments on our proposal and our responses are set forth below.

Comment: We received several comments that supported CMS establishing an add-on payment adjustment for pediatric ESRD patients. Most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the higher costs associated with providing for the unique care needs and specialized support required for renal dialysis services in the ESRD PPS pediatric population. Physician commenters cited the unique challenges in caring for this population that are not reflected in the current ESRD PPS payment models. Numerous commenters expressed their support for using an ESRD PPS add-on payment adjustment to improve patient access and equity among this vulnerable subpopulation of patients with ESRD. A pediatric ESRD facility noted that money invested in this population lowers avoidable adverse outcomes and complications from ESRD and facilitates a faster path towards transplantation, ultimately yielding both cost savings and healthier adults.

Response: We thank the commenters for their support and dedication to improving access and equity for the pediatric patient population with ESRD receiving renal dialysis services.

Comment: We received several comments regarding the proposed TPEAPA payment amount, calculation, and length of payment period. Most commenters supported the implementation of the 30 percent add-on payment adjustment as a reasonable estimate of the unaccounted-for costs incurred in treating pediatric ESRD patients. An LDO expressed concern that PSM does not provide for an accurate computation of the costs incurred in providing specialized pediatric care; while a pediatric nephrology society agreed that in the absence of accurate pediatric cost data, the PSM methodology seems reasonable. A pediatric nephrology society reported the 30 percent add-on to be consistent with anecdotal cost data collected by the society from around the country. An LDO urged CMS to implement a three-year period of analysis after the proposed 30 percent adjustment. Another LDO requested more transparency on the data and assumptions used to calculate the pediatric adjustment.

Response: We thank the commenters for their support and suggestions. Payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of pediatric patients receiving renal dialysis services paid for under the ESRD PPS. Obtaining reliable data on the additional costs that pediatric patients with ESRD incur would facilitate the creation of a permanent payment adjustment based on resource use to bring relative Medicare payments more in line with relative costs. We recognize that while our use of PSM unavoidably leads to larger variance in parameter estimates because only a small subset of the broader provider population is utilized in the estimation, this approach is useful because it provides a means of comparison with less biased estimates and as suggested by commenters the 30 percent estimate is in line with anecdotal data. We plan to share data and assumptions through notice-and-comment rulemaking for potential future pediatric payment adjustments to ESRD facilities.

Comment: Most commenters urged CMS to reconsider implementing the payment adjustment as a budget neutral add-on. An LDO expressed that it would be inappropriate to cut payment rates for service provided to adult patients, whose population is comprised of a significant percentage of patients from racial or ethnic minority groups, of low-socioeconomic status, and living in medically underserved areas. A health system expressed concerns that the add-on payment adjustment would shift funding away from ESRD facilities exclusively providing adult services. An LDO expressed that applying the add-on in a budget-neutral manner would effectively penalize all ESRD facilities for the inability of existing cost report data to improve payment accuracy. A nephrology society expressed concerns that while younger patients require more support, that does not mean that adults requiring dialysis require less support than they are already receiving. A non-profit dialysis association expressed that the budget neutral application of the adjustment is contrary to the Administration's stated health equity goals, because it would cut payments for one medically vulnerable group to increase payments for another medically vulnerable group.

Response: We examined the potential impact of the proposed TPEAPA as a budget neutral adjustment. As we noted in the CY 2024 ESRD PPS proposed rule, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be budget neutral under the ESRD PPS, but we believe in this instance that budget neutrality is appropriate due to the way this adjustment is derived. As explained in section II.B.1.g.(4) of this final rule, this TPEAPA is primarily for costs that 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. We explained that the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. CMS has therefore determined it to be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. We note that the adjustment would decrease the ESRD PPS base rate by a budget neutrality factor of 0.999503, a sum total of $0.14, due to the application of the budget neutrality factor. We further note that the adjustment does not rely on any assumption that resource use by adult patients has decreased over time; rather it assumes that the ESRD PPS payment rate as applied to adults has since its inception incorporated some amount of costs that were more properly attributable to treatment of pediatric ESRD patients. The TPEAPA therefore makes the ESRD PPS payment more reflective of relative costs by reallocating payments associated with those costs from the payment amounts for adults to pediatric ESRD patients.

Comment: An ESRD facility urged CMS to extend the add-on payment adjustment to pediatric AKI patients to ensure these patients receive the same additional support.

Response: We appreciate the suggestion to apply the TPEAPA to pediatric AKI patients. As we discussed in the CY 2017 ESRD PPS final rule, we have 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. Therefore, we have not historically

applied these ESRD PPS adjustments and policies to AKI payments (81 FR 77959). We did not propose to apply the TPEAPA to pediatric AKI patients for the same reason.

Comment: We received several additional comments regarding the TPEAPA implementation. Commenters suggested that CMS create and implement pediatric ESRD-specific metrics for the pediatric ESRD programs. A pediatric nephrology society requested CMS utilize means of communication such as the Medicare Learning Network to educate children's hospitals on completing costs reports. A professional nursing association urged CMS to promote a shift towards pediatric ESRD dialysis care moving towards home-based settings. The association also urged investment into the field of pediatric nephrology, as there are limited qualified health care providers and recommended the inclusion (we assume in cost reports) of pediatric nurse practitioners. The association also recommended CMS consider direct patient labor categories when determining costs for pediatrics, as there are additional training and requirements necessary for the pediatric population. As an extension of labor categories, the association noted the shortage of pediatric nephrologists and suggested that CMS include pediatric nurse practitioners who can assist in meeting the needs of the youngest and most vulnerable individuals on dialysis. These commenters did not specify how CMS should include pediatric nurse practitioners or how such inclusion would relate to the ESRD PPS bundled payment.

Response: We thank the commenters for their input. As the TPEAPA is a temporary adjustment until we can fully analyze the costs associated with pediatric dialysis, we did not include any proposals regarding shifts to home-based settings, or the inclusion of a pediatric nurse practitioner in the CY 2024 ESRD PPS proposed rule. However, as we continue to analyze how best to collect pediatric specific metrics and the payment for Pediatric ESRD Patients to facilitate future refinements, we will consider these comments for potential future ESRD PPS payment policies. We appreciate the suggestion about using Medicare Learning

Networks to educate children's hospitals on completing costs report. CMS is considering a number of options on how best to provide educational outreach on this topic.

Final Rule Action: We did not receive any comments on our proposal to revise the language of § 413.235(b) to use the term "Pediatric ESRD Patients" to improve clarity. As such we are finalizing this change as proposed. In addition, after consideration of the comments received and for reasons outlined in the CY 2024 ESRD PPS proposed rule and previously in this section of the final rule, we are finalizing our proposal to establish this new TPEAPA on a budget-neutral basis. Under our authority at section 1881(b)(14)(D)(iv) of the Act, we will adjust the per treatment base rate for Pediatric ESRD Patients to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during CYs 2024, 2025, and 2026. CMS is codifying this payment adjustment in the regulations at § 413.235(b)(2). The budget-neutrality factor for the CY 2024 TPEAPA is 0.999503. This change will be effective January 1, 2024, as proposed.

h. Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS

(1) Background

As discussed in the CY 2023 PFS final rule (87 FR 69710), many drugs and biological products that are payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for industry,[22] a single-dose container is designed for use with a single patient as a single injection or infusion. The labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the

[22] https://www.fda.gov/media/117883/download.

labeling instructs a health care provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the Medicare Part B JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs.[23,24] The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in federally qualified health centers (FQHCs) or rural health clinics (RHCs).

In the CY 2023 PFS final rule (87 FR 69718 through 69719), we codified our existing policy as discussed in the prior paragraph in Chapter 17 of the Medicare Claims Processing Manual,[25] and required that billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, beginning January 1, 2023. These changes were promulgated in connection with the implementation of the discarded drug refund program under section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021). In that same CY 2023 PFS final rule (87 FR 69722), we responded to commenters who requested we exempt

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[23] CR6603: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf.
[24] MLN Matters® Number MM9603: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm96033.pdf.
[25] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf

drugs paid for under the ESRD PPS bundled payment from the discarded drug refund policy. One commenter expressed concern regarding how implementation of the discarded drug refund might inadvertently impact ESRD products, including those used by home dialysis patients. In response to those comments, we clarified that units for drugs that are packaged under the Medicare ESRD PPS were not subject to the JW modifier policy or the discarded drug refund.

In the same CY 2023 PFS final rule, CMS also finalized a proposal to require billing providers to report the JZ modifier for all such drugs with no discarded drug amounts, beginning no later than July 1, 2023. Specifically, as discussed in the CY 2023 PFS proposed rule (87 FR 46058), we proposed to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. We stated that to align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single-dose containers or single-use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. Table 9 provides additional information about these modifiers.

TABLE 9 – JW and JZ Short and Long Descriptors

MODIFIER	**SHORT DESCRIPTOR** (28-character limit)	**LONG DESCRIPTOR**
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

We explained that on all claims for single-dose containers or single-use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We noted that we believed the JZ modifier requirement would not increase burden on the provider, because under the current JW modifier policy, the provider already needs to determine whether there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. We finalized the JZ

modifier requirement in the CY 2023 PFS final rule. Lastly, we noted in the CY 2023 PFS final rule that we would begin claims edits for both the JW and JZ modifier beginning October 1, 2023 (87 FR 69179). Additional details can be found in Chapter 17 of the Medicare Claims Processing Manual and the JW/JZ modifier frequently asked questions (FAQ) document.[26]

(2) Current Reporting of the JW Modifier under the ESRD PPS

As we discussed in the CY 2024 ESRD PPS proposed rule, the Medicare Part B JW modifier policy generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) 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. The only exception is for oral-only drugs, as defined at § 413.234(a), which are currently paid separately under Medicare Part D. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. We noted that although the ESRD PPS includes certain add-on payment adjustments such as the TDAPA and TPNIES, these are adjustments to the ESRD PPS base rate and therefore part of the single payment made under the ESRD PPS; these payment adjustments are not separate payments. For example, as described in our TDAPA implementation guidance issued August 4, 2017, and updated January 10, 2018, available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf, the methodology used to calculate the per treatment payment amount incorporates the cost of the drugs that are paid for using the TDAPA.

[26] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

Although renal dialysis drugs and biological products paid for under the ESRD PPS are not considered "separately billable" and are not subject to the general Part B JW modifier policy discussed in the prior paragraph, CMS has previously issued guidance on the use of the JW modifier on ESRD PPS claims for certain circumstances. Chapter 8, section 60.4.5.1 of the Medicare Claims Processing Manual pertains to self-administered supplies of ESAs.[27] Under current guidance, when billing for discarded amounts of drugs in accordance with the policy in chapter 17 of this manual, section 40.1, the provider must bill for discarded amounts on a separate line item with the modifier JW. The line-item date of service should be the date of the last covered administration according to the plan of care or, if the patient dies, use the date of death. More specifically, in Chapter 17, section 40.1 of the Medicare Claims Processing Manual,[28] we state that multi-use vials are not subject to payment for discarded amounts of drug or biological products, with the exception of self-administered ESAs by Method I home dialysis patients, for whom an ESRD facility furnishes and bills for renal dialysis services.[29] Current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. We noted that separate payment is not made for ESAs under the ESRD PPS; however, ESAs are eligible for outlier payments when the criteria in § 413.237 are met.

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[27] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf.
[28] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.
[29] Prior to the ESRD PPS, a Medicare ESRD beneficiary could elect to obtain home dialysis equipment and supplies from a supplier that was not a Medicare approved dialysis facility. This was referred to as Method II home dialysis. In the CY 2011 ESRD PPS final rule (75 FR 49061), we stated that all costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model, and we stated that effective January 1, 2011, all home ESRD patients would be considered Method I home patients and all Medicare payments for home dialysis services would be made to the ESRD facility.

Most recently, the March 15, 2022, Change Request[30] that established the TDAPA for Korsuva® (difelikefalin) instructs facilities to use the JW modifier to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS. We noted that based on the latest available data at the time of the CY 2024 ESRD PPS proposed rule, nearly 40 percent of the TDAPA expenditures for those drugs that were reported in 2022 represented discarded amounts reported using the JW modifier, which represented approximately $1.3 million in TDAPA expenditures for discarded amounts of difelikefalin. Overall, our analysis of Medicare claims data from 2017 to 2021 found that approximately 2 percent of ESRD PPS claims indicate discarded or unused portions of drugs or biological products through use of the JW modifier. We estimated that the total amount of unused product billed from 2017 to 2021 and paid for under the ESRD PPS is approximately $22 million.

We explained in the CY 2024 ESRD PPS proposed rule that, under our current policy, we do not reduce the single payment under the ESRD PPS for any discarded amounts of renal dialysis drugs or biological products that are reported with the JW modifier. Furthermore, when calculating any adjustments to the ESRD PPS base rate for the TDAPA or outlier payments, we include all units of renal dialysis drugs and biological products billed on the claim for which an adjustment is made, including any discarded amounts of such drugs and biological products. Additionally, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling.[31] Additionally, we explained that

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

[31] We explained in the CY 2011 PFS final rule (75 FR 73466) that we had become aware of situations where manufacturers intentionally included a small amount of overfill in drug containers, and that this overfill is provided at no extra charge to the provider. We also noted that we understood the intent of the intentional overfill was to compensate for product loss during the proper preparation and administration of a drug. We explained that ASP calculations are based on data reported by manufacturers, including ‘‘volume per item’’. Therefore, providers may only bill for the amount of drug product actually purchased and the cost that the product represents (75 FR 73467).

consistent with prior rulemaking, under our authority in section 1881(b)(14)(D)(ii) of the Act, we were adopting the average sales price (ASP) policy on overfill for purposes of calculating the outlier payment. That is, we adopted a policy to exclude overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling from consideration for the purposes of calculating outlier payments. We stated we believe the use of the ASP policy for purposes of calculating the outlier payment is appropriate because we believe overfill does not represent a cost to the ESRD facility; thus, overfill should not factor into our determination of outlier payments.

In summary, our longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units. That is, the current ESRD PPS payment policy is consistent with the broader Medicare Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling.

(3) ESRD PPS Policy for Reporting of Discarded Amounts of Renal Dialysis Drugs and Biological Products

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42464) and in section II.B.1.j of this final rule, we are undertaking analysis of ESRD PPS claims and cost report data to better understand the patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries. We stated in the proposed rule that in considering potential refinements to the ESRD PPS case-mix adjustments in the future, it is important to understand and have consistent data about the costs associated with the quantities of the renal dialysis drugs and biological products that are used by ESRD beneficiaries. This is consistent with our longstanding policy principles, which are reflected by our policy for billing for unused amounts of renal dialysis drugs and biological products under the ESRD PPS. 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. We noted that any billing system changes to effectuate this change needed to be made as soon as possible, as this requirement had been in effect since the ESRD PPS began in 2011. This policy is also discussed in the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 11, section 20.3.C.[32]

Consistent with our longstanding billing policies for unused amounts of drugs and biological products and consistent with the requirements for the uniform use of the JW modifier for all claims for separately payable drugs under Part B since 2017, to more effectively identify and monitor billing and payment for discarded amounts of drugs, in the CY 2024 ESRD PPS proposed rule, we proposed to require ESRD facilities to report accurate and consistent data about discarded amounts of single-dose renal dialysis drugs and biological products paid under the ESRD PPS. Further, section 1881(b)(2)(B) of the Act requires the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by ESRD facilities in furnishing renal dialysis services to beneficiaries with ESRD, and to determine payment amounts for Part B services furnished by such ESRD facilities.

We noted that, under our longstanding policy, payment is made under the ESRD PPS bundled payment for discarded amounts of renal dialysis drugs and biological products, and such discarded amounts are included in the calculation of the ESRD PPS base rate and any applicable adjustments, such as the TDAPA and the outlier adjustment. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final rule for separately payable Part B drugs, we proposed to require that beginning no later than

[32]https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf

January 1, 2024, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We also proposed that ESRD facilities must document any discarded amounts in the beneficiary's medical record. Additionally, we proposed to require ESRD facilities to report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2024. We proposed to codify these reporting requirements in regulation at § 413.198(b)(5) and (6).

We proposed the amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is administered would be billed on one line (reflected as billing units in the unit field) and any discarded amounts would be billed on a separate line with the JW modifier (reflected as billing units in the unit field). If a renal dialysis drug or biological product from a single-dose container or single-use package is administered and there are no discarded amounts, then we proposed that a single line would be billed on the claim form with the JZ modifier and the billing units in the unit field. Therefore, on all claims for renal dialysis drugs and biological products from single-dose containers or single-use packages payable under the ESRD PPS, we proposed that either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We proposed that claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as un-processable until claims are properly resubmitted.[33] We also stated that if this proposal is finalized, CMS would

[33] Under the basic requirements for all claims at § 424.32(a)(1), a claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions. Chapter 1 of the Medicare Claims Processing Manual, section 70.2.3.1 states that submissions that are found to be incomplete or invalid are returned to the provider (RTP).

publish information about which HCPCS codes would be identified as single-dose containers or single-use package renal dialysis drugs and biological products subject to required reporting of the JW or JZ modifier. We also stated that we would plan to issue guidance regarding additional operational considerations and billing instructions specific to the reporting requirements for these products.

We further clarified that, under our proposal, ESRD facilities would not be required to document in the beneficiary's medical record when there are no discarded amounts. We reiterated in the CY 2024 ESRD PPS proposed rule that, as discussed in the CY 2023 PFS final rule (87 FR 69722), units for renal dialysis drugs and biological products that are bundled under the Medicare ESRD PPS would not be subject to the Medicare Part B discarded drug refund program and would continue to be exempted from the Medicare Part B discarded drug refund. We also clarified that for any oral-only drugs, as defined in § 413.234(a), to the extent that any such drugs are produced in single-dose containers or single-use packaging, this proposed reporting requirement would not apply until such drugs are paid for under the ESRD PPS.

We stated that we believe this reporting requirement would enable CMS to obtain more reliable information about the extent to which the costs of providing renal dialysis drugs and biological products represent amounts that beneficiaries use as well as amounts that are discarded. We explained that we believe this is particularly important because under Medicare Part B, beneficiaries are responsible for paying a 20 percent coinsurance. As noted previously, nearly 40 percent of TDAPA expenditures in CY 2022 represented discarded amounts of renal dialysis drugs and biological products. Medicare beneficiaries, therefore, paid approximately $260,000 in copayments for these discarded amounts. While this currently represents a small amount of payments overall, the cost for discarded renal dialysis drugs and biological products is borne by a very small population of beneficiaries. We stated that it is important for CMS to understand the full scope of expenditures, including expenditures that may be incurred by beneficiaries, for discarded amounts of renal dialysis drugs and biological products in the future,

which may be more expensive or more widely used than the current drug that is being paid for using the TDAPA under the ESRD PPS. Thus, we did not propose in the CY 2024 ESRD PPS proposed rule to alter payments to ESRD facilities based on the amounts of discarded renal dialysis drugs and biological products reported, but noted that data collected through adoption of the JW and JZ modifier reporting requirements discussed in that section of the proposed rule may inform future payment policies, which would be proposed through future notice and comment rulemaking if appropriate.

Based on our analysis of ESRD PPS claims, as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we stated that we believe the JW modifier requirement reflects current practices for ESRD facilities and would not significantly increase burden for ESRD facilities. Additionally, we stated that we believe the JZ modifier requirement would not increase burden on ESRD facilities, because under the current guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Furthermore, we noted that while renal dialysis drugs and biological products that are paid under the ESRD PPS are not considered separately payable, ESRD facilities are permitted to bill and receive separate payment using the AY modifier for drugs and biological products that are not related to the treatment of ESRD. Although we noted that renal dialysis drugs and biological products paid under the ESRD PPS are not subject to the Medicare Part B drug refund program or the current JW or JZ reporting requirements, any separately payable drugs, or biological products that ESRD facilities bill for using the AY modifier would be subject to such policies under Medicare Part B. Therefore, we explained that we believe most ESRD facilities should already be reporting the JW and JZ modifiers in such circumstances and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well. We

invited comments on this assumption and on the proposed JW and JZ reporting requirements for the ESRD PPS.

We received public comments on our proposal to require the reporting of the JW and JZ modifiers on ESRD PPS claims. The comments on our proposal and our responses are set forth below.

Comment: Several commenters raised concerns about the lead time needed to operationalize the proposed changes to report the JW and JZ modifiers on ESRD PPS claims. Commenters expressed that a minimum of six months after the publication of detailed guidance would be needed to reprogram systems and train staff to comply with the proposed requirements. Other commenters noted that, especially for independent ESRD facilities, a longer lead time of one year may be appropriate. Specifically, commenters expressed that ESRD facilities would need to implement extensive changes to their policies and procedures, including aligning information from numerous independent medical record systems, and that such activities could not begin in earnest until detailed guidance about these reporting requirements is available. Several commenters urged CMS to commit to publishing guidance by January 1, 2024, and to modify the effective date of the proposed JW and JZ modifier reporting requirement to begin no earlier than January 1, 2025.

Response: We thank commenters for their detailed comments regarding the operational changes needed to comply with the proposed reporting requirement. As commenters pointed out, although ESRD facilities may have processes in place to track amounts of discarded drugs, these processes may not be uniformly applied to all drugs. We recognize the importance of providing ESRD facilities the appropriate amount of time to adjust systems and train staff to expand the scope of drugs to which existing processes are applied. In light of the operational needs that commenters described, we are modifying the effective date of this reporting requirement to begin January 1, 2025, instead of January 1, 2024. Commenters indicated that for certain independent facilities, 1 year would provide sufficient time to train staff and update

systems as needed to comply with the reporting requirements we are finalizing in this final rule. We believe extending the effective date of the requirement by 1 year strikes an appropriate balance between the need to collect this data and ESRD facilities' need to make operational changes. We intend to publish detailed operational guidance regarding this requirement no later than January 1, 2024.

Comment: Many commenters stated that although they understand and agree with CMS's need to better understand patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries, they did not agree that the proposed collection of information about the JW and JZ modifiers on claims was appropriate or relevant. Several commenters expressed their belief that Medicare beneficiaries do not incur additional coinsurance for renal dialysis drugs and biological products that are paid under the ESRD PPS bundled payment, and therefore information about discarded amounts would not be relevant to ESRD PPS payment. Several commenters encouraged CMS to withdraw the proposed reporting requirement.

Response: We appreciate the concerns raised by commenters. We are not withdrawing the proposed reporting requirement. We do not agree with the commenters' assertion that discarded amounts of renal dialysis drugs and biological products paid under the ESRD PPS have no impact on payment, or that Medicare beneficiaries do not incur additional coinsurance for such discarded amounts. As we discussed in the CY 2024 ESRD PPS proposed rule, certain ESRD PPS payment adjustments, specifically the outlier adjustment and the TDAPA, are dependent upon the amount of renal dialysis drugs and biological products billed on an ESRD PPS claim. For renal dialysis drugs and biological products from single-dose containers or single-use packaging which are eligible for such payment adjustments, discarded amounts contribute directly to increased ESRD PPS payment as well as increased beneficiary copays. Furthermore, because the ESRD PPS base rate includes payment for renal dialysis drugs and biological products, discarded amounts of renal dialysis drugs and biological products from

single-dose containers and single-use packaging contribute to overall increases in the ESRD PPS base rate and the amount of beneficiary coinsurance.

Comment: Several commenters expressed concerns about the application of the proposed reporting requirements for home dialysis patients and for any oral-only drugs from single-dose containers or single-use packaging that may, after January 1, 2025, be paid under the ESRD PPS. Commenters expressed concern about ESRD facilities' ability to accurately document the discarded amounts of such drugs and biological products that are not administered at the ESRD facility. One commenter noted that CMS's current policy applies to a very limited number of patients and ESAs, but the proposed expansion of this policy could apply to a broader range of ESAs, calcimimetics, intravenous iron, and more products. The same commenter noted that most home dialysis patients use multi-use vials, to which the current JW requirement does not apply. Commenters urged CMS to exempt oral-only drugs and renal dialysis drugs and biological products used by home dialysis patients from the proposed reporting requirements or clarify that ESRD facilities can report the amount of such drugs in good faith.

Response: We thank commenters for their detailed comments regarding the applicability of the proposed reporting requirement for renal dialysis drugs and biological products paid under the ESRD PPS that are administered outside of an ESRD facility. Consistent with our longstanding policy discussed in the CY 2016 ESRD PPS final rule (80 FR 69033), 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. Accordingly, with respect to reporting discarded amounts of renal dialysis drugs and biological products that are administered to home dialysis patients and oral forms of renal dialysis drugs and biological products, ESRD facilities should use the best information they have in determining the amount expected to be discarded in a given month, including fill information from the pharmacy and the patient's plan of care. Consistent with current guidance in Chapter

17, section 40.1 of the Medicare Claims Processing Manual, ESRD facilities must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. In response to the commenter's statement about the use of multi-use vials by home dialysis patients, we are reiterating that discarded amounts should only be reported for drugs and biological products from single-dose containers or single-use packaging. ESRD facilities should not report discarded amounts of renal dialysis drugs or biological products from multi-use vials. Discarded amounts of renal dialysis drugs and biological products from multi-use vials should not be billed on ESRD PPS claims.

Comment: Many commenters requested that CMS provide additional clarity about how information about discarded drug amounts may be used in the future to inform payment policy. Commenters pointed out that packaging for drugs and biological products is controlled by manufacturers and FDA, rather than by ESRD facilities, and expressed concern that data collected under this proposed reporting policy would be used in the future to reduce ESRD PPS payments. Commenters stated that ESRD facilities are already incentivized, by the nature of the ESRD PPS, to minimize the amount of discarded renal dialysis drugs and biological products to the extent possible. One commenter stated that the underlying issue of waste can only be solved by holding the manufacturers responsible. Some commenters requested clarification on whether CMS intends to apply penalties for non-compliance with the JW and JZ modifier reporting requirements.

Response: As we noted in the CY 2024 ESRD PPS proposed rule, we did not propose any reduction to ESRD PPS payments based on the amounts of discarded renal dialysis drugs and biological products reported using the JW modifier. As we noted in the CY 2024 ESRD PPS proposed rule, we intend to analyze information about discarded amounts in the broader context of changes to the ESRD PPS case-mix adjustments and may propose changes in future

rulemaking if appropriate. We appreciate and agree with commenters' assertions that ESRD facilities have limited control over the amount of discarded renal dialysis drugs and biological products, and that ESRD facilities are required to discard any remaining amounts from a single-dose container or single-use packaging that are not used by the patient. As we discussed in the CY 2024 ESRD PPS proposed rule, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling. We recognize that manufacturers of renal dialysis drugs and biological products are ultimately responsible for decisions about packaging, which drive the magnitude of discarded amounts. As some commenters noted, current provisions at §§ 414.902 and 414.940, which require refunds from manufacturers for discarded amounts of drugs, apply only to separately payable drugs and biological products and do not apply to drugs and biological products paid for under the ESRD PPS. We believe that collecting more complete information about discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging will help CMS to more fully evaluate the impact that such discarded amounts have on both Medicare payments and beneficiary copayments.

Lastly, we are reiterating that we are not applying any penalties for noncompliance with this reporting requirement for discarded amounts; however, as we noted in the CY 2024 ESRD PPS proposed rule (88 FR 42455), claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as un-processable until the claims are properly resubmitted.

Final Rule Action: We are finalizing the proposed reporting requirement for discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging, with a modified effective date of January 1, 2025. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final

rule for separately payable Part B drugs, we are finalizing that beginning no later than January 1, 2025, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We are also finalizing that ESRD facilities must document any discarded amounts in the beneficiary's medical record. Additionally, we are finalizing that ESRD facilities must report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2025. We are finalizing a modification to the proposed regulation text to clarify that for renal dialysis drugs and biological products from single-dose containers and single-use packaging that are administered to home dialysis patients or that are oral forms of renal dialysis injectable drugs, the ESRD facility should report the amount of such drugs and biological products expected to be discarded. We are finalizing our proposal to codify these reporting requirements in regulation at § 413.198(b)(5) and (6), with changes to indicate that the January 1, 2025, effective date applies to each of these requirements.

i. New Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

(1) Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at § 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed

since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done to add new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available, so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all the drugs and biological products within these categories, because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified, and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077). We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the productivity-adjusted ESRDB market basket update is used to increase the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products. We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In the CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised the regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ‘‘parent NDA’’ is a Type 3, 5, 7, or 8, effective January 1, 2020.

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

be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a potential pathway toward a potential ESRD PPS base rate modification (83 FR 56935). For the complete history of the TDAPA policy, including the pricing methodology, see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

(2) Request for Information in the CY 2023 ESRD PPS Proposed Rule

In the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we summarized the concerns of interested parties and issued a request for information about methods that could be used to develop an add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA. We explained that since 2019, dialysis associations and pharmaceutical representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. We noted that these interested parties have asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, like what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, these interested parties cautioned that uncertainty about payment could affect

ESRD facility adoption of these drugs and biological products during the TDAPA period. We noted that to date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. We stated that there have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result, CMS does not yet have data on other drugs or biological products to evaluate the specific risks and access challenges that interested parties have raised.

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

We also noted that price changes to the ESRD PPS bundled payment are updated annually by the productivity-adjusted ESRDB market basket update, which includes a pharmaceutical cost category weight. In addition, we explained that our analysis of renal dialysis

drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time for some high volume formerly separately billable renal dialysis drugs, relative to overall ESRDB market basket growth. Therefore, we stated that we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

We noted that section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(1) for pediatric providers of services and renal dialysis facilities; (2) by a geographic index, such as the index referred to in section 1881(b)(12)(D), as the Secretary determines to be appropriate; and (3) for providers of services or renal dialysis facilities located in rural areas. Regarding the patient access concerns that we discussed in the CY 2023 ESRD PPS proposed rule, we stated that we were considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary coinsurance payment under ESRD PPS.

In the CY 2023 ESRD PPS proposed rule, we presented four potential methods that we were considering, which we noted could be used to develop an add-on payment adjustment for these drugs and biological products. We noted that the methods presented differed in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for methodological inclusion in a potential add-on payment adjustment. We further noted that under the potential options presented, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

Following the discussion in the CY 2023 ESRD PPS proposed rule about these potential methodologies, we issued a request for information within that proposed rule (87 FR 38523) to

seek feedback from the public on the need for an add-on payment adjustment of this kind and the potential methodologies for calculating such an add-on payment adjustment. We noted that while we would not be responding to specific comments submitted in response to this RFI, we intended to use this input to inform future policy development. We stated that any potential payment policies related to this RFI would be proposed through a separate notice and comment rulemaking.

We provided a high-level summary of responses to this RFI in the CY 2023 ESRD PPS final rule (87 FR 67219 through 67220) and noted that we would publish more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources. We noted that we received 27 public comments regarding our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large, non-profit health system; and MedPAC.

In the CY 2023 ESRD PPS final rule, we stated that most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of new renal dialysis drugs and biological products, and that most commenters stated that they supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. However, we noted that MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. We also noted that MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment.

We further noted in the CY 2023 ESRD PPS final rule that several commenters stated they supported reconciling the expenditure of the new renal dialysis drug or biological product

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

(3) Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products after the TDAPA Period Ends

As discussed previously, 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. Based on the public comments received regarding the RFI in the CY 2023 ESRD PPS proposed rule,[34] we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42458) that we believe it is appropriate to propose, beginning January 1, 2024, an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We noted that this proposed payment adjustment would not apply to new renal dialysis drug or biological products used to treat or manage a condition for which there is not an ESRD PPS functional category, because we have already established a policy to modify the ESRD PPS base rate for such products, if appropriate, after the TDAPA period ends, to account for the products in the ESRD PPS bundled payment (§ 413.234(c)(2)(i)).

We stated that we agreed with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs. We noted that several commenters asserted that the outlier adjustment and the ESRDB market basket updates

[34] https://www.cms.gov/files/document/cy-2023-esrd-pps-payment-after-tdapa-rfi-summary-comments.pdf.

cannot adequately account for these costs, and several organizations noted that if renal dialysis drugs and biological products with significant costs were adopted under the outlier policy, 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 stated that we recognize 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, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries. Additionally, we described several comments that raised concerns about the ability of the ESRDB market basket update to account for the cost of new renal dialysis drugs and biological products. These commenters referred to a Moran study[35] suggesting that the drug price proxies used in the ESRDB market basket have not adequately accounted for the costs of non-ESA drugs under existing functional categories. We explained that while we continue to believe that the market basket price proxies are the best available information for projecting the future price growth of renal dialysis drugs and biological products, and that they provide an adequate mechanism for projecting future ESRD PPS price growth, we recognize that there is additional uncertainty about future trends in the expenditures for new renal dialysis drugs and biological products, including trends in pricing and utilization of such drugs and any functionally equivalent substitutes such as generic drugs.[36] We stated that we believe these trends could be more effectively analyzed by collecting additional ESRD facility cost data following the 2-year TDAPA period. We stated that we recognize that although the TDAPA for drugs and biological products in existing ESRD PPS functional categories enables ESRD facilities to incorporate new renal dialysis drugs and

[35] Kidney Care Partners. August 4, 2022. Comment Letter. https://kidneycarepartners.org/wp-content/uploads/2022/08/KCP-PPS-Comment-Letter-Part-1-Final.pdf. Accessed May 16, 2023.
[36] https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.

biological products into their businesses, additional support may be needed to assure continued access to such drugs and biological products for Medicare beneficiaries and to support ESRD facilities' long-term planning and budgeting. We also recognized the importance of providing an appropriate pathway for ESRD facilities to incorporate new renal dialysis drugs and biological products into their business operations. We noted that in the CY 2019 ESRD PPS final rule in which we first established the 2-year TDAPA period for new renal dialysis drugs and biological products in an existing ESRD PPS functional category (83 FR 56934), we acknowledged that ESRD facilities have unique circumstances regarding incorporation of new drugs and biological products into their standards of care. For example, we stated that when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies in their care plans. We noted that newly launched drugs and biological products can be unpredictable regarding their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. In the CY 2024 proposed rule, we stated that we continue to believe the 2-year TDAPA period is appropriate and achieves its stated goals. However, we also recognized that continuity and predictability is an integral part of ESRD facilities' ongoing business operations. We stated that we agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We therefore proposed to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs. For ease of reference, we proposed to refer to this add-on payment adjustment as the post-TDAPA add-on payment adjustment. We stated that our goals for the post-TDAPA add-on payment adjustment are to

support Medicare beneficiaries' access to new renal dialysis drugs or biological products that are used to treat or manage a condition for which there is an ESRD PPS functional category and that are therefore considered included in the ESRD PPS bundled payment. We also stated that we want to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period. In addition, we explained that in accordance with the goals of prospective payment under the ESRD PPS, our goal for the post-TDAPA add-on payment adjustment is to incentivize ESRD facilities to be efficient in the use of resources.

We proposed to calculate the post-TDAPA add-on payment adjustment following the methodology described in the following subsections for any new renal dialysis drug or biological product that is paid for using the TDAPA under § 413.234(c)(1). We proposed that the post-TDAPA add-on payment adjustment would be applied for a period of 3 years following the end of the TDAPA period for those products. We stated that we believe a 3-year payment period would provide sufficient time for CMS to analyze cost reports that include costs for the new renal dialysis drug or biological product paid for using the TDAPA under the ESRD PPS, to incorporate changes as appropriate to the ESRDB market basket price proxies. 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. We stated that the proposed 3-year payment period for the post-TDAPA add-on payment adjustment would allow CMS to evaluate how the new drug or biological product affects the overall mix of renal dialysis drugs and biological products in the ESRDB market basket and to determine the appropriate price proxies for such new drug or biological product. We noted that for new renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate, the TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less

than 2 years. Similarly, as described earlier in this paragraph, we proposed a 3-year payment period for the post-TDAPA add-on payment adjustment, which would enable the collection and analysis of sufficient Medicare cost report information and would address the concerns that commenters raised about the effectiveness of the ESRDB market basket price proxies to reflect the prices of new renal dialysis drugs and biological products going forward by allowing CMS to incorporate data showing trends in use over an adequate period of time. Additionally, we stated that we believe a 3-year period for the post-TDAPA add-on payment adjustment would be appropriate and consistent with the transition period that we finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013 to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS, where full implementation of the ESRD PPS payment would occur beginning in the fourth year, CY 2014. We proposed a similar timeline to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional categories, which are not eligible for a modification to the ESRD PPS base rate. Based on the experience of ESRD facilities during the 4-year phase-in from CY 2011 to CY 2014, ESRD facilities would be familiar with this timeline for phasing in major changes that impact their long-term planning and budgeting. Lastly, in the interest of transparency, we noted that this 3-year period would provide time for analysis of utilization data for public awareness about the potential need for refinements to the ESRD PPS. Therefore, we proposed to calculate and apply the post-TDAPA add-on payment adjustment for a period of 3 years following the end of the TDAPA period, with no post-TDAPA add-on payment adjustment calculated beginning in the 4th year.

We proposed that this post-TDAPA add-on payment adjustment would not be budget neutral, as discussed later in this section of the final rule. We noted that this post-TDAPA add-on payment adjustment, if finalized, would be calculated for Korsuva®, the only renal

dialysis drug currently receiving the TDAPA, and that payment of this post-TDAPA add-on payment adjustment, if finalized, would begin April 1, 2024, at the end of the TDAPA period for Korsuva®.

We received several public comments on our proposal to establish a post-TDAPA add-on payment adjustment beginning in CY 2024. The comments on our proposal and our responses are set forth below.

Comment: Many commenters, including LDOs, drug manufacturers, patient advocacy organizations, coalitions of dialysis organizations, and patients, expressed support for establishing a post-TDAPA add-on payment adjustment. Commenters expressed that adequate payment is necessary to support Medicare beneficiaries' access to both current and future new and innovative renal dialysis drugs and biological products.

Response: We appreciate the support for the proposed post-TDAPA add-on payment adjustment. We agree with commenters about the importance of adequate payment. As we discussed in the CY 2024 ESRD PPS proposed rule and in the following section of this final rule, we believe the proposed payment methodology provides a significant level of payment that adequately supports beneficiaries' access to drugs and biological products after the TDAPA period ends, while sharing a significant portion of the cost with ESRD facilities, thereby incentivizing ESRD facilities to allocate resources efficiently.

Comment: MedPAC reiterated several concerns that it previously raised in response to the RFI on this topic in the CY 2023 ESRD PPS proposed rule. First, MedPAC reiterated its strong opposition to the establishment of a post-TDAPA add-on payment adjustment as proposed, stating that such a payment adjustment would be duplicative of payment under the ESRD PPS base rate. MedPAC specifically identified that when Mircera® (an ESA) became available in 2015, beneficiary access to the new drug was not impeded when the agency included it in the ESRD PPS bundled payment (in a budget-neutral manner). Between 2015 and 2020, use of Mircera® significantly and steadily increased. MedPAC further noted that, with respect to

Mircera®, one LDO announced its intent to have more than 70 percent of the company's ESA patients (110,000 patients) switched to Mircera® (from epoetin alfa) by the end of the first quarter of 2016, and sources suggest that this LDO reduced its total ESA costs. In addition, MedPAC also reiterated its concerns that CMS would not apply a clinical superiority standard when implementing the post-TDAPA payment adjustment policy and stated that beneficiaries and taxpayers would pay for a new drug without evidence that the new product is an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the ESRD PPS.

Response: We thank MedPAC for its comments. We recognize and agree with MedPAC about the importance of avoiding making payments under a post-TDAPA add-on payment adjustment that would be duplicative of payment under the ESRD PPS base rate or that would undermine competition between new and existing renal dialysis services. We anticipate that the post-TDAPA add-on payment adjustment will provide appropriate payment that supports Medicare beneficiaries' access to new renal dialysis drugs and biological products, create stability in payments to ESRD facilities after the end of the TDAPA, and appropriately align incentives to promote competition between new and existing renal dialysis services. The proposed post-TDAPA add-on payment adjustment would not be duplicative of payment under the ESRD PPS base rate, because it would specifically support access to new renal dialysis services at the level observed during the most recent 12 months, providing a glidepath for new renal dialysis drugs and biological products in existing functional categories following the TDAPA, since under § 413.234(c)(1), there is no modification to the ESRD PPS base rate. As further discussed below, the proposed application of a risk-sharing methodology would account for existing substitute drugs and biological products included in the ESRD PPS.

There are several important distinctions between the historical inclusion of Mircera® into the ESRD PPS bundled payment and the inclusion of renal dialysis drugs and biological products in existing ESRD PPS functional categories that receive TDAPA payment, for which we have

proposed to calculate the post-TDAPA add-on payment adjustment beginning in CY 2024. First, when Mircera® was incorporated into the ESRD PPS bundled payment, CMS had not yet established any TDAPA policies, which are integral to the current ESRD PPS drug designation process. As we previously stated, section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment, which CMS finalized in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027) and codified in our regulations at § 413.234. Under current law, new renal dialysis drugs and biological products in existing functional categories which qualify for TDAPA payment are generally paid for using the TDAPA for a period of 2 years, after which such drugs and biological products are considered included in the ESRD PPS base rate with no modification to the base rate. As we stated in the CY 2024 ESRD PPS proposed rule, we recognize continuity and predictability are integral parts of ESRD facilities' ongoing business operations. We stated that we agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We therefore proposed to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs.

Importantly, we note that under current regulations at § 413.234, Mircera® would not have been eligible for payment under the TDAPA, because it was approved under an NDA type that is excluded from TDAPA eligibility under § 413.234(e). In contrast to renal dialysis drugs and biological products that are paid for using the TDAPA, Mircera® was seen as a direct and less expensive substitute for existing renal dialysis drugs included in the ESRD PPS, specifically Amgen's anemia management drug Epogen®.[37] Accordingly, as MedPAC noted in its comment letter, ESRD facilities broadly adopted Mircera® into their business practices without the need for additional payment. However, as explained earlier, we do not consider Mircera® to be an

[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090042/

appropriate comparison to new renal dialysis drugs and biological products for which we propose to calculate the post-TDAPA add-on payment adjustment, because under current regulation Mircera® would not be eligible to receive either the TDAPA or a post-TDAPA add-on payment adjustment.

As we stated in the CY 2024 ESRD PPS proposed rule, we anticipate that the structure of the proposed post-TDAPA payment methodology will serve to incentivize the use of drugs that represent a substantial improvement over existing drugs, which will promote competition between new and existing renal dialysis drugs and biological products and drive down prices of such new renal dialysis drugs and biological products over time. We expect that our methodology for the post-TDAPA add-on payment adjustment will incentivize ESRD facilities' efficient use of resources, because payment for an individual claim will not be dependent on individual utilization of the new renal dialysis drug or biological product. Accordingly, we anticipate that under our methodology, for new renal dialysis drugs and biological products that are not a substantial clinical improvement over existing renal dialysis drugs and biological products, utilization will diminish over time and the amount of the post-TDAPA add-on payment adjustment will decline accordingly.

In addition, we stated in the CY 2024 ESRD PPS proposed rule that we recognize that continuity and predictability is integral to ESRD facilities' operations, and we do not think that this principle applies only to renal dialysis drugs and biological products that show a substantial clinical improvement. As we previously explained in the CY 2023 ESRD PPS final rule (87 FR 67189), the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician. As we further explained in the CY 2023 ESRD PPS final rule, the functional category structure helps to ensure the ESRD patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD

patient, including differing pharmaceutical profiles, comorbidities, contra-indications with other drugs the patient may be taking, and personal patient preference (87 FR 67189). We do not think that limiting the post-TDAPA add-on payment adjustment based on CMS's determination of substantial clinical improvement would align with this stated intent of the ESRD PPS functional category framework to support broad access to all renal dialysis service drugs. We further note that the current TDAPA exclusion criteria under § 413.234(e) consider FDA's determination of the drug's NDA type or approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is less subjective than a determination of substantial clinical improvement. Therefore, we continue to be of the view that the proposed methodology most appropriately balances the need to provide adequate payment with the concerns that MedPAC raised regarding duplicative payment and clinical superiority or substantial clinical improvement.

Comment: Many commenters expressed concerns about the proposed 3-year duration for the post-TDAPA add-on payment adjustment. Several commenters stated that the 3-year period would create a new payment cliff at the end of the 3-year post-TDAPA period and advocated for a permanent, non-budget neutral payment adjustment.

Response: We appreciate the concerns that commenters raised about the proposed 3-year period for the post-TDAPA add-on payment adjustment. We recognize that the policy would not permanently maintain increased payments for new renal dialysis drugs and biological products that receive the TDAPA, and we do not believe that such a permanent increase in payments would be appropriate. The TDAPA for renal dialysis drugs and biological products in existing functional categories is inherently transitional in nature and therefore not permanent. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products. We also explained that the TDAPA provides additional payments for such associated costs and promotes competition

among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. Accordingly, we proposed a post-TDAPA add-on payment adjustment beginning in CY 2024 that is similarly transitional in nature and which provides a glidepath for inclusion of such new renal dialysis drugs and biological products into the ESRD PPS. In the CY 2024 ESRD PPS proposed rule, we stated that a 3-year period for the post-TDAPA add-on payment adjustment would be consistent with the transition period that was finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013, with full implementation in CY 2014, to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS. We proposed a similar timeline for the post-TDAPA add-on payment adjustment to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional categories, which are not eligible for a modification to the ESRD PPS base rate.

Comment: MedPAC encouraged CMS to clarify why an additional period of 3 years is appropriate for the proposed post-TDAPA add-on payment adjustment, as compared to the established 2-year TDAPA period for new renal dialysis drugs and biological products in existing functional categories. MedPAC stated that a post-TDAPA period is not needed to collect and analyze cost report data, and that if CMS has concerns about the price proxies for ESRD drugs used in the ESRDB market basket, CMS can conduct the necessary analyses, without creating the post-TDAPA add-on payment adjustment policy. In addition, MedPAC questioned the utility of current cost reports to evaluate whether the ESRDB market basket accounts for price changes of new ESRD drugs, since Medicare cost reports do not require providers to report the cost of each new item or product paid under a TDAPA or a TPNIES.

Response: As we previously discussed, we proposed to pay the post-TDAPA add-on payment adjustment for a period of 3 years following the payment of TDAPA for 2 years, to allow more complete cost reporting information to become available. CMS routinely rebases and revises the ESRDB market basket and price proxies, usually every four to five years, incorporating more recent cost report information. We agree with MedPAC that a post-TDAPA period is not strictly necessary to collect more recent cost report information. However, as we stated in the CY 2024 ESRD PPS proposed rule, we think that providing a post-TDAPA add-on payment adjustment during this period would provide stability in ESRD PPS payments while CMS analyzes such information.

The existing 2-year TDAPA period provides useful information about ESRD facilities' spending on drugs and biological products paid for using the TDAPA, but due to lags in the timing of when ESRD facilities submit their cost reports, such data would not become available in ESRD facilities' cost report information until after the end of the TDAPA period. For example, CMS generally uses Medicare cost report data that lags by approximately 3 to 4 years prior to the rulemaking year. Therefore, complete Medicare cost report data for CY 2023 or CY 2024 could be used to consider changes to market basket cost categories, cost weights, and price proxies for the CY 2026 or CY 2027 rulemaking cycle. As proposed, the post-TDAPA add-on payment adjustment would begin to be paid on April 1, 2024, based on utilization of Korsuva®, the only renal dialysis drug currently receiving the TDAPA, and would end no later than March 31, 2027. CMS would be able to analyze Medicare cost report data for CY 2023 and CY 2024 to consider changes to the ESRDB market basket for CY 2027 rulemaking, if appropriate. The proposed post-TDAPA add-on payment adjustment would provide appropriate payment stability for ESRD PPS payments to ESRD facilities during the intervening years, which would support beneficiaries' continued access to new renal dialysis drugs and biological products.

With respect to the question of the utility of Medicare cost report data, we think that more recent cost reports, which would include information about total drug spending across categories, would provide meaningful information about how new renal dialysis drugs and biological products affect ESRD facilities' costs. Although TDAPA and TPNIES costs are not reported separately, if spending for new renal dialysis drugs and biological products is driving significant increases in ESRD facilities' costs, more recent Medicare cost report data will inform CMS's understanding of how such spending affects the ESRDB market basket composition. We would also evaluate Part B spending data to determine the mix of the types of drugs and the appropriate price proxy based on changes to the relative mix of drugs used in the ESRD facility setting. Nevertheless, we recognize the limitations of the current Medicare cost reports that MedPAC identified, and we may consider changes in the future to improve the data that we collect through the Medicare cost report.

Final Rule Action: After consideration of the comments, we are finalizing as proposed to establish, 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 is paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment will be applied for a period of 3 years following the end of the TDAPA period for those products.

(a) Calculation of the post-TDAPA add-on payment adjustment

As discussed earlier in this section of the final rule, we proposed to establish a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. In the CY 2024 ESRD PPS proposed rule, we proposed to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments beginning at the end of a new renal dialysis drug or biological product's TDAPA period. Specifically, we proposed that the post-TDAPA add-on payment adjustment would begin 8 calendar quarters after the beginning of the first calendar quarter in which

TDAPA payment is made for the new renal dialysis drug or biological product in an existing ESRD PPS functional category and would end no later than the 12th calendar quarter after the last calendar quarter in which TDAPA payment is made. We stated that we believe our calculation of the post-TDAPA add-on payment adjustment would be the most appropriate to address the patient access concerns we discussed in the CY 2023 ESRD PPS proposed rule and in this section of the final rule, and the most consistent with the principles of prospective payment. We stated that this proposal would apply the patient-level adjustment factors to the post-TDAPA add-on payment adjustment amount paid on each claim, which would ensure that ESRD PPS payment would support access to new renal dialysis drugs and biological products for beneficiaries with conditions that are costlier to treat, in alignment with our goals as stated earlier in this final rule. We proposed to codify the payment of the post-TDAPA add-on payment adjustment as part of the per treatment payment amount at § 413.230(f). We proposed to codify the methodology for calculating the post-TDAPA add-on payment adjustment at § 413.234(g). We proposed to make additional changes under § 413.234(b) and (c) to address payment of the post-TDAPA payment adjustment.

In determining the calculation of the post-TDAPA add-on payment adjustment, we considered the comments that we received regarding the RFI in the CY 2023 ESRD PPS proposed rule. Some commenters expressed that new and innovative drugs may only be used by a small percentage of the dialysis population and suggested that an add-on payment adjustment should address patient-specific needs to support access.

First, we considered calculating the post-TDAPA add-on payment adjustment as the average cost for patients that used the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS and applying the post-TDAPA add-on payment adjustment only to claims that include the new renal dialysis drug or biological product. However, we were concerned that such an approach would not align with the principles of prospective payment under the ESRD PPS. As we noted previously, a central objective of the

ESRD PPS (and of prospective payment systems in general) is for ESRD facilities to be efficient in their resource use. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and CMS acknowledges there will be patients whose treatment costs at an ESRD facility will be more or less than the ESRD PPS payment amount. Additionally, we were concerned that such an approach would result in a substantial cost burden for beneficiaries who use the new renal dialysis drug or biological product, because they incur a 20 percent coinsurance under Part B for renal dialysis services. We stated that we do not believe this approach would align with our priorities to reduce drug costs for Medicare beneficiaries. In contrast, our proposed methodology would apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments, which would result in a minimal increase in per-treatment coinsurance amounts for all beneficiaries. As discussed later in this section, we proposed to apply the ESRD PPS patient-level adjustments to the post-TDAPA add-on payment adjustment for each treatment.

Next, we considered applying the post-TDAPA add-on payment adjustment based only on claims from ESRD facilities that used the new renal dialysis drug or biological product during the TDAPA period. However, like the previous option, we stated that we believe limiting application of this add-on payment adjustment to claims from ESRD facilities that include the new renal dialysis drug or biological product would be inconsistent with the principles of prospective payment. As we discussed in the CY 2011 ESRD PPS final rule, there are patients whose medical treatment results in more costly care as well as those with less costly care, and the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient (75 FR 49045). Further, we were concerned that limiting the post-TDAPA add-on payment adjustment to claims from ESRD facilities that use the new renal dialysis drug or biological product could result in substantial overestimation of the post-TDAPA add-on payment adjustment, if more ESRD facilities begin using the new renal dialysis drug or biological product. As we discuss later in this final rule, we proposed to apply this post-TDAPA add-on

payment adjustment in a non-budget neutral manner. Therefore, we stated in the CY 2024 ESRD PPS proposed rule that we were concerned that an overestimation of the post-TDAPA add-on payment adjustment could result in an inappropriate increase in Medicare expenditures. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. We stated that we believe after the end of the TDAPA period, ESRD facilities will have made appropriate changes in their business models to adopt such products, and therefore any approach to a post-TDAPA add-on payment adjustment should apply equally to all ESRD PPS treatments, in order to apply the appropriate incentive structures for ESRD facilities' utilization of renal dialysis drugs and biological products and to continue to promote competition among the products within the ESRD PPS functional categories, including the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS. Furthermore, we stated that we believe that such an approach would help to support access to new renal dialysis drugs and biological products to the widest scope of beneficiaries. This is in line with CMS's commitment to advance health equity by supporting access to renal dialysis services.

Accordingly, we proposed to apply the post-TDAPA add-on payment adjustment to each ESRD PPS treatment, and to adjust it for patient characteristics. In other words, the post-TDAPA add-on payment adjustment would be multiplied by the ESRD PPS patient-level adjustments under § 413.235. We stated that we believe this approach would appropriately adjust aggregate ESRD PPS payment to account for the new renal dialysis drugs and biological products in a way that is consistent with the principles of prospective payment and would

support beneficiary access to new renal dialysis drugs and biological products by recognizing the additional patient-specific needs associated with the existing ESRD PPS case-mix adjusters. We noted that to calculate an appropriate post-TDAPA add-on payment adjustment, we would apply a case-mix standardization factor to the post-TDAPA add-on payment adjustment amount as discussed in the following paragraphs.

In addition, we explained that we considered the public comments regarding the need to reconcile estimated expenditures for a new renal dialysis drug or biological product with the declines in expenditures for related drugs. We noted that commenters expressed support for establishing a methodology that would consider the decline in estimated expenditures for drugs that are clinically or empirically related to the new renal dialysis drug or biological product. We explained that such a methodology would be highly complex and less transparent than other potential options that commenters suggested. We also explained that commenters in the past noted various ideas that CMS would need to consider when attempting to establish the offsetting financial effects of drugs and biological products that are either clinically or empirically related to the new renal dialysis drug or biological product. For example, most commenters suggested that CMS use drugs with the same FDA clinical indication to offset the payment adjustment, in the interest of transparency and objectivity. However, some commenters, including MedPAC, noted that they do not believe that FDA determinations or ESRD PPS functional categories should be the basis of eligibility for the post-TDAPA payment adjustment, as CMS should make these determinations based on the specific needs of the Medicare population. We stated that we believe such considerations based on specific population needs could be less transparent than alternative approaches, especially in situations when there could, in the future, be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments. We stated that we anticipate it would be challenging for CMS to determine, within the annual rulemaking timeframes, the extent to which changes in the utilization of existing renal dialysis drugs and biological products are clinically or empirically related to utilization of a new

renal dialysis drug or biological product paid for using the TDAPA. We noted that the latest available data at the time of the proposed rulemaking included less than a full year of TDAPA utilization. We explained that we anticipate that as additional data are collected, CMS will be able to analyze trends and may be able to retrospectively determine the extent of any substitution effects between new and existing renal dialysis drugs and biological products. Furthermore, we noted that the calculation of these offsets could involve multiple overlapping periods of time, which would further increase complexity and reduce transparency. As an alternative, we explained that we considered MedPAC's suggestion to align the methodology closer to that of the ESRD PPS TPNIES, wherein CMS pays a reduced percentage of the estimated incremental cost of a new product as a risk-sharing mechanism with ESRD facilities and to provide a disincentive for significant increases in drug prices. Under the TPNIES, CMS calculates the TPNIES amount as 65 percent of the MAC-determined price for certain new and innovative equipment and supplies (§ 413.236(f)). We stated that we believe this approach would have the same general effect of accounting for declines in other drug expenditures, while being significantly less complex and more transparent. In the CY 2020 ESRD PPS final rule that established the 65 percent cost-sharing proportion for the TPNIES, we stated that the goal of the TPNIES was to support ESRD facility use of new and innovative renal dialysis equipment and supplies (84 FR 60692). In that same CY 2020 ESRD PPS final rule, we further stated in response to comments that we believe that we need to balance this goal with sharing risk for the new product (84 FR 60697). We noted 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. Additionally, we stated that our goal is also to incentivize efficient use of resources, consistent with the principles of prospective payment under the ESRD PPS. We explained that we believe applying a cost-sharing proportion of 65 percent to the post-TDAPA add-on payment adjustment would effectively achieve these goals, because it would provide a significant level of

payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to efficiently allocate resources by sharing a significant portion of the cost with ESRD facilities. Furthermore, we stated that this 65 percent cost-sharing factor would serve to further reduce the minimal cost-sharing burden of new renal dialysis drugs and biological products for beneficiaries, under the post-TDAPA add-on payment methodology. Lastly, we noted that for home dialysis machines that are capital-related assets that qualify for the TPNIES, our policy is to apply an offset to account for such capital-related assets in the ESRD PPS base rate. As we discussed previously, we considered applying an offset to the post-TDAPA add-on payment adjustment; however, we believe that considerations based on specific population needs could be less transparent than applying a simple 65-percent risk-sharing percentage. Additionally, we noted that in the future, there could be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments, which would further increase complexity and reduce transparency. We solicited comments on whether there are other ways CMS could consider calculating an offset amount for the post-TDAPA payment adjustment. Alternatively, we sought comment on if there are other ways CMS could ensure any growth in post-TDAPA add-on payment adjustment amounts is reasonable, such as not allowing increases to exceed inflation or other relevant metrics.

We proposed to calculate the post-TDAPA add-on payment adjustment annually, based on the latest available full calendar quarter of average sales price (ASP) data, which would be consistent with the current policy for determining the basis of payment for the TDAPA. We stated that under current policy, finalized in the CY 2020 ESRD PPS final rule (84 FR 60679), we pay the TDAPA based on 100 percent of ASP. If ASP is not available, we base the TDAPA payment adjustment on wholesale acquisition cost (WAC), and if WAC is not available, then we base payment on invoice pricing. As we stated in the CY 2020 ESRD PPS final rule, we continue to believe that after the TDAPA period, calculating the post-TDAPA add-on payment adjustment for new renal dialysis drugs based on ASP, as compared to WAC or invoice pricing,

would be the most appropriate choice for the ESRD PPS, and would strike the right balance in supporting ESRD facilities in their uptake of innovative, new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We proposed to address the annual calculation of the post-TDAPA add-on payment adjustment in the annual proposed and final ESRD PPS rules for future years.

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42472), under current TDAPA policy, if CMS stops receiving ASP during the TDAPA period, then CMS will stop paying the TDAPA after 2 calendar quarters. Similarly, we explained that if drug manufacturers were to stop submitting ASP data for products that are included in the calculation of the post-TDAPA add-on payment adjustment, and we had to revert to basing calculation of the post-TDAPA add-on payment adjustment on WAC or invoice pricing, we believe we would be overpaying for the add-on payment adjustment. Therefore, we proposed to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. Because the post TDAPA add-on payment adjustment would be calculated annually rather than quarterly, we proposed that if CMS does not receive the latest full calendar quarter of ASP data for a drug that would be included in the calculation of the post-TDAPA add-on payment adjustment, then CMS would not include that drug in the calculation of the post-TDAPA add-on payment adjustment for any future years. We also proposed that if CMS stops paying the TDAPA for a drug or biological product because CMS stops receiving the latest full calendar quarter of ASP data, then we would not include that drug or biological product in the calculation of the post-TDAPA add-on payment adjustment for the next CY or any future CY. Consistent with our policy for calculating the TDAPA, as discussed in section II.B.1.k of the proposed rule, we proposed that in situations when a manufacturer reports zero or negative sales, we would consider CMS to have received the latest full calendar quarter of ASP data, but we would calculate the post-TDAPA payment adjustment based on WAC, or if WAC is not available, on invoice pricing, in such circumstances.

Finally, we proposed that for each of the 3 years for which this post-TDAPA add-on payment adjustment would be paid, we would update the amount of the post-TDAPA add-on payment adjustment by the productivity-adjusted ESRDB market basket update to account for estimated future input price changes faced by ESRD facilities. We solicited comment on whether it would be more appropriate to consider using the growth in the price proxy for the pharmaceuticals cost category in the ESRDB market basket, rather than the productivity-adjusted ESRDB market basket update. We also provided a detailed set of steps for calculating the amount of the proposed post-TDAPA add-on payment adjustment for CY 2024, which we calculated at $0.0961 for the proposed rule. We solicited comments on this proposed methodology for a post-TDAPA add-on payment adjustment and its appropriateness for CY 2024 and future years.

We received public comments on our proposed methodology for calculating the post-TDAPA add-on payment adjustment. The comments on our proposal and our responses are set forth below.

Comment: Many commenters, including LDOs, drug manufacturers, and patient advocacy organizations, expressed concerns that the proposed methodology would not support access to new and innovative renal dialysis drugs and biological products. Commenters stated that the proposed amount would provide a level of funding that supports the provision of drugs and biological products currently paid for using the TDAPA to only a small proportion of patients and would not support expanded access to such drugs. One commenter stated that CMS policy must recognize that practice follows payment and provided an example of certain payment policy changes in the SNF PPS, specifically the recent transition from the SNF Resource Utilization Group payment system to the Patient-Driven Payment Model (83 FR 39162), which the commenter stated drove subsequent utilization patterns in that system by reducing incentives for overutilization of certain rehabilitative therapies.

Response: We disagree with commenters who stated that the amount of the proposed post-TDAPA add-on payment adjustment would not support access to new and innovative renal dialysis drugs and biological products. Because the proposed methodology is based on the latest available price and utilization information, we believe it provides an adequate level of funding to maintain access to new renal dialysis drugs and biological products after the end of the TDAPA period. We note that the proposed amount of the post-TDAPA add-on payment adjustment for CY 2024 reflects utilization of current TDAPA drugs by a small proportion of ESRD beneficiaries, amounting to less than 1 percent of all treatments. Although the payment per treatment is a relatively small amount, an ESRD facility's aggregate payments under the proposed post-TDAPA add-on payment adjustment methodology would nonetheless help to support the utilization for new renal dialysis drugs and biological products at the level of utilization observed during the TDAPA period. We note that, as discussed later in this final rule, we are calculating the final amount of the post-TDAPA add-on payment adjustment for CY 2024 to be significantly higher than the CY 2024 ESRD PPS proposed rule, based on the latest available price and utilization data.

Lastly, we appreciate the concerns that the commenter raised regarding utilization patterns as the result of payment policies, and we are acutely aware of the importance of establishing payment adjustments in the ESRD PPS that are aligned with the principles of prospective payment. We anticipate that the post-TDAPA payment methodology that we are finalizing will provide an appropriate level of funding to support access to new renal dialysis drugs and biological products after the end of the TDAPA, without providing a direct incentive to use any particular new drug or biological product, which we anticipate could result in overutilization.

Comment: MedPAC stated that although it strongly disagrees with the implementation of a post-TDAPA add-on payment adjustment, it recognizes that CMS's proposed per claim add-on payment approach provides better incentives for more judicious use of a new renal dialysis drug

rather than a per use add-on payment approach. MedPAC reiterated that paying on a per unit basis for a drug incentivizes its use (to the extent clinically possible) and recommended that if CMS finalizes the post-TDAPA add-on payment adjustment, the agency should proceed with a per claim add-on payment. MedPAC also expressed support for the proposed 65 percent risk-sharing percentage as an incentive for price competition.

Response: We appreciate MedPAC's qualified support for the proposed methodology. We agree with MedPAC that the proposed per-treatment methodology would appropriately align incentives for ESRD facilities to be efficient with their resources, and as a result it would foster competition between new and existing renal dialysis drugs and biological products. We also agree that the proposed application of a risk-sharing percentage would provide a further incentive for price competition between drugs within an ESRD PPS functional category. As we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42462), we anticipate that the proposed risk sharing percentage of 65 percent would be appropriate, as it would provide a significant level of payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to allocate resources efficiently.

Comment: Several commenters advocated for an alternative methodology that would calculate an add-on payment adjustment based on the average cost for patients that use the new renal dialysis drug or biological product. Commenters stated that the proposed methodology for the post-TDAPA add-on payment adjustment, and the structure of the ESRD PPS overall, do not address the needs of the non-average patient. Several commenters drew parallels to the comprehensive ambulatory payment classification (C-APC) complexity adjustment in the Hospital OPPS as an example of a payment policy that adjusts payment based on patient characteristics.

Response: We appreciate the suggested methodology for which these commenters advocated but do not agree that such a methodology would be appropriate, because it would directly incentivize utilization of a particular drug or biological product, which can result in

overutilization. As we discussed earlier in this final rule, we believe that the proposed methodology provides the most appropriate incentives for ESRD facilities to be efficient with resources, while providing an appropriate level of payment that supports access to new renal dialysis drugs and biological products.

Additionally, we disagree with several of the premises that commenters offered with respect to the proposed methodology for calculating the post-TDAPA add-on payment adjustment. Specifically, commenters stated that both the proposed post-TDAPA methodology and the ESRD PPS are designed to meet the needs of the average patient and do not meet the needs of the non-average patient. In fact, the ESRD PPS base rate is not constructed to address the needs of the average patient, but rather to provide a level of payment that reflects the average per-treatment costs of renal dialysis services. As we discussed in the CY 2011 ESRD PPS final rule (75 FR 49037), in response to concerns that bundling payment for drugs like EPO and oral medications would limit nephrologists from prescribing what is necessary, we stated that the ESRD PPS would establish a bundled payment system based on the average cost of care with adjustments that target more payment to more resource intensive ESRD patients. We further explained that in situations where costs for treating patients exceed an established threshold, the outlier policy would apply. Later in the same CY 2011 ESRD PPS final rule (75 FR 49047) we explained that the ESRD PPS provides an opportunity for ESRD facilities to make financially sound decisions while providing necessary care, recognizing that some patients may utilize less renal dialysis items and services while others may use more. In other words, while some patients cost more than average and others cost less, an ESRD facility's aggregate payments under the ESRD PPS are reflective of the overall cost of providing renal dialysis services to its patients. The ESRD PPS includes patient-level and facility-level adjustments that better align payment with resource use for facilities that incur higher costs due to their patient population or geographic location.

We do not believe that the OPPS C-APC complexity adjustment is an appropriate comparison to the proposed post-TDAPA payment amount, which as we previously noted will be applied in a non-budget-neutral manner and is intended to provide a transitional level of payment that supports ESRD facilities' long-term planning and budgeting and supports beneficiaries' access to new renal dialysis drugs and biological products. In contrast, the OPPS C-APC complexity adjustment is budget neutral under the OPPS and is intended to provide increased payment when certain service combinations represent a complex, costly, or more resource-intensive version of the primary service. As an example, we believe a more appropriate payment mechanism to recognize the additional costs of treating ESRD patients with pruritus may be a patient-level adjustment under the ESRD PPS. As we discuss in section II.B.1.j of this final rule, we are collecting additional information on dialysis duration and may consider future revisions to the ESRD PPS case-mix adjustments, if appropriate.

Comment: Several commenters responded to our comment solicitation on the methodology for applying the productivity-adjusted ESRDB market basket update, or an alternative update factor, to the proposed post-TDAPA add-on payment adjustment. Commenters generally advocated for applying a pharmaceutical price proxy, rather than the productivity-adjusted ESRDB market basket update, stating that a pharmaceutical price proxy would be more representative of anticipated future price growth for new renal dialysis drugs and biological products. Commenters requested clarification about whether CMS would recalculate the post-TDAPA add-on payment adjustment annually for each of the three years, in addition to applying an update factor as proposed. Several commenters requested that CMS calculate the post-TDAPA add-on payment adjustment at the end of the TDAPA period, and then annually update that amount based on an update factor such as a pharmaceutical price proxy. MedPAC expressed concern about a payment methodology in which the payment amount would only increase and suggested alternative approaches to update the amount of the post-TDAPA add-on payment adjustment annually.

Response: We thank commenters for their comments regarding the proposed update methodology for the post-TDAPA add-on payment adjustment. We proposed to use the most recent available price and utilization information to determine a per-treatment amount for each of the three years during which a post-TDAPA add-on payment adjustment would apply. We are clarifying in this rule that we would annually recalculate the post-TDAPA add-on payment adjustment, based on the most recent available price and utilization information at the time of rulemaking. Accordingly, the post-TDAPA add-on payment adjustment amount could increase or decrease from year to year, depending on changes in pricing and utilization. We note that although we proposed to apply the productivity-adjusted ESRDB market basket update, we proposed to do so only for the purpose of updating the post-TDAPA add-on payment adjustment to reflect anticipated prices in the target year. We did not propose, and are not finalizing, the application of an update factor to update the amount of the post-TDAPA add-on payment adjustment from one payment year to the next.

We appreciate the comments recommending the use of the pharmaceutical price proxy rather than the productivity-adjusted market basket update. We agree with commenters that a pharmaceutical price proxy would more effectively track the change in prices for new renal dialysis drugs and biological products than would the market basket update. We are finalizing that for each year that we calculate a post-TDAPA add-on payment adjustment, we will apply the projected growth in the ESRDB market basket price growth for pharmaceuticals, which reflects the weighted blend of the ESA and non-ESA price proxies in the 2020-based ESRDB market basket, to reflect anticipated pricing for the target year. We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67149) for a detailed discussion of the construction of this price proxy.

Comment: Several commenters opposed the application of a 65 percent risk sharing percentage and urged CMS to instead calculate and apply an offset based on actual utilization of related drugs. Many commenters suggested that CMS limit the calculation of an offset to the post-TDAPA add-on payment adjustment that accounts for the actual spending for products that

are in the same ESRD PPS functional category as the new renal dialysis drug or biological product and are directly impacted by the drug or biological product.

Response: As we discussed in the CY 2024 ESRD PPS proposed rule, we did not propose to calculate an offset based on utilization, because we are concerned that this approach would be more burdensome and less transparent than the proposed 65 percent risk-sharing percentage. We do not believe it would be appropriate to limit the calculation of an offset to just drugs and biological products in the same functional category, because we recognize that utilization of drugs in one functional category can affect the utilization of drugs in other functional categories. For example, utilization of drugs in the bone and mineral metabolism functional category can indirectly affect the incidence of itching among dialysis patients. However, if we were to apply a per-treatment offset based on changes in spending for all formerly separately billable drugs and biological products, it would be difficult to determine definitively which reductions in spending were related to a new renal dialysis drug or biological product.

Comment: One commenter pointed out that the CY 2024 ESRD PPS proposed rule does not indicate whether the ESRD PPS outlier adjustment would apply to products for which a post-TDAPA add-on payment adjustment is calculated.

Response: We appreciate the request for clarification regarding outlier eligibility for drugs and biological products during the post-TDAPA period. 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 are clarifying 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 are further clarifying that under current policy, Korsuva®, the only renal dialysis drug whose TDAPA period will end in CY 2024, will not be considered an eligible outlier ESRD 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).

Final Rule Action: After considering the comments, we are finalizing as proposed the methodology to calculate the amount of the post-TDAPA add-on payment adjustment, except that, as noted previously, we will apply the price growth of the pharmaceutical cost category, reflecting a weighted blend of the ESA and non-ESA price proxies in the 2020-based ESRDB market basket, to adjust the amount of the post-TDAPA add-on payment adjustment to reflect anticipated pricing for the target year rather than using the productivity-adjusted ESRDB market basket update. Therefore, we will use the following calculation to determine the amount of the post-TDAPA add-on payment adjustment to be applied to each ESRD PPS treatment.

- Step 1, using the most recent available 12 months of claims data, calculate the total expenditure of the new renal dialysis drug or biological product being paid for using the TDAPA under the ESRD PPS. Total expenditure is calculated by multiplying the latest available full calendar quarter of ASP data for the new renal dialysis drug or biological product by the quantity of units billed. If CMS does not receive the latest available calendar quarter of ASP data for a drug or biological product, then CMS would not apply the post-TDAPA add-on payment adjustment for that drug or biological product. As we noted earlier, if the latest available full calendar quarter of ASP data reflects zero or negative sales, CMS will calculate the post-TDAPA add-on payment adjustment based on WAC, or if WAC is not available, invoice pricing.

- Step 2, divide the total expenditure of the new renal dialysis drug or biological product from Step 1 by the total number of ESRD PPS treatments furnished during the same 12-month period as used in Step 1. The resulting quotient from Step 2 is the post-TDAPA add-on payment adjustment amount for each treatment, before applying the reduction factor to account for case-mix standardization, as described in Step 4.

- Step 3, calculate the dollar amount of the total aggregate case-mix adjusted post-TDAPA add-on payment adjustment amount by multiplying the post-TDAPA add-on payment adjustment amount from Step 2 by the applicable patient-level adjustments for each ESRD PPS treatment furnished during the 12-month period.
- Step 4, divide the aggregate case-mix adjusted add-on payment adjustment amount from Step 3 by total expenditure from Step 1. The resulting quotient is the reduction factor applied to the post-TDAPA add-on payment adjustment amount to account for case-mix standardization.
- Step 5, apply the reduction factor from Step 4 to the post-TDAPA add-on payment adjustment amount from Step 2.
- Step 6, apply the 65 percent risk-sharing factor to the amount from Step 5 to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount.
- Step 7, multiply the case-mix adjusted post-TDAPA add-on payment adjustment amount by the growth in the ESRDB market basket price proxy for pharmaceuticals to account for anticipated price growth to the target year.

We are amending § 413.234 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 will use to determine the post-TDAPA add-on payment adjustment amount, as described previously. In addition, we are amending § 413.230 by adding reference to the post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

We will follow these steps to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount for CY 2024 and future years, when appropriate. We will include in the calculation of the case-mix adjusted post-TDAPA add-on payment adjustment amount any new renal dialysis drugs and biological products in existing ESRD PPS functional categories that are eligible for payment using the TDAPA described in § 413.234(c). We will begin making

payment under this new post-TDAPA add-on payment adjustment 8 calendar quarters after the beginning of the TDAPA payment period for the new renal dialysis drug or biological product. Payment of the post-TDAPA add-on payment adjustment will end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product.

(b) Example of the final post-TDAPA add-on payment adjustment calculation for CY 2024

Following the methodology finalized in the previous section, we will apply a post-TDAPA add-on payment adjustment to all ESRD PPS treatments beginning April 1, 2024, when the TDAPA payment period for Korsuva® ends. We will calculate the amount of this post-TDAPA add-on payment adjustment based on the most recent available 12 months of utilization data for Korsuva® and the most recent available 12 months of ESRD PPS claims data for this final rule. As we proposed, we will use updated data for this ESRD PPS final rule. We will apply the ESRD PPS patient-level adjustment factors for determining the amount of the post-TDAPA add-on payment adjustment for each ESRD PPS claim.

Based on the latest available data, which includes utilization of Korsuva® from July 2022 through June 2023, we estimate that total expenditure for Korsuva® is $11,948,389 and that 28,450,178 total ESRD PPS treatments were furnished during the same time period. In addition, as discussed earlier in this final rule, we are finalizing the application of the growth in the ESRDB market basket price proxy for pharmaceuticals to adjust the amount of the post-TDAPA add-on payment adjustment to reflect anticipated pricing for CY 2024. The ESRDB pharmaceutical price proxy used for this CY 2024 ESRD PPS final rule is 1.3 percent. Accounting for the existing ESRD PPS patient-level adjustment factors and the TPEAPA as discussed in section II.B.1.g of this final rule, the reduction to the post-TDAPA add on payment adjustment to account for case-mix standardization for this time period is 0.901653. Accordingly, we will calculate a case-mix adjusted post-TDAPA add-on payment adjustment for CY 2024 equal to (($11,948,389) / (28,450,178)) x (0.901653) x (0.65) x (1.013) = $0.2493.

Estimates for the impact of this post-TDAPA add-on payment adjustment for CY 2024 are included in section VII.D.5 of this final rule.

(c) Considerations related to budget neutrality for the post-TDAPA add-on payment adjustment

As discussed in the CY 2024 ESRD PPS proposed rule and earlier in this final rule, the ESRD PPS includes other add-on payment adjustments based on the authority in section 1881(b)(14)(D)(iv) of the Act, which are not statutorily required to be budget neutral. In the case of existing add-on payment adjustments under the ESRD PPS, these generally account for costs that were not included in cost reports used for the construction of the ESRD PPS bundled payment. These include items that either did not exist at the time of the construction of the ESRD PPS bundled payment, like new drugs and equipment, or services that were not commonplace that the add-on payment adjustment is meant to encourage, like home dialysis training. In the proposed rule, we stated that we expect this increased payment would support ESRD facilities in providing the new renal dialysis drug or biological product to all beneficiaries for whom it is reasonable and medically necessary. We noted that we believe it is also important to support access to new renal dialysis drugs and biological products while minimizing the financial impact to beneficiaries, who incur a 20 percent coinsurance for renal dialysis services under the ESRD PPS.

As discussed previously, we considered and proposed this new post-TDAPA add-on payment adjustment in response to concerns that a sudden decrease in payment for certain new renal dialysis drugs and biological products after the end of the TDAPA period could negatively affect Medicare beneficiaries' access to such new renal dialysis drugs and biological products. Although we have noted that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we stated that proposing a budget neutral payment adjustment would not be appropriate for the post-TDAPA add-on payment adjustment. Because we proposed to apply the post-TDAPA add-on payment adjustment to every ESRD PPS treatment, budget neutralizing this final add-on

payment adjustment would effectively undo the adjustment and leave aggregate payments at the same level they would have been without an adjustment, which as we previously noted could negatively affect beneficiaries' access to such drugs and biological products. In contrast, applying this add-on payment adjustment in a non-budget neutral manner would increase aggregate ESRD PPS expenditures to a level that reflects the most recent 12 months' utilization of the new renal dialysis drug or biological product, which we believe would support beneficiary access. By applying the post-TDAPA add-on payment adjustment in a non-budget neutral way, we would effectively maintain expenditures for these new renal dialysis drugs and biological products at 65 percent of the level of expenditures paid during the TDAPA period. We stated that we believe this approach would provide consistency and predictability in a way that would support beneficiaries' continued access to new renal dialysis drugs and biological products, while appropriately reducing expenditures for such drugs after the TDAPA period ends both for the Medicare program and for individual beneficiaries, as discussed earlier in this section. Accordingly, we proposed that this post-TDAPA add-on payment adjustment would not be budget neutral. We invited comments on the budget neutrality aspect of this proposal.

Comment: Several commenters expressed support for applying the post-TDAPA add-on payment adjustment in a non-budget neutral way. These commenters agreed with CMS that calculating the post-TDAPA add-on payment budget neutrally would be counterproductive, as it would effectively undo the impact of the proposed adjustment.

Response: We agree, and we thank the commenters for their support.

Final Rule Action: After considering the comments we received, we are finalizing the application of the post-TDAPA add-on payment adjustment as a non-budget neutral payment adjustment, beginning for CY 2024.

j. Requirement of "Time on Machine" Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis

We proposed certain new recordkeeping and cost reporting requirements for outpatient maintenance dialysis at proposed § 413.198(b)(5). Specifically, we proposed to require patient-level reporting on resource use involved in furnishing hemodialysis treatment in-center in ESRD facilities that would serve to apportion composite rate costs for use in the case-mix adjustment. Importantly, this new data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined single-equation estimation methodology. The integrity of the ESRD PPS is dependent on our ability to monitor payment accuracy and make refinements to the payment system, as needed. Under this proposal, CMS would require ESRD facilities to report information on ESRD PPS claims for renal dialysis services about the duration of time in minutes that ESRD beneficiaries spend in center receiving hemodialysis treatment (hereafter referred to in this section as "time on machine"). We would use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS would also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include patient age, body mass index (BMI), body surface area (BSA), and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to identify any disparities from a health equity perspective that may support proposing in future rulemaking new patient-level adjustment factors, including potential social determinants of health (SDOH) factors. As described in section II.B.1.h of this final rule, we proposed the addition of § 413.198(b)(5), which states that ESRD facilities must submit data and information in the formats established by CMS for the purpose of estimating patient-level and facility level variation in resource use. Under this paragraph, we proposed to require ESRD facilities to report "time on machine" as when a patient the begins dialysis treatment and ends dialysis treatment. We proposed to require ESRD facilities to report this information using the D6 value code on ESRD PPS claims.

(1) Background

(a) Statutory Authorities for Recordkeeping, Cost Reporting, and Case-Mix Adjustments Under the ESRD PPS

Section 1881(b)(2)(B) of the Act generally directs the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other economical and equitable basis, payment amounts for Medicare part B services furnished by such providers and facilities to individuals with ESRD. To that end, CMS promulgated § 413.198,[38] which specifies certain recordkeeping and cost reporting requirements for ESRD facilities that meet the conditions for coverage under 42 CFR part 494.[39] The recordkeeping and cost reporting requirements at § 413.198 enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis and support the two-equation payment model that is currently used as the basis for the ESRD PPS.

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may consider patient weight, BMI, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We implemented this statutory requirement in § 413.235, which sets forth certain patient characteristics for which the per treatment ESRD PPS base rate may be adjusted, specifically where those patient characteristics result in higher costs for ESRD facilities. The patient characteristics at § 413.235(a) include: patient age, BSA, low BMI, onset of renal dialysis (new patient), and co-morbidities. The Secretary is also authorized, under section 1881(b)(14)(D)(iv) of the Act, to apply such other payment adjustments under the ESRD PPS as the Secretary determines appropriate. Per § 413.196, we publish notice of any proposed changes to payment adjustments,

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[38] We note that § 413.198 was promulgated prior to the establishment of the ESRD PPS. It was initially set forth in 1983 at 42 CFR 405.441 (48 FR 21254), to implement section 2145 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35). Section 405.441 was later redesignated in 1986 as 42 CFR 413.174 (51 FR 34790-01), and the requirements were moved again, from § 413.174 to § 413.198, in a reorganization of subpart H of part 413 (62 FR 43657).

[39] Likewise, under section 1881 of the Act, CMS established related data and information requirements at 42 CFR 494.180(h).

including adjustments to the composite rate,[40] in the **Federal Register**. We last updated the payment multipliers for the ESRD PPS patient-level adjustment factors in the CY 2016 ESRD PPS final rule (80 FR 68968, at 68973 through 68984), for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for facilities treating a low volume of patients with ESRD.

Finally, the collection of data from ESRD claims, cost reports and record keeping, has been instrumental in identifying underserved populations and establishing that ESRD disproportionately affects African American/Black men relative to their share of the total population. The proposal to collect and evaluate time on machine data would provide additional information concerning resource use to enable CMS to identify, assess, and address potential health disparities. This proposal therefore may support the Secretary's efforts to evaluate race and ethnicity data and provide recommendations for improving the quality of the data, as required under section 1809 of the Act, previously discussed in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49108 through 49113).

In the CY 2024 ESRD PPS proposed rule (88 FR 42464 through 42472), we noted that, if the proposed requirement to collect time on machine data were to be finalized, we would issue corresponding guidelines. We stated that such guidance would provide instructions regarding the applicable administrative requirements for reporting a value code on an electronic claim, here value code D6, connected to the number of minutes of hemodialysis treatment provided in-center in an ESRD facility. We further noted that the National Uniform Billing Committee (NUBC) has approved and is prepared for ESRD facilities' use of value code D6 on claim form

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[40] As explained in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49032), the composite rate is the method by which CMS determines prospectively the amounts of payments for renal dialysis services furnished by providers of services and by renal dialysis facilities to individuals in a facility and to such individuals at home. The composite rate is a single composite weighted formula that is combined with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix.

CMS-1450 (UB-04) (OMB-0938-0997) to report the total number of minutes of hemodialysis provided during the billing period.

(b) Case-Mix Adjustments Background and the Two-Equation ESRD PPS Model

The ESRD PPS includes patient-level adjustments that adjust the ESRD PPS base rate for certain patient characteristics. The current ESRD PPS case-mix adjustments are derived from a case-mix adjustment model involving two equations. In the CY 2011 ESRD PPS final rule (75 FR 49083), we discussed the two-equation methodology used to develop the adjustment factors that would be applied to the ESRD PPS base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. One significant limitation, which in large part drove the development of the two-equation model, was that there was no way to reliably identify, using claims data, the costs for composite rate services—that is, items and services such as staff labor, dialysate, capital-related assets such as renal dialysis machines, and certain drugs and laboratory tests that are used in the provision of outpatient maintenance dialysis for the treatment of ESRD and that were 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.

In the CY 2016 ESRD PPS final rule, we updated the payment multipliers for the ESRD PPS patient-level adjustment factors for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for ESRD facilities treating a low-volume of ESRD patients (80 FR 68968 at 68973 through 68984). In that CY 2016 ESRD PPS final rule, we discussed and responded to several public comments in which commenters

expressed concerns about the continued use of the two-equation model (80 FR 68974 through 68976). One comment from MedPAC suggested that CMS develop a one-equation model for the ESRD PPS. In response, we noted that the ESRD PPS is not currently able to utilize a one-equation method, because ESRD facilities do not report charges associated with the components of renal dialysis treatment costs that vary across patients such as time on machine. In other words, patient-level claims provide line-item detail on the use of the formerly separately billable services but do not provide any information regarding variation across patients in the use of the formerly composite rate services. In addition, we stated that we believed that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid an ESRD PPS base rate (that is, composite rate payment) to account for those costs that were never itemized on a claim but were reported through the cost report (80 FR 68975 through 68976).

(c) Background on CMS Efforts to Explore the Use of "Time on Machine" Data to Refine the Case-Mix Adjustment Model

Interested parties, including MedPAC, have long expressed concerns about the complexity of the two-equation model underpinning the ESRD PPS and have questioned the validity of assuming that the composite rate costs for all patients at an ESRD facility are the same. 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. Additionally, interested parties have expressed concerns that the existing case-mix adjustors might not correlate well with the current cost of renal dialysis treatment and have encouraged CMS to explore a refinement.

In response, CMS has explored the feasibility of collecting time on machine data on patient claims from ESRD facilities and the potential for using such data. These efforts include: a Technical Expert Panel (TEP) held on December 6, 2018, a Request for Information (RFI) published in the ESRD PPS CY 2020 ESRD PPS proposed rule (84 FR 38399), and more

recently, an RFI published in the ESRD PPS CY 2022 proposed rule (86 FR 36322, 36399 through 36400). In addition, CMS issued sub-regulatory guidance in Transmittal 10368, from September 24, 2020, to begin collecting time on machine data, but it later rescinded that guidance.

(i) Technical Expert Panel (TEP) December 2018

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a TEP was held on December 6, 2018, to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. In that CY 2020 ESRD PPS proposed rule, we discussed the purpose of the TEP and the topics that were discussed, including several data collection options.[41]

In the CY 2020 ESRD PPS proposed rule, we noted that CMS's data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. The data contractor provided examples of ways that longer duration of renal dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. The analysis suggested that additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and that patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs. We noted that, under current reporting practices, there are no data on the patient-and treatment-level variation in the cost of composite rate items and services. We explained that these findings underscore the

[41] The final TEP report from December 2018 and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

CMS published the findings from the December 2018 TEP in a report dated June 2019.[42] The 2018 TEP report provided examples of ways that extended treatment duration could affect cost components. First, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb[43] (now the ESRD Quality Reporting System, or EQRS) and facility cost per-minute data from cost reports to infer differences in costs reported across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of $62.62. Overall, it was found that costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, except for cost report drugs.[44]

CMS presented further discussion into collection of time on machine data for each dialysis session in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), where we further identified this potential data set as a singular option that would provide sufficient data to develop a refined case-mix adjustment model. If renal dialysis session time were reported for each renal dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in

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[42] The final TEP report from December 2018 is found directly at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/downloads/esrd-pps-tep-summary-report-june-2019.pdf.

[43] In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CrownWeb is now "EQRS"—that is, the ESRD Quality Reporting System (OMB Control Number 0938-1289).

[44] Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.

composite rate costs could be attributed to two discrete categories: differences due to renal dialysis treatment duration (measured in units of time); and differences unrelated to treatment duration. To alleviate concerns from interested parties, we noted that time on machine data would not be used to directly adjust ESRD PPS payment, rather, it would be used to apportion composite rate costs (currently only observable at the facility level to the patient or treatment level) for use in the case-mix adjustment. Time on machine data 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.

We further explained that, in the December 2018 TEP, the data contractor proposed two approaches to collect time on machine data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) (now EQRS) on delivered renal dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN); or (2) have ESRD facilities report time on machine data on Medicare claims. For the latter, we suggested that time on machine data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each renal dialysis treatment or by updating the definition of the existing revenue center code for renal dialysis treatments so that the units correspond to treatment time instead of the number of treatments. We noted that ESRD facilities already reported to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that ESRD facilities currently collect time on machine data.[45] Moreover, we stated that we were aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every renal dialysis treatment, minimizing additional burden of reporting this metric on claims.

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[45]Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: https://www.cms.gov/files/document/cy-2021-final-technical-specifications-20201130.pdf.

The December 2018 TEP participants preferred that the data be collected on Medicare claims (84 FR 38398). They did not support using the then-existing CROWNWeb data for time on machine data, as there were too many questions about its completeness and timeliness. They agreed that if time on machine data is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. We explained that the TEP participants cautioned that reporting time on renal dialysis on the claims would place additional burden on ESRD facilities. However, we stated that we believed that, for ESRD facilities with EHRs, the burden associated with the collection of renal dialysis treatment time is expected to be small and temporary, because the information is already being collected. We noted that collecting time on machine data could be difficult to accomplish for ESRD facilities that do not use EHRs. Lastly, we stated that some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

(ii) Request for Information (RFI) in the CY 2020 ESRD PPS Proposed Rule

In addition to presenting the findings from the December 2018 TEP, we solicited comments in the CY 2020 ESRD PPS proposed rule (84 FR 38399) on the option of collecting time on machine data. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782), commenters responding to the RFI opposed the use of time on machine data, maintaining that other factors were more directly related to cost of treatment. Commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients' special circumstances and comorbidities and not to treatment duration. Regarding patient-level factors contributing to high costs of care, commenters expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care and opposed the use of time on machine data as a single, patient-level factor to estimate variation in composite rate costs. Some commenters expressed the objection

that use of this measure would not be productive because there was great homogeneity in treatment times across patients.

(iii) CMS Sub-Regulatory Guidance in Transmittal 10368 (September 24, 2020) (Now Rescinded)

In Transmittal 10368, published September 24, 2020, CMS instructed the MACs to implement a new value code D6, which reflects the total number of minutes of dialysis provided during the billing period. See Transmittal 10368, CR 11871 (*Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine*), effective January 1, 2021. At the same time, CMS announced a new requirement for ESRD facilities to report value code D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments. Shortly after making these contractor directions public, CMS issued a Medicare Learning Network (MLN) Matters guidance document (MLN Matters No. MM11871) advising ESRD facilities of the new requirement to include treatment time on claims. However, after a large dialysis organization submitted a petition[46] pursuant to the HHS Good Guidance Practices Regulation,[47] HHS issued a finding that notice-and-comment rulemaking was required for CMS to impose such a requirement. Consequently, CMS rescinded Transmittal 10368 and replaced it with Transmittal 10576, dated January 20, 2021, withdrawing the requirement for reporting time on the dialysis machine with value code D6. Although the guidance to report time on machine data was rescinded, the value code D6 for the time on machine in minutes remains approved by the NUBC and remains on CMS's claim form CMS-1450 (UB-04) (OMB-0938-0997), in a deactivated status.

(iv) Request for Information (RFI) in the CY 2022 ESRD PPS Proposed Rule

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[46] The petition (dated December 23, 2020) is attached as Exhibit A to HHS's petition response (January 8, 2021) which can be found at https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf.

[47] The HHS "Good Guidance Practices" final rule appeared in the **Federal Register** on December 7, 2020 (85 FR 78770) and was later rescinded July 25, 2022 (87 FR 44002).

CMS revisited the topic of time on machine in the 2020 TEP and discussed the case-mix adjusters.[48] Interested parties continued expressing concerns that the existing case-mix adjustors might not align with resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues. We sought additional public input in the ESRD PPS CY 2022 proposed rule, requesting information on the methodology used to calculate the case-mix adjustment (86 FR 36322, 36399 through 36400) and the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim.[49]

We received similar comments on this RFI to those expressed in response to the CY 2020 ESRD PPS proposed rule. As discussed in the CY 2022 ESRD PPS final rule, commenters cited concerns that apportioned composite rate costs (such as labor and capital related costs) from the cost reports, used in the case-mix adjustments, were currently only observable at the facility-level and did not include patient or treatment-level variations.

Like previously mentioned concerns regarding the collection of time on machine data, commenters suggested this data element would be burdensome and complex (especially for those dialyzing at home) and would not identify high-cost patients. They stated that what little variation might be identified would not be worth the burden of collecting the information. In addition, these commenters stated that ESRD facilities' staffing is based on prescribed time, not on the actual time a patient is on the machine. They stated that the prescription approach is the most rational way to determine staffing levels, because ESRD facilities do not have time on machine in advance. According to these commenters, ESRD facilities would only have the prescribing physician's prescription to use.

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

[49] We published a summary of the responses to the CY 2022 ESRD PPS RFI (86 FR 36322, 36399 through 36400) for the current case-mix methodology in the ESRD PPS CY 2022 final rule (86 FR 61874, 61997) and provided greater detail on CMS's website at https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.

A provider advocacy organization opposed the use of time on machine data for purposes of ESRD PPS primarily because certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. They expressed significant concern that use of time on machine data for differentiating treatment cost variability creates inappropriate incentives for certain ESRD facilities to "game the system" by: (1) putting patients on renal dialysis longer than necessary; or (2) placing patients on the cheapest dialyzer and keeping them on it for all five possible hours of dialysis. Another small renal dialysis organization agreed, pointing out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient. Most of the labor for renal dialysis treatments is putting the patient on and taking the patient off dialysis. Therefore, in both previously described scenarios, the commenter asserted that cost would remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and they generally cannot force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

A small renal dialysis organization within a large non-profit health system commented that reporting treatment times would be difficult and confusing and identified many factors that would need to be addressed by CMS, including: identifying renal dialysis start time, early removal from renal dialysis, inadvertent lack of time on machine information, data inclusion on a claim form, and staff training. They also expressed concern about the reporting of time on machine creating opportunities for ESRD facilities to game the system by having the renal dialysis run a few extra minutes to move into the next highest level.

Several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Some comments recommended removal of the comorbidity adjustments, because they report the adjustments are not utilized. They recommended CMS refine the age and weight (BSA and BMI) adjusters to better capture and designate higher cost patients. Many commenters expressed the belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. A non-profit renal dialysis association recommended that CMS minimize resources devoted to adjusters. The commenters suggested including only the minimum needed to deliver quality patient care, restore significant funding to the ESRD PPS base rate for the benefit and care of all beneficiaries, and focus retained adjusters only on those that are clearly linked to patient cost of care or clear barriers to access. Specifically, they recommended that CMS: retire the remaining comorbid case mix adjusters; revise the weight adjusters to maintain a low-BMI adjuster; create a high-BMI adjuster; eliminate the BSA adjuster; retire the age adjuster (which they believe is not methodologically sound and does not resonate with clinician or renal dialysis facility experience of care); maintain the adjuster for low volume facilities; consider expanding the adjuster to a second tier of facilities providing fewer than 6,000 treatments per year; eliminate the rural adjuster; and maintain the onset of renal dialysis adjuster to support the resource intensive needs of patients starting dialysis. Other commenters stated it would be too preliminary to eliminate the case-mix adjusters entirely, and instead they recommended that CMS initiate a discussion of the adjusters that are true drivers of high costs and how the use of adjusters can be operationalized for practical purposes. One payment adjustment that was universally supported by commenters was the onset adjustment.

MedPAC recommended that CMS develop a one-equation regression model in place of the two-equation model currently used as the basis for the ESRD PPS. MedPAC also recommended that CMS consider removing the comorbidity adjustments and revise the body size

adjustment. MedPAC further recommended that CMS address the inherent correlation between BSA and BMI by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are calculated based on patient height and weight. MedPAC's analyses found that BSA and BMI values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented. We reiterated in the CY 2022 ESRD PPS final rule our current inability to implement such a model given the absence of data on the charges associated with the components of renal dialysis treatment costs that vary across patients in the use of the formerly composite rate services. A non-profit renal dialysis association agreed with MedPAC.

(2) Health Equity Considerations Supporting the Proposed Collection of Time on Machine Data

In the CY 2024 ESRD PPS proposed rule (88 FR 42468), we stated that CMS prioritizes expansion of the collection, reporting, and analysis of standardized data as a key means to advance health equity.[50] We explained that by increasing our understanding of the needs of those we serve, CMS aims to ensure all individuals have access to equitable care and coverage. We noted that CMS's proposal to collect time on machine data supports these priorities. We stated that we believe the proposed data reporting requirements would support our ability to assess whether, and to what extent, our programs and policies may perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities.

As noted previously, as part of CMS's December 2018 TEP and in the ESRD PPS CY 2020 final rule, CMS's EQRS data (formerly collected under CROWNWeb) is reported once per patient-month. CMS's proposal to collect time on machine data, which would require duration of treatment data reported for every renal dialysis treatment, would provide a more granular set of standardized data for analyzing (and potentially apportioning) composite rate

[50] https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity.

costs for use in the case-mix adjustment. We noted that we would also look to time on machine data as a source to monitor claims data and identify disparities in care that could be mitigated by potential future adjustments that would incentivize equitable care within the framework of the ESRD PPS.

As we noted in the CY 2024 ESRD PPS proposed rule, ESRD PPS reform is an ongoing multi-year effort to refine payment adjustments and methodologies under the ESRD PPS. Section 1881(b)(2)(B) of the Act provides that the Secretary shall prescribe in regulations any methods and procedures to determine the amounts of payments to be made for part B services (which include renal dialysis services), on a cost-related basis or other economical and equitable basis. Section 1881(b)(14)(D) of the Act requires the ESRD PPS to include a payment adjustment based on case mix that may consider various patient characteristics and other appropriate factors.

Since the establishment of the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030), CMS has been engaged in ongoing monitoring and analysis of the ESRD PPS. CMS publishes these monitoring results regularly.[51] CMS's monitoring activities have involved analysis of ESRD facility cost reports and patient claims to determine the most accurate adjustments and methodologies as well as to identify trends in beneficiary health outcomes. Similarly, we noted that the proposal in the CY 2024 ESRD PPS proposed rule to collect more-detailed standardized data (that is, the proposed time on machine reporting) than is presently available for analysis supports our ability to evaluate potential disparities in health care provided to our beneficiaries.

Presently, CMS adjusts the per-treatment ESRD PPS base rates to account for variation in the case mix, as set forth in § 413.235. These adjustments account for patient age, BSA, low BMI, onset of renal dialysis (new patient), and comorbidities (for example, sickle cell anemia),

[51] Since the implementation of the ESRD PPS in January 2011, CMS has monitored outcomes, through a claims-based monitoring program, for Medicare beneficiaries receiving outpatient maintenance dialysis. See https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring.

as specified by CMS. We explained in the CY 2024 ESRD PPS proposed rule that the data and information that inform these adjustments are derived from cost reports, which are submitted to CMS on the facility level. However, we noted that time on machine data would be provided to CMS at the patient level on patient claims. This change would shift CMS's focus to a more patient-centered paradigm. We stated that we believe time on machine data would provide the insights we need to develop (and propose) potential amendments to the payment multipliers for the current, and potential future, patient-level adjustments, including new SDOH factors or health conditions (such as profound post-dialytic exhaustion) as patient-level adjustments. More immediately, however, time on machine data would significantly enhance CMS's insight into whether our current payment adjusters are appropriately aligning with actual resource use for individuals and communities who are underserved or disadvantaged and who may have multiple patient-level characteristics that necessitate longer renal dialysis times.

For example, CMS is aware of anecdotal evidence and published studies showing that patients with the comorbidity of sickle cell anemia may need a longer renal dialysis treatment time as well as additional resources from medical staff to attend to the manifestations of sickle cell that occur during dialysis. In fact, renal dialysis patients with sickle cell anemia may have frequent pain attacks during the actual renal dialysis treatment.[52] Such an attack, known as a vaso-occlusive pain crisis, precipitates a series of medical interventions involving intravenous fluids, analgesia, as well as the treatment of any precipitant and/or acute comorbid state.[53] CMS would be able to use time on machine data for patients with sickle cell anemia to evaluate its alignment with the patient-level adjuster for the corresponding co-morbidity.

In addition to re-evaluating and potentially updating the payment multiplier for the patient-level adjuster for the co-morbidity of sickle cell anemia, we noted that we anticipate that

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[52] Benjamin Jacob et al. Management of the Dialysis Patient with Sickle Cell Disease (Seminars in Dialysis 14 July 2015, https://doi.org/10.1111/sdi.12403).

[53] Derebail VK, Lacson EK Jr, Kshirsagar AV, Key NS, Hogan SL, Hakim RM, et al.: Sickle trait in African American hemodialysis patients and higher erythropoiesis-stimulating agent dose. *J Am Soc Nephrol* 25: 819– 826, 2014.

there could be other instances where patients need more time on renal dialysis to avoid uncomfortable post-dialytic sequela, such as profound post-dialytic exhaustion. In instances of profound post-dialytic exhaustion, for example, CMS would evaluate the forthcoming time on machine data for the potential correlations between additional hemodialysis treatment time and decreased incidence of profound post-dialytic exhaustions, which may have cost implications. We stated that we are aware there may be a need for a future patient-level payment adjuster associated with post-dialysis fatigue.

(3) Requirement for Reporting Time on Machine Data to Evaluate Accuracy of Current Payment Adjusters Aligned with Resource Use

In the CY 2024 ESRD PPS proposed rule (88 FR 42469), we proposed to require patient-level reporting on resource use involved (time on machine) in furnishing in-center hemodialysis treatment in ESRD facilities, which would serve as a proxy to apportion composite rate costs (capital, labor, and administrative costs, as well as drugs, laboratory tests, and supplies necessary to administer the dialysis treatment) for use in the case-mix adjustment. This would allow us to more precisely estimate the average costs of the various earlier-mentioned components of a renal dialysis treatment that cannot currently be captured because payment for these items is bundled, and claims data do not contain detail on the use of these items and services. We stated that CMS would review the patient-level resource use data, including time on machine data, to evaluate and monitor the accuracy of the methods and procedures, including the payment methodology for the patient-level adjustment factors, enhancing the integrity of the ESRD PPS. In addition, we stated that CMS would evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which may include age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, we stated that CMS would review the data for its potential to identify any disparities from a health equity perspective and to support the future proposal of any new patient-level adjustment factors, including potential SDOH factors. We noted that such data may also be used

to inform potential future refinements to the facility-level adjustment factors, if appropriate. We stated that per § 413.196, we would publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate, in the **Federal Register**.

(a) Changes to 42 § 413.198

We proposed to amend § 413.198 by adding language at § 413.198(b)(5) that would require each ESRD facility to submit data and information, under existing paragraph § 413.198(b)(3) describing allowable costs, of the types and in the formats established by CMS, for the purpose of estimating patient-level and facility-level variation in resource use, such as data and information on the duration of hemodialysis treatment (that is, time on machine data) involved in furnishing hemodialysis treatment in center in an ESRD facility. For additional context, we noted that, under § 413.198(b)(3), allowable cost is the reasonable cost related to renal dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the ESRD facility in furnishing the renal dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. Reasonable cost includes both direct and indirect costs and normal standby costs.

We also proposed to update § 413.198(a) by adding a reference to section 1881(b)(14) of the Act to acknowledge the statutory provisions for the ESRD PPS.

(b) Additional Background Considerations for, and Comments and Responses thereto on, the Proposed Reporting of Time on Machine Data

As we noted in the CY 2024 ESRD PPS proposed rule, CMS reviewed past comments from its TEPs and RFIs and considered the approach of our now-rescinded sub-regulatory guidance in Transmittal 10368 and the complexities of reporting the number of minutes of hemodialysis treatment on patient claims. With this background in mind, we further refined our proposed requirements at § 413.198(b)(5) in a way that would result in the reporting of the most useful, high value data.

Considering past comments questioning the feasibility and accuracy of time on machine reporting for home dialysis patients, we proposed a reporting requirement that would only apply to patients receiving an in-center hemodialysis treatment. We explained that we believe this approach would ensure greater uniformity to the recording process and thus greater consistency in the data reported.

CMS also considered past comments responding to its RFI in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782) regarding patient-level factors that contribute to high costs of care. We stated that we agree with commenters that expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care.

We noted in the CY 2024 ESRD PPS proposed rule that we agree that the payment multipliers for patient-level adjusters should be grounded in strong evidence, and we recognize that each patient will have unique needs, with some being more costly to treat and others with fewer costs, given their medical backgrounds. We emphasized and again clarified that time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments.

We also considered comments suggesting that a "time on machine" data element would not identify high-cost patients and comments suggesting such a data element would not be productive as described earlier in this section. We stated that we agree with commenters that treatment times and costs may be similar across most patients based on our analysis and the comments of TEP participants. However, we would not expect to find that ESRD facilities are treating ESRD patients in a homogeneous fashion, but on a case-by-case basis determined by patient-centered plans of care. We noted that a review of CY 2016 cost report data, conducted as part of the December 2018 TEP,[54] showed that overall costs of renal dialysis services (within the

[54] As presented on Slide 42 from the December 2018 TEP, overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.

ESRD facility cost reports) increased with longer treatment times, and that this pattern was consistent for the individual cost report components.

We stated in the CY 2024 ESRD PPS proposed rule that we anticipate that the data that would become available under the proposed requirement, if finalized, for reporting time on machine data would provide insight into meaningful, measurable variabilities in certain costs associated with patient-level characteristics.

We stated that the significance of the time on machine data is dependent upon the collection of data from a preponderance of patient claims for in-facility hemodialysis. We further noted that while most patient claims may come from patients with similar profiles and treatment plans, the needs of the more complex and resource-intensive patients can only be identified by CMS through the collection of patient-level data from across the ESRD PPS patient population. We stated that complex and resource-intensive patients are frequently encountered in the ESRD dialysis treatment setting, but it is not possible to obtain precise estimates of the higher costs of these patients' hemodialysis treatments from currently reported data. We identified that cost reports and claims are the two data sources from which per treatment costs can be estimated. Since cost reports aggregate data at the facility level, we explained that patient-level differences in resource use are not detectable as higher medical needs, and related costs are masked by averages. Further, analysis of claims data from 2016 found that roughly 99 percent of ESRD facilities reported 10 or fewer distinct charge values across all patients and treatment modalities.[55] Routinely collected, ESRD patient population-based data on time on machine for each in-facility hemodialysis treatment would enable CMS to assess variation in the use of composite rate items and services at the patient level and to identify high-need and high-

[55] See page 9 of the December 2018 TEP Report at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf. See also Slide 27 from the December 2018 TEP Presentation at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.
And see Slide 30 from the December 2019 TEP Presentation at https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2019.pdf.

cost patients. In addition, the time on machine data set would enable CMS to further determine what trends or causal relationships may exist between certain patient-level characteristics and the number of minutes of hemodialysis treatment received by such patients. CMS would evaluate whether specific patient characteristics are associated with increased length of dialysis treatment, which contribute to cost.

We also considered comments that the costs to ESRD facilities for providing dialysis treatment could be better measured by looking at costs based on prescribed time, and not on the actual time a patient is on the dialysis machine. The commenters stated their view that looking to prescribed time(s) would be the most rational way to determine staffing levels (and costs), because ESRD facilities plan for dialysis session length based on the prescribed time. Although CMS recognizes ESRD facilities' labor practices to align staffing with the stated prescription times, CMS is concerned that, for some patients, their prescription times are not aligning with actual usage and thus may not be the best predictor of ESRD facilities' costs. For example, we noted that we are aware that patients who experience severe itching or have certain psychological disorders may be less likely to receive dialysis for the full prescribed time. For such patients, only the collection of time on machine data for the number of minutes of hemodialysis treatment received would facilitate CMS's understanding of their complex needs and the implications for the ESRD PPS. For such patients, a pattern of shorter treatment times may ultimately result in worse patient outcomes and higher patient costs to the ESRD facility as well as to Medicare. We stated that CMS is also aware that patients with certain characteristics, such as higher BSA quartiles, may be more likely to need longer dialysis times.[56] Additionally, CMS has been made aware of instances in which ESRD facilities may avoid treating complex patients or patients with higher costs generally (thereby favoring average or lower cost patients). We noted that prescribed dialysis times would not provide insight into costs for dialysis sessions for patients

[56] See slide 31 from the 2020 ESRD TEP presentation, which can be found here: https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf.

whose individual needs or circumstances might necessitate a dialysis treatment time that differs in practice from the prescribed dialysis time. Therefore, identifying actual resource usage, as correlated with the needs, health outcomes, and patient-level characteristics of complex patients would enable CMS to better align the payment multipliers with resource use within the ESRD PPS.

We stated that we anticipate that our proposed requirement would generate the data we would need to evaluate a potential adjustment of the payment multipliers for patient level adjustments, thereby allowing us to counteract possible financial disincentives to serving those patients. We noted that we expect that such adjustments may thereby enhance access to renal dialysis services for such resource-intensive patients. We also believe that collecting time on machine data is preferable to collecting prescribed times, since we recognize that patients' actual experiences do not always align with their doctors' orders.

We recognized that a new reporting requirement would require uniformity in its implementation across ESRD facilities. We noted that the proposed "time on machine" requirement is for the reporting of the number of minutes of hemodialysis treatment a beneficiary receives, and it refers to only the minutes (reported in whole minutes) spent dialyzing, while the patient is connected to the dialysis machine. We stated that we would address such details in operational guidance.

We received numerous public comments on our proposal in the CY 2024 ESRD PPS proposed rule to require reporting of time on machine data from a broad array of interested parties. Commenters included professional associations, advocacy organizations, large dialysis organizations, independent and regional dialysis providers, individual physicians, other healthcare providers, and patients.

The majority of the commenters generally opposed the requirement, but some commenters expressed support. Many commenters were supportive of CMS's effort to develop a patient cost model and to pursue future refinements that would advance health equity in the ESRD PPS.

However, commenters questioned the utility of time on machine data and expressed concern for the additional administrative burden collecting and reporting the data would entail. Commenters expressed concerns about the adverse effects on specific populations. The comments on our proposal and our responses are set forth below.

Comment: Some commenters expressed support for establishing a patient cost model that is based on a single patient-level cost variable. MedPAC reiterated its support for collection of time on machine data, which the commission previously noted in their comments on the CY 2022 ESRD PPS proposed rule. MedPAC agreed with CMS that these data could be used in the future to apportion composite rate costs (including labor and capital-related costs) that are currently only observable at the facility-level to the patient- or treatment- level for use in case-mix adjustment. One large dialysis organization expressed appreciation for CMS's acknowledgement that the current two-equation payment model has intricacies that can be mitigated by moving toward a single patient-level cost variable. This commenter asserted that using a patient-level cost variable would more accurately align treatment cost to payment. Further, the commenter urged transparency and inclusion of the dialysis community in moving forward with the development of a patient-level cost variable.

Response: CMS appreciates the support expressed by MedPAC and other commenters for moving toward a patient cost model. As we discussed in the CY 2024 ESRD PPS proposed rule and reiterate in this final rule, the proposed requirement for reporting time on machine data is the first step toward creating the kind of patient cost model that commenters acknowledged would have advantages over the current cost model. As we discuss later in this final rule, we intend to analyze time on machine data for the purposes of creating a patient-level cost variable for potential future refinement to the ESRD PPS case mix adjusters. We intend to undertake further rulemaking in subsequent years to address various considerations, including the methodology for allocating composite rate costs to patients for the development of a patient-level cost variable. Interested parties would have the opportunity to comment on the methodology

used in CMS's analysis to support such development at that time. We look forward to actively engaging with the public throughout that process in the future.

Comment: Several commenters, including a network of dialysis organizations, State regional offices, a non-profit organization of ESRD networks, an individual commenter, a national organization of patients and kidney health care professionals, MedPAC, an ESRD facility, and patients advocated for evaluating disparities in the ESRD PPS, to refine case-mix adjusters in a way that would improve payment accuracy, promote health equity, and ensure quality of patient care. A national organization of patients and kidney health care professionals voiced support for aligning patient characteristics and co-morbidities more accurately to case-mix adjusters to establish that patients are receiving patient-centered care.

One commenter explained that his research has demonstrated that slower, longer dialysis sessions have a positive impact on patient health and mortality. In addition, several commenters described serious issues with shortened dialysis treatments contributing to reduced quality of care. One patient reported an incident in which they lost consciousness during treatment and no staff member responded. Several patients indicated they did not receive education regarding home modalities for years after beginning dialysis treatment. Two patients reported disregard and lack of education by physicians. Several patients reported additional quality of care issues, including starting dialysis treatment late or being removed from dialysis treatment early, being requested to move their treatment time frequently, being moved to another ESRD facility for treatment, and even being requested to skip dialysis treatment.

Response: We appreciate the support for advancing health equity and quality of care through refinements to the ESRD PPS case mix adjusters. We believe that time on machine data, which we proposed to collect beginning January 1, 2025, would support CMS's analysis of disparities and support potential future refinements to advance health equity. Time on machine data can help inform CMS's understanding of the relationship between resource use and many of the issues reported by patients related to lack of staff time to address education or side effects of

dialysis treatments. Monitoring time on machine data will enable CMS to address patient concerns about the possibility of being removed from treatment early or started late and receiving shortened treatments. Any potential new case-mix adjusters or changes to the case-mix adjusters would be the subject of separate rulemaking, and as we noted earlier in this final rule, interested parties would have the opportunity to comment on the methodology used in CMS's analysis to support such development at that time.

Comment: MedPAC recommended that CMS consider the collection of time on machine data for Medicare Advantage (MA) dialysis beneficiaries, as the share of dialysis beneficiaries enrolled in MA plans now exceeds 40 percent. Doing so, MedPAC explained, would enable the agency to identify, assess, and address potential health disparities among both FFS and MA beneficiaries.

Response: We appreciate the recommendation from MedPAC to collect time on machine data for MA beneficiaries, but we note that the collection of data related to services provided to beneficiaries enrolled in MA is outside the scope of this final rule.

Comment: Several commenters, including a coalition of dialysis organizations, a non-profit kidney care alliance, and a non-profit dialysis organization, raised various concerns about the validity and sufficiency of time on machine data for the purpose of measuring patient resource use. One large dialysis organization requested details about how CMS would validate the time on machine data it proposes to collect. Several commenters claimed that shorter time on machine does not correlate with lower costs, and that time on machine data is not an accurate predictor of facility-level composite rate costs, since time on machine does not capture the full scope of services rendered. Specifically, commenters noted that time on machine fails to capture services provided before and after the actual dialyzing time, such as time spent working with social workers. Commenters expressed concern that use of such data would misinform payment model refinements.

Commenters also noted that patient characteristics such as pain, co-morbidities, or an inability to adhere to the prescribed length of dialysis time, all contribute to variation in time on machine. A coalition of dialysis organizations asserted that the costs of all these patients would remain the same regardless of their time on machine. Several commenters expressed concern regarding the accuracy of data for patients that require the dialysis treatment to be suspended or for dialysis treatment to be ended early due to medical or other needs. One non-profit treatment and research center expressed that some patients may have personal needs that require working with staff while they are not connected to a dialysis machine, that some patients may need to have dialysis treatment interrupted for a variety of needs, such as mechanical issues, bathroom breaks, and blood pressure issues; therefore, some patients do not complete the full dialysis treatment ordered by the physician.

Various commenters, including a professional organization of nephrologists, a non-profit dialysis association, and a large dialysis organization, suggested that CMS exclude certain types of dialysis from the proposed reporting requirement because of concerns about data quality. Commenters suggested excluding time on machine data collection for home dialysis patients, AKI patients, and nocturnal dialysis patients. Furthermore, several commenters expressed their concern that underserved or disadvantaged populations would be allocated fewer resources because of inaccuracies in time on machine data. Specifically, commenters noted that pediatric patients require highly individualized prescription time due to patient size and blood volume, which would not be indicative of health disparities. Lastly, one large dialysis organization requested that CMS track disasters and remove any data related to shortened treatments from the data.

Response: We appreciate the concerns that commenters raised regarding the validity and sufficiency of the data. Many of the concerns that commenters raised about potential issues of data quality can be addressed through CMS's analysis of the data. We note that methodological

considerations related to allocating costs based on time on machine data or any other data would be addressed in future notice and comment rulemaking.

First, regarding the question about how CMS intends to validate the data, it is not clear whether the commenter is referring to validating that ESRD facilities are reporting accurate and complete information, or ensuring the statistical validity of aggregated data CMS uses for analysis. In the former case, as we noted in the CY 2024 ESRD PPS proposed rule, requiring reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items represent expenses for medically necessary services. CMS reserves the right to request documentation from the provider validating the time on machine data, and to recoup payment if this documentation is not provided or supportable, as well as to take other administrative actions, as appropriate. We note that prescription data and historically reported monthly time on machine data is available in EQRS and can be used for the purposes of comparison. In the case of ensuring the statistical validity of data used for future analysis, we note that CMS has historically applied statistical trims to remove outlier values and erroneous data and could employ similar methods for future analyses.

As commenters rightly pointed out, time on machine data does not account for costs that ESRD facilities incur before and after the time spent dialyzing. As we previously discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), patient-level differences in composite rate costs could be attributed to two discrete categories: differences due to renal dialysis treatment duration (measured in units of time); and differences unrelated to treatment duration. The collection of time on machine data for each dialysis session would support the development of a patient-level cost model, with respect to the portion of composite rate costs that are attributable to dialysis duration. We would consider additional data and information to inform our allocation of costs that are not related to dialysis duration, such as time spent with social workers. Importantly, however, without a measure of dialysis duration, which we have

proposed to collect as time on machine data reported on claims, it would not be possible to develop a comprehensive patient-level cost model in the future.

We disagree with the commenter that the cost to care for patients is unchanged regardless of pain, co-morbidities, or adherence to prescribed dialysis treatment schedule based on time on machine. CMS published the findings from the December 2018 TEP in a report dated June 2019.[57] The 2018 TEP report provides clear evidence that in general, longer treatment duration is associated with higher costs. First, as discussed in the 2018 TEP report, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb[58] (now EQRS) and facility cost per-minute data from cost reports to infer differences in costs across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of $62.62. Overall, it was found that costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, except for cost report drugs.[59]

Lastly, we recognize that the unique needs of particular subpopulations such as pediatric patients, AKI patients, nocturnal patients, and patients with social needs may affect time on machine data. We intend to consider such patient characteristics when proposing a methodology for allocating composite rate costs in the future. We do not believe it would be appropriate to

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[57] The final TEP report from December 2018 is found directly at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/downloads/esrd-pps-tep-summary-report-june-2019.pdf.

[58] In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CROWNweb is now "EQRS"—that is, the ESRD Quality Reporting System (OMB Control Number 0938-1289).

[59] Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf.

exclude these subpopulations from the analysis entirely, because doing so would result in refinements to the ESRD PPS that in no way account for the unique needs of these subpopulations. Rather, we intend to look for ways to analyze and understand the impacts of such patient characteristics on treatment duration. For example, because commenters have indicated time on machine may be shortened due to social factors, we would encourage ESRD facilities to use Z codes when submitting ESRD PPS claims as appropriate to note when social factors affect treatment time or other aspects of treatment. For instance, if a patient has transportation issues necessitating removal from treatment early, the ESRD facility could include Z59.82 (Transportation insecurity), or if the patient has difficulty in understanding the education provided related to the importance of completing treatments the ESRD facility could use Z55 (Problems related to education and literacy) to indicate the psychosocial need to be addressed. The coding of this type of information, when clinically appropriate, would support CMS's efforts to understand the impact of social determinants of health, and other factors, on treatment duration and patient-level cost.

Comment: Many commenters stated that collecting time on machine data would place a significant administrative burden on ESRD facilities, including for facilities that utilize EHR systems, but especially for smaller facilities and facilities that lack EHR capabilities. Commenters expressed that the time-consuming task of reporting time on machine would add to ESRD facilities' costs and would have a negative impact on time available for patient care during a prolonged period of workforce shortage.

Several commenters suggested alternative data sources that CMS could consider using in order to avoid the burden associated with the proposed collection of time on machine on claims. Some commenters suggested that existing CrownWeb (now EQRS) clinical data on time on machine, collected once monthly in conjunction with blood urea nitrogen (BUN) laboratory testing, could be used instead, reducing the burden on providers to collect data for each treatment. A non-profit kidney care alliance indicated while time on machine data may be

interesting, there may be superior alternatives as a proxy to apportion composite rate costs; however, they did not provide any alternatives to time on machine as a proxy. Some commenters encouraged the use of physician prescribed time, rather than actual time on machine, as it reflects how ESRD facilities are staffed. One commenter suggested defining time on machine as blood volume processed >0, as this would enable CMS to capture resources expended on sequential ultrafiltration.

Several other commenters suggested limiting the scope of the proposed data collection to reduce burden. Some commenters suggested limiting time on machine data collection to a subset of dialysis facilities or treatments. MedPAC urged CMS to be mindful of the potential for increased administrative burden on ESRD facilities and consider collecting these data for a finite period of time, only as long as needed to explore refining the payment adjustment factors.

Response: We acknowledge that collecting time on machine data will increase administrative burden for ESRD facilities, especially those for whom the collection of such data will have to be done manually. However, we do not agree that the proposed reporting requirement will substantially impact time available for patient care, as some commenters suggested. We anticipate that ESRD facilities will employ medical records technicians or similar non-direct-care staff to aggregate time on machine data and report it on claims. Furthermore, as we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42466), for facilities that have already automated the collection of machine-generated data directly into the patient electronic medical record, this burden should be minimal. CMS will work to provide timely operational guidance about the reporting requirement for time on machine information so that facilities may prepare their information technology (IT) or EHR systems or other processes to collect and report complete time on machine data by January 1, 2025. We have revised our burden estimate in the regulatory impact analysis in section VII.D.2.a of this final rule to reflect the additional burden associated with aggregating time on machine data from the patient record and reporting it on the claim.

We appreciate commenters' suggestions regarding alternative sources of data. As we discuss earlier in this final rule, we believe time on machine is the most appropriate source of data for our proposed purpose. In contrast to the sources that commenters suggested, time on machine data would provide more comprehensive information about the actual quantity of dialysis that a patient receives each month. As we have previously noted, past analysis has demonstrated a statistically significant relationship between a patient's total time on machine and resource utilization.

In addition, we appreciate the suggestion to limit time on machine data collection to a subset of dialysis facilities to drive the revision of case-mix adjusters. However, we believe this would be counterproductive, because analysis of a subset of facilities could skew the data and impact the accuracy of case-mix adjusters for the ESRD PPS in its entirety. We also appreciate the recommendation from MedPAC to limit the duration of data collection to the length of time necessary to develop methodology to use for case-mix adjustment. Without collection, review, and assessment of the time on machine data, we cannot provide an estimate of the length of time CMS will need to collect the data. We will consider the recommendation from MedPAC and the level of burden that reporting places on ESRD facilities in the future. We intend to monitor and potentially propose modifications to this policy, as appropriate, through future notice and comment rulemaking.

(c) Using a Medicare Claims Data Field to Report Time on Machine Data

In the CY 2024 ESRD PPS proposed rule (88 FR 42471), we proposed that ESRD facilities report the number of minutes of hemodialysis treatment received in center in an ESRD facility using the D6 value code on the Medicare 72X type of bill (TOB) that is part of CMS's claim form CMS-1450 (UB-04) (OMB-0938-0997). While our proposal limited the time on machine reporting requirement to in-center claims, to address the concerns previously raised by interested parties about the burden and complexity of home dialysis reporting, we noted that time

on machine for home dialysis data could nonetheless be voluntarily reported using the D6 value code on claims.

This approach would address long-standing concerns, including such concerns raised by MedPAC and other interested parties, that CMS should move to a one-equation model. We stated that we agree with interested parties that a single-equation model, to be constructed at the patient level, would reduce the complexity of the current model, and would better align payment with costs. The current two-equation model's payment adjusters are derived using weighted averages of the coefficients from the facility-level and patient-level equations. Because the composite rate items currently comprise roughly 90 percent of the payment, we stated that we are seeking a more detailed understanding of patients' utilization of such treatment resources. We noted that we anticipate that the time on machine data would provide a useful proxy for these composite rate items.

Furthermore, we noted that the proposal to collect time on machine data on patient claims would address past comments on whether such a reporting requirement could create perverse incentives for ESRD facilities to amend actual reported time on machine. Another past commenter expressed concern about whether an ESRD facility might have the renal dialysis run a few extra minutes to increase the payment. However, we noted that requiring the reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items presented represent medically necessary expenses. The False Claims Act (31 U.S.C. 3729 to 3733) establishes civil liability for knowingly presenting a false or fraudulent claim to the government for payment.

We noted that if the requirement to report time on machine information on claims is finalized, we would issue operational guidance in support of the requirement. We stated that such guidance would describe the applicable instructions for reporting a value code (in this case,

the D6[60] value code) connected to the number of minutes of hemodialysis treatment provided to a patient in center.

The majority of the commenters expressed concerns about the need for specific operational guidance and about exclusions and missing data. The comments on our proposal and our responses are set forth below.

Comment: Several commenters, including a non-profit kidney care alliance, a coalition of dialysis providers, and large dialysis organizations requested clarification about the scope and specifications of the proposed reporting requirement. Commenters requested CMS to clarify its proposed definition of time on machine and how ESRD facilities would be expected to collect and report such data under the proposed requirement. A coalition of dialysis providers stated that there are inconsistencies in the methodology used across health care providers for the collection of time on machine data and that CMS will need to provide guidance to ensure data is accurately provided. Two large dialysis organizations recommended CMS define time on machine data collection using an approach like that used in the ESRD Measures Specification Manual associated with the ESRD QIP.[61] One large dialysis organization recommended using "clock time" to measure time on machine. We note that the commenter did not specify a meaning for the term "clock time"; however, we interpret this to mean the total number of minutes between the beginning of dialysis and the end of dialysis, without accounting for any interruptions. Clock time, the commenter suggested, could be utilized by all ESRD facilities, since it would not require networked electronic medical records. Another large dialysis organization requested confirmation that ESRD facilities would be required to report time on machine for all in-center dialysis treatments, including those provided under special circumstances for patients who normally perform dialysis treatments at home.

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[60] Value code D6 on claim form CMS-1450 (UB-04) (OMB-0938-0997), for reporting the total number of minutes of dialysis provided during the billing period.
[61] https://www.cms.gov/files/document/cy-2023-final-technical-specifications-20230613.pdf

Response: We appreciate these requests for clarification from the commenters. Although we intend to publish detailed operational guidance, we are taking the opportunity in this final rule to respond directly to the questions that commenters posed. First, while we appreciate the recommendation that we use the ESRD Measures Specification Manual as a guide to define data collection, we note that the manual does not define time on machine in a way that is useful for our purposes. Rather, for the purposes of this reporting requirement, we are clarifying that we generally define time on machine as the total number of minutes between the beginning of dialysis and the end of dialysis, without accounting for any interruptions, which we believe one commenter referred to as "clock time", as noted earlier. We do not intend for ESRD facilities to track minutes for interruption during dialysis due to frequent alarms or when a patient is removed from dialysis treatment to go to the bathroom, nor do we expect facilities to subtract those minutes of interruption from the time on machine that is reported. We expect these episodes to be infrequent and time-limited, and generally not a significant driver of aggregate variation in total time on machine between patients. Thus, time on machine for each dialysis treatment can be calculated by subtracting the time the dialysis treatment started from the time the treatment ended. For each ESRD PPS claim, the ESRD facility should report in the D6 value code the total number of minutes across all treatments provided to the patient during the billing period, which is typically a month. Lastly, regarding the comment about in-center dialysis treatments provided under special circumstances for patients who normally perform dialysis treatments at home, we are clarifying that time on machine data must be reported for all dialysis treatments that are provided in-center, even if the patient usually uses a home modality. In such circumstances, the ESRD facility should be billing for in-center dialysis treatments on a separate claim from any home dialysis treatments, with the appropriate indicators to reflect that the treatment is being provided in-center.

Comment: Several commenters requested clarification about how to report time on machine in various exceptional circumstances. One large dialysis organization stated that CMS

should provide guidance regarding how to report time on machine during certain infrequent anomalous circumstances such as power outages, network failures, mechanical issues or failures, or emergency circumstances when treatments must be shortened. One large dialysis organization requested CMS to differentiate between when time on machine data is captured manually and when it is captured electronically. Commenters also expressed concern about whether ESRD facilities would be paid for treatments for which time on machine was missing and requested that payment should not be withheld for missing time on machine data (that is, claims with no D6 value). One large dialysis organization requested CMS consider allowing an error rate of ten percent of total treatments to allow for unforeseen circumstances.

Response: We appreciate the concerns that commenters raised about exceptional circumstances. We recognize that circumstances such as power outages, network failures, mechanical issues or failures, emergency circumstances, and human error can result in disruptions to standard workflows and consequently, missing time on machine data for individual dialysis treatments. We are clarifying that since data for time on machine is reported as an aggregate value for all dialysis treatment sessions in one month, we will not return claims that lack reporting of individual sessions. We will only return claims that have nothing reported in the D6 value code. Therefore, although we appreciate the suggestion to allow a ten percent error rate, we believe it is neither necessary nor appropriate to do so.

At this time, we have not established any specific indicators to differentiate between time on machine that is collected manually versus electronically. Nor have we established any identifiers for circumstances when a patient needs to end his or her dialysis session earlier than the prescribed time; however, as we discussed earlier in this final rule, we believe additional information already reported on claims, such as ICD-10 codes, could provide relevant context for such circumstances. We may consider developing additional indicators to identify circumstances like the ones that commenters described, and we would discuss any such changes in future notice and comment rulemaking.

(d) Use of Time on Machine Data for the ESRD PPS

In our CY 2024 ESRD PPS proposed rule (88 FR 42470), we emphasized and again clarified that time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments. Rather, we stated that time on machine data would allow for patient-specific calculation of costs for composite rate services, including labor costs, costs for the use of renal dialysis machines and related equipment, and costs for such items as dialysate and other essential supplies. We noted that, in this way, time on machine data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined, single-equation estimation methodology. The refined, single-equation regression analysis (currently under development) would still be used to determine the inclusion/exclusion and magnitude of payment multipliers for patient-level case-mix flags that are associated with higher costs. We wrote that final payment adjustments would still only depend on existing patient-level case-mix adjustors, rather than a factor directly derived from time on machine data.

Several of the commenters expressed concerns about how the resultant time on machine data would be used in the model refinement process to potentially determine payment. The comments on our proposal and our responses are set forth below.

Comment: Several commenters requested further clarification about how CMS intends to use the time on machine data. A not-for-profit dialysis organization expressed concern that reporting time on machine data would lead to a payment methodology based on minutes of dialysis provided.

Response: In the proposed rule and this final rule, we have clearly stated how data collected from time on machine will be used. We will use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS will also evaluate whether the data could be used to inform future refinements to the existing

patient-level adjustment factors set forth at § 413.235(a), which include patient age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, CMS will review the data for its potential to identify any disparities from a health equity perspective that may support proposing, in future rulemaking, new patient-level adjustment factors, including potential SDOH factors.

(e) Request for Information About Effective Date

In the CY 2024 ESRD PPS proposed rule, we proposed a January 1, 2025, effective date for this new reporting requirement. We stated that we are aware that all ESRD facilities record the time a patient has received hemodialysis treatment into a patient's medical record, and that, for most ESRD facilities, this time is automatically recorded into the patient's EHR. We noted that we further understand that ESRD facilities can transfer data from EHRs into the patient-specific claims that are submitted to Medicare for payment. However, we recognized that some ESRD facilities with limited resources may need to make modifications to their record keeping and reporting systems to facilitate the transfer of a patient's recorded hemodialysis treatment time in the patient's medical record to the Medicare claim. Although we did receive a past comment indicating that a facility's implementation time would involve training staff on how to count and track time, we stated that we do not expect that the manual recording of a patient's hemodialysis treatment time into their health record is widespread. Finally, we noted that ESRD facilities are already reporting extensive information from patient EHRs into Medicare institutional claim form CMS-1450 (UB-04) (OMB-0938-0997), and we would not expect implementation to be overly burdensome to ESRD facilities. We stated that we recognize that some ESRD facilities would need to establish a new pathway from patient EHRs to the Medicare claim form, in addition to making simpler programming updates to add a field for the total number of minutes of dialysis provided during the billing period. Based on our findings in the TEP from December 2018, we noted that we anticipate that the implementation challenges that ESRD facilities might experience would be small and temporary, as a patient's time receiving dialysis treatment is already collected for the patient's medical record. We solicited

comment on whether an earlier effective date, such as January 1, 2024, would be feasible and would provide ESRD facilities with adequate time to implement this new reporting requirement.

The majority of the commenters expressed concerns about the ability to make the necessary changes to internal IT systems by a January 1, 2024, reporting requirement. The comments on our proposal and our responses are set forth below.

Comment: Commenters expressed strong opposition to any start date earlier than January 1, 2025. A large dialysis organization expressed that making the necessary operational changes to report time on machine data would require considerable effort and would not be possible prior to January 1, 2025. Several commenters called for CMS to allow for at least one year before implementation for ESRD facilities, including large dialysis organizations, to program the new requirements into their IT and EHR systems, and to provide comprehensive guidance before finalizing this policy. A few commenters also suggested that operational guidance be issued in conjunction with the CY 2024 ESRD PPS final rule, and that implementation of the proposed time on machine reporting requirement be delayed until interested parties have an opportunity to comment on such guidance.

Response: CMS understands the concerns that commenters raised regarding lead time needed to develop IT systems and processes in order to collect and report accurate and complete time on machine data. As we noted in the CY 2024 ESRD PPS proposed rule, we have proposed an implementation date of January 1, 2025, for this reporting requirement to provide what we believe will be sufficient lead time for ESRD facilities to make these necessary changes to their systems and operations. Commenters indicated that it would take 1 year for ESRD facilities to update their systems after the provision of operational guidance due to systems updates and staff education. We believe that the 1 year implementation timeline strikes a balance between the need to collect this data and ESRD facilities' need to make operational changes.

We also appreciate the concerns of commenters who requested specific operational guidance, and the opportunity to comment on such guidance, before the effective date of the

proposed reporting requirement. In this final rule, we have addressed many of the operational questions that commenters posed. Additionally, as we noted earlier in this final rule, we intend to issue detailed operational guidance no later than January 1, 2024. This operational guidance will address topics such as instructions for the collection and reporting of time on machine data, detailed billing requirements, including the types of ESRD PPS claims subject to required reporting of the D6 value code, and guidance on how to proceed when time on machine for a qualifying treatment is missing or otherwise unavailable. The proposed 1-year lead time between the issuance of detailed operational guidance and the effective date of the proposed reporting requirement will afford CMS the opportunity to engage in further dialogue with interested parties about such guidance during the CY 2025 rulemaking cycle. CMS has responded to specific concerns about operational guidance earlier in this section of this final rule. Further guidance will be provided by the MACs. Additionally, interested parties may reach out to CMS to request meetings to discuss and resolve specific concerns.

Final Rule Action: We are finalizing our proposal to require the reporting of in-center hemodialysis duration on ESRD PPS claims, beginning January 1, 2025. Specifically, we are finalizing our proposal to require ESRD facilities to report "time on machine," with certain changes to clarify that ESRD facilities are required to report the number of minutes between the start and end of hemodialysis treatment, without accounting for interruptions, a beneficiary receives during the billing period in center in an ESRD facility. We are finalizing our proposal to require ESRD facilities to report this information using the D6 value code on ESRD PPS claims. We are codifying this requirement in regulation at § 413.198(b)(5)(i). As discussed in section II.B.1.h of this final rule, we are finalizing the addition of § 413.198(b)(5), which states that ESRD facilities must submit data and information in the formats established by CMS for the purpose of estimating patient-level and facility level variation in resource use.

(4) Technical Change to § 413.198

We proposed to fix a typographical error in § 413.198(b)(3)(iii), which currently refers to "luxury items or servicess". We proposed to change this to "luxury items or services". CMS did not receive any comments regarding correcting this typographical error in § 413.198(b)(3)(iii). We are finalizing our proposal to revise the typographical error in § 413.198(b)(3)(iii), which currently refers to "luxury items or servicess" to "luxury items or services".

k. Clarification to TDAPA Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on the wholesale acquisition cost (WAC) or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (2), stops submitting a full calendar quarter of ASP data into CMS. We explained that once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, we stated that if we began paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would

stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

We adopted this conditional policy to avoid overpaying for the TDAPA on an ongoing basis and to ensure that TDAPA payment is based on the most appropriate data, that is, ASP. Specifically, we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349) and final rule (84 FR 60680) that we were concerned about (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

In the CY 2024 ESRD PPS proposed rule (88 FR 42472), we discussed that our existing regulation at § 413.234(c) does not specifically address the application of the TDAPA conditional policy in situations in which the manufacturer of the new renal dialysis drug or biological product submitted ASP data to CMS and reported zero or negative sales. Zero or negative sales may occur for a variety of reasons, including no sales, recalls of a product, or repurchases of sold products. In the CY 2012 PFS final rule (76 FR 73296), CMS clarified that zero or negative values are valid for ASP, ASP units, and WAC. Therefore, when such a scenario occurs for separately payable Medicare Part B drugs, we consider the submission of zero or negative sales to fulfill the reporting requirements of manufacturer ASP data to CMS as set forth in sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act. We noted that in situations when zero sales are submitted, CMS guidance[62] instructs the manufacturer to report "0.000" for the ASP and the number of ASP units. The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the U.S. FDA, are based either on the published WAC or

[62] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.

invoice pricing (except under OPPS, where the payment allowance limit is 95 percent of the published average wholesale price (AWP)). In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication 100-04, Chapter 17, section 20.4 Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.[63] Therefore, for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we clarified that we consider CMS to have received the latest full calendar quarter of ASP data, and we would not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Medicare Part B drugs, we would set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

Comment: We received two comments on our proposal to clarify the ASP data submission requirement. Both commenters, a coalition of dialysis organizations and a drug manufacturer, agreed with CMS that a submission reflecting zero or negative sales should not lead to a discontinuation of TDAPA payment. Both commenters supported this clarification. The comment from the coalition of dialysis organizations stated that this policy would support continued patient access to a drug or biological product that is in the TDAPA period. The comment from the drug manufacturer expressed further support for the use of WAC, or if WAC is not available, invoice pricing, when ASP data is not usable for the purposes of determining the TDAPA payment amount and post-TDAPA payment amount.

Response: We thank commenters for their support and for their insight into the importance and impact of this policy.

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[63] Medicare Claims Processing Manual Chapter 17, section 20.1.3 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.

Final Rule Action: We are finalizing the clarification to the TDAPA ASP payment policy as proposed; for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we consider CMS to have received the latest full calendar quarter of ASP data, and we will not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Medicare Part B drugs, in such circumstances, we will set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Clarifications and Application for CY 2024 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we would provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the FDA on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take

effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we would use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or

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

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

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

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

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we would announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for certain new and innovative renal dialysis equipment or supplies. We stated that the TPNIES is paid for two CYs. Following payment of the TPNIES, the ESRD PPS base rate

will not be modified, and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

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

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354)

that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID-19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

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

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.[64] We finalized that this amount would be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

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

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified, and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative,

[64] The CY 2023 TPNIES offset amount was $9.79. CMS finalized a CY 2024 TPNIES offset amount of $10.00, as discussed in section II.B.1.e of this final rule.

meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

2. Clarifications Regarding CMS's Evaluation of the TPNIES Eligibility Criteria

This section of the final rule discusses clarifications to our policies for evaluating the TPNIES eligibility criteria under § 413.236(b).

a. Sequential Order of CMS Review of the TPNIES Eligibility Criteria (§ 413.236(b))

As stated previously, we consider whether a new renal dialysis supply or equipment meets the TPNIES eligibility criteria as part of the annual ESRD PPS rulemaking and announce the results in ESRD PPS final rule. To qualify for the TPNIES, an applicant must meet each of the TPNIES eligibility criteria set forth in § 413.236(b)(1) through (6). An applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES.

In the CY 2021 ESRD PPS final rule, we focused our analysis of the TPNIES eligibility criteria on those that were not met. That is, for the Theranova Dialyzer, we included our analysis of how the applicant did not meet the innovation criterion under § 413.236(b)(5), and for the Tablo® cartridge, we included our analysis of how the applicant did not meet the newness criterion under § 413.236(b)(2) and innovation criterion under § 413.236(b)(5) (85 FR 71444 through 71464). In the CY 2022 and CY 2023 ESRD PPS final rules, we expanded our analysis to include our determination as to whether the applicants met each of the six criteria. In doing so, we analyzed the TPNIES eligibility criteria in the sequence that is provided in § 413.236(b)(1) through (6) (86 FR 61889 through 61906 and 87 FR 67193 through 67216).

In the CY 2024 ESRD PPS proposed rule (88 FR 42475 through 42476), we stated that we are clarifying that our analysis of the TPNIES eligibility criteria would continue to proceed in sequential order. Specifically, in the annual ESRD PPS proposed rule, we would continue to summarize the information from the application regarding each of the six eligibility criteria and include any questions or concerns that we identify during our analysis of the application.

Based on information provided by the applicant and from public comments during the annual ESRD PPS rulemaking cycle, we would continue to analyze the TPNIES eligibility criteria in sequential order in the annual ESRD PPS final rule. However, the change that we proposed is that once it has been established that one criterion has not been met, we would not discuss or make specific determinations on the subsequent criteria for that item in the annual ESRD PPS final rule. We noted that the criteria set forth in § 413.236(b) are intentionally listed in the order in which they appear. The first criterion is foundational in that an equipment or supply that is not a renal dialysis service would not be paid for under the ESRD PPS and therefore would not fit within the TPNIES payment pathway. As such, it would not be pertinent to evaluate the remaining TPNIES criteria for that item. TPNIES criteria two through four are objective and not subject to interpretation in that they each require date evidence to demonstrate newness, commercial availability, and the submission of a HCPCS application, respectively. The TPNIES innovation criterion under § 413.236(b)(5) requires the most significant CMS evaluation. We explained that, under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In doing so, we consider various non-objective circumstances in our review of the TPNIES applications, including the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD (86 FR 61905). We noted that we believe it is prudent to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria.

As described previously in the background section of this final rule, the TPNIES innovation criterion in § 413.236(b)(5) incorporates the substantial clinical improvement criteria in the IPPS regulations at § 412.87(b)(1) for the new technology add-on payment (NTAP). This

sequential approach for reviewing eligibility criteria is also in place for the NTAP pathway. The FY 2009 IPPS final rule (73 FR 48561 through 48563) discussed the way in which CMS evaluates the NTAP eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. The NTAP cost criterion is not applicable in analyzing TPNIES eligibility. However, consistent with our approach under NTAP, we stated that we believe that the most prudent use of CMS resources would be to reserve our analysis and determination regarding whether a new equipment or supply meets the TPNIES innovation criterion by representing a substantial clinical improvement over existing technologies until after we determine the new equipment or supply meets the earlier criteria.

Under this proposal, we would first determine whether an equipment or supply meets the renal dialysis service criterion in § 413.236(b)(1) and present our analysis of this first criterion in the final rule. In instances where CMS determines that § 413.236(b)(1) has been met, we would proceed in assessing the newness criterion in § 413.236(b)(2) and present our analysis of this second criterion in the final rule. In instances where CMS determines that § 413.236(b)(2) has been met, we would proceed in assessing whether the commercial availability criterion in § 413.236(b)(3) has either been met or the applicant expects that it will be met by January 1 of the particular CY and present our analysis of this third criterion in the final rule. In instances where CMS determines that § 413.236(b)(3) has been met or the applicant expects that it will be met by January 1 of the particular CY, we would proceed in assessing the HCPCS Level II code application criterion in § 413.236(b)(4) and present our analysis of this fourth criterion in the final rule. In instances where CMS determines that § 413.236(b)(4) has been met, we would proceed in assessing the innovation criteria in §§ 413.236(b)(5) and 412.87(b)(1) and present our analysis of this fifth criterion in the final rule. In instances where CMS determines that

§ 413.236(b)(5) has been met, we would proceed in assessing the non-capital-related asset (except home dialysis machines) criterion in § 413.236(b)(6) and present our analysis of this sixth criterion in the final rule. In instances where CMS determines that § 413.236(b)(6), as well as each of the five preceding criteria in § 413.236(b)(1) through (5) as discussed previously have been met, the equipment or supply would qualify for and would be paid for under the ESRD PPS using the TPNIES per § 413.236(d) beginning in the year that is the subject of the rulemaking.

In summary, we proposed to clarify that as CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to demonstrate having met one of the eligibility criteria, the item would be ineligible for the TPNIES. We would limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria that have been determined to have been met. We would not include the analysis of the remaining criteria in the final rule. This policy would be effective January 1, 2024 and would apply to our analysis of TPNIES applications for CY 2025 payment.

We received six comments regarding our proposed clarification of the sequential order of CMS review of the TPNIES eligibility criteria at § 413.236(b). These comments and CMS's responses are set forth below.

Comment: One commenter supported our proposal with the understanding that all criteria would be discussed in full in the annual ESRD PPS proposed rule. Other commenters requested CMS confirmation that we would continue to summarize the information from each TPNIES application, including any questions and concerns regarding each of the six eligibility criteria, in the annual CY ESRD PPS proposed rule. Commenters also requested clarification that in the annual CY ESRD PPS final rule, CMS would limit its analysis to the criterion not met as well as any preceding criteria that are met. Several other commenters expressed concern that our proposal would deny applicants CMS's analysis of each criterion, eliminating the

opportunity for the public to review the latter eligibility criteria and limiting applicants' ability to correct deficiencies prior to the next TPNIES application cycle.

Response: We thank the commenters for their input and confirm that we will continue to include our analysis of each TPNIES eligibility criterion in sequential order in the annual CY ESRD PPS proposed rule. We believe that identifying our comments or concerns with each of the eligibility criteria in the proposed rule provides the public with sufficient information and ample opportunity to review and respond to our analysis and provides the applicant with the opportunity to correct deficiencies, as needed.

If a TPNIES applicant who is denied reapplies in a later application cycle, we will continue to provide a full analysis of all the eligibility criteria once again in the annual ESRD PPS proposed rule to allow the applicant an opportunity to correct any additional deficiencies for all the eligibility criteria, as needed.

As stated in the CY 2024 ESRD PPS proposed rule (88 FR 42475), an applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES. Therefore, we believe that reviewing the TPNIES eligibility criteria in sequential order allows CMS to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria. This approach is consistent with the way that NTAP applications are assessed in the annual IPPS rule.

Final Rule Action: After consideration of the public comments received, we are finalizing our clarification regarding the sequential order of CMS review of the TPNIES eligibility criteria as proposed. In the annual ESRD PPS proposed rule, we will continue to summarize the information from the application regarding each of the six eligibility criteria and include any questions or concerns that we identify during our analysis of the application. As CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to

demonstrate having met one of the eligibility criteria, the item will be ineligible for the TPNIES. We will limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria and will not include the analysis of the remaining criteria in the final rule. This policy will be effective January 1, 2024 and will apply to our analysis of TPNIES applications for CY 2025 payment.

b. Clarifications Regarding the TPNIES Newness Criterion (§ 413.236(b)(2))

As stated previously, applicants must meet the newness criterion in § 413.236(b)(2) to qualify for the TPNIES. CMS defines the TPNIES newness criterion at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. In the CY 2024 ESRD PPS proposed rule (88 FR 42476), we clarified two distinct aspects of the criterion that are consistent with our current TPNIES policies and would not represent any changes to the eligibility criteria: (1) the 3-year newness period and (2) FDA marketing authorization.

First, with respect to the 3-year newness period, we stated in the CY 2021 ESRD PPS final rule that by defining new as within 3 years beginning on the date of the FDA marketing authorization, we limit eligibility for the TPNIES to new technologies but allow prospective TPNIES applicants 3 years beginning on the date of FDA marketing authorization in which to submit their applications (85 FR 71410 through 71464).

To further clarify the timeframe during which a prospective TPNIES applicant is eligible to apply, in the CY 2024 ESRD PPS proposed rule (88 FR 42476), we proposed to modify our regulation to specify that the applicant would have 3 years from the date of FDA marketing authorization to apply for the TPNIES, based on the date the application is submitted. We noted that this modification is consistent with current policy, and while it is not a change in policy, we believe that clarifying the regulation text would help to eliminate any confusion about the 3-year newness period. As indicated in § 413.236(c), February 1 prior to the particular CY is the annual TPNIES application submission deadline. We proposed to clarify that the 3-year newness period is only for submission of the complete application. An applicant does not have to ensure that

CMS renders its determination through notice and comment rulemaking within the 3-year newness period. Specifically, we proposed to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization.

Second, with respect to the requirement in § 413.236(b)(2) that the equipment or supply must have FDA marketing authorization, we proposed to clarify that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. As described on the FDA website, the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act established three regulatory classes for medical devices: Class I, Class II, and Class III. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.[65] Most Class 1 and some Class II devices, as noted on FDA's website, are exempt from premarket notification (510(k)) requirements, subject to certain limitations.[66] As we stated in the CY 2023 ESRD PPS final rule (87 FR 67202 through 67023), devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and effectiveness for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, generally a Class I or Class II device that is exempt from 510(k) requirements still must comply with certain regulatory controls (known as ''general controls'') to provide a reasonable assurance of safety and effectiveness for such devices. In limiting the TPNIES policy to items that have received FDA marketing authorization, we intended to exclude devices that lack FDA marketing authorization (87 FR 38511). In the absence of evidence that the renal dialysis equipment or

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[65] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing. Accessed on March 14, 2023.

[66] Food & Drug Administration. Class I and Class II Device Exemptions. Available at: https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions. Accessed on May 30, 2023.

supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received 11 comments on our proposed clarifications regarding the TPNIES newness criterion at § 413.236(b)(2). These comments and CMS's responses are set forth below.

Comment: In general, commenters supported both TPNIES clarifications. Commenters supported our proposal to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization and stated that basing the three-year newness period on the date of the TPNIES application submission, and not the date of CMS's determination through notice and comment rulemaking would ensure that months of eligibility are not taken up by the determination process.

With respect to our proposal that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES, one commenter stated that this policy would limit access to the TPNIES. The commenter stated that because exempt devices must still comply with general controls to provide a reasonable assurance of safety and effectiveness, these devices have no need to apply for FDA marketing authorization, and an FDA determination should not exclude these devices from the TPNIES. This commenter asserted that CMS should incentivize innovation in the ESRD space by allowing all relevant and appropriate technologies an opportunity to apply for the TPNIES.

Response: We appreciate the commenters' overall support for our clarifications regarding the TPNIES newness criterion. Regarding our proposed clarification that an equipment or supply with FDA Exempt status would not meet the newness criterion, we emphasize that for the purposes of the TPNIES, we rely on FDA marketing authorization to ensure that devices have met regulatory standards that provide a reasonable assurance of safety and effectiveness. While a Class I or Class II device that is exempt from 510(k) requirements

still must comply with certain regulatory controls (known as "general controls") to provide reasonable assurance of safety and effectiveness for such devices, we do not believe devices with Exempt status offer the level of assurance that is provided with FDA marketing authorization. As such, we maintain that our original intent was to exclude devices that lack FDA marketing authorization (87 FR 38511).

Final Rule Action: After considering public comments, we are finalizing as proposed our proposal to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization. We are also finalizing as proposed our proposed clarification that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. In the absence of evidence that the renal dialysis equipment or supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received one application for the TPNIES for CY 2024. A discussion of the application is presented below.

3. CY 2024 TPNIES Application for Buzzy® Pro

Pain Care Labs™ submitted an application for the TPNIES for Buzzy® Pro for CY 2024. Buzzy® Pro is one of several models of the Buzzy® device. The Buzzy® device is intended to control pain associated with needle procedures and for temporary relief of minor injuries. Buzzy® Pro is a palm-sized external use vibration device used with unique ice packs and is intended to temporarily desensitize and physiologically block pain associated with dialysis cannulation. The applicant stated that dialysis cannulation pain affects 12 to 80 percent of

dialysis patients and is a substantial contributor to reduced quality of life.[67,68] The applicant further stated that cannulation pain is associated with fear of the cannulation process, the decision to undergo hemodialysis and sometimes the hemodialysis itself.

The applicant described the steps for using Buzzy® Pro during dialysis: (1) thread the hands free strap or regular tourniquet through the ice pack and the device so that the ice pack is on the concave side of the device; (2) attach the device and the ice directly over the site; (3) activate the vibration toggle switch and leave in place 30 to 120 seconds; (4) during cannulation, move the device proximally so the dot on the side opposite the switch is 2 to 3 cm proximal to the cannulation site; (5) clean the site per cannulation protocol; and (6) remove the device after the painful part of procedure is completed.

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

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis. We consider Buzzy® Pro a renal dialysis service under § 413.171.

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

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that it is seeking 510(k) marketing authorization from the FDA for a new utility and design of Buzzy® created for dialysis fistulae sites, patented in 2022 under the name Buzzy® Pro. To be eligible for the TPNIES, the applicant must apply within 3 years of the FDA

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[67] Kosmadakis G, Amara I, Costel G. Pain on arteriovenous fistula cannulation: A narrative review. Semin Dial 2021;34(4):275-84 doi: 10.1111/sdi.12979 [published Online First: 20210507].

[68] Kosmadakis G, Amara B, Costel G, Lescure C. Pain associated with arteriovenous fistula cannulation: Still a problem. Nephrol Ther 2022;18(1):59-62 doi: 10.1016/j.nephro.2021.05.002 [published Online First: 20210618].

marketing authorization date and receive FDA marketing authorization by the HCPCS Level II deadline of July 3, 2023.

The applicant submitted the indications for use portion of its FDA 510(k) application that identifies Buzzy® as all Buzzy® models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal and Pro to control pain associated with needle procedures including dialysis and the temporary relief of minor injuries. The applicant provided supplemental information in a document titled "510(k) Summary" that included a comparison table of the Predicate Device (K130631) to the Subject Device (K202993). The document indicated that only the Buzzy® Pro model is recommended for dialysis. The document also indicated that Buzzy® Pro is identical to the predicate device in terms of materials, vibration motor, circuitry, functionality, and intended use; differs only in shape but is comparable in size to the predicate device; and Buzzy® Pro is distinguished by its rectangular shape to offer users a more professional looking alternative to the bee-shape of the other device. In the CY 2024 ESRD PPS proposed rule, we stated that we would be interested in better understanding the way in which the Buzzy® Pro, that is the subject of this TPNIES application, differs from the other Buzzy® models and whether Buzzy® Pro is indicated for adult versus pediatric patients, or both. We noted that to satisfy the newness criterion, the FDA 510(k) marketing authorization must have been issued within 3 years covering the specific device and model that is the subject of the TPNIES application. We invited public comment on this issue in the proposed rule.

Comment: The applicant submitted a comment to demonstrate that the device meets the newness criterion. With respect to our question regarding the way in which the Buzzy® Pro, which is the subject of this TPNIES application, differs from the other Buzzy® models, the applicant provided a table comparing Buzzy® Pro and predicate Buzzy® devices and stated that Buzzy® Pro is identical to the predicate devices in terms of materials, vibration motor, circuitry, functionality, curvature to fit the angle of the arm, and the mnemonic design with a "dot" to put near the "shot." The applicant stated that Buzzy® Pro is thinner, lighter, and has dual arms to

attach to the cannulation site compared to the predicate device; and Buzzy® Pro offers users a more professional looking alternative to the bee-shape of the other device.

With respect to FDA marketing authorization, the applicant indicated that Buzzy® Pro received FDA 510(k) approval on May 15, 2023, to control pain associated with needle procedures (for example, injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections).

Response: We appreciate the applicant's clarification regarding Buzzy® Pro's similarity to its predicate devices and confirmation of FDA marketing authorization. Based on the information provided by the applicant, we agree that Buzzy® Pro meets the newness criterion.

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

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect, the applicant stated that it expects Buzzy® Pro would be commercially available immediately after receiving FDA marketing authorization.

Comment: The applicant submitted a comment indicating that as of May 15, 2023, Buzzy® Pro is commercially available.

Response: Based on the information provided by the applicant, Buzzy® Pro meets the commercial availability criterion.

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

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 3, 2023, the applicant stated that it intends to apply by the deadline.

Comment: The applicant submitted a comment indicating that the HCPCS Level II code application was submitted to CMS on July 1, 2023.

Response: We appreciate the applicant's confirmation of having submitted the HCPCS Level II code application and confirm that CMS received the application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

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

(1) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant presented two substantial clinical improvement claims. First, the applicant stated that Buzzy® Pro controls needle pain for dialysis. Specifically, per the applicant, Buzzy® Pro makes cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Second, the applicant stated that Buzzy® Pro reduces needle fear.

With respect to the claim that Buzzy® Pro controls needle pain for dialysis, the applicant stated that currently, the most effective options for dialysis cannulation pain are the topical anesthetic, EMLA® and vapocoolant spray.[69] Per the applicant, systematic reviews recommend against vapocoolant use due to lack of efficacy[70] and EMLA® incurs $15 cost per use and takes 1 hour to become effective. The applicant asserted that the Buzzy® device has been shown to be superior to vapocoolant spray[71] and equivalent to topical anesthetics EMLA® and LMX® at a fraction of the cost and time.[72,73] The applicant stated that while ice is effective for reducing

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[69] Çelik G, Özbek O, Yılmaz M, Duman I, Özbek S, Apiliogullari S. Vapocoolant spray vs lidocaine/prilocaine cream for reducing the pain of venipuncture in hemodialysis patients: a randomized, placebo-controlled, crossover study. Int J Med Sci 2011;8(7):623-7 doi: 10.7150/ijms.8.623 [published Online First: 20111012].

[70] Hogan ME, Smart S, Shah V, Taddio A. A systematic review of vapocoolants for reducing pain from venipuncture and venous cannulation in children and adults. J Emerg Med 2014;47(6):736-49 doi: 10.1016/j.jemermed.2014.06.028 [published Online First: 20140829].

[71] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705-10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

[72] Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy® device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].

[73] Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. Pediatr Emerg Care 2017 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].

dialysis pain for both adults and children, it is messy and inferior. The applicant further stated that a Buzzy® device cannulation study in adults found that ice is only 10 percent of the effect, with the mechanical gate control neuromodulation (vibration) providing 90 percent of the pain relief.[74]

With respect to the claim that Buzzy® Pro reduces needle fear, the applicant stated that 25 to 47 percent of chronic kidney patients have needle fear.[75] The applicant further stated that CDC recommends vibrating cold devices for needle fear in children, and cold devices with a buzzer for adults.[76] The applicant also stated that meta-analyses demonstrate significant fear reduction with Buzzy® device,[77] and a New Zealand study demonstrated improved adherence to Bicillin injections with fear reduced 50 percent after three uses of Buzzy® device.[78] The applicant also stated that Buzzy® device is indicated by Health Canada to "control pain and fear from needles" and is used for fearful dialysis patients in the Netherlands.

The applicant submitted 33 unique sources of evidence with its application in support of its claims of substantial clinical improvement. Thirty of the sources that were submitted examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. One article examined the effect of cryotherapy on pediatric pain management at the arteriovenous fistula site during hemodialysis.[79] Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or more specifically the device that is the subject of this

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[74] Abidin NH. Assessing The Effectiveness Of A Thermomechanical Device (Buzzy®) In Reducing Venous Cannulation Pain In Adult Patients. Middle East Journal of Anesthesiology 2018;25(1):61-67.
[75] Duncanson E, Le Leu RK, Shanahan L, et al. The prevalence and evidence-based management of needle fear in adults with chronic disease: A scoping review. PLoS One 2021;16(6):e0253048 doi: 10.1371/journal.pone.0253048 [published Online First: 20210610].
[76] Easy to Read: Needle Phobia. Available at: https://www.cdc.gov/ncbddd/humandevelopment/covid-19/needle-phobia/index.html. Accessed March 9, 2023.
[77] Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy® Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. Clin J Pain 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].
[78] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112-7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].
[79] Attia, A., Hassan, A. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. International Journal of Nursing Sciences 2017; (4) 46-51.

TPNIES application, Buzzy® Pro, in managing dialysis related pain or fear, it was not directly applicable to the applicant's substantial clinical improvement claims. One article evaluated the effectiveness of distraction cards, in pediatrics in reducing pain and anxiety during intramuscular injection.[80] Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or the Buzzy® Pro device in managing dialysis-related pain or fear, it was not directly applicable to the applicant's substantial clinical improvement claims. One document labeled as Dutch guidelines was submitted in non-English text and thus, was not readily accessible to our review team.

The applicant also submitted a list of references, referred to as a literature review, that pertained to the applicant's products, among which, the Buzzy® device was listed as relieving or reducing needle pain and fear and for needle procedures and for musculoskeletal pain.

In a document titled "Summary of Clinical Evidence – relief of needle pain and fear," the applicant presented the study objectives and key features of 29[81] of the 30 submitted sources that examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. The document identified several additional sources that were not submitted by the applicant. Finally, the applicant submitted a document titled "Buzzy Fear reduction rationale and table" that duplicated information already captured in the "Summary of Clinical Evidence – relief of needle pain and fear" document. Table 10 lists the 29 sources that were both identified by the applicant in the "Summary of Clinical Evidence – relief of needle pain and fear" document and that were submitted. We have not included sources that were mentioned by the applicant, but not submitted to us.

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[80] Sahiner, N., Turkmen, A. The Effect of Distraction Cards on Reducing Pain and Anxiety During Intramuscular Injection in Children. Worldviews on Evidence-Based Nursing 2019; 1-6.

[81] The following source was not included in the summary table: Redfern RE, Chen JT, Sibrel S, Effects of Thermomechanical Stimulation during Vaccination on Anxiety, Pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. J Pediatr Nurs.2018.38: 1-7.

TABLE 10: Applicant's Substantial Clinical Improvement Sources

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1138 P: 3 – 18 y/o (2) O: Anxiety reduction F: Systematic Review and Meta-analysis N=1138 P: 2-17y	Buzzy	(1) Self-Reported pain reduction -1.11; 95% [CI]: -1.52 to -0.70; P<0.0001) Of 4 studies only assessing lab draws, IV catheter/venipuncture procedures (SMD: −1.30; 95% CI: −1.84 to −0.76 P<0.00001) (2) (Pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001), anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001)	Ballard A Khadra C, Adler S, Doyon- Trottier E, Le May S. *Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis*. Clin J Pain. 2019 June; 35(6):532-543.
O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1479 P: 2 – 18 y/o	Multiple devices	Meta-regression demonstrated a significant negative correlation of pain score with age. For children at 8.5 years, cold vibration reduced the pain score by 0.13 averagely for every increment in year compared with controls (MD -0.13; 95% CI: -0.25, -0.01)	Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. *Using vibrating and cold device for pain relievers in children: a systematic review and meta-analysis of randomized controlled trials*. J Pediatr Nurs. 2021 Mar 15; 61:23-33.
O: Pain relief for cannulation in pediatrics F: RCT: Buzzy compared to LMX topical anesthetic N=173 P: 18 months – 17 y/o	Buzzy M-stim only	There were no statistically significant differences among treatment groups based on the observational measures of pain or the self-report measures of pain. Findings support the use of both mechanical vibration and topical anesthetic as effective in children regardless of age group or sex.	Bahorski JS, Hauber RP, Hanks C, Johnson M, Mundy K, Ranner D, Stoutamire B, Gordon G. *Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study*. Int J Nurs Stud. 2015 Oct;52(10):1553-64.
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 P: 4 – 18 y/o	Buzzy	Vascular access success more likely w/ Buzzy: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040); Self-reported pain scores lower with Buzzy: (-2; 95% CI, -4 to 0) than with vapocoolant (p=.029). Parent reported pain scores lower with Buzzy (-2; 95% CI -4 to -2) than vapocoolant (p=.005).	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. *An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department.* Pediatr Emerg Care. 2011 Dec;27(12):1151-6.
(1) O: Pain relief in adult vascular access F: RCT: Buzzy v. Vapocoolant N=31 P: 18+ Years Hospital employees (2) O: Pain relief with cannulation on the dorsum of hand F: Crossover trial rated with VAS N=31 P: Adult healthcare workers	Buzzy	(1) In a crossover trial, Buzzy reduced angiocath placement pain (mean 9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) compared to vapocoolant (mean 7.9 mm, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) (2) Each 20mm of pre-procedural fear increased the likelihood of a successful intervention pain relief (odds ratio 2, P=0.043).	Baxter AL, Leong T, Mathew B. *External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device*. Clin J Pain. 2009 Oct;25(8):705-10.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Pain and anxiety relief in vascular access procedures in children F: RCT: Buzzy, Buzzy + Cartoons, Cartoons alone, Control/nothing. N=150 P: Mean age 9.4 years (2) O: Fear reduction using Buzzy v. Cartoons v. Nothing v. Buzzy + Cartoons F: RCT N=150 P: Pediatric 5-12 years	Buzzy	(1) Pain: "Buzzy was highly effective in children younger than 9 (p=0.04). Also, a significant efficacy was recorded in the Buzzy and Cartoon group (p=0.04) for the nurse's perception of the child's pain, and in the Buzzy group for the mother's perception of the child's pain (p=0.002)." Anxiety: "Particularly, the difference was statistically significant in the Buzzy (p=0.03) and the Buzzy and animated Cartoon groups (p=0.02) for nurses' perception of the child's anxiety, and in the Buzzy group for mothers' perception of anxiety (p=0.03)." (2) (Children's Emotional Manifestation Scale for anxiety: per nursing and mother evaluation) Nothing -0.26 v. Buzzy -0.86 P=.03. Nothing -0.26 v. Buzzy + Cartoons -0.89 P=.02 Nothing -0.26 v. Cartoons alone -.073 P=.09).	Bergomi P, Scudeller L, Pintaldi S, Dal Molin A. *Efficacy of Non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audio-visual distraction and External Cold and Vibration*. J Pediatr Nurs. 2018 Sep-Oct; 42: e66-e72.
O: Pain reduction comparison in children during vascular access F: RCT: Buzzy, Bubbles, and Control N=96 P: 3 – 6 y/o	Buzzy	Pain scores were lower in the groups of Buzzy and blowing soap bubbles than the control group. There was no statistical difference between Self Report, Parent Report, Nurse Report, or Researcher Report between Buzzy and Bubbles. The differences between Buzzy or Bubbles and Control was significant for all P=.0000.	Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. *Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial.* J Perianesth Nurs. 2019 Feb 20 S1089-9472(18)30414-3.
O: Superiority trial of pain relief during vascular access F: RCT: Buzzy, Handheld computer distraction N=200 P: 4-12 y/o	Buzzy	No significant difference between a handheld computer distraction and Buzzy, median (IQR) = 3.0 (1.0–4.8) and 2.0 (1.0–4.8), respectively, P = 0.72.	Cozzi G, Crevatin F, Dri V, Bertossa G, Rizzitelli P, Matassi D, Minute M, Ronfani L, Barbi E. *Distraction Using Buzzy or Handheld Computers During Venipuncture*. Pediatr Emerg Care. 2018 Dec 27.
O: Pain relief during pediatric vascular access F: RCT: Virtual Reality (VR) versus Buzzy N=121 P: 7 - 12 y/o	Buzzy	Buzzy resulted in lower pain than VR and significantly better than control, P = 000). Buzzy n=40; 1.5 +/- .2SD versus VR n=41; 2 +/- .2SD, p<.0001).	Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. *Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year- old Children During Phlebotomy: A Randomized Controlled trial*. J Perianesth Nurs. 2018 Mar 17.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain Relief for vascular access with Buzzy, Buzzy + Distraction, Distraction, and Control F: RCT: 4 arm trial N=218 P: 6 - 12 y/o	Buzzy	All groups using Buzzy had significantly reduced pain (P < 0.001) compared to the control group. Lowest pain measured w/Buzzy in combination w/DistrAction Cards.	Inal S., Kelleci M. *The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing*. Pediatr Emerg Care. 2020 Feb;36(2):66-69.
(1) O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 - 12 y/o (2) O: Pain and anxiety relief with lab draws F: RCT using Child Pain Scale N=120 P: 6-12y/o	Buzzy	(1) Lower pain (p < .001) and anxiety (p < .001 w/ Buzzy) compared to the control group. (2) (Lower pain (p < .001) and anxiety with Buzzy. CAPS Parent reported 1.61(Buzzy) v. 3.36 (Control) (p < .001))	Inal S, Kelleci M. *Relief of pain during blood specimen collection in pediatric patients*. MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45. PMID: 22895207.
(1) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o (2) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o	Buzzy	"A significant difference was found between the intervention and control groups in terms of levels of pain during and after phlebotomy in favor of the Buzzy group (p<0.05)." (2) ("children in the Buzzy group were less frightened during phlebotomy (CFS 1.33 v. 2.66 p < 0.05)." "There was a significant difference between intervention and control groups fear levels in favor of the Buzzy group during phlebotomy (p< 0.05)."	Küçük Alemdar D, Yaman Aktaş Y. *The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy*. J Pediatr Nurs. 2019 Jan 30 S0882-5963(18)30352- X.
O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y	Buzzy	Pain was less than expected in 44/50 Buzzy patients and 0/50 control, and more than expected in no Buzzy patients and 6/50 control (P<.000), with overall less pain (1.04 v 5.32) and greater satisfaction. (95.3 v 2.12) P<.001. There was no difference in pulse, state, or trait anxiety before or after cannulation.	Pakiş Çetin S, Çevik K. *Effects of Vibration and Cold Application on Pain and Anxiety During Intravenous Catheterization*. J Perianesth Nurs. 2019 Aug:34(4):701-709.
O: Pain relief during vascular access in children with cognitive impairment F: RCT: Buzzy v. Control N=70 P: Median age – 9 y/o	Buzzy	"Reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group (p = 0.003)."	Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. *Analgesia by cooling vibration during venipuncture in children with cognitive difficulties*. Acta Paediatr. 2016 Jan;105(1): e12-6.
O: Efficacy of Buzzy for pain reduction in children F: RCT N=72 P: 3 – 10 y/o	Buzzy	Buzzy pain 3.65 vs Magic Glove 4.67 (p=.039).	Susam V. Friedel M, Basile P, Ferri P, Bonetti L. *Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial*. Acta Biomed. 2018 Jul 18;89(6-S):6-16.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Effect of Buzzy, distraction cards, and balloons in reducing pain and anxiety in children receiving procedure requiring vascular access F: RCT N=180 P: 7 – 12 y/o (2) O: Fear reduction with venipuncture F: RCT with CFS N=180 P: pediatrics 9.3 +/- 1.9 years	Buzzy	(1) Lowest pain scores with Buzzy (1.90±1.34) vs Distracting cards (3.17±2.13) vs Balloon inflating (2.83±1.41) vs control (4.15±1.29), (p=0.012) (2) (Fear with Children's Fear Scale lowest with Buzzy (0.61) versus control (3.17), one way ANOVA with 4 arms p=.13 "clinically significant rather than statistically significant." – p <.0001 if Buzzy compared to control, p=.003 if compared to Balloon inflating (CFS 1.19).	Tork HM *Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department*. Am J Nursing Science 2017 Feb;6(2):26- 32.
O: Effect of vibration on outpatient vascular access in children F: Retrospective review N=64 P: 4 – 18 y/o	Buzzy	"21 of the 26 [phlebotomists'] (80.8%) responses provided indicated that the device made the procedure easier; the other 5 claimed that it had no effect."	Whelan HM, Kunselman AR, Thomas NJ, Moore J, Tamburro RF. *The impact of a locally applied vibrating device on outpatient venipuncture in children*. Clin Pediatr (Phila). 2014Oct;53(12):1189-95.
(1) O: Effect of vibration in reducing needle pain in children F: Systematic review N= 264 P: 0 - 18 y/o (2) O: Identify, evaluate and synthesize evidence of the effectiveness of vibratory stimulation to reduce needle-related procedural pain in children aged 18 years and younger. F: Systematic Review N=n/a P: 0 – 18 y/o	Buzzy	(1) "The effect size for the Buzzy tended to be higher than that for the other devices." "Buzzy self-rated pain (n=): -0.94, [95% CI]: -1.54, -0.35) p<.00001. [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to - 0.20 p<.00001) was significant." (2) Comparison devices DentalVibe and Vibrational Anesthesia Device used primarily or exclusively for Dental procedures. "The effect size for the Buzzy tended to be higher than that for the other devices. Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18)."	Ueki S, Yamagami Y, Makimoto K. *Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review*. JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463.
O: Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors F: Abstract N=90 P: Adult men	Buzzy	"Results indicate that the use of the Buzzy device was an effective method of reducing the pain of phlebotomy and increasing phlebotomy satisfaction in healthy adult male blood donors." [N=90, Pain 20.93 +/- 15.1 versus 35.23 +/- 19.3, p=.004, satisfaction Buzzy 76.0 +/- 23.7 v. 55.26 +/- 34.8 control, (p =.031)].	Yilmaz D., Heper Y., Gözler. *Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors. Pain Management Nursing*. 2017 Aug;18(4):260-267. PMID: 28601479.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
(1) O: Pain relief during intraoral injections using FLACC F: RCT N=50 P: 5-10 y/o (2) O: Oral dental injections F: RCT FLACC N=50 P: 5-10 years	Buzzy	(1) Conclusion: "Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures". 1.4 Buzzy, 3.96 Conventional using FLACC, p<.05 (2) "Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures." FLACC 1.4 Buzzy, 3.96 Conventional, p<.05	Suohu T, Sharma S, Marwah N, et al. A Comparative Evaluation of Pain Perception and Comfort of a Patient Using Conventional Syringe and Buzzy System. Int J Clin Pediatr Dent 2020;13(1):27-30.
O: Pain and anxiety relief for cannulation F: RCT VAS anxiety VAS pain N=176 P: 7-12 y/o	Buzzy	(WBFS pain Buzzy 2.75, Control 5.7 p=0.000, VAS pain Buzzy 1.66, Control 4.09 p=.000; VAS anxiety Buzzy 0.94, Control 2.09 p=.000; VAS observer anxiety Buzzy 0.92, Control 2.14 p=.000.).	Canbulat N, Ayhan F, Inal S. *Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients*. Pain Manag Nurs. 2015 Feb;16(1):33-9.
O: Pain and anxiety relief for vascular access with Child Fear Score F: RCT Virtual Reality v. Distraction cards v. Buzzy v control N=142 P: 7-12 y/o	Buzzy	"According to all raters, the Buzzy® group had the lowest mean CFS score, followed by the VR, DC, and control groups (p < 0.05)."	Erdogan B, Ozdemir AA. *The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality and Buzzy (Randomized Controlled Trial)*. J Pediatr Nurs. May-Jun 2021;58:e54-e62.
O: Pain, fear and anxiety from vaccination F: Systematic Review 27 articles N=n/a P: 4 – 15 years	Buzzy	"This review found consistent evidence for reduction in pain, distress and/or fear with interventions that combined cooling and vibrating together…" [pooled data not reported].	Lee VY, Caillaud C, Fong J, Edwards KM. *Improving vaccine-related pain, distress or fear in healthy children and adolescents-a systematic search of patient-focused interventions*. Hum Vaccin Immunother. 2018;14(11):2737-2747.
O: Anxiety and pain reduction with cannulation F: RCT Buzzy v control N=105 P: Elective Surgical Adults	Buzzy	(In subjects who reported higher pre procedure anxiety, the experimental [Buzzy] group reported lower pain (0.84 ± 0.50) than the control group (3.92± 0.58).	Redfern RE, Micham J, Sievert D, Chen JT. *Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study*. J Infus Nurs. 2018 Sept/Oct;41(5):294-300.
O: Pain relief with flu vaccination F: RCT VAS, 10-point satisfaction scale N=497 P: Adult employees influenza vaccine clinic	Buzzy	(pain 0.87 v 1.12 p=.035, better than previous experiences 62% Buzzy 23.9% control p<.0001.) "Buzzy can be used in adult patients to reduce pain during immunization and is especially effective in those with high levels of anxiety."	Redfern RE, Micham J, Seegert S, Chen JT. Influencing Vaccinations: A Buzzy *Approach to Ease the Discomfort of a Needle Stick – a prospective, Randomized Controlled Trial*. Pain Management Nursing, 2019 Apr;20(2):164-169.
O: Reduction in fear and pain with Bicillin injections F: Observational prospective interventional trial N=118 P: Teens and Adults	Buzzy	(Nonadherent group offered Buzzy, LA bicillin, or both; overall pain and fear reduced 50%, Special needle phobia clinic able to be disbanded.)	Russell K, Nicholson R, Naidu R. *Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board*. J Paediatr Child Health. 2014 Feb;50(2):112-7.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	**Test Article**	**Results**	**Reference Title**
O: To investigate the effect of the Buzzy application on pain and satisfaction during injections. F: RCT N=65 P: Average age 52	Buzzy	(Pain 74% reduced, satisfaction 95 v. 84. P<.001 both favor Buzzy).	Sahin M. *Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections*. Pain Management Nurs2018 Dec:19(6):645.
O: Immunization pain and fear reduction Buzzy v. control with TdAP F: RCT Children Fear Scale N=104 P: 7-year-olds	Buzzy	Buzzy: 0.58 +/- 0.63 v. 1.96 +/- 1.13 p=.001 Finding: The experimental group showed significantly lower pain and anxiety levels than the control group during immunization. Conclusions/implications for practice: The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.	Sahiner NC, Inal S, Akbay AS. *The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children*. J Perianesth Nurs. 2015 Jun;30(3):228-35.
O: Buzzy Bubbles Shotblocker or nothing for IM injections F: RCT 4 arm N=160 P: 5-10 years	Buzzy	Results: A significant difference was found between the intervention and control groups in terms of levels of pain and fear during IM injection. Pain and fear were notably less in the group of children receiving the Buzzy intervention. Discussion: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.	Yilmaz G, Almdar DK. *Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial.* J Emerg Nurs. 2019 Sep;45(5):502-511.

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

As discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42484 through 42485), we summarized our specific concerns regarding application of the substantial clinical improvement criteria under §§ 413.236(b)(5) and 412.87(b)(1) in connection with the submission.

As stated previously, the applicant must demonstrate that the equipment or supply meets at least one of the following three substantial clinical improvement criteria in order to be eligible for the TPNIES: (1) the item offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment; (2) the item offers the ability to diagnose a medical condition in the patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods; or (3) the item significantly improves clinical

outcomes relative to services or technologies previously available. The applicant stated that Buzzy® Pro makes dialysis cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Therefore, in the proposed rule, we noted our belief that the applicant was targeting the clinical outcomes criterion (previously noted number (3)). The applicant also stated that Buzzy® Pro reduces needle fear. In the proposed rule, we also noted that we did not identify evidence within the application or the submitted materials documenting improved clinical outcomes related to depression or dialysis adherence but would be interested in reviewing such evidence.

With respect to the submitted evidence, we noted that it did not appear that the studies reflected the use of (1) Buzzy® Pro, the device that is the subject of the TPNIES application, nor (2) Buzzy® Pro in the context of dialysis cannulation. Specifically, the applicant submitted an application for Buzzy® Pro, indicating that Buzzy® Pro is a new design created for dialysis fistulae sites, patented in 2022. However, the sources submitted were dated prior to the 2022 new design patent date for dialysis fistulae sites. As such, we stated that it appeared that the sources submitted reflected the use of a predecessor Buzzy® device. In addition, while the applicant's "Summary of Clinical Evidence" document presented sources as evaluating Buzzy® Pro's efficacy in managing vascular access pain or fear, we noted that none of these sources appear to evaluate vascular access in the context of dialysis cannulation. The studies evaluated pain and fear in the context of other types of needle procedures, including vaccine or medication injections, blood specimen collection, and intravenous catheter insertion.

We noted that it was unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear. There are several unique features to dialysis cannulation that may limit generalizability. These include the need for regular punctures several times per week, the maintenance of cannulation for several hours during dialysis treatments, the use of substantially

larger needle sizes in dialysis, and complications that are associated with frequent vascular access cannulation, such as infections and thrombosis. As such, we questioned whether outcomes could reasonably be extrapolated as applicable to patients undergoing dialysis cannulation.

As identified in the table, most of the studies provided in support of the applicant's claims reflect pediatric patient experiences. We noted that pediatric patients comprise a small proportion, just 0.14 percent, of the total Medicare ESRD patient population (87 FR 67222). As such, we noted that the data that was heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population.

While the applicant stated that the Buzzy® devices are less expensive than topical anesthetic, we noted that cost is not an eligibility criterion for the TPNIES.

We also noted that it was unclear whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting. To the extent that the device or its components are intended for use among multiple patients, we noted that we would be interested in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population. Additionally, we noted that we were not aware of any data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses but would be interested in the results of such data.

In addition, the applicant stated that currently, the most effective options for dialysis cannulation pain are topical anesthetics and vapocoolant spray. We noted that we would be interested in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments.

We invited public comments on whether the Buzzy® Pro meets the substantial clinical improvement criteria for the TPNIES.

Comment: We received a comment from the applicant in support of a TPNIES approval for Buzzy® Pro. The applicant stated that there are seven literature-supported parameters by which Buzzy® Pro meets the substantial clinical improvement criteria, any one of which independently would satisfy the standard. The applicant presented the following table highlighting the ways in which Buzzy® significantly improves clinical outcomes relative to renal dialysis services previously available.

Buzzy® Pro Areas of Substantial Clinical Improvement	
Criterion + Source	**Specific Improvement**
Peer-reviewed publications of Buzzy	
1. A more rapid beneficial resolution of the disease process treatment (412.87(b)(1)(ii)(C)(4))	5 minutes for pain management compared to 1h 10 minutes with EMLA saves 169 hours/year
2. Improved quality of life (412.87(b)(1)(ii)(C)(6))	a. Decreased pain compared to vapocoolant spray b. Faster equivalent pain relief with EMLA c. Decreased fear compared to other interventions d. Pain relief access for patients with buttonholes
3. Reduction in at least one clinically significant adverse event (412.87(b)(1)(ii)(C)(1))	a. 25% reduction in severe vasovagal symptoms b. Vasodilation with potential reduction of vessel wall trauma.
Publications of impact of pain and depression addressed by improved availability + pain control	
4. Decrease in the number of future hospitalizations (412.87(b)(1)(ii)(C)(3))	Adherence to regular cannulation reduces hospitalization – Buzzy improves adherence.[82]
5. Improved quality of life (412.87(b)(1)(ii)(C)(6))	Increased feelings of control are correlated with reduced depression.

With respect to the more rapid beneficial resolution of the disease process treatment, the applicant stated that chronic patients consider a reduction in their procedural time a clinically significant improvement.

With respect to improved quality of life, the applicant stated that Buzzy® devices have been shown to be clinically superior to vapocoolant spray for pain relief in adults and

[82] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112-7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

children,[83,84] and that vapocoolant spray lacks efficacy and is associated with potential risks of frostbite or triggering a sickle cell crisis. The applicant stated that EMLA is effective for cannulation pain but requires 60 minutes to become effective and is associated with potential risks, including petechiae and skin breakdown from the occlusive dressing used after applying the cream. The applicant stated that Buzzy® is equivalent to the topical anesthetics EMLA and LMX by patient and parent report and at a fraction of the time.[85,86,87,88]

The applicant stated that Buzzy® decreases fear as compared to other interventions, citing multiple meta-analyses indicating that Buzzy® reduces fear and anxiety in pediatric venipuncture[89,90] and that Buzzy® was also effective in adult venipuncture patients with needle fear or anxiety.[91,92] The applicant referred to a generic recommendation for "buzzing devices" for adult needle fear on the CDC website.[93]

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[83] Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. Pediatr Emerg Care 2011;27(12):1151-6 doi: 10.1097/PEC.0b013e318237ace4.
[84] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705-10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].
[85] Bahorski JS, Hauber RP, Hanks C, et al. Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study. Int J Nurs Stud 2015;52(10):1553-64 doi: 10.1016/j.ijnurstu.2015.05.014 [published Online First: 20150610].
[86] Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy(®) device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. Int J Nurs Stud 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].
[87] Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. Pediatr Emerg Care 2019;35(6):419-25 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].
[88] Baxter AL, Cohen LL, Tsze D. Buzzy versus EMLA: Abstract omits clinical noninferiority and time and cost savings: A commentary on Lescop et al. (2021). Int J Nurs Stud 2021;121:104011 doi: 10.1016/j.ijnurstu.2021.104011 [published Online First: 20210626].
[89] Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. Clin J Pain 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].
[90] Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. Using Vibrating and Cold Device for Pain Relieves in Children: A Systematic Review and Meta-analysis of Randomized Controlled Trials. J Pediatr Nurs 2021;61:23-33 doi: 10.1016/j.pedn.2021.02.027 [published Online First: 20210316].
[91] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. Clin J Pain 2009;25(8):705-10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].
[92] Redfern RE, Micham J, Sievert D, Chen JT. Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study. J Infus Nurs 2018;41(5):294-300 doi: 10.1097/nan.0000000000000294.
[93] https://www.cdc.gov/ncbddd/humandevelopment/covid-19/needle-phobia/healthcare-providers.html Accessed September 8, 2023.

The applicant stated that 43 percent of dialysis patients experienced pain despite EMLA use[94] and that Buzzy® patients like the sense of control of being able to hold the device in the right spot for the best pain relief.

In support of the claim that Buzzy® reduces at least one clinically significant adverse event, the applicant stated that vibration over 150Hz results in vasodilation, which can reduce the likelihood of a needle side-walling a vein, causing pain or vasovagal stimulation.[95] The applicant referred to a recent study presented in 2023, which found that in 360 teenagers who received vaccination,[96] Buzzy® reduced severe vasovagal symptoms 25 percent and improved vasodilation, potentially reducing vessel wall trauma.

The applicant also provided responses to CMS's concerns identified in the CY 2024 proposed rule. In response to the CMS concern regarding a lack of evidence documenting improved clinical outcomes related to depression or dialysis adherence, the applicant stated that increased feelings of control are correlated with reduced depression. The applicant specified that because studies of patients with chronic pain with or without depression have identified self-efficacy as a primary component of effective interventions[97] and because chronic pain and depression are common in dialysis patients,[98,99] a fast intervention that allows self-adjustment and relief optimization should be more appropriate and effective among patients receiving dialysis than among patients undergoing single, small gauge, and less risky cannulations. The applicant

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[94] https://www.youtube.com/watch?v=1moJgluvS7c&t=350s
Accessed September 8, 2023.
[95] Skoglund CR. Vasodilatation in human skin induced by low-amplitude high-frequency vibration. Clin Physiol 1989;9(4):361-72.
[96] Smith MJ, Broder KR, Chung RJ, et al. Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple Clinic-Based Interventions: a Randomized-Controlled Trial. Pediatric Academic Societies Meeting. Washington, D.C., 2023.
[97] Borsbo B, Gerdle B, Peolsson M. Impact of the interaction between self-efficacy, symptoms and catastrophising on disability, quality of life and health in with chronic pain patients. Disability and rehabilitation 2010;32(17):1387-96 doi: 10.3109/09638280903419269 [published Online First: 2010/06/02].
[98] Davison SN, Jhangri GS. The impact of chronic pain on depression, sleep, and the desire to withdraw from dialysis in hemodialysis patients. J Pain Symptom Manage 2005;30(5):465-73 doi: 10.1016/j.jpainsymman.2005.05.013.
[99] Masià-Plana A, Juvinyà-Canal D, Suñer-Soler R, Sitjar-Suñer M, Casals-Alonso C, Mantas-Jiménez S. Pain, Anxiety, and Depression in Patients Undergoing Chronic Hemodialysis Treatment: A Multicentre Cohort Study. Pain Manag Nurs 2022;23(5):632-39 doi: 10.1016/j.pmn.2022.03.005 [published Online First: 20220422].

stated that adherence to regular cannulation reduces hospitalization.[100] The applicant also stated that needle fatigue can lead to nonadherence to a treatment plan and that nonadherence increases healthcare costs, emergency department visits, disease complications, and in extreme cases, the likelihood of death.[101]

In response to the CMS concern that the sources submitted reflected the use of a predecessor Buzzy® device, the applicant stated that because Buzzy® Pro received FDA 510(k) approval on May 15, 2023, there are no studies specific to Buzzy® Pro.

In response to the CMS concern that it is unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear, the applicant asserted that because emergency department venipuncture studies typically involve anxiety, they are appropriate comparators for dialysis, where anxiety is common. The applicant further noted that many dialysis studies do not find a benefit the first time an intervention is attempted. The applicant also stated that adult dialysis cannulation studies that use vapocoolant and topical anesthetic do not evaluate anxiety, and the only studies evaluating anxiety and dialysis cannulation used lavender oil as a comparator.

In response to the CMS interest in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments, the applicant provided the following two summary tables and stated that the numbers given in the tables allow relative comparison between interventions and the pain reported with dialysis cannulation and adult emergency department trials of Buzzy®. The first table summarizes studies of pain or anxiety

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[100] Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health 2014;50(2):112-7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

[101] Lee K, Kim D, Lee H, Lee E. The effect of using vapocoolant spray for pain reduction in arteriovenous fistula cannulation among patients undergoing hemodialysis: A randomized control trial. Appl Nurs Res 2023;71:151674 doi: 10.1016/j.apnr.2023.151674 [published Online First: 20230317].

relief specific to dialysis cannulation and identifies the significant differences in bold text. The second table summarizes Buzzy® outcomes including pain, anxiety, and vasovagal symptom relief in various types of cannulations and identifies the significant differences in bold text.

Cannulation Studies in Dialysis (significant differences in bold)			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Dialysis pain Randomized crossover trial N= 41 Scale: NRS (0-10)	Vapocoolant or Lidocaine spray or Placebo	**Vapocoolant** -2.29 (95%CI -4.17 to -0.43) Lidocaine Spray NS	Khosravi BMC Anesthesiol 2023(1):69[14]
O: Dialysis: Randomized crossover trial N= 41 Scale: VAS (0-100)	Vapocoolant or EMLA or Placebo	**EMLA -18.1** (10.7 +/- 10.6 VC -14.4 14+/-12.4 Control 28.8+/17.9	Çelik G. Int J Med Sci 2011;8(7):623-7[15]
O: Dialysis: Open crossover design N=38	Vapocoolant Or Placebo Or no treatment	**Vapocoolant** 2.98+/-1.53 Placebo 4.04+/-1.82 No treatment 4.45+/-1.31	Lee 2023 Appl Nurs Res June;71:151674[16]
O: Dialysis: Randomized controlled N=90 NRS (0-10)	EMLA or Valsalva or Control	**EMLA -4.13**(-5.44 – (-2.82)) VM -2.9(-4.2 – (-1.59))	Babamohamadi H, Ev Based Complem med 2022:8383021 e.[17]
O: Dialysis: Prospective crossover N=32	EMLA or Ice Cubes x 5 minutes	"Significant reduction in pain in favor of **[ice cubes]**."	Kortobi L. Saudi J Kidney Dis Trans 202;31(3):597-603[18]
O: Dialysis: Open Crossover Trial N=34 NRS	Lavender Oil or Placebo or Control	**Lavender** 2.91+/-1.69 No intervention 4.59 Placebo 4.18+/-1.66	Ghods A. Comp Ther Med 2015;23(3):325-330[19]
O: Dialysis Randomized Crossover trial N= 74 NRS STAI (anxiety)	Lavender Oil or Placebo	No difference first time **Lavender -2.68 (p=.002)** Anxiety correlated w/ pain	Sahin s. Pain Mgmt Nursing 2021;22(4):519-515[20]

Cannulation Studies using Buzzy® (significant differences in bold)			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain relief for cannulation *F: Vibration v cold v sham v both* *N: 184 18-65 years of age*	**4-arm Buzzy trial pain relief vibration v. cold v. combination**	**Buzzy v. + cold:** 33.92 **Buzzy alone**: 34.18 Sham + cold: 39.16 Sham no cold: 43.21 **P=.016 overall v. sham**	Abadin N. M East J Anesthesiology 2018 25(1)
O: Pain relief for cannulation F: RCT: Buzzy compared to **LMX topical anesthetic** N=173 18 months – 17 y/o	**Buzzy M-stim only NO ICE** v. LMX4	Findings support the use of **both mechanical vibration and topical anesthetic as effective**	Bahorski JS, Hauber RP, et al. Int J Nurs Stud. 2015 Oct;52(10):1553-64[21]
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 4 – 18 y/o	Buzzy v. Vapocoolant	Self-report (-2; 95% CI, -4 to 0) (p=.029) Parent report (-2; 95% CI -4 to -2 (p=.005) **Favor BUZZY** **Vascular access success more likely w/ Buzzy**: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040)	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Baeyer CL. Pediatr Emerg Care. 2011 Dec;27(12):1151-6[22]

Cannulation Studies using Buzzy® (significant differences in bold)			
Study Description	**Test Article**	**Results**	**Reference Title**
O: Pain relief and cannulation success in vascular access F: Crossover trial N=30 P: adults	Buzzy Vapocoolant	**Buzzy** -9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) 100% first stick success Vapocoolant: NS pain reduction, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) 7.14% cannulation failure (vapocoolant)	Baxter AL, Leong T, Mathew B. Clin J Pain. 2009 Oct;25(8):705-10[23]
O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 – 12 y/o	Buzzy Control	**Lower pain (p < .001) and anxiety (p < .001 w/ Buzzy) compared to the control group.**	Inal S, Kelleci M. MCN Am J Matern Child Nurs. 2012 Sep;37(5):339-45.[24]
O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y	Buzzy Control	Pain: **BUZZY 1.04** c:5.32 Pain **less than** expected: **BUZZY** 44/50 C 0/50 Pain **more than** expected: BUZZY 0/50 **C 6/50** (P<.000) Satisfaction **BUZZY** (95.3 v 2.12) P<.001.	Pakiş Çetin S, Çevik K. J Perianesth Nurs. 2019 Aug:34(4):701-709[25 26]
O: Venipuncture pain with **anxious adults** F: RCT N=105 P: adults mean 63Y	Buzzy v Control	**Pain with high needle anxiety:** Buzzy: 0.84+/- .5 Control: 3.92+/- 0.58	Redfern RE J infusion nursing 2018 41(5):295[26]
O: Pain and Individual Satisfaction in **Blood Donation phlebotomy** F: Abstract N=90 P: Adult men	Buzzy Control	**BUZZY** 20.93 +/- 15.1 Control 35.23 +/- 19.3, p=.004 Satisfaction (p =.031)] Buzzy 76.0 +/- 23.7 Control 55.26 +/- 34.8	Yilmaz D., Heper Y., Gözler. Pain Management Nursing. 2017 Aug;18(4):260- 267.[27]
Vasovagal symptoms with vaccination F: RCT N=340 10-14y	Buzzy + Video v. Standard care	BUZZY 36% presyncope Control 48% presyncope **25% reduction (p=.02)**	Smith M. PAS 2023 (A) NCT04772755[28]

In response to the CMS concern that the data heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population, the applicant referred to materials submitted with its application and asserted that these demonstrate significant pain and fear reduction with the Buzzy® device, superiority to vapocoolant, and equivalency to topical anesthetics but in a shorter period of time. The applicant stated that five independent peer reviewed studies on adult venipuncture using Buzzy® demonstrate the following: vibration is the primary active ingredient; improved efficacy in patients with needle fear; superiority to vapocoolant spray; and pain reduction and improved satisfaction.

In response to our clarification that cost is not a TPNIES eligibility criterion, the applicant acknowledged our clarification but stated that cost is a barrier to the use of EMLA.

The applicant compared the cost of EMLA at $6.48 per cannulation to the cost of Buzzy® at $0.375 per cannulation. The applicant concluded that increased access to pain relief is a substantial clinical benefit that is not currently available due to cost.

In response to the CMS question as to whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting, the applicant stated that Buzzy® and Buzzy® Pro are made of medical grade plastic in accordance with ISO-13485 and MDSAP standards and can be disinfected with chlorhexidine, alcohol swabs, or any hospital grade cleanser in accordance with the requirements applied to a stethoscope or blood pressure cuff. The applicant further noted that the ice packs are medical grade, intended for a single patient, but can be reused hundreds of times. Per the applicant, the straps are also intended for single-patient use but can be used multiple times in a home setting.

The applicant stated that infection control varies widely based on regional idiosyncrasies and may involve the use of an infection control bag around the ice pack; not using the ice pack; using an infection control bag around both the device and the ice pack; having patients bring their own ice pack; giving the ice pack to the patient following the procedure; or discarding the ice pack.

In response to the CMS interest in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population and the CMS interest in data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses, the applicant stated that to date, with conservatively over 114,000,000 needle procedures, there are no reported instances of Buzzy® being associated with a vascular access mishap. Per the applicant, the standard risks of vascular damage may be reduced because of the vasodilation. The applicant also stated that because the device goes proximal to the cannulation site when it is being cleaned and accessed, there is never a time

when Buzzy® is placed on the area of recent cannulation. The applicant also stated that Buzzy® has been used for dialysis in the Netherlands for four years with only positive reports of efficacy, efficiency, and safety.

The applicant also provided additional information explaining the pain transmission process and its belief that that Buzzy® Pro's mechanical stimulation is an innovative approach in pain management. Specifically, the applicant stated that pain is transmitted to the spine on fast pain nerves and that local mechanisms to reduce pain transmission from skin to spine include lidocaine, cold spray or ice. Per the applicant, as cold travels to the brain on slow C-fibers it activates pain inhibition, which is most effective when applied at temperatures ranging from 0-4C, for a duration of 30 seconds or more, and when applied proximal or distant to the area of pain. The applicant also identified the mechanical stimulation of the fibers which transmit touch sensations as a mechanism for reducing pain, noting that optimal stimulation occurs between 180 and 250Hz. Per the applicant, Buzzy® units provide mechanical stimulation using a 200 Hz vibration motor.

The applicant also presented a new substantial clinical improvement claim, asserting that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for currently available treatment options. Specifically, the applicant stated that cost and time are barriers to patients accessing the currently available treatment options for dialysis cannulation pain control and asserted that Buzzy® Pro addresses these barriers. As stated previously, the applicant compared the cost of EMLA at $6.48 per cannulation to the cost of Buzzy® at $0.375 per cannulation and concluded that Buzzy® addresses the cost barrier to patients accessing dialysis cannulation pain relief. The applicant also asserted that the time requirement for using EMLA reduces the likelihood of its use in busy dialysis clinics or if the patient comes in late. The applicant stated that because patients prescribed EMLA for home application prior to treatment at the dialysis clinic often misuse the product, they are unresponsive to EMLA. Per the applicant, Buzzy® works on contact and can easily be applied by the patient. The applicant

stated that given the short, 30 to 60 second duration of pain relief obtained from vapocoolant spray, needle pain is a barrier to receiving treatment in the home setting. The applicant also stated that the pain from the mechanical pressure of the dialysis needle inside the vessel cannot be treated with EMLA or vapocoolant spray. The applicant stated that because Buzzy® Pro works proximally to the pain, it is effective for patients who otherwise are unable to access pain control.

We also received several comments from patient advocates supporting the applicant's two substantial clinical improvement claims that Buzzy® Pro reduces pain and anxiety associated with dialysis. A few commenters offered anecdotal experience regarding the use of Buzzy® Pro in the context of dialysis cannulation and stated that Buzzy® Pro's benefits are supported by peer-reviewed scientific literature. Commenters stated that Buzzy® Pro would promote patient choice by providing fast onset dialysis cannulation pain relief without the hassles and expense of topical anesthetics. One commenter suggested that the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey should be updated to capture patient experience with dialysis cannulation pain.

Response: We appreciate the applicant and other commenters' input regarding whether Buzzy® Pro meets the TPNIES innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1). While the applicant stated that there are seven literature-supported parameters by which Buzzy® Pro meets the substantial clinical improvement criteria, it was not clear to us to which parameters or sources of literature the applicant was referring.

In response to our request for evidence of improved clinical outcomes related to depression or dialysis adherence, the applicant stated that because increased feelings of control are correlated with reduced depression, an intervention that allows for self-adjustment and relief should be more effective among patients receiving dialysis than patients undergoing other types of needle cannulations. However, the applicant did not provide direct evidence that interventions

to reduce pain in dialysis populations would subsequently reduce depression or that Buzzy® Pro specifically reduces depression. In addition, while the applicant stated that adherence to regular cannulation reduces hospitalization, the evidence cited by the applicant does not pertain to improved dialysis adherence or reductions in hospitalizations. We are not aware of evidence demonstrating that the use of Buzzy® Pro is associated with the clinical outcome of improved dialysis adherence. Therefore, our request for evidence of improved clinical outcomes related to depression or dialysis adherence associated with the use of Buzzy® Pro in the dialysis patient population has not been sufficiently addressed.

We appreciate the applicant's confirmation that the evidence submitted pertained to studies of the predicate device, Buzzy® and that there are no studies specific to Buzzy® Pro. We also appreciate the applicant's responses to our concern about the absence of evidence that evaluates Buzzy® Pro's efficacy in managing pain or fear in the context of dialysis cannulation rather than in the context of non-dialysis needle procedures. The applicant asserted that emergency department venipuncture studies typically involve anxiety and are therefore appropriate comparators for dialysis, where anxiety is common. We do not believe that the presence of anxiety renders emergency department venipuncture a suitable proxy for dialysis cannulation. In addition, the applicant did not address the unique features of dialysis or the differences between venipuncture and dialysis cannulation that may limit generalizability, including the use of substantially larger needle sizes in dialysis, repeated cannulations thrice weekly, continued cannulation throughout a dialysis session, and complications associated with frequent vascular access cannulation such as infections and thrombosis. As such, we do not believe it is possible to extrapolate outcomes achieved with Buzzy® Pro in the context of non-dialysis needle procedures to dialysis cannulation.

We also appreciate the comments from patient advocates offering anecdotal experience with Buzzy® Pro in the context of dialysis cannulation but would be especially interested in additional detail, including the numbers of patients involved and the specific outcomes that they

experienced from Buzzy® Pro. While some commenters asserted that Buzzy® Pro's benefits for the renal dialysis patient population are supported by peer-reviewed scientific literature, because such sources were not provided by the commenters, we were unable to verify these assertions.

While Buzzy® Pro may demonstrate similar results to that of its predicate devices, our primary concern regarding the lack of direct evidence that Buzzy® results in pain or fear reduction in the context of dialysis cannulation pain or fear has not been sufficiently addressed.

In response to our request for studies comparing Buzzy® Pro to topical anesthetics or vapocoolant spray and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments, the applicant's first summary table reflects outcomes specific to dialysis but does not reflect experiences with Buzzy® Pro. While the second table reflects outcomes specific to Buzzy®, it does not capture experience in the dialysis setting. Not all studies included in the summary tables shown previously in this rule were provided with the application or public comment. However, none of the studies appear to specifically examine Buzzy® Pro's efficacy in improving clinical outcomes of dialysis patients as compared to topical anesthetics or vapocoolant spray.

Regarding our concern that data in support of the applicant's claims may have limited generalizability to the non-pediatric majority of the ESRD patient population, the applicant reiterated references from its application to independent peer reviewed studies on adult venipuncture using Buzzy®. These studies compared Buzzy® to no intervention and Buzzy® to vapocoolant or cold interventions. We also note that the applicant referred to a source labeled "Abedin et. al.," but we did not receive the study or the complete citation for this source. Because the studies did not compare Buzzy® to lidocaine and did not take place in the dialysis setting, the applicant has not sufficiently addressed our concern about the generalizability of these studies.

Regarding the applicant's additional evidence since the application submission, we acknowledge the reference to the 1989 study pertaining to vasodilation in human skin and the

2023 study pertaining to the prevention of post-vaccine syncope. While these studies were not submitted to us, similarly to the evidence previously submitted, it does not appear that they assessed the efficacy of Buzzy® Pro in the context of dialysis cannulation.

We appreciate the applicant's clarification regarding use among single vs. multiple patients in the ESRD facility setting and confirmation that to date, there are no reported instances of Buzzy® being associated with a vascular access mishap. However, because the applicant did not specify the percentage of the 114,000,000 needle procedures performed with Buzzy® that pertained to dialysis cannulation, our concern about the lack of data examining the risk of harm to the access site or any other adverse events associated with the use of Buzzy® Pro in the renal dialysis patient population has not been sufficiently addressed.

For the reasons noted previously, we do not believe that there is sufficient evidence to demonstrate that Buzzy® Pro significantly improves clinical outcomes relative to renal dialysis services previously available.

With respect to the applicant's new substantial clinical improvement claim that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we acknowledge that patients may appreciate the option of a rapid acting form of dialysis cannulation pain relief. While the applicant stated that Buzzy® offers a more rapid beneficial resolution of the disease process treatment than currently available options, the applicant did not provide additional evidence demonstrating the clinical superiority of Buzzy® Pro over topical lidocaine in the context of dialysis cannulation. Although the applicant stated that lidocaine requires an hour to take full effect, it did not provide evidence that Buzzy® Pro is superior to lidocaine after shorter time frames in the dialysis setting, that shorter timeframes do not provide adequate pain control with topical lidocaine, or that patients are unable to apply lidocaine an hour before their scheduled dialysis treatment. With respect to the applicant's assertion that the higher cost of EMLA as compared to Buzzy® is a barrier to pain relief, we note that because topical lidocaine is included in the pain management category of drugs/biological

products included in the ESRD PPS, dialysis facilities would be expected to provide it when determined necessary for the treatment of graft site pain. While cost may be a practical barrier to access for some patients, we do not equate this barrier with either unresponsiveness or ineligibility. In summary, based on the information provided, we are not able to conclude that there is sufficient evidence to demonstrate that Buzzy® Pro offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

Finally, we note that the comment suggesting that the CAHPS Survey should be updated to capture patient experience with dialysis cannulation pain is beyond the scope of this proposed rule.

In accordance with TPNIES policy and § 412.87(b)(1)(i), we consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In addition, per § 412.87(b)(1)(iii), CMS considers a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii).

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2024 ESRD PPS proposed rule, and comments submitted by the public, we have determined that Buzzy® Pro has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. For the reasons discussed previously, we conclude that Buzzy® Pro does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

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

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis

machines, we note that Buzzy® Pro does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.[102]

Comment: The applicant submitted a comment indicating that Buzzy® Pro is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.

Response: We agree that Buzzy® Pro does not meet the definition of a capital-related asset under § 413.236(a)(2).

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that Buzzy® Pro meets all eligibility criteria to qualify for the TPNIES for CY 2024. As a result, Buzzy® Pro will not be paid for using the TPNIES per § 413.236(d). We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to submit their applications for the TPNIES. Based on the Buzzy® Pro FDA marketing authorization date of May 15, 2023, the applicant may be eligible to apply for the TPNIES for CYs 2025, 2026, or 2027, and CMS would review any new information provided for the applicable rulemaking cycle.

4. Other Public Comments on the TPNIES

We received several comments regarding the TPNIES policies, including the length of the TPNIES payment period and suggestions for new payment adjustments. Commenters urged CMS to extend the TPNIES payment period to at least three years to allow for two full years of data collection, and then increase the ESRD PPS base rate to account for the new technology. Commenters suggested that CMS issue an RFI seeking public feedback on a post-TPNIES add-on payment adjustment and adopt a post-TPNIES payment adjustment in future rulemaking.

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

Commenters suggested revisions to existing TPNIES policies, such as extending the TPNIES to all capital-related assets, expanding the TPNIES for home dialysis devices that are acquired through operating leases, removing the TPNIES offset amount, and developing further guidance explaining the way in which CMS evaluates TPNIES applicants' substantial clinical improvement data.

Commenters suggested that we clarify the way in which MACs determine and provide payment rates for items approved for the TPNIES. Commenters suggested that these rates should be provided no later than March 31 of the first year of TPNIES eligibility and that MACs should provide clear and timely TPNIES claims processing guidance to the dialysis facilities.

Finally, we received comments suggesting that CMS develop a Transitional Laboratory Add-on Payment Adjustment (TLAPA) to incentivize innovation in laboratory services for beneficiaries with ESRD.

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.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2024. As described in the CY 2023 ESRD PPS final rule, payment for the one item approved for the TPNIES, the Tablo® Hemodialysis System, as described by HCPCS code E1629, expires on December 31, 2023 (87 FR 67216). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2024.

Comment: Several commenters requested that CMS extend the TPNIES payment period for the Tablo® Hemodialysis System beyond the December 31, 2023, end date to December 31, 2024. Commenters stated that implementation difficulties with the first CMS-approved TPNIES

application resulted in lower than anticipated uptake of the Tablo® System. Commenters stated that MACs demonstrated variable levels of understanding about the Capital Related Assets (CRA) for the TPNIES and that providers lacked clear guidance on what information ESRD facilities were to include on their claims. The commenters stated that these challenges contributed to claim denials and an administrative burden on ESRD facilities.

Response: CMS did not propose to extend the 2-CY TPNIES payment period as established in § 413.236(d)(1) in the CY 2024 ESRD PPS proposed rule, and we are not finalizing any such change in this final rule. However, we acknowledge the commenters' concerns pertaining to TPNIES claims processing related matters and have issued Change Request 12347 to the MACs outlining the way in which the CRA for the TPNIES is calculated for claims processing purposes.[103] In addition, in August 2022, CMS instructed MACs to adjust ESRD claims following CMS deployment of a corrected ESRD Pricer and to ensure that their systems were properly set up to suspend the claim for manual pricing. CMS provided a Medicare Learning Network (MLN) article instructing providers on how to submit Tablo® Systems claims.[104] This article was supplemented with an MLN Connects newsletter reminding providers to submit the invoice for the CRA for the TPNIES to their MAC and report the appropriate revenue code and HCPCS code with modifier on the claim for treatments in which the CRA for the TPNIES was used. Providers were also reminded to address any issues returned to them by their MAC and resubmit the effected claims.[105]

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[103] Change Request 12347. Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS). https://www.cms.gov/files/document/r11533otn.pdf

[104] MLN Matters Article. Implementation of the Capital Related Assets (CRA) Adjustment for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS). https://www.cms.gov/files/document/mm12347-implementation-capital-related-assets-cra-adjustment-transitional-add-payment-adjustment-new.pdf.

[105] MLN Connects Newsletter. ESRD: Submitting Dialysis Claims the Include Capital Related Assets Eligible for the TPNIES https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-09-14-mlnc#_Toc145581414.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2024

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved Korsuva® (difelikefalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,[106] dated March 15, 2022, and available at: https://www.cms.gov/files/document/r11295CP.pdf.

In July 2023, after the CY 2024 ESRD PPS proposed rule appeared in the **Federal Register** on June 30, 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.

Table 11 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2024: Korsuva® (difelikefalin) that was approved for the TDAPA effective in CY 2022, and Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023. Table 11 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and end dates.

TABLE 11: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)	4/1/2022	3/31/2024
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	10/1/2023	9/30/2025

III. Calendar Year (CY) 2024 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

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

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. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2024 Payment for Renal Dialysis Services Furnished to Individuals with AKI.

The CY 2024 ESRD PPS proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to

Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (88 FR 42430-42544), referred to as the "CY 2024 ESRD PPS proposed rule," appeared in the June 30, 2023 version of the **Federal Register**, with a comment period that ended on August 25, 2023. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2024. We received 10 public comments on our proposal. In this final rule, we provide a summary of each proposed provision, a summary of public comments received and our responses to them, and the policies we are finalizing for CY 2024 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2024

1. CY 2024 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 can bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this final rule, the ESRD PPS base rate is $271.02, which reflects the application of the CY 2024 wage index budget-neutrality adjustment factor of 0.999534 and the CY 2024 ESRDB market basket percentage increase of 2.4 percent reduced by the productivity adjustment of 0.3 percentage point, that is, 2.1 percent. Accordingly, we are finalizing a CY 2024 per treatment payment rate of $271.02 (($265.57 × 0.999534) × 1.021 = $271.02) for renal dialysis services furnished by ESRD facilities to individuals with AKI. This final payment rate is further adjusted by the wage index, as discussed in the next section of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI renal 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 and discussed in section II.B.1.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that 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.

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. The comments on our proposal and our responses are set forth below.

Comment: Some commenters expressed support for the CY 2024 proposed payment rate for individuals with AKI, which is to say the commenters supported increasing payments for AKI by the proposed productivity-adjusted ESRDB market basket update of 1.7 percent. Many commenters requested that CMS allow for AKI patients to select home dialysis modalities by eliminating the current prohibition. Some commenters also expressed concerns that the proposed market basket increase is insufficient to account for inflation. One commenter suggested that

any forecast error adjustment applied to the ESRD PPS should also be applied to payments for AKI patients.

Response: We appreciate the commenters' support for the proposed CY 2024 productivity-adjusted ESRDB market basket update of 1.7 percent. We acknowledge the request for AKI patients to select home dialysis modalities, and we thank commenters for their input. We note that currently, CMS will only pay for renal dialysis services at an ESRD facility for patients with AKI, and we did not propose to change this policy in the CY 2024 ESRD PPS proposed rule. Current AKI dialysis payment policy was implemented under the CY 2017 ESRD PPS final rule (81 FR 77866 through 77872, and 77965). Over the years, we have received several comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI. We have solicited comments in the recent past, including in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408), when we requested information regarding potentially modifying the site of renal dialysis services for patients with AKI and payment for AKI in the home setting. CMS continues to believe that this population requires close medical supervision by qualified staff during their dialysis treatment. We recognize commenters' concerns that the proposed ESRDB market basket update is insufficient given inflation. As discussed in section II.B.1.a.(2)(c) of this final rule, we believe the final CY 2024 ESRDB market basket update using the 2020-based ESRDB adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services and is technically appropriate to use as the ESRD PPS payment update factor, which determines the payment rate for renal dialysis services furnished to patients with AKI at ESRD facilities. We appreciate the commenter's suggestion that any forecast error adjustment applied to payments under the ESRD PPS should also be applied to payments for AKI patients. As discussed in section II.B.1.a.(2)(e) of this final rule, we are not finalizing a forecast error adjustment for the ESRD PPS for several reasons, but we will consider this suggestion for potential future rulemaking.

Final Rule Action: We are finalizing our proposal to base the AKI payment rate on the finalized ESRD PPS base rate, adjusted by the ESRD facility's wage index. Specifically, the final CY 2024 ESRD PPS base rate is $271.02 as finalized in section II.B.1.d of this final rule. Accordingly, we are finalizing a CY 2024 per treatment payment rate of $271.02 for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we are finalizing our proposal to apply the updated the ESRD PPS wage index for CY 2024 payments for renal dialysis services furnished by ESRD facilities to individuals with AKI as finalized in section II.B.1.b of this final rule.

IV. 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 previous ESRD QIP rules at: 75 FR 49030; 76 FR 628; 76 FR 70228; 77 FR 67450; 78 FR 72156; 79 FR 66120; 80 FR 68968; 81 FR 77834; 82 FR 50738; 83 FR 56922; 84 FR 60648; 85 FR 71398; 86 FR 61874; and 87 FR 67136.

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

B. Updates to the Regulation Text for the ESRD QIP

1. Revision to the Definition of "Minimum Total Performance Score (mTPS)" at § 413.178(a)(8)

In the CY 2019 ESRD PPS final rule, we codified a number of key terms used in the ESRD QIP at § 413.178(a) of our regulations (83 FR 56980 through 56982). One of these terms is "minimum total performance score" (mTPS), which we defined at § 413.178(a)(8) "with respect to a payment year"[107] as "the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility

[107] In the CY 2023 ESRD PPS final rule, we revised § 413.178(a)(8) to exempt PY 2023 (87 FR 67229).

performance on all clinical measures and the median of national ESRD facility performance on all reporting measures."

In the CY 2024 ESRD PPS proposed rule, we stated that we have recently reevaluated this definition and determined that it should be revised to more accurately capture how we calculate the median of national ESRD facility performance on reporting measures (88 FR 42487). We noted that, although we use data prior to the performance period to calculate these medians, the data may not be from the same time period, or "baseline period" (see § 413.178(a)(2)) used to calculate the 50th percentile of national ESRD facility performance on the clinical measures. Instead, our policy has been to calculate the median of national ESRD facility performance on the ESRD QIP reporting measures using the most recently available data prior to the applicable performance period for the payment year. If there were no data available prior to the first performance period of a new reporting measure, as was the case for the Clinical Depression Screening and Follow-Up reporting measure, we would use a proxy median for purposes of including the reporting measure in our calculation of the mTPS. We stated that we selected the values for these proxy medians based on the availability of previous measure data, a facility's familiarity with similar measures or requirements, and considerations regarding a facility's ability to comply with new reporting measure requirements during the initial performance periods for a new reporting measure.

In the CY 2024 ESRD PPS proposed rule, we proposed to update the definition of "minimum total performance score" at § 413.178(a)(8) so that it accurately captures these policies (88 FR 42487). We also proposed that, with respect to the adoption of future reporting measures, including the reporting measures proposed in the CY 2024 ESRD PPS proposed rule, if there is an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data to calculate the median. We stated our belief that this proposal will provide facilities with additional predictability and transparency regarding our calculation of the mTPS

for a payment year. We noted that, although many facilities score much higher than zero during the initial performance periods of a new reporting measure, we believe that setting the proxy median at zero where we do not have sufficient data available will account for the possibility that new reporting measures may have different reporting requirements. For example, a new reporting measure may require a facility to report new or additional data in CMS's ESRD Quality Reporting System (EQRS) to be eligible for scoring on the reporting measure. Additionally, a new reporting measure may require that a facility reconsider its internal processes to comply with the reporting requirements and be eligible for scoring. In the proposed rule, we stated that we believe that using a median of zero for new reporting measures would ensure that the mTPS is calculated based on the worst-case scenario, rather than assuming a median higher than what may be observed once data are available. We noted that setting the proxy median at zero until we have sufficient data available to calculate the median would allow the timely inclusion of a new reporting measure in the ESRD QIP measure set, as well as our calculation of the mTPS, while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting.

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

Comment: A few commenters expressed support for the proposed update to the definition of mTPS, as it will allow for timely inclusion of new reporting measures and encourage facilities to report data.

Response: We thank commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal as proposed.

2. Codification of the ESRD QIP Measure Adoption, Retention, and Removal Policies

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed

and finalized. In the CY 2019 ESRD PPS final rule (83 FR 56983 through 56985), we finalized eight measure removal factors for the ESRD QIP, and we refer readers to that final rule for details. We also finalized a policy to retain a measure for certain specified reasons, such as when a particular measure addresses a gap in quality so significant that removing the measure could result in poor quality or when a measure addresses a statutorily-required topic, even if one or more of the measure removal factors applies. In the CY 2013 ESRD PPS final rule (77 FR 67475), we also finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure, immediately notify ESRD facilities and the public through the usual communication channels (including listening sessions, memos, email notification, and website postings), and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle.

In the CY 2024 ESRD PPS proposed rule, we proposed to revise § 413.178(c) such that it incorporates these measure adoption, retention, and removal policies (88 FR 42487). We proposed that existing § 413.178(c)(1) through (5) would be consolidated and renumbered as § 413.178(c)(1)(i) through (v), and we would add a new § 413.178(c)(1)(vi), which would codify our policy to adopt measures for the ESRD QIP beyond those that address the topics described at § 413.178(c)(1)(i) through (v). We also proposed to codify at § 413.178(c)(2) our policies regarding the use of endorsed measures. We proposed to codify at § 413.178(c)(3) our policy regarding the updating of measure specifications. Additionally, we proposed to codify at § 413.178(c)(4) our policy regarding measure retention. Finally, we proposed to codify at § 413.178(c)(5) our policies regarding measure removal. We stated our belief that these proposals will make it easier for interested parties to find these policies and will further align the ESRD QIP regulations with the regulations we have codified for other quality reporting programs.

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

Comment: A few commenters expressed support for the proposals to codify existing measure adoption, retention, and removal policies, noting that these updates will provide transparency for evaluating measures.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed.

C. Updates to Requirements Beginning with the PY 2026 ESRD QIP

1. PY 2026 ESRD QIP Measure Set

In the CY 2024 ESRD PPS proposed rule, we proposed to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026 (88 FR 42499 through 42500). We also proposed to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026 (88 FR 42489 through 42494). The previously finalized and proposed new measures are summarized in Table 12 of the proposed rule (88 FR 42488). We describe the previously finalized measures and the measures we are finalizing in this final rule in Table 12. The technical specifications for each of these measures can be found in the CMS ESRD Measures Manual for the 2023 Performance Period.[108]

TABLE 12: Previously Finalized and Newly Finalized Measures for the PY 2026 ESRD QIP Measure Set

Consensus-Based Entity[109] (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

[108] https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf.
[109] 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[109] (CBE) #	Measure Title and Description
	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.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
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 The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
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 course.
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.

*We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
**We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.
*** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

2. Adoption of the Facility Commitment to Health Equity Reporting Measure Beginning with the PY 2026 ESRD QIP

a. Background

In the CY 2024 ESRD PPS proposed rule, we stated that significant and persistent disparities in healthcare outcomes exist in the U.S. (88 FR 42489). For example, belonging to a racial or ethnic minority group, being a member of the lesbian, gay, bisexual, transgender, and

queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, being a person with a disability or disabilities, or being near or below the poverty level, is often associated with worse health outcomes.[110,111,112,113,114,115,116,117,118,119] Numerous studies have shown that among Medicare beneficiaries, individuals who are racial and ethnic minorities often receive lower quality hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[120,121,122,123,124,125] Readmission rates in the Hospital Readmissions Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute

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[110] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675-681. Available at: doi:10.1001/jama.2011.123.
[111] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ*, 346. Available at: https://doi.org/10.1136/bmj.f521.
[112] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med*, 371(24), 2298-2308. Available at: doi: 10.1056/NEJMsa1405003.
[113] Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health Affairs*, 40(2), 307-316. Available at: https://doi.org/10.1377/hlthaff.2020.02142.
[114] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.
[115] HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: https://minorityhealth.hhs.gov/report-congress-minority-health.
[116] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.
[117] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.
[118] Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health*, 25(6), 586-593. doi: 10.1089/jwh.2015.5517
[119] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology*, 35(4), 351–355. https://doi.org/10.1037/hea0000268
[120] CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: .
[121] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.
[122] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis., 73(12), 2107-15. Available at: doi:10.1136/annrheumdis-2013-203494.
[123] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc., 67(8), 1672-1679. Available at: https://doi.org/10.1111/jgs.15960.
[124] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675-681. Available at: doi:10.1001/jama.2011.123.
[125] Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. Ann Surg., 259(6), 1086-1090. Available at: doi: 10.1097/SLA.0000000000000326.

myocardial infarction.[126,127,128,129,130] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality healthcare.[131] Evidence of differences in quality of care received by people from racial and ethnic minority groups show worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.[132] Additionally, inequities in the drivers of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[133]

In the CY 2022 ESRD PPS proposed rule (86 FR 36362 through 36369), we requested information on our Equity Plan for Improving Quality in Medicare (also referred to as the CMS Framework for Health Equity),[134] which outlines our commitment to close health equity gaps through improved data collection, measurement, and analysis of disparities across programs and policies. The request for information requested public comment regarding the potential

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[126] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. Am Heart J., 162(2), 254–261 e253. Available at: https://doi.org/10.1016/j.ahj.2011.05.009

[127] Centers for Medicare & Medicaid Services. (2014). Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures.

[128] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf

[129] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at MinorityServing Institutions. Ann Am Thorac Soc., 10(6), 680–684. Available at: https://doi.org/10.1513/AnnalsATS.201307-223OT.

[130] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[131] Nelson AR. (2003). Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. The Annals of thoracic surgery, 76(4), S1377-S1381. doi: 10.1016/s0003-4975(03)01205-0.

[132] Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. (2010). Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. Social Science & Medicine, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

[133] Department of Health and Human Services. (2021). Healthy People 2020: Disparities. Available at: www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.

[134] Centers for Medicare and Medicaid Services. (2022). CMS Framework for Health Equity 2022-2032. Available at: https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf. Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf. Accessed on February 20, 2023. See also, Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input. Accessed on February 20, 2023.

stratification of quality measure results by race and ethnicity and the potential creation of a hospital or facility equity score in CMS quality reporting and value-based purchasing programs, including the ESRD QIP. In the CY 2024 ESRD PPS proposed rule, we stated that we received many responses to that request for public comment (88 FR 42489), and we referred readers to the CY 2022 ESRD PPS final rule for summaries of those comments (86 FR 61934 through 61937). We noted in the CY 2022 ESRD PPS final rule the value of these comments in the continuing development of our health equity quality measurement efforts, and we stated that we would take the comments into account for future development and expansion of our health equity quality measurement efforts.

The Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission have independently concluded that facility leadership plays an important role in promoting a culture of quality and safety.[135,136,137] AHRQ research shows that facility boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.[138] The Joint Commission found that a leader who is committed to prioritizing and making patient safety visible through every day actions is a critical part of creating a true culture of safety, which in turn fosters an organizational culture in which patients are treated with dignity and respect.[139] Because CMS is also working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are also committed to supporting healthcare organizations in building a culture of safety *and*

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[135] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: https://psnet.ahrq.gov/primer/leadership-role-improving-safety.
[136] Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf.
[137] See information on launch of new "Health Care Equity Certification" in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/.
[138] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: https://psnet.ahrq.gov/primer/leadership-role-improving-safety.
[139] Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf.

equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from dialysis facility executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals for dialysis facilities. Studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.[140,141,142] A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.[143] We believe this conclusion also applies to dialysis facilities, and that the commitment of dialysis facility leadership to health equity would result in a reduction of health disparities in the ESRD population.

Our belief that a leadership commitment to health equity can lead to a reduction of health disparities is also supported by research conducted by the Institute for Healthcare Improvement (IHI), which studied 23 health systems throughout the U.S. and Canada. The IHI's research showed that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.[144] This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a

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[140] Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Qual Saf., 27(3), 218-225. doi:10.1136/bmjqs-2017-006574.

[141] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. doi:10.1186/s12913-017-2078-6.

[142] Keroack MA, Youngberg BJ, Cerese JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. Acad Med., 82(12), 1178-86. doi: 10.1097/ACM.0b013e318159e1ff.

[143] Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. The Milbank quarterly, 91(4), 738-70. doi:10.1111/1468-0009.12032.

[144] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.

leader-driven priority alongside organizational development structures and processes.[145] Based upon these findings, we believe that dialysis facility leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity goals and ensuring high-quality care at dialysis facilities is accessible to all. Based on this well-developed body of evidence, in the proposed rule we proposed to adopt an attestation-based structural reporting measure, Facility Commitment to Health Equity, for the ESRD QIP beginning with PY 2026 (88 FR 42490).

The first pillar of our strategic priorities[146] reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (see Table 13) using a suite of organizational competencies aimed at achieving health equity for all patients, including but not limited to patients who belong to racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of dialysis facility leadership commitment to them is foundational.

We proposed to adopt the measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP (88 FR 42490). We noted that disparities in health equity are tied to worse patient outcomes in the ESRD community. For example, individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely

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[145] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556.

[146] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.

to reduce CKD risk through recommended treatment goals.[147,148,149,150] Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.[151] Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.[152] We stated that we believe that this measure is an appropriate measure of ESRD quality of care because it would improve facilities' awareness of the tie between their structural practices and their patient outcomes by reporting these data, thus informing facility practices such that their patients attain better outcomes. We also stated our belief that the proposed measure would incentivize facilities to collect and utilize their data to identify their own critical equity gaps, implement plans to address said gaps, and ensure that they dedicate resources to addressing those gaps. Facilities could analyze data to understand, for example, whether there are any demographic factors (such as race, national origin, primary language, and ethnicity), or social drivers of health (such as housing status and food security) that may be affecting access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address

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[147] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: https://usrds-adr.niddk.nih.gov/2022.
[148] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499861/.
[149] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et.al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213-223. doi:10.1111/sdi.12589.
[150] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.
[151] Norton, J. M., Moxey-Mims, M. M., Eggers, P. W., Narva, A. S., Star, R. A., Kimmel, P. L., & Rodgers, G. P. (2016). Social Determinants of Racial Disparities in CKD. Journal of the American Society of Nephrology : JASN, 27(9), 2576–2595. https://doi.org/10.1681/ASN.2016010027.
[152] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.

a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

The five questions of the structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[153] We have already adopted this measure for the Hospital Inpatient Quality Reporting (IQR) Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201) for a discussion of the measure in that program. In the proposed rule, we stated that, other than replacing the term "hospital" with the term "facility," the measure is identical to the Hospital IQR Program measure. The Facility Commitment to Health Equity measure is aligned with the Meaningful Measures Area of "Equity of Care" and the Meaningful Measures 2.0 goal to "Leverage Quality Measures to Promote Equity and Close Gaps in Care" because it seeks to assess structural health equity issues that could inform facility practices such that their patients attain better outcomes. This measure also supports the Meaningful Measures 2.0 objective to "[c]ommit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity" because the measure would incentivize facilities to identify their own healthcare equity gaps from a structural perspective.

b. Overview of Measure

The Facility Commitment to Health Equity reporting measure assesses dialysis facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for all populations, including those that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, this includes, but

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[153] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.

is not limited to: racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 13 includes the five attestation domains and the elements within each of those domains for which we had proposed a facility would report an affirmative attestation in order for the facility to receive points for that domain.

TABLE 13: Proposed Facility Commitment to Health Equity Measure's Five Attestations

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.

Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients.* Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, including chief executives and the entire facility** board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After publication of the 2022 MUC List, we clarified the language in Domain 4: "Health disparities are evidence that high quality care has not been delivered *equitably* to all patients."
** After publication of the 2022 MUC List, we identified that Domain 5 incorrectly referred to the "hospital board of trustees" instead of the "facility board of trustees," and therefore updated the language in Domain 5 to be more applicable to the ESRD QIP.

c. Measure Calculation

The Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of commitment. For a facility to affirmatively attest "yes" to a domain, and receive points for that domain, the facility would need to determine that it engages in all of the activities that are included as elements under the domain. A facility that engages in all of the activities for a domain would report an affirmative attestation by answering "yes" to the attestation-based question for that domain. There is no option for a facility to answer "yes" in response to an attestation-based question for a domain if the facility engages in some, but not all, of the activities included as domain elements, and there is also no option for a facility to answer "no" in response to any attestation-based question for a domain. The measure would be expressed as a fraction, and a facility can score either 0, 2, 4, 6, 8, or 10 for the performance period, depending on the number of domains to which a facility positively attests. In the proposed rule, we proposed that the measure denominator would be "ten," with each domain being represented as two points out of that total ten points, and that the numerator would be calculated as two points for each "yes" answer the facility reports which are then summed together (88 FR 42493). We stated that we chose to award facilities two points for each

affirmative response to an attestation-based question so that the maximum number of points a facility could receive for the measure is ten, which is the same maximum number of points that a facility can receive on other ESRD QIP measures.

For example, for Domain 1 ("Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority"), a facility would evaluate and determine whether its strategic plan satisfies all of the elements described in (A) through (D) (see Table 13). If the facility's plan satisfies all four of these elements, the facility would respond "yes" to the attestation-based question for Domain 1 and receive two (2) points for that response. If the facility determined that its strategic plan satisfies elements (A) and (B) but not (C) and (D), the facility would not be able to respond "yes" to Domain 1 and would not receive any points for that domain.

The numerator is calculated as the sum of the points the facility earns for responding "yes" to the attestation-based questions. For example, a facility that responds "yes" to all five attestation-based questions would receive the maximum 10 points (two points for each of the five "yes" responses). A facility that responds "yes" to three of the attestation-based questions would receive six points.

We proposed that the Facility Commitment to Health Equity reporting measure would be added to the Reporting Measure Domain (88 FR 42493). We noted that technical specifications for the measure can be found in the ESRD QIP CY 2024 Technical Measure Specifications, which are available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip/061_technicalspecifications. Consistent with case minimums we have adopted for our other ESRD QIP reporting measures, we proposed that facilities must have 11 qualifying patients and a CCN open date before September 1 of the performance period that applies to the program year in order to be eligible for scoring on the Facility Commitment to Health Equity reporting measure.

d. Data Submission and Reporting

In the proposed rule, we proposed to require facilities to submit data needed to calculate the Facility Commitment to Health Equity measure once on an annual basis using CMS's ESRD Quality Reporting System (EQRS) beginning with PY 2026 (88 FR 42494). We proposed that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, for the PY 2026 ESRD QIP, facilities would need to report data on the measure by the end of the December data reporting month in CY 2024. As described in Table 17 of the proposed rule (88 FR 42504) and reproduced in Table 18 of this final rule, we proposed performance standards for the Facility Commitment to Health Equity reporting measure. We also proposed a 12-month performance period for the measure, and note that we did not receive any comments on this aspect of the measure proposal. We further proposed that facilities would be required to follow the submission and reporting requirements for web-based measures for the ESRD QIP posted on the QualityNet website: https://qualitynet.cms.gov/esrd/esrdqip.

e. Review by the Measure Applications Partnership

The Facility Commitment to Health Equity measure was included as a measure under consideration for the ESRD QIP on the publicly available "List of Measures Under Consideration for December 1, 2022" (MUC List), a list of measures under consideration for use in various Medicare quality programs.[154] The CBE-convened Measure Applications Partnership (MAP) Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC2022–027) in detail on December 6-7, 2022.[155] The Health Equity Advisory Group expressed concern that this is more of a "checklist" measure that may not directly address health inequities at a systemic level, but the advisory group generally agreed that

[154] Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[155] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

a structural measure such as this one represents progress toward improving equitable care.[156] In addition, on December 8 through 9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List, and the MAP Hospital Workgroup reviewed the 2022 MUC List on December 13 through 14, 2022.[157] The MAP Hospital Workgroup recognized that reducing health care disparities would represent a substantial benefit to overall quality of care, but expressed reservations about the measure's link to clinical outcomes; the MAP Hospital Workgroup members voted to conditionally support the measure for rulemaking pending: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.[158] Thereafter, the MAP Coordinating Committee deliberated on January 24 through 25, 2023 and ultimately voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking with the same conditions.[159]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is

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[156] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[157] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[158] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[159] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the facility-specific results for the Facility Commitment to Health Equity reporting measure on an annual basis through our *Care Compare* website at: https://www.medicare.gov/care-compare/. We stated that we anticipate making the first public report available in January 2026.

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

Comment: Several commenters expressed support for the Facility Commitment to Health Equity measure. A few of these commenters appreciated the Facility Commitment to Health Equity measure as a step towards requiring demonstration of equitable policies and practices. One commenter noted that the measure will help facilities assess commitment to health equity by focusing on relevant organizational competencies. One commenter, emphasizing the importance of strong, diverse, and committed leadership in advancing health equity goals at the facility level, stated that the measure would incentivize facilities to identify and address equity gaps. One commenter noted that the measure is a low burden first step to address inequity, supports Meaningful Measures 2.0, and focuses on SMART goals which are the basis for measuring improvement in health outcomes.

Response: We thank commenters for their support of our proposal to adopt the Facility Commitment to Health Equity reporting measure. We agree that the measure assesses a facility's commitment to health equity and is intended to encourage facilities to understand their own health equity gaps so they can improve patient outcomes.

Comment: A few commenters expressed support for public reporting of the measure.

Response: We thank the commenters for their support.

Comment: A few commenters who supported the adoption of the Facility Commitment to Health Equity measure also offered suggestions for possible expansion of the measure. A few commenters recommended expanding the scope of the measure to specifically ensure that facilities identify and address equity in access to home dialysis. One commenter recommended that the measure eventually be expanded to capture a greater depth of information that would provide more meaningful data to CMS and patients. The commenter also recommended that CMS include health equity requirements as part of the Conditions for Coverage for the Medicare program, which could potentially be used to require that facilities collect and stratify data on certain demographic elements. One commenter encouraged CMS take actions to further enable nurses to support health equity efforts, noting their critical role in patient engagement while balancing administrative burden.

Response: We thank commenters for their suggestions, which we will consider as we continue to develop potential future policies on this topic.

Comment: One commenter expressed support for the Facility Commitment to Health Equity measure but recommended that CMS ensure that there are no unintended consequences, such as disincentivizing facilities from operating in areas that may have greater health disparities.

Response: We appreciate the commenter's support and will monitor this measure, as we do all ESRD QIP measures, for any unintended or adverse outcomes associated with implementation.

Comment: Several commenters stated that it was unclear how the Facility Commitment to Health Equity measure would result in a reduction of social inequities. A few commenters expressed concern that the measure lacks follow-up and does not require facilities to take specific action upon identifying health equity gaps. A few commenters expressed concern that, without additional requirements for facilities to make changes based on identified health equity gaps, the Facility Commitment to Health Equity measure may only serve as a checklist measure

rather than incentivizing change at the systemic level. One commenter expressed concern that the Facility Commitment to Health Equity measure is not relevant to the ESRD QIP because the measure was developed for the hospital setting. One commenter expressed concern that the measure would not promote meaningful action in patient care because it is not clinical.

Response: We believe this measure is an important foundational measure for improving health equity for the facility's entire patient population, which may include patients that have been underserved by the healthcare system. As we discussed in section IV.C.2.a. of the proposed rule, there is substantial research showing differences in care and experiences among underserved populations (88 FR 42489 through 42491). The measure is intended to encourage facilities to analyze their own data to understand whether there are demographic factors or other social drivers of health that may be contributing to the health outcomes experienced by their patients so they can develop solutions to improve those outcomes for all of their patients. We believe that adopting the measure for dialysis facilities will help improve access to care and outcomes for the ESRD population by making facilities more aware of certain potential opportunities for improvement. We also believe that a commitment to health equity by dialysis facility leadership can foster organizational competencies aimed at achieving health equity for the facility's patients. Although the Facility Commitment to Health Equity reporting measure is not a clinical measure, the measure could improve facility awareness of the tie between its structural practices and its patient outcomes, which we believe will lead to improved clinical outcomes for patients.

Comment: Although commenters appreciated the importance of a commitment to health equity and expressed support for CMS's efforts to address health equity, a few commenters expressed concern that the Facility Commitment to Health Equity measure needs to be developed further prior to inclusion in the ESRD QIP so that it is more meaningful to the ESRD population and care setting. One commenter requested that CMS engage with stakeholders in the ESRD community to improve the measure so that it is more applicable to the dialysis facility setting.

Response: The Facility Commitment to Health Equity measure is a structural measure that is designed to apply across multiple healthcare settings. The five measure domains (that is, equity is a strategic priority, data collection, data analysis, quality improvement, and leadership engagement) apply to dialysis facilities. Specifically, dialysis facilities collect data and analyze data for quality improvement purposes. Facilities also establish organizational plans that define practices and policies that impact health equity. We believe strong and committed leadership from dialysis facility leadership is essential and can play a role in advancing equity goals for facilities. Although we appreciate commenters' desire that the measure be tailored further to the ESRD population and setting, we believe that the measure sufficiently addresses a facility's leadership and its commitment to health equity in a way that encompasses the needs of that population and setting. The measure is intended to provide information to facilities on the level of unmet need among their patients by encouraging facilities to identify and address potential health equity gaps. We believe this measure is an important step toward assessing facility leadership commitment and a fundamental step toward closing the gap in equitable care for the facility's patients. We will continue to monitor the measure as it is implemented to ensure that it is meaningful to the ESRD community.

Comment: A few commenters recommended that CMS submit the measure to the CBE for review and endorsement to ensure that it is useful and meaningful for the ESRD population and care setting.

Response: While we recognize the value of CBE endorsement review, and plan to submit this measure for CBE endorsement in the future, measures of health equity are a priority for CMS, and we believe it is important to implement this measure as soon as possible. We note that under section 1881(h)(2)(B)(ii) of the Act the Secretary may specify a measure that is not endorsed by a CBE as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and

therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies. We believe the Facility Commitment to Health Equity measure establishes an important foundation to prioritize the achievement of health equity among facilities.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed measure requirements and recommended that CMS weigh the potential impact on patient health outcomes against this new administrative burden. A few commenters stated that certain types of facilities, such as rural and small facilities, may lack the resources to implement this measure and, as a result, could be unfairly penalized. One commenter stated that compliance with the new measure will require substantial training and additional staff support. One commenter expressed concern that the reporting requirements associated with the proposed measure would take resources away from patient care.

Response: We recognize the commenters' concerns about burden of new measure requirements in the ESRD QIP and believe that our data submission requirements pose minimal burden on facilities given that facilities will have 14 months to report the measure with respect to each performance period. We believe this measure reporting timeline will provide facilities with ample time to submit data in a timely manner. We also believe the benefits of this measure outweigh the burden of reporting it.

Comment: One commenter requested that facilities receive full credit for attestation, regardless of whether the facility negatively or positively attests to each given domain. The commenter noted that this would be consistent with other reporting measures in the ESRD QIP measure set, which award points for reporting the data, rather than the results of the reported data.

Response: We believe this measure is an important step towards assessing leadership commitment to health equity and a fundamental step towards identifying and closing gaps in quality outcomes. We also believe that a facility should not receive the maximum 10 points on the measure for a performance year if it cannot affirmatively attest to all five domains. We

believe that the proposed scoring methodology is consistent with the scoring methodology we have adopted for the MedRec reporting measure, which requires that facilities report that medication reconciliation was performed and documented by an eligible professional during the reporting period in order to be awarded the maximum number of points for the measure (83 FR 57009 and 57011).

Comment: One commenter recommended removing the term "priority" from Domain 1 to avoid implying that there are populations who are not priorities.

Response: We agree with the commenter that a facility's entire patient population should have access to high quality ESRD care. However, we disagree with commenter that the term "priority" should be removed, as we believe the element focuses on populations that the facility may identify as having experienced health disparities at that particular facility. A facility has discretion to identify its own priority populations and develop its own solutions to support its equity goals. Therefore, we are finalizing the reference to "priority populations" in Domain 1 as proposed.

Comment: Several commenters recommended that CMS update the measure specifications in Domain 2 so that facilities without certified EHR technology are able to positively attest to all domains, noting that dialysis facilities are not required to use certified EHR technology and may not have it available. These commenters expressed concern that public reporting of measure results for facilities that do not positively attest to all domains because they are without access to certified EHR technology could lead the public to misinterpret the results as a lack of commitment to health equity. A few commenters recommended that CMS revise the language to remove the reference to certified EHR technology to provide flexibility regarding the type of data technology used while retaining the requirement to input the data into structured fields. One commenter requested clarification regarding whether it will accept Electronic Data Interchange (EDI) in the EQRS for this measure.

Response: We thank commenters for their feedback. Although the majority of dialysis facilities use some type of EHR technology, we acknowledge that dialysis facilities are not currently required to use EHR technology certified by the Office of the National Coordinator for Health Information Technology (ONC) to comply with the requirements of the ESRD QIP. We agree with commenters that the proposed language in Domain 2 may prevent facilities from affirmatively attesting to Domain 2 if they can only affirmatively attest to the elements in (A) and (B). Therefore, we are finalizing a revision to the elements of Domain 2 so that facilities can affirmatively attest to that domain if they use EHR technology that is not certified by ONC. This updated language is provided in Table 14 below and states, "(C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using EHR technology." Although we encourage facilities to use certified health IT to promote interoperability and health information exchange across the healthcare system, we are not requiring dialysis facilities to use certified EHR technology for purposes of reporting this measure. We note that EHR technology may include EDI, and therefore EDI may be accepted as part of the EHR technology requirements included under Domain 2.

Comment: One commenter noted the relatively short timeframe for implementation and potential for error in data collection and reporting due to the complexity of the new data collection and reporting requirements. One commenter expressed concern regarding the element under Domain 3 that the facility have facility performance dashboards to affirmatively attest to that domain beginning with PY 2024, noting that such dashboards require thoughtful development to ensure that they are appropriately designed for lower patient volumes and account for potential clinically-related factors.

Response: We believe that facilities should have sufficient time to implement any structural processes they need to report the measure. However, to the extent a facility may need to implement new data collections or update its systems to enable it to affirmatively attest to

Domain 3 or any other domain, a facility will have until two months after the end of each 12-month performance period to submit its attestations for that performance period in EQRS. In addition, a facility can report an affirmative attestation for a domain as long as it satisfies the elements of the domain at any time during the applicable performance period.

Comment: One commenter stated that all facilities participating in the ESRD Network Program should meet the Domain 4 requirement that facilities engage in quality activities and recommended that all dialysis facilities receive automatic credit for this domain.

Response: We believe it is necessary for each dialysis facility to review its health equity practices under each domain and attest to each domain separately, including Domain 4. If a facility participates in quality improvement activities focused on reducing health disparities as part of a facility's participation in an ESRD Network, then a facility may affirmatively attest under Domain 4.

Comment: A few commenters observed that the language in Domain 5 does not apply to many individual dialysis facilities, as they are part of national groups and therefore do not have facility-level CEOs or boards of trustees. A few commenters also requested clarification as to whether the Facility Commitment to Health Equity measure requirements would apply to each individual dialysis facility separately, or whether they would apply to the larger organization which includes the individual dialysis facility. One commenter expressed concern regarding the potential burden imposed on small facilities if compliance with the Facility Commitment to Health Equity measure would be required at the facility level and recommended that small facilities be exempt from Facility Commitment to Health Equity reporting requirements, or that CMS allow such facilities that are part of a larger organization to use the organization's strategic plan to satisfy measure requirements. One commenter expressed concern that facility-level analysis of disparities may be insufficient to identify and address gaps in the dialysis setting as these facilities serve more geographically homogenous populations than other types of healthcare facilities, such as hospitals.

Response: We thank commenters for their feedback and are finalizing a modified version of the Domain 5 elements. Whereas the originally proposed language for Domain 5 required that facilities attest to leadership engagement at the facility level only, we agree that facilities should be able to attest to leadership engagement under Domain 5 if their senior leadership engages in the Domain 5 elements and that engagement applies to the facility, regardless of whether those senior leaders operate at only the facility or at a larger organization that includes the facility. Accordingly, we are finalizing that the referenced facility senior leadership could be, but are not required to be, the facility's own chief executives or its board of trustees.

Regarding commenters' requests for clarification as to whether the measure requirements would apply to each individual dialysis facility separately, or whether they would apply to the larger organization which includes the individual dialysis facility, we note that we proposed for the Facility Commitment to Health Equity reporting measure to apply to individual facilities. For all five measure domains, an individual facility may attest to both facility-level efforts as well as activities that are implemented by the individual facility as part of a larger organization's policies. For individual facilities that are part of larger organizations, we note that this may include leadership engagement at the larger organizational level as well as leadership engagement at the individual facility level. Specifically, the reporting measure would require facilities to review their own activities in relation to the five measure domains to identify ways to address disparities within the patient population they serve. We believe this revision will apply more broadly to accommodate the unique organization structures across facilities.

The elements of the Facility Commitment to Health Equity Measure, including the revised language for Domains 2 and 5, are provided in Table 14.

TABLE 14: Facility Commitment to Health Equity Measure's Finalized Five Attestations

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using EHR technology.*
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	

Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, such as, but not limited to, chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity.** (B) Our facility senior leadership, such as, but not limited to, chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After consideration of public comments, we are refining the language in Domain 2 to remove the requirement that EHR technology must be "certified" to affirmatively attest to the elements of that domain.
** After consideration of public comments, we are refining the language in Domain 5 to provide flexibility regarding the type of leadership that may be engaged in these efforts.

Comment: One commenter expressed concern regarding the Facility Commitment to Health Equity measure, stating that the measure essentially served as a back-door mandate to require that facilities perform a specific activity and did not provide facilities with flexibility to achieve the ultimate goal of the measure.

Response: We disagree with the commenter. We believe this measure is an important foundation for improving health equity in the provision of ESRD care. We believe that each of the domains provides flexibility for facilities to affirmatively attest without imposing overly narrow or prescriptive requirements. Although facilities will be required to affirmatively attest to each of the elements for a domain to receive points for that domain, a facility has the discretion to determine what activities will satisfy each element. We encourage facilities to analyze their own data to improve their awareness of whether there is a tie between their structural practices and the outcomes experienced by their patients, with the goal of attaining better outcomes for all of their patients.

Final Rule Action: After considering public comments, we are finalizing the adoption of the Facility Commitment to Health Equity reporting measure with language refinements to the elements in Domains 2 and 5 as described in Table 14 of this final rule, beginning with PY 2026.

3. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with PY 2026

a. Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a novel (new) coronavirus that causes a disease named "coronavirus disease 2019" (COVID–19).[160] Subsequently, the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure was adopted across multiple quality reporting programs including the ESRD QIP (87 FR 67244 through 67248), the Hospital IQR Program (86 FR 45374), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396). COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.13 million deaths in the United States as of June 19, 2023.[161] In recognition of the ongoing significance and complexity of COVID–19, the Secretary renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.[162] While the PHE expired on May 11, 2023, HHS has stated that the public health response to COVID–19 remains a public

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[160] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx.

[161] CDC. COVID Data Tracker. Accessed June 19, 2023. Available at: https://covid.cdc.gov/covid-data-tracker/#datatracker-home. We note that we have updated in this final rule the number of cases and deaths provided in the proposed rule, which stated that "COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.1 million deaths in the United States as of March 27, 2023." (88 FR 42494).

[162] U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.

health priority with a whole of government approach to combatting the virus, including through vaccination efforts.[163]

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67244) and in our Revised Guidance for Staff Vaccination Requirements,[164] vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including dialysis facilities, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Prior to the publication of the CY 2023 ESRD PPS final rule on November 7, 2022, the FDA had approved or issued emergency use authorizations (EUAs) for COVID–19 vaccines for adults manufactured by Pfizer-BioNTech,[165] Moderna,[166] and Janssen.[167] The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older, and the Pfizer-BioNTech vaccine was authorized for ages 12 and older. The FDA issued an approval for the Pfizer-BioNTech vaccine, now marketed as Comirnaty, on August 23, 2021.[168] Additionally, the FDA issued approval for the Moderna vaccine, marketed as Spikevax, on

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[163] U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

[164] Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO-23-02-ALL. October 26, 2022. Available at: https://www.cms.gov/files/document/qs0-23-02-all.pdf.

[165] Food and Drug Administration. (December 2020). FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[166] Food and Drug Administration. (December 2020). FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

[167] Food and Drug Administration. (February 2021). FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[168] Food and Drug Administration. (August 2021). FDA Approves First COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

January 31, 2022[169] and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.[170] The FDA also issued EUAs for single booster doses of the then-authorized COVID–19 vaccines. As of November 19, 2021,[171][172][173] a single booster dose of each COVID–19 vaccine was authorized for all eligible individuals 18 years of age and older. EUAs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in in March 2022.[174] FDA first authorized the use of a booster dose of bivalent or "updated" COVID–19 vaccines from Pfizer-BioNTech and Moderna in August 2022.[175] Since the publication of the CY 2024 ESRD PPS proposed rule, the 2023-2024 updated Pfizer-BioNTech, Moderna, and Novavax COVID–19 vaccines were recommended by CDC for use in the United States.[176] The 2023-2024 updated COVID–19 vaccine more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID–19 that may have decreased over time.

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[169] Food and Drug Administration. (January 2022). Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.
[170] Food and Drug Administration. (July 2022). Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted.
[171] Food and Drug Administration. (September 2021). FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. Available at: https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations.
[172] Food and Drug Administration. (October 2021). Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines.
[173] Food and Drug Administration. (November 2021). Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters.
[174] Food and Drug Administration. (March 2022). Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and.
[175] Food and Drug Administration. (August 2022). Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use. We note that, as of September 12, 2023, the bivalent COVID-19 vaccines are no longer FDA authorized. FDA. (September 11, 2023). FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating. The bivalent COVID-19 vaccines have been replaced with the updated 2023-2024 (XBB-variant) COVID-19 vaccines.
[176] CDC. (October 4, 2023). Stay Up to Date with COVID-19 Vaccines. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

We stated in the CY 2023 ESRD PPS final rule that HCP are at risk of carrying COVID-19 infection to patients, experiencing illness or death themselves as a result of contracting COVID-19, and transmitting COVID-19 to their families, friends, and the general public (87 FR 67244). While the impact of COVID-19 vaccines on asymptomatic infection and transmission is not yet fully known, there is now robust data available on COVID–19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over 6 months for adults over age 18 without immunocompromising conditions.[177] During a SARS-COV–2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated.[178] Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS–COV–2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[179] Vaccines have also been highly effective in real-world conditions preventing COVID–19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[180] In the presence of high community prevalence of COVID–19, residents of nursing homes with low staff vaccination

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[177] CDC. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions – United States, March-August 2021. Available at: https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

[178] CDC. (September 10, 2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S. Jurisdictions, April 4-July 17, 2021. Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm.

[179] CDC. (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-COV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance – Eight U.S. Locations, December 2020-August 2021. Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm.

[180] Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. New England Journal of Medicine. 2021 Dec 16;385(25):e90. Available online at: https://pubmed.ncbi.nlm.nih.gov/34551224/.

coverage had higher rates of COVID–19 cases and COVID–19 related deaths than those among residents of nursing homes with high staff vaccination coverage.[181] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, including hospitalization and death.

As SARS–COV–2 persists and evolves, our COVID–19 vaccination strategy must remain responsive. When we finalized adoption of the COVID–19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, we stated that HCP should be counted as vaccinated if they received COVID–19 vaccination any time from when it first became available in December 2020 (87 FR 67247). We noted that a completed vaccination course, defined for purposes of the measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used, and that the NHSN application automatically calculates the total value for "Any completed COVID–19 vaccine series." We also stated that, as vaccination protocols continue to evolve, we would continue to work with the CDC to update relevant measure specifications as necessary. Since we finalized the COVID–19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, new variants of SARS-COV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.[182] Vaccine manufacturers initially responded to the Omicron variant by developing bivalent COVID–19 vaccines, which included a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.[183] These booster doses of the bivalent COVID–19 vaccines were shown to increase immune response to SARS–COV–2 variants, including Omicron, particularly in individuals who

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[181] McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. New England Journal of Medicine. 2022 Jan 27;386(4):397-398. Available online at: https://pubmed.ncbi.nlm.nih.gov/34879189/.
[182] Food and Drug Administration. (August 2021). Variants of the Virus. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.
[183] Food and Drug Administration. (November 2022). COVID–19 Bivalent Vaccine Boosters.

are more than 6 months removed from receipt of their primary series.[184] We noted in the proposed rule that the FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech[185] and one from Moderna[186], and strongly encouraged anyone who is eligible to consider receiving a booster dose with a bivalent COVID–19 vaccine to provide better protection against currently circulating variants.[187] Since the publication of the CY 2024 ESRD PPS proposed rule, an updated 2023-2024 formulation of COVID–19 vaccine has been approved that more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID–19 that may have decreased over time.[188] Updated COVID–19 vaccine doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination,[189] [190] with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[191] Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across facilities.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the

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[184] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1-735.e3. Available online at: https://pubmed.ncbi.nlm.nih.gov/35143997/.
[185] Food and Drug Administration. (November 2022). Pfizer-BioNTech COVID–19 Vaccines. Available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines.
[186] Food and Drug Administration. (November 2022). Moderna COVID–19 Vaccines. Available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines.
[187] Food and Drug Administration. (August 2022). Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.
[188] CDC. (October 4, 2023). Stay Up to Date with COVID-19 Vaccines. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.
[189] Prasad N et al. (May 2022). Effectiveness of a COVID-19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant - United States, February 14-March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 2022 May 6;71(18):633-637. Available online at: https://pubmed.ncbi.nlm.nih.gov/35511708/.
[190] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1-735.e3. Available online at: https://pubmed.ncbi.nlm.nih.gov/35143997/.
[191] Ibid.

availability of vaccine efficacy data, EUAs and Biologics License Application approvals issued by the FDA for updated 2023-2024 formulations of the vaccine, the continued presence of SARS–COV–2 in the United States, and variance among rates of updated vaccinations, it is important to modify the COVID–19 Vaccination Coverage Among HCP measure to reflect recent updates that explicitly specify for HCP to receive primary series and updated vaccine doses in a timely manner. As the COVID–19 pandemic persists, we continue to believe that monitoring and surveillance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. In the CY 2024 ESRD PPS proposed rule, we proposed to modify the COVID–19 Vaccination Coverage Among HCP measure to replace the term "complete vaccination course" with the term "up to date" in the HCP vaccination definition (88 FR 42496). We also proposed to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including updated vaccine doses, beginning with PY 2026. As we stated in the CY 2023 ESRD PPS final rule (87 FR 67245), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular outcome.

b. Overview of Updated Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in settings such as dialysis facilities, and the measure is reported via the CDC's NHSN.

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67245 through 67246) for more information on the initial review of the measure by the Measure Applications Partnership (MAP). We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022-2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, the MAP's Hospital Workgroup discussed the modified measure. The Hospital Workgroup stated that the revision of the current measure captures up-to-date vaccination

information in accordance with CDC recommendations updated since its initial development. Additionally, the Hospital Workgroup appreciated that the respecified proposed measure of the target population is broader and simplified from seven categories of HCP to four.[192] During review, the Health Equity Advisory Group highlighted the importance of COVID–19 measures and questioned whether the measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural facilities may not have employee health software.[193] The measure developer acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on the provider. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if the COVID–19 vaccination strategy becomes seasonal. The revised measure received conditional support for rulemaking from both the MAP workgroups pending testing indicating the measure is reliable and valid, and endorsement by the consensus-based entity (CBE).[194] The MAP noted that the previous version

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[192] Centers for Medicare & Medicaid Services. MAP 2022-2023 Preliminary Analysis Worksheet. 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/sites/default/files/map-preliminary-recommendations-2022-2023.xlsx.

[193] Centers for Medicare & Medicaid Services. MAP 2022-2023 Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[194] 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.

of the measure received endorsement from the CBE (CBE #3636)[195] and that the CDC intends to submit the updated measure for endorsement.

(1) Measure Specifications

This reporting measure includes at least one week of data collection a month for each of the three months in a quarter. The denominator is the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC. Facilities report the following four categories of HCP to NHSN:

1. Employees: includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.

2. Licensed independent practitioners (LIPs): This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a direct paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

3. Adult students/trainees and volunteers: This includes all medical, nursing, or other health professional students, interns, medical residents, and volunteers aged 18 or over who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.

4. Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or

[195] We note that the reference provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now as follows: Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.

services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the COVID–19 Vaccination Coverage Among HCP measure.[196] The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.[197] There are no changes to the denominator exclusions.

The numerator of the modified measure is the cumulative number of HCP in the denominator population who are considered up to date with recommended COVID–19 vaccines. Facilities would refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf. In the proposed rule, we provided the example that HCP would be considered up to date during the applicable performance period for the ESRD QIP if they met one of the following criteria:

1. Individuals who received an updated bivalent[198] booster dose, or

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series[199] less than 2 months ago.

We note that since publication of the proposed rule, the CDC's definition for up to date vaccination has evolved. HCP would be considered up to date during the applicable

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[196] For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID-19 Vaccination Protocol, Weekly COVID-19 Vaccination Module for Healthcare Personnel available at: https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf

[197] CDC. (2022). Contraindications and precautions. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.

[198] In the CY 2024 ESRD PPS proposed rule, we noted that the updated (bivalent) Moderna and Pfizer-BioNTech boosters targeted the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on September 2, 2022. As of the CY 2024 ESRD PPS proposed rule, we also noted that the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older. Since the proposed rule was published, the bivalent COVID-19 vaccines are no longer FDA authorized. FDA. (September 11, 2023). FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating. The bivalent COVID-19 vaccines have been replaced with the updated 2023-2024 (XBB-variant) COVID-19 vaccines.

[199] Although in the CY 2024 ESRD PPS proposed rule we indicated that completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine (88 FR 42496), we note that the Janssen/J&J COVID–19 vaccine is no longer being used in the United States. For further information, please see CDC. (2023). Janssen (Johnson & Johnson) COVID–19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html.

performance period for the ESRD QIP if they met the following criteria:

1. Individuals who received an updated[200] vaccine dose.

We refer readers to https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf for more details on the measure specifications.

We noted in the proposed rule that the updated COVID–19 Vaccination Coverage Among HCP measure would remain a reporting measure. The updates to measure weighting for PY 2026 and PY 2027 are discussed further in sections IV.C.6 and IV.D.7 of this final rule.

(2) Consensus-Based Entity Endorsement

The current version of the measure in the ESRD QIP received CBE endorsement (CBE #3636, "Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel") on July 26, 2022. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In developing the CY 2024 ESRD PPS proposed rule, we reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception for non-CBE-endorsed measures applies. The CDC, as the measure developer, is pursuing endorsement for the modified version of the measure.

c. Data Submission and Reporting

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[200] The 2023-2024 updated Pfizer-BioNTech, Moderna, and Novavax COVID-19 vaccines were recommended by CDC for use in the United States. The 2023-2024 updated COVID-19 vaccine more closely targets the XBB lineage of the Omicron variant and could restore protection against severe COVID-19 that may have decreased over time. Individuals are also considered up to date if they received a bivalent vaccine or a Novavax vaccine within the last 2 months, or if they received a Novavax vaccine after completing a primary series. For further details, please see: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67246) for information on data submission and reporting for the measure. We did not propose any changes to the existing data submission requirements.

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

Comment: Several commenters expressed support for the proposal to modify the COVID–19 Vaccination Coverage Among HCP reporting measure. Several of these commenters noted that vaccination is a critical tool to protect the health of HCP and patients. One commenter expressed support for the proposed modification, noting that continued tracking of up-to-date vaccination status is important to help facilities prepare for infectious threats. One commenter expressed support for the proposed update because it will align the requirements between agencies.

Response: We thank the commenters for their support. We agree that vaccination plays a critical part of HHS's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track rates of vaccination among HCP through quality measurement across care settings, including the dialysis facility setting, to protect healthcare workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities.

Comment: Several commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden for facilities. A few commenters recommended that the measure exclude staff who are not directly employed by the facility to reduce tracking burden. One commenter noted that the reporting burden associated with the measure was disproportionate to its weight as part of the ESRD QIP measure set.

Response: We acknowledge commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We

note that given the highly infectious nature of the virus that causes COVID–19, we believe it is important to encourage all eligible personnel within the facility, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the facility which may affect resource availability and have a negative impact on patient access to care. We note that the proposed updates to the COVID–19 Vaccination Coverage Among HCP reporting measure do not include a change to the definition of HCP, and that facilities have been reporting the COVID–19 Vaccination Coverage among HCP measure since January 1, 2022. With regard to the commenter's concern about the proportionality of the measure's reporting burden to its measure weight within the ESRD QIP, we note that the burden associated with a given measure is only one of several factors taken into consideration when determining the weight of the measure within the ESRD QIP. 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).

Comment: One commenter also supported aligning reporting with that for Influenza Vaccination Coverage Among HCP if the COVID–19 vaccination strategy becomes seasonal. One commenter recommended requiring annual reporting at the end of the respiratory season.

Response: We thank the commenter for this suggestion. As we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42497), the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and the measure developer intends to utilize a similar approach with respect to the modified version of the measure if the COVID–19 vaccination strategy becomes seasonal. For that reason, we may consider aligning reporting for the COVID–19 Vaccination Coverage Among HCP reporting measure with the Influenza Vaccination Coverage Among HCP measure in the future. We continue to monitor COVID–19 as part of our public health response and will consider information we collect to inform any potential action that may address seasonality in future rulemaking.

Comment: One commenter recommended that the measure get CBE review and endorsement prior to inclusion in the ESRD QIP.

Response: The current version of the measure received CBE endorsement (CBE #3636, "Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel") on July 26, 2022. As we stated in the CY 2024 ESRD PPS proposed rule (88 FR 42497 through 42498), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For this CY 2024 ESRD PPS rule cycle, we reviewed CBE-endorsed measures. While the current, CBE-endorsed version of the measure is available, the modified version of the measure more completely accounts for the availability of booster and bivalent doses which were not yet developed when the current version of the measure was adopted. Having given due consideration to CBE-endorsed measures, we believe the exception for non-CBE-endorsed measures under section 1881(h)(2)(B)(ii) of the Act applies. The measure steward, CDC, has submitted the modified measure to the CBE for endorsement and it is currently under review.

Comment: A few commenters expressed concern regarding the COVID–19 Vaccination Coverage Among HCP reporting measure, stating that facilities should not be held responsible for a HCP's decision to get vaccinated because those decisions are beyond the facility's control.

Response: We understand the commenters' concern that there are many factors outside of a facility's control that could affect vaccination coverage among a facility's HCP; however, we believe that all facilities face such concerns and that public reporting of these data can help patients and their caregivers identify which facilities have better vaccination coverage among their HCP. We wish to emphasize that the measure does not require that HCP actually receive

the COVID-19 vaccine. The COVID–19 Vaccination Coverage Among HCP measure only requires reporting of vaccination rates.

Comment: A few commenters recommended removing the COVID–19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set. One commenter believed that the measure should be removed because the PHE has ended and CMS has also ended staff vaccination requirements related to COVID-19 vaccination. One commenter stated that the measure should be removed because it is outside the scope of the ESRD QIP.

Response: As commenters noted, the PHE for COVID–19 expired on May 11, 2023.[201] However, the expiration of the PHE for COVID-19 has no bearing on this measure because vaccination continues to be an essential tool in preventing COVID–19 transmission, and we believe that monitoring and surveillance of vaccination rates through measure performance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making.

Final Rule Action: After considering public comments, we are finalizing our proposal to modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure.

4. Conversion of the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning with the PY 2026 ESRD QIP

In the CY 2015 ESRD PPS final rule, we finalized the adoption of the Clinical Depression Screening and Follow-Up reporting measure, beginning in PY 2018 (79 FR 66200 through 66203). As we noted in the CY 2015 ESRD PPS final rule, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. Adoption of a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, was and still is an opportunity to improve the health of patients with ESRD.

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[201] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

In the CY 2024 ESRD PPS proposed rule, we proposed to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure and to adopt a new methodology for scoring that measure as a clinical measure (88 FR 42498). We stated our belief that this proposed update would help to ensure that the measure is scored in a manner that more closely aligns with current clinical guidelines for depression screening and follow-up because it narrows the number of conditions on which a facility can earn points.

Clinical guidelines indicate that providers should both screen for depression and develop a follow-up plan for patients who test positive for depression.[202] Screening for depression is an important aspect of ESRD patient care, especially because ESRD and depression may present with similar symptoms, including but not limited to fatigue, poor appetite, headaches, and lack of focus.[203] Developing a follow-up plan for patients who screen positive for depression is equally important because ESRD patients may not be aware that they can seek treatment or that such treatment could be beneficial.[204] Under the specifications of the current Clinical Depression Screening and Follow-Up reporting measure, facilities are required to report one of six conditions with respect to each eligible patient, and we calculate the measure rate for the facility as the percentage of eligible patients for which the facility reports one of those six conditions. The six conditions are as follows:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.

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[202] KDOQI clinical practice guidelines for cardiovascular disease in dialysis patients| Volume 45, SUPPLEMENT 3, 16-153, April 2005. https://doi.org/10.1053/j.ajkd.2005.01.019.
[203] PCORI Evidence Update. Treating Depression When You're on Dialysis (for Patients). July 2021. Available at: https://www.pcori.org/sites/default/files/PCORI-Evidence-Update-for-Patients-Treating-Depression-When-Youre-on-Dialysis.pdf.
[204] Michael J Fischer, Elani Streja, Jui-Ting Hsiung, Susan T Crowley, Csaba P Kovesdy, Kamyar Kalantar-Zadeh, Wissam M Kourany, Depression screening and clinical outcomes among adults initiating maintenance hemodialysis, Clinical Kidney Journal, Volume 14, Issue 12, December 2021, Pages 2548–2555, https://doi.org/10.1093/ckj/sfab097.

- Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is not documented, and no reason is given.

In the proposed rule, we did not propose to revise any of these conditions. However, we proposed that we would convert the measure to a clinical measure and award credit to facilities only if they report one of the following four of those six conditions:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.

In the proposed rule, we noted that if a facility selects one of the other two conditions (that is, "Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given" and "Screening for clinical depression is not documented, and no reason is given"), the facility would not receive credit in the numerator (88 FR 42498). We stated that we believe this proposed update is important because it would assess facility performance on both the clinical depression screening and the follow-up plan, to the extent that one is needed, and would also incentivize facilities to report the reason for either not documenting that they screened for clinical depression, or why they do not

possess documentation of a follow-up plan. We believe that the performance score calculation methodology changes we proposed to the Clinical Depression Screening and Follow-Up reporting measure would have a greater impact on fostering care coordination among providers and improving patient outcomes by incentivizing the documentation of depression screenings and follow-up plans, or alternatively requiring facilities to provide a reason why no screening or follow-up plan was documented. This measure update would also align with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[205] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[206] We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to increase efficiency, reduce burden, and close gaps in care. In the CY 2024 ESRD PPS proposed rule, we noted that the proposed updates to the Clinical Depression Screening and Follow-Up measure would support these efforts and would align with several Meaningful Measures Areas, including "Seamless Care Coordination" and "Behavioral Health," as we believe that incentivizing the documentation of follow-up plans would encourage care coordination efforts to support the behavioral health outcomes of ESRD patients (88 FR 42499). We stated that the proposed modifications would also align with the Meaningful Measures 2.0 goal to "Leverage measures to drive outcome improvement through public reporting and payment programs" because we believe that converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure would help to drive outcome improvement through the ESRD QIP. Additionally, in the proposed rule we stated that this proposed measure update would align with efforts to develop a

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[205] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.

[206] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization. We note that Meaningful Measures 2.0 is still under development.

Universal Foundation[207] that would help implement the vision outlined in our National Quality Strategy[208] and is fundamental to achieving several of the agency's quality and value-based care goals.[209] We noted that our proposal to update the Clinical Depression Screening and Follow-Up measure would help to align the measure that is used in the ESRD QIP with the measure identified for use across multiple programs as part of the Behavioral Health domain of the Universal Foundation measure set.[210]

We also proposed to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, and to move that measure to the Care Coordination Measure Domain beginning with that payment year (88 FR 42499). We proposed to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure because we believe that our proposed update to the performance score calculation aligned with that of a clinical measure. We proposed to move the Clinical Depression Screening and Follow-Up measure from the Reporting Measure Domain to the Care Coordination Measure Domain because the updated clinical measure would no longer be appropriate for inclusion under the Reporting Measure Domain. We note that we did not propose to change eligibility requirements for the measure. We discuss our updates to measure domains and weights for PY 2026 in section IV.C.6 of this final rule.

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

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[207] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS — The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2215539.

[208] Schreiber M, Richards AC, Moody-Williams J, Fleisher LA. The CMS National Quality Strategy: a person-centered approach to improving quality. Centers for Medicare and Medicaid Services, June 6, 2022 (https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality).

[209] Jacobs D, Fowler E, Fleisher L, Seshamani M. The Medicare value-based care strategy: alignment, growth, and equity. Health Affairs, July 21, 2022 (https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity).

[210] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher, L. Aligning Quality Measures across CMS — The Universal Foundation. The New England Journal of Medicine, February 1, 2023. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2215539.

Comment: Several commenters expressed support for the proposal to convert the Clinical Screening and Follow-Up reporting measure to a clinical measure. A few of these commenters expressed support for the proposed update because it will help to better identify and treat clinical depression in ESRD patients. One commenter noted that the proposed change will better align the measure with current clinical guidelines for depression screening and follow-up.

Response: We thank commenters for their support.

Comment: Several commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden.

Response: Although we would be converting the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure and changing the methodology to score it as a clinical measure, we did not propose any changes that would change the reporting process or burden associated with the Clinical Depression Screening and Follow-Up measure. Although facilities would be scored differently and would be required to provide follow-up documentation or a reason no screening or follow-up has been documented to receive credit on the measure, they would continue to report data for this measure to EQRS in the same manner. We believe converting this measure to a clinical measure is important because it will assess facility performance on the measure in a way that is more meaningful to patient health outcomes, and that the potential beneficial impact on patient health outcomes outweighs the potential burden to facilities that may need to update their clinical depression screening and follow-up practices to receive credit for the measure. However, we will continue to monitor for potential unintended consequences.

Comment: Several commenters expressed concern regarding the ability of current facility staff to effectively support patients with clinical depression, noting that many facilities are under-resourced. A few commenters recommended establishing supports (such as allowing co-located mental health providers to bill Medicare) prior to converting the measure. A few

commenters expressed concern regarding the meaningfulness of the Clinical Depression Screening and Follow-Up clinical measure, noting that many ESRD patients live in areas where there is a shortage of mental health care professionals and therefore would likely have difficulty accessing appropriate follow-up care following a positive depression screen.

Response: We thank the commenters for their feedback. We believe the updated scoring methodology has the potential to foster better care coordination and improve patient outcomes because it awards points facilities if they report that they documented follow-up plans for eligible patients who screened positive for clinical depression. As a documented outline of care for a positive depression screening, a follow-up plan may take into account a patient's ability to access follow-up care. However, we acknowledge that there might be circumstances, such as a lack of community resources, that may be beyond the facility's control, and the measure does not require the facility to ensure that the patient completed a follow-up plan.

Comment: A few commenters expressed concern about potential lack of patient privacy at facilities impacting the ability to engage effectively with the patient's care team to support mental health care needs. One commenter expressed concern that patients may feel pressured to participate in clinical depression screening surveys due to the proposed measure updates, and that a positive result on the screening may lead to patient stigma and impact future care.

Response: We appreciate commenters' concern and agree that protecting patient privacy is imperative. We note that the updated Clinical Depression Screening and Follow-Up clinical measure does not impose additional or new requirements on facilities that would interfere with a patient's right to privacy, and such information would be part of the patient's medical record and subject to same privacy protections as the patient's other medical information. The measure does not require patients to participate in a screening, and we have no reason to believe that facilities would pressure their patients into participating. Consistent with existing measure guidance, a patient would be considered "not eligible" for purposes of the measure if the patient's medical records document that the patient declined to participate in a clinical

depression screening and would, therefore, be excluded from the measure cohort.[211] However, we will continue to monitor for potential unintended consequences.

Comment: One commenter expressed concerns regarding the timing of screening, stating that this would require screening all patients during the first quarter and stated that this is not clinically appropriate for some patients and not feasible for others due to fluctuating first dates of dialysis, hospitalizations, and other reasons. The commenter recommended including a denominator exclusion for "patient stopped treatment at the facility prior to scheduled screening" prior to adoption of this measure as a clinical measure.

Response: Facilities are required to report measure data before the close of the clinical month of December in EQRS each year, so patient screening may take place at any time during the 12-month period of performance. We note that, to be eligible for the measure, a patient must be treated at a facility for at least 90 days. However, a facility is not precluded from screening its patients during that initial 90-day period, and we would encourage facilities to do so as part of their overall patient health assessments. Therefore, we do not think the suggested denominator exclusion is necessary.

Comment: A few commenters recommended removing the Clinical Depression Screening and Follow-Up measure from the ESRD QIP altogether. A few commenters recommended moving the measure to Dialysis Facility Compare because it would more effectively provide beneficiaries with useful information about facility performance on the measure. A few commenters expressed the belief that the measure should be removed from the ESRD QIP because it is topped out.

Response: We believe that the Clinical Depression Screening and Follow-Up measure remains an important part of the ESRD QIP measure set and that the public reporting of facility performance scores on the measure provides patients and caregivers with helpful information. Including the Clinical Depression Screening and Follow-Up measure in the ESRD QIP also

[211] https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf.

incentivizes facilities to improve their performance on the measure, which we believe will ultimately result in better patient outcomes. Although we acknowledge that the measure, in its current iteration as a reporting measure with six conditions, may be topped out, we proposed to update the conditions needed to receive credit and to convert the measure to a clinical measure. Under our previously adopted methodology (79 FR 66174), a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (TCV) of less than or equal to 0.1. To determine whether a clinical measure is topped out, we initially focus on the top distribution of facility performance on each measure and note if their 75th and 90th percentiles are statistically indistinguishable. Then, to ensure that we properly account for the entire distribution of scores, we analyze the truncated coefficient of variation (TCV) for the measure. As PY 2026 would be the first year that the Clinical Depression Screening and Follow-Up clinical measure would be included in the ESRD QIP, we do not have the clinical national measure performance data necessary to perform a topped-out analysis at this time.

Final Rule Action: After considering public comments, we are finalizing our proposals to update the Clinical Depression Screening and Follow-Up measure and to convert it to a clinical measure beginning with PY 2026 as proposed.

5. Removal of Two Measures from the ESRD QIP Measure Set, Beginning with PY 2026

In the CY 2024 ESRD PPS proposed rule, we stated that we have undertaken efforts to review the existing ESRD QIP measure set to ensure continued clinical impact and effectiveness of the measures on facility performance (88 FR 42499). Based on that analysis and our evaluation of the Program's measures, we proposed to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026.

a. Removal of the Ultrafiltration Rate Reporting Measure from the ESRD QIP Measure Set Beginning with PY 2026

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure (81 FR 77912 through 77915). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing hemodialysis (HD), because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. When we added this measure to the ESRD QIP, we believed the documentation of the ultrafiltration measurements would ultimately contribute to the quality of the patient's ESRD treatment (81 FR 77912 through 77915).

In the CY 2024 ESRD PPS proposed rule, we noted that more recent studies have indicated that the Ultrafiltration Rate reporting measure may not result in the intended patient outcomes (88 FR 42499). For example, a patient's body size may be a confounding, possibly explanatory factor for the relationship between higher UFR and increased mortality.[212] Additionally, although the Ultrafiltration Rate reporting measure captures a patient's UFR measurements reported monthly, the mortality risks associated with high UFR may be due to the frequency or number of HD sessions with high UFR.[213] We stated our belief that these findings show that the documentation of a patient's ultrafiltration measurements through the current Ultrafiltration Rate reporting measure may not necessarily indicate the quality of a patient's ESRD treatment and tracking the ultrafiltration rate as a quality indicator may influence decision-making regarding dialysis treatment. Therefore, a facility's performance on the

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[212] John T. Daugirdas and Daniel Schneditz. Seminars in Dialysis: Hemodialysis Ultrafiltration Rate Targets Should Be Scaled to Body Surface Area Rather than to Body Weight. 2017.

[213] Jose E. Navarrete, Ajai Rajabalan , Jason Cobb , and Janice P. Lea. Proportion of Hemodialysis Treatments with High Ultrafiltration Rate and the Association with Mortality. Kidney360 3: 1359–1366, 2022. doi: https://doi.org/10.34067/KID.0001322022

measure may not accurately reflect the quality of care provided. Accordingly, in the proposed rule we proposed to remove this measure from the ESRD QIP measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) beginning with the PY 2026 ESRD QIP (88 FR 42499).

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

Comment: Several commenters expressed support for our proposal to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set. A few commenters agreed that the measure should be removed because UFR measurement may not necessarily reflect the quality of a patient's HD session. A few commenters expressed support for removing the measure because it would enable a more individualized approach to clinical decision-making regarding fluid management and allow flexibility to provide care that is specific to a patient's individual case. A few commenters expressed support for removing the measure because they believe that the measure is topped out.

Response: We thank commenters for their support. Although we do not believe that the measure is topped out, we do agree with commenters that the Ultrafiltration Rate reporting measure is appropriate for removal because the measure may not reflect quality of care provided and removing the measure from the ESRD QIP measure set would support a more individualized approach to fluid management.

Comment: Several commenters noted the importance of fluid management and recommended ways to continue encouraging facilities to monitor patient-level UFR data. A few commenters recommended that CMS expand the Ultrafiltration Rate reporting measure to collect data on patient symptoms experienced during and between treatments as well to better understand the relationship between UFR and patient outcomes. One commenter recommended that CMS convert the Ultrafiltration Rate reporting measure to a clinical measure. One

commenter recommended that the measure be modified to address the confounding factors associated with high UFR.

Response: We thank commenters for their recommendations. Given the importance of fluid management to ESRD treatment, we encourage facilities to continue monitoring patient UFR data to ensure patient safety and improve HD care for ESRD patients. Although we are removing the Ultrafiltration Rate reporting measure because we do not believe that performance or improvement on the measure itself results in better patient outcomes, we may consider alternative measures which address confounding factors associated with high UFR in future rulemaking.

Comment: Several commenters expressed concern regarding the proposed removal of the Ultrafiltration Rate reporting measure, stating that high UFR is associated with health complications and the measure incentivizes patient safety. One commenter posited that the decline in hospitalization events and ED visits for ESRD patients on hemodialysis between 2019 and 2020 could be attributed to the implementation of the Ultrafiltration Rate reporting measure in 2019. The commenter noted that most HD machines are designed to facilitate the tracking of patient UFR data, and that it is important for staff to review and analyze this patient data to address symptoms and/or medical complications. One commenter noted there was no clinical support for high UFR.

Response: We encourage facilities to continue monitoring patient UFR data to ensure patient safety and improve hemodialysis (HD) care for ESRD patients. Although we are removing the Ultrafiltration Rate reporting measure because we believe that performance or improvement on the measure itself does not result in better patient outcomes, we believe that facilities will continue to monitor patient UFR data as part of a patient's ESRD treatment.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on

patient health outcomes against potential administrative burden. One commenter specifically expressed concern regarding the burden impact on rural facilities due to the lack of resources.

Response: We do not believe that removing a measure from the ESRD QIP will impose additional burden on facilities.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026 as proposed.

b. Removal of the Standardized Fistula Rate Clinical Measure from the ESRD QIP Measure Set

In the CY 2018 ESRD PPS final rule, we adopted the Standardized Fistula Rate clinical measure (82 FR 50774 through 50777). Along with the Long-Term Catheter Rate clinical measure, we stated that the two vascular access measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients may exhaust their options for an AV fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all vascular access options. The Standardized Fistula Rate measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option by accounting for that possibility in the current measure specifications. In the CY 2018 ESRD PPS final rule, we stated that this paired incentive structure that relies on both measures reflects consensus best practice and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade (82 FR 50777).

In the CY 2024 ESRD PPS proposed rule, we noted that since the CY 2018 ESRD PPS final rule, there have been several changes to what many experts consider to be best practices with respect to vascular access in ESRD patients due to improvements in the care of ESRD patients overall, changes in patient demographics, and increasing patient longevity (88 FR 42500). Guidance published in 2019 by the National Kidney Foundation's Kidney Disease

Outcome Quality Initiative (KDOQI) reflects updated best practices.[214] The KDOQI's 2019 guidance notes that prior guidelines and initiatives have emphasized a "fistula first" approach to vascular access choice due to the AV fistula's associations with better short-term results compared with other vascular access types.[215] However, the 2019 guidance also notes that more recent data have challenged these associations because of the high complication rates of AV fistula maturation failure requiring intervention. The guidance also encourages a more holistic, long-term approach to dialysis access that strives to preserve patient vasculature and avoid unnecessary procedures and complications. Therefore, following re-evaluation of this Fistula First approach, the KDOQI's 2019 guidance concludes that the Fistula First approach should no longer be considered a clinical best practice. Instead, the KDOQI's 2019 guidance concludes that a patient-centered approach to hemodialysis vascular access that is based on a consideration of the patient's needs and dialysis access eligibility is preferred. Providers should consider what would be most appropriate for the individual patient, including that AV fistula may not always be most appropriate based on the individual patient's needs.

After considering these evolving best practices and the KDOQI's 2019 guidance, in the proposed rule we stated that we have determined that the Standardized Fistula Rate Clinical Measure does not provide patients and their healthcare providers the necessary level of flexibility to choose the most suitable AV access (88 FR 42500). We noted our belief that patients, in consultation with their healthcare providers, should have the flexibility to choose AV access (either AV fistula or AV graft) where appropriate to their specific patient characteristics and treatment plans. This determination should be based on the healthcare provider's best clinical judgment that considers the vessel characteristics, patient comorbidities, health circumstances, and patient preference. Accordingly, we proposed to remove the Standardized Fistula Rate

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[214] Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.
[215] KDOQI clinical practice guidelines for vascular access. Am J Kidney Dis. 2006;48:S176-S247.

clinical measure from the ESRD QIP measure set beginning with PY 2026 under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice).

We stated in the proposed rule that we continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter, and that evidence shows that long-term catheters should only be used when all other AV access options have been exhausted (88 FR 42500).[216] We also expressed our continued belief that it is important to track the use of long-term catheters, minimize their use where possible, and incentivize best practices for vascular access. For those reasons, we did not propose to remove the Long-Term Catheter Rate clinical measure.

In the proposed rule, we also proposed to remove the reference to the Vascular Access Type Measure Topic and to assign the total weight of that topic (12 percent) solely to the Long-Term Catheter Rate clinical measure (88 FR 42500), as described in Table 15 of the proposed rule. We proposed to assign the total weight to the Long-Term Catheter Rate clinical measure because we believe this continues to be an important measure of facility performance tied to improved patient outcomes. We noted our belief that our proposal to assign the total 12 percent weight to the Long-Term Catheter Rate clinical measure reflected our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate.

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

Comment: Many commenters expressed support for the proposed removal of the Standardized Fistula Rate clinical measure from the ESRD QIP. Several of these commenters noted that removing the Standardized Fistula Rate clinical measure would enable clinicians to support the vascular access care treatment options that are most appropriate for their individual

[216] Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.

patients. Several commenters stated that the continued focus on long-term catheter rates through the Long-Term Catheter Rate clinical measure will sufficiently address reduction of catheters. One commenter stated that removing the measure will reduce costs by not incentivizing clinicians to perform procedures that may be unnecessary, painful, or have a low likelihood of success. One commenter expressed the belief that the measure should be removed because it is topped out.

Response: We thank commenters for their support. Although we do not believe that the measure is topped out, we do agree with commenters that the Standardized Fistula Rate clinical measure is appropriate for removal because the measure no longer aligns with current clinical guidelines or best practices and that removing the measure will support a more individualized approach to vascular access care.

Comment: Although a few commenters expressed support for the proposed removal, the commenters recommended that CMS continue to monitor AV fistula and AV graft rates.

Response: We thank the commenters for their support, and we will continue to monitor trends in ESRD patient data and quality of care.

Comment: One commenter did not support removal of the measure. The commenter stated that they believe there is strong evidence that AV fistula utilization is associated with better outcomes and is superior to AV grafts and tunneled catheters. This commenter recommended lowering the performance standard for the Standardized Fistula Rate clinical measure and stated that this would indirectly make the use of AV grafts less punitive without removing the measure while still allowing individualized care for each patient. This commenter expressed concern that removal of the measure will further incentivize the use of AV grafts instead of AV fistula due to higher costs associated with grafts because of more frequent procedures. This commenter expressed concern that these new incentives will cause significant reductions in fistula utilization with adverse consequences.

Response: We agree with the commenter that AV fistulas are the preferred vascular access treatment option in cases where it is appropriate based on the individual patient's needs, and we continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter. Although we will continue to monitor trends in AV fistula and AV graft utilization, we believe that removing the Standardized Fistula Rate clinical measure will provide flexibility to determine which vascular access treatment option is most appropriate based on the patient's specific characteristics and treatment plans.

Comment: A few commenters expressed concern regarding the increased weight of the Long-Term Catheter Rate clinical measure in the ESRD QIP. One commenter noted that, particularly among small or rural facilities, long-term catheter rates may be impacted by factors beyond a facility's control, such as physician availability, surgeon appointment openings, and operating room availability. One commenter recommended that CMS update the Long-Term Catheter Rate clinical measure to account for the increased prevalence of two-step fistula placements, which may impact long-term catheter rates. One commenter recommended several patient exclusions be added to the denominator of the Long-Term Catheter Rate clinical measure to account for different situations in which AV fistula or AV graft placement is not appropriate based on the patient's clinical case or individual preferences. The commenter stated that such exclusions would help to make the measure more patient-centered and meaningful, reflecting that the "right" vascular access is different for every patient.

Response: We appreciate commenters' concern. However, we believe the Long-Term Catheter Rate clinical measure continues to be an important measure of facility performance tied to improved patient outcomes. The increased weight of the Long-Term Catheter Rate clinical measure reflects our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate. Although we acknowledge that long-term catheter usage may be appropriate in certain circumstances depending on a particular patient's clinical

case, we believe the Long-Term Catheter Rate clinical measure continues to align with current clinical guidelines and incentivizes best practices in vascular access treatment for ESRD patients. However, we will also continue to monitor the impact of our updated policy, as well as trends in the use of two-step fistula placements.

Comment: A few commenters expressed concern regarding the reporting burden associated with the proposed changes, recommending that CMS weigh the potential impact on patient health outcomes against potential administrative burden. One commenter specifically expressed concern with the burden impact on rural facilities due to the lack of resources.

Response: We do not believe that removing a measure from the ESRD QIP will impose additional burden on facilities.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026 as proposed.

6. Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS final rule (87 FR 67251 through 67254), we finalized revisions to the ESRD QIP measure domains beginning with PY 2025. Specifically, we added the Reporting Measure Domain and updated measure domains and measure weights across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. The measure domains and weights we finalized in the CY 2023 ESRD PPS final rule were depicted in Table 14 of the CY 2024 ESRD PPS proposed rule (88 FR 42501) and are depicted in this final rule in Table 15.

TABLE 15: Previously Finalized PY 2026 ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00

Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Clinical Depression Screening and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

As discussed previously, we are finalizing our proposals that beginning with PY 2026, the Clinical Depression Screening and Follow-Up reporting measure will be converted to a clinical measure and included in the Care Coordination Measure Domain, the Standardized Fistula Rate clinical measure will be removed from the Clinical Care Measure Domain, the Ultrafiltration Rate reporting measure will be removed from the Reporting Measure Domain, and the Facility Commitment to Health Equity reporting measure will be added to the Reporting Measure Domain. To accommodate the new numbers of measures in the Care Coordination Measure Domain, Clinical Care Measure Domain, and Reporting Measure Domain, in the CY 2024 ESRD PPS proposed rule, we proposed to update the individual measure weights in each of these domains (88 FR 42501).

We stated our belief that these proposed updates to the individual measure weights would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also further incentivizing improvement on clinical measures. For example, for the Care Coordination Measure Domain, we proposed to update the measure weights for the SHR clinical measure and the SRR clinical measure to accommodate the inclusion of the proposed Clinical Depression Screening and Follow-Up clinical measure. We stated that we believe these newly proposed measure weights would strike an appropriate balance between the importance of facility performance on the SHR clinical measure and the SRR clinical measure on measuring patient outcomes, while also reflecting the

impact of the proposed Clinical Depression Screening and Follow-Up clinical measure on patient quality of care. Additionally, we noted in the proposed rule that the Vascular Access Type Measure Topic is currently weighted at 12 percent and includes both the Standardized Fistula Rate clinical measure and the Long-Term Catheter Rate clinical measure. We proposed to remove the Standardized Fistula Rate clinical measure and the Vascular Access Type Measure Topic, and we also proposed to weight the Long-Term Catheter Rate clinical measure at 12 percent. We noted our belief this proposal would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. We also stated that we continue to believe that patient outcomes improve when they receive the most clinically appropriate vascular access treatment option, and that long-term catheters should only be used when other vascular access treatment options are not feasible. Consistent with our approach in the CY 2023 ESRD PPS final rule (87 FR 67251 through 67253), 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 (88 FR 42501 through 42502). In light of these proposed updates to measures within the Reporting Measure Domain, we stated that we would weight each measure equally at 2 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we proposed to change the number of measures in three of the domains and the weights of certain individual measures in those domains, we did not propose to change the weights of the five domains themselves because we believe the updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. In the CY 2024 ESRD PPS proposed rule, the previously finalized and newly proposed measures weights that would be included in each domain, along with the proposed new measure weights, for PY 2026 were depicted in Table 15 (88 FR 42502).

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

Comment: A few commenters expressed concern regarding the proposed updates to the individual measure weights within the Clinical Care Measure Domain. One commenter expressed concern regarding the proposed updates to the weight of the Long-Term Catheter Rate clinical measure, recommending that CMS re-weight the Long-Term Catheter Rate clinical measure at 9 percent and the STrR clinical measure at 10 percent within the Clinical Care Measure Domain. One commenter stated that because catheters are clinically appropriate for some patients, the measure weight for the Long-Term Catheter Rate clinical measure should not be updated and the remaining weight should be distributed among the other measure domains.

Response: We appreciate commenters' concerns. However, we believe that the Long-Term Catheter Rate clinical measure continues to be an important measure of facility performance tied to improved patient outcomes and that the increased weight would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. The increased weight of the Long-Term Catheter Rate clinical measure reflects our view that long-term catheter use is the least-favored vascular access treatment option and should be avoided where more clinically preferable vascular access treatment options would be appropriate. We will also take commenters' recommendations regarding specific measure weights into consideration for future rulemaking, but believe that the proposed weights are appropriate at this time to incentivize quality improvement in clinical measures.

Comment: One commenter recommended that CMS increase the weight of the Reporting Measure Domain, noting the burden of complying with reporting measure requirements.

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.

Final Rule Action: After considering public comments, we are finalizing our proposals to update the measure domains and measure weights for the PY 2026 ESRD QIP as proposed, and therefore, provide the newly finalized ESRD QIP measure domains and measure weights in Table 16.

TABLE 16: Newly Finalized ESRD QIP Measure Domains and Weights for PY 2026

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	9.00
SRR clinical measure	9.00
PPPW measure	6.00
Clinical Depression Screening and Follow-Up measure*	6.00
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**
Facility Commitment to Health Equity measure**	2.00
Hypercalcemia reporting measure	2.00
MedRec reporting measure	2.00
NHSN Dialysis Event reporting measure	2.00
COVID-19 HCP Vaccination reporting measure	2.00

*We are finalizing our proposal to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
**We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

7. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with

respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (§ 413.178(a)(12)).

In the CY 2023 ESRD PPS final rule (87 FR 67259 through 67260), we set the performance period for the PY 2026 ESRD QIP as CY 2024 and the baseline period as CY 2022. In the proposed rule, we estimated the performance standards for the PY 2026 clinical measures in Table 16 using data from CY 2021, which was the most recent data available (88 FR 42502). For certain measures previously suppressed for the PY 2023 performance period due to significant impacts on the measure related to the COVID-19 public health emergency (87 FR 67225 through 67237), we used CY 2019 data. We are updating these performance standards for all measures, using CY 2022 data, in this final rule, in Table 17.

TABLE 17: Performance Standards for the ESRD QIP Clinical Measures for PY 2026

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 Comprehensive	94.33%*	97.61%*	99.42%*
Standardized Readmission Ratio[a]	34.27*	26.50	16.19
NHSN BSI	0.734	0.248	0
Standardized Hospitalization Ratio[b]	166.60	129.14	87.98
Standardized Transfusion Ratio[b]	48.29	26.19	8.86
PPPW	8.12%*	16.73%*	33.90%*

Clinical Depression**	87.10%	94.29%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%*	67.90%*	79.15%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.87%	63.22%	72.83%
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	51.01%	64.86%	78.86%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.58%	69.42%	84.09%
*Values are the same final performance standards for those measures for PY 2025. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2026 because they are higher standards than the PY 2026 numerical values for those measures. **We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning in PY 2026, as discussed in section IV.C.4 of this final rule.			

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measure: 2022 EQRS; SRR, SHR: 2022 Medicare claims; STrR: 2022 Medicare claims; Kt/V: 2022 EQRS; Hypercalcemia: 2022 EQRS; NHSN: 2022 CDC; ICH CAHPS: CMS 2022; PPPW: 2022 EQRS and 2022 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2022 EQRS.

In addition, we summarize in Table 18 our requirements for successful reporting on our previously finalized reporting measures for the PY 2026 ESRD QIP and our proposed requirements for successful reporting of the Facility Commitment to Health Equity reporting measure. We address comments regarding our proposed reporting requirements for the Facility Commitment to Health Equity reporting measure in section IV.C.2 of this final rule.

TABLE 18: Requirements for Successful Reporting of the Previously Finalized and Newly Proposed ESRD QIP Reporting Measures for PY 2026

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
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values

Measure	Reporting Frequency	Data Elements
COVID-19 Vaccination Coverage Among HCP*	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received an up to date vaccination course against SARS-CoV-2.
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

* We are finalizing our proposal to update the COVID-19 Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.
** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

8. Eligibility Requirements for the PY 2026 ESRD QIP

Our previously finalized minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 18a of the CY 2024 ESRD PPS proposed rule (88 FR 42505), and provided in Table 19a.

TABLE 19a: Previously Finalized Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	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
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)**	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Ultrafiltration (Reporting)***	11 qualifying patients	Before 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

* We are finalizing our proposal to remove the Standardized Fistula Rate clinical measure beginning in PY 2026, as discussed in section IV.C.5 of this final rule, and removed from Table 19b.
** We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure and convert it to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
*** We are finalizing our proposal to remove the Ultrafiltration Rate reporting measure beginning in PY 2026, as discussed in section IV.C.5 of this final rule, and removed from Table 19b.
**** We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.

In the CY 2024 ESRD PPS proposed rule, we proposed to add eligibility requirements for the new Facility Commitment to Health Equity reporting measure, as well as other proposed updates to the ESRD QIP measure set beginning with the PY 2026 ESRD QIP, as reflected in Table 18b in the proposed rule (88 FR 42504 through 42506).

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

Comment: One commenter expressed continued concern regarding the potential to unfairly penalize small facilities due to eligibility requirements and encouraged CMS to engage with the community to better support small facilities.

Response: We acknowledge the commenter's concern and will continue to monitor the impact of all ESRD QIP measures on small facilities to ensure they are not unfairly penalized due to eligibility requirements associated with a given measure.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed. Since we are finalizing our proposal for the new measure as proposed, as well as finalizing other proposed updates to the ESRD QIP measure set beginning with the PY 2026 ESRD QIP, our newly finalized minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 19b.

TABLE 19b: Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2026

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
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
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (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.	

* We are finalizing our proposal to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
** We are finalizing our proposal to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this final rule.
*** We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

9. Payment Reduction Scale for the PY 2026 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) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Under our current policy, which is codified at § 413.177 of our regulations, 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 (76 FR 634 through 635).

In the proposed rule, we stated that for PY 2026, we estimated using available data that a facility must meet or exceed a mTPS of 52 to avoid a payment reduction (88 FR 42507). We noted that the mTPS estimated in the proposed rule is based on data from CY 2021 and CY 2019 instead of the PY 2026 baseline period (CY 2022) because CY 2022 data were not yet available. We presented the estimated payment reduction scale in Table 19 of the CY 2024 ESRD PPS proposed rule (88 FR 42507). We stated our intention to update the mTPS for PY 2026, as well as the payment reduction ranges for that payment year, in this CY 2024 ESRD PPS final rule. We have now finalized the payment reductions that will apply to the PY 2026 ESRD QIP using updated CY 2022 data. The mTPS for PY 2026 will be 53, and the finalized payment reduction scale is shown in Table 20.

TABLE 20: Updated Payment Reduction Scale for PY 2026 Based on the Most Recently Available Data

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

D. Updates to Requirements Beginning with the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

Under our current policy, we generally retain all measures once adopted for a payment year for subsequent payment years. In the proposed rule, we proposed to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027. As discussed in sections IV.D.2 and IV.D.3 of this final rule, we are finalizing these measure proposals and provide the finalized PY 2027 ESRD QIP measure set in Table 21.

TABLE 21: Newly Finalized PY 2027 ESRD QIP Measure Set

Consensus-Based Entity (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.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
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 End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure

Consensus-Based Entity (CBE) #	Measure Title and Description
	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 course.
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, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

* We are finalizing our proposal to add the Screening for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.2 of this final rule.
** We are finalizing our proposal to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this final rule.

2. Adoption of the Screening for Social Drivers of Health Reporting Measure Beginning with PY 2027

Our commitment to supporting facilities in building equity into their health care delivery practices is, in part, focused on empowering their workforce to recognize and eliminate health disparities that disproportionately impact their patients who have health-related social needs (HRSNs). HRSNs are significant risk factors associated with worse health outcomes as well as increased health care utilization.[217] We believe that the identification of HRSNs among facility patients has two significant benefits. First, research has shown that certain HRSNs disproportionately impact populations that have historically been underserved by the healthcare system and screening helps identify individuals who may have HRSNs.[218] Due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities in addressing persistent

[217] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion. Accessed: November 23, 2021.
[218] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed:
January 18, 2022. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.

disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, we believe HRSN screening by facilities could enable them to engage in meaningful collaboration with other healthcare providers and community-based organizations as part of a more holistic approach to addressing health equity gaps that negatively impact their ESRD patients, which may also eventually result in implementing and evaluating related innovations in health and social care delivery among these facilities, healthcare providers and community-based organizations.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), we finalized the adoption of two evidence-based measures in the Hospital Inpatient Quality Reporting (IQR) Program, the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health measures. These two Social Drivers of Health measures support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. These measures also encourage hospitals to systematically collect HRSN data. We have also finalized a policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their Health Risk Assessment (HRA) using questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740), as well as adopted the Screening for Social Drivers of Health measure in the Merit-based Incentive Payment System (87 FR 70054 and 70055).

In the CY 2024 ESRD PPS proposed rule, we stated that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority (88 FR 42509).[219] We noted our belief that the Screening for Social Drivers of Health reporting measure aligns with *The CMS Quality Strategy*

[219] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.

Goals for effective care coordination and prevention and treatment of chronic conditions.[220] We stated that the Screening for Social Drivers of Health reporting measure would enable facilities to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes. Improvement in risk identification has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to populations with greatest risk, and improve the facility's quality of care through the facility taking steps to mitigate poor health outcomes by improving their care coordination efforts.[221,222,223,224] These data could help facilities improve their care coordination efforts, including by understanding what HRSNs might be contributing to poor patient outcomes so that facilities can direct resources, as appropriate, toward referring their patients to resources that might be able to help them resolve their HRSNs.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[225,226,227,228,229] Such differences persist across geography and

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[220] Centers for Medicare & Medicaid Services. (2021) CMS National Quality Strategy. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy

[221] Baker, M. C., Alberti, P. M., Tsao, T. Y., Fluegge, K., Howland, R. E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: https://doi.org/10.1377/hlthaff.2020.01742.

[222] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290-299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752.

[223] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.

[224] Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/.

[225] Seligman, H. K., & Berkowitz, S. A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: https://pubmed.ncbi.nlm.nih.gov/30444684/.

[226] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.

[227] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.

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

[229] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

healthcare settings irrespective of improvements in quality of care over time.[230,231,232] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[233,234,235] Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.[236,237]

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.[238,239] The COVID–19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.[240,241] Emerging evidence has shown that specific social risk factors are directly associated

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[230] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.

[231] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.

[232] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf.

[233] Institute of Medicine. (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/18951.

[234] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. (2016). Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.

[235] CDC. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed November 17, 2021.

[236] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open.* 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

[237] Khullar, D., Schpero, W. L., Bond, A. M., Qian, Y., & Casalino, L. P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. https://doi.org/10.1001/jama.2020.13129.

[238] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: https://usrds-adr.niddk.nih.gov/2022.

[239] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et.al., (2021). Initial Effects of COVID-19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444-1453. doi: https://doi.org/10.1681/ASN.2021010009.

[240] CDC. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed November 17, 2021.

[241] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et.al., (2021). Initial Effects of COVID-19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444-1453. doi: https://doi.org/10.1681/ASN.2021010009.

with health outcomes and health care utilization and costs.[242,243,244,245] Of particular concern among people with ESRD are HRSNs that have an effect on treatment outcomes, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.[246,247]

We believe that improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD, and subsequently lead to improvements in quality performance for dialysis and other health care providers. We believe that the Screening for Social Drivers of Health reporting measure would help inform facilities of the impact of HRSNs in people with ESRD by assessing the proportion of adult patients who are screened for social drivers of health in five core domains: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we sought public comment on the potential future inclusion of the Screening for Social Drivers of Health measure in the ESRD QIP (87 FR 38554 through 38556). For a summary of the comments we received, as well as our responses, we refer readers to the CY 2023 ESRD PPS final rule (87 FR 67265 through 67268). In the CY 2023 ESRD PPS final rule, we stated that we were considering whether to incorporate measures that assess screening for health-related social needs into the ESRD QIP measure set (87 FR 67264).

In the CY 2024 ESRD PPS proposed rule, we proposed to adopt the Screening for Social Drivers of Health reporting measure under section 1881(h)(2)(A)(iv) of the Act, which gives the

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[242] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.
[243] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883-893. doi: 10.1111/1475-6773.13283.
[244] Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. Diabetes Care 41: 933-939. https://doi.org/10.2337/dc17-1812.
[245] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25385.

[246] *Ibid.*
[247] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.

Secretary broad authority to specify measures for the ESRD QIP (88 FR 42510). As discussed previously, disparities in health equity are tied to worse patient outcomes in the ESRD community. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. Therefore, we believe it is appropriate to require facilities to report data on this measure because the intent of the proposed measure is to incentivize facilities to collect and utilize their data to identify the impact of HRSNs in their ESRD patient population, including whether there is a relationship between those HRSNs and the outcomes experienced by their patients with those HRSNs. Screening data collected by the facility could inform their provision of care such that they improve the outcomes experienced by patients with HRSNs. Facilities could analyze their screening data to understand whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. While the measure does not require facilities to take specific actions following an HRSN screening, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also noted that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

Under our Meaningful Measures Framework,[248] the Screening for Social Drivers of Health reporting measure, along with the Screen Positive Rate for Social Drivers of Health reporting measure discussed in section IV.D.3 of this final rule, addresses the quality priority of "Work with Communities to Promote Best Practices of Healthy Living" through the Meaningful Measures Area of "Equity of Care." Additionally, consistent with Meaningful Measures 2.0, these measures address the "healthcare equity" priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures,

[248] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.

including to "develop and implement measures that reflect social and economic determinants."[249] Development and proposal of these measures also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[250] We also believe these measures address the quality priority "Promoting Effective Prevention and Treatment of Chronic Disease" through the Meaningful Measures Area "Management of Chronic Conditions," by improving a facility's ability to assess and implement effective care coordination for its patients. For example, data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.[251, 252] Identification of patients with transportation difficulties could encourage facilities to provide information to these patients about available community-based transportation services that could help these patients with their transportation needs. We also believe that the measures would encourage facilities to incorporate HRSN screening into their routine care, which would in turn improve their ability to understand the full needs of their patients, including those who may need additional care coordination but might be reluctant to otherwise seek assistance due to concerns about personal stigmatization.

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.[253,254] In 2017, CMS's Center for Medicare and Medicaid

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[249] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization. We note that Meaningful Measures 2.0 is still under development.
[250] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.
[251] *Ibid.*
[252] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021. We note that, following publication of the CY 2024 ESRD PPS proposed rule, the USRDS has published its 2022 annual report, which is available at: https://usrds-adr.niddk.nih.gov/2022.
[253] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open.* 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.
[254] Khullar, D., Schpero, W. L., Bond, A. M., Qian, Y., & Casalino, L. P. (2020). Association Between Patient Social

Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of community-dwelling Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on their health outcomes and related healthcare utilization and costs).[255,256,257,258] The CMS Innovation Center developed the AHC Model based on evidence that addressing HRSNs through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.[259] HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.[260,261] Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.[262,263,264] The AHC Model had a 5-year period of performance that began in May 2017 and concluded in April 2022, with beneficiary screening beginning in the summer of 2018

Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. https://doi.org/10.1001/jama.2020.13129.

[255] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.

[256] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.

[257] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[258] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: https://innovation.cms.gov/innovation-models/ahcm.

[259] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.

[260] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[261] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.

[262] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.

[263] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.

[264] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203-212, doi: 10.3945/an.112.003277.

following an implementation period.[265,266] Evaluation of the AHC Model data is still underway, and the most recent evaluation was published in the second AHC Model evaluation report on May 18, 2023.[267]

While social risk factors may have a significant impact on health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[268,269,270,271] The persistent interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[272,273] In their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.[274] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19

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[265] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.
[266] We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.
[267] RTI International. (2023). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt.
[268] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed November 23, 2021.
[269] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.
[270] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290-299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752.
[271] The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf. Accessed December 8, 2021.
[272] Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.
[273] Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.
[274] The Physicians Foundation. (2019). Viewpoints: Social Determinants of Health. Available at: https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf. Accessed December 8, 2021.

pandemic.[275,276]

The following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries under the AHC Model: 1) food insecurity; 2) housing instability; 3) transportation needs; 4) utility difficulties; and 5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: 1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; 2) ability for a given HRSN to be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admissions; and 3) evidence that a given HRSN is not systematically addressed by healthcare providers.[277] In addition to established evidence of their association with health status, risk, and outcomes, these five domains were also selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.[278,279,280]

These five evidence-based HRSN domains informed our development of the Screening for Social Drivers of Health reporting measure, as well as a second measure, Screen Positive Rate for Social Drivers of Health reporting measure. These domains are described in Table 22.

TABLE 22: Five Core HRSN Domains Used in the Screening for Social Drivers of Health Reporting Measure and the Screen Positive Rate for Social Drivers of Health Reporting Measure

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[275] CDC. (2020). CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html. Accessed November 17, 2021.

[276] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed November 23, 2021.

[277] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[278] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[279] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: https://innovation.cms.gov/innovation-models/ahcm.

[280] Kamyck, D., Senior Director of Marketing. (2019). CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: https://blog.activatecare.com/news.

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[281,282] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services.[283,284] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[285,286,287]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[288,289] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing.[290] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[291,292]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[293] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with

[281] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399-404. PMID: 30222918; PMCID: PMC6426124.
[282] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.
[283] Seligman, H. K., & Berkowitz, S. A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: https://pubmed.ncbi.nlm.nih.gov/30444684/.
[284] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285.
[285] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.
[286] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399-404. PMID: 30222918; PMCID: PMC6426124.
[287] Dean, E. B., French, M. T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. Health Services Research, 55(S2), 883–893. Available at: https://doi.org/10.1111/1475-6773.13283.
[288] Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.
[289] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.
[290] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.
[291] Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.
[292] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379 – 387. Available at: https://jech.bmj.com/content/jech/73/5/379.full.pdf.
[293] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285.

Domain	Description
	impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations.[294,295,296,297]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[298] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[299]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[300] Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[301,302]

The Screening for Social Drivers of Health reporting measure assesses screening of the same HRSNs.

In the proposed rule, we proposed that facilities would be able to choose a screening tool for purposes of this measure or otherwise screen their patients using a method of their choosing in order to give facilities the flexibility to accommodate the population they serve and their

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[294] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23285.
[295] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.
[296] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.
[297] Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: https://doi.org/10.1377/hlthaff.2012.0170.
[298] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379 – 387. Available at: https://jech.bmj.com/content/jech/73/5/379.full.pdf.
[299] Wright, B. J., Vartanian, K. B., Li, H. F., Royal, N., & Matson, J. K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: https://doi.org/10.1377/hlthaff.2015.0393.
[300] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.
[301] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf.
[302] Larimer, M. E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: https://doi.org/10.1001/jama.2009.414.

individual needs (88 FR 42513).[303,304] We noted that the 10-item AHC Health-Related Social Needs Screening Tool that AHC Model participants used to identify HRSNs in the five core domains (described in Table 22) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries was tested across varied care-delivery sites in diverse geographic locations across the U.S.[305,306] Facilities may wish to consider using that tool because it has been found to be both reliable and valid, including high inter-rater reliability and concurrent and predictive validity.[307] Moreover, the screening tool can be implemented in a variety of places where patients seek healthcare, including dialysis facilities.[308] However, as stated previously, we did not propose to require facilities to use this tool, or any other specific tool, for purposes of the Screening for Social Drivers of Health reporting measure.

b. Overview of Measure

The Screening for Social Drivers of Health measure assesses the percentage of patients age 18 and older that a dialysis facility screens for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, facilities would provide: (1) the number of patients admitted to the facility who are 18 years or older during the applicable performance period who are screened for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients at the facility who are 18 years or older

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[303] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison. Accessed January 18, 2021.

[304] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion. Accessed January 18, 2021.

[305] More information on the HRSN Screening Tool is available at: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.

[306] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.

[307] Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. J Family Med Prim Care. 2020 Sep; 9(9): 5026–5034. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/.

[308] CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.

during the applicable performance period and who are not excluded from the measure. In the proposed rule, we proposed to add this measure to the Reporting Measure Domain beginning with PY 2027 (88 FR 42514). We discuss measure domains and weights for PY 2027 in section IV.D.7 of this final rule.

Measure specifications for this measure are currently available on the QualityNet website at: https://qualitynet.cms.gov/esrd/esrdqip.

(1) Cohort

The cohort for the Screening for Social Drivers of Health reporting measure is all patients, aged 18 years and older, who are treated at the facility during the applicable performance period and not eligible to be excluded from the measure.

(2) Numerator

The numerator is calculated as the number of patients who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened during the performance period for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(3) Denominator

The denominator is calculated as the number of patients at the dialysis facility and who are 18 years or older on the first day of the performance period. The following patients are excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf.

c. Measure Calculation

The Screening for Social Drivers of Health measure is calculated as the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are

screened by the facility for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the 1st day of the performance period (January 1st) at that dialysis facility. In the proposed rule, we proposed a 12-month period of performance for the measure, and facilities would be required to report annually (88 FR 42514). We proposed that a facility would be scored according to the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Screened for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients During the Performance Period}}\right] \text{x } 10$$

We believe that this scoring policy would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be based on circumstances beyond a facility's control.

d. Data Submission and Reporting

In the proposed rule, we proposed to require facilities to report this measure on an annual basis beginning with PY 2027 (88 FR 42514). In alignment with the policy we finalized for the Hospital IQR Program, we would allow facilities flexibility to select their own screening tool or method to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Potential sources of these data for incorporation in a tool could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Additionally, multiple screening tools exist and are publicly available. Facilities could refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.[309,310] SIREN contains descriptions of the content and

[309] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison. Accessed January 18, 2021.

[310] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

characteristics of various tools, including information about intended populations, completion time, and number of questions. We encourage facilities to consider digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207), where we noted that the use of certified health IT can support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care.

We proposed that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures (88 FR 42514). For example, the deadline for submission in PY 2027 would be the end of the December data reporting month in CY 2025.

e. Review by the Measure Applications Partnership

We included the Screening for Social Drivers of Health reporting measure as a measure under consideration for the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.[311] The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screening for Social Drivers of Health measure (MUC 2022–053) in detail and at the same time as the Screen Positive Rate for Social Drivers of Health measure on December 6-7, 2022 (discussed below).[312] The Health Equity Advisory Group expressed support for the data collection related to social drivers of health, but raised concerns about public reporting of the data and redundancy in asking for the same information of patients. In addition, on December 8-9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on

[311] Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[312] Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations. Health Equity Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

December 13-14, 2022.[313] The Rural Health Advisory Group noted some potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.[314] Thereafter, the MAP Coordinating Committee deliberated on January 24 and 25, 2023, and ultimately voted to conditionally support the Screening for Social Drivers of Health reporting measure for rulemaking with the same conditions.[315]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the

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[313] Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[314] Centers for Medicare & Medicaid Services. (2022). 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports. For Information on the GRAVITY project, please see https://thegravityproject.net/.

[315] Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the facility-specific results for the Screening for Social Drivers of Health measure on an annual basis through our *Care Compare* website at: https://www.medicare.gov/care-compare/. We stated that we anticipate making the first public report available in January 2027.

We invited public comment on this proposal. The comments we received and our responses are set forth below. We address comments that broadly referred both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in this section as well.

Comment: Several commenters expressed support for the Screening for Social Drivers of Health reporting measure, noting that it would help to provide facilities with additional information to help identify and address health disparities in ESRD patients. A few commenters noted that identifying patient social risk factors will allow care providers and community organizations to work together to improve care delivery.

Response: We thank commenters for their support.

Comment: Several commenters expressed support for the proposed Screening for Social Drivers of Health reporting measure and recommended additional changes to the measure specifications. A few of these commenters suggested that the measure screen for additional HRSNs, such as financial needs and caregiver burdens. One commenter, noting the critical role of nurses in cultivating trust and communication with patients as being necessary to help identify and address health disparities among patients while also balancing administrative burden, recommended that CMS take additional actions that would further enable nurses to comprehensively address HRSNs across care settings. One commenter stated that patients who

are unable to complete screenings and do not have a legal guardian or caregiver able to complete the screening on their behalf are extremely vulnerable and recommended dialysis facilities be encouraged to support these patients in resource identification.

Response: We thank commenters for their support and will take their recommendations under consideration for future rulemaking. We selected the proposed five HRSN domains based on the successful use of these domains in the screening that was done under the AHC Model. We note that while the Screening for Social Drivers of Health measure requires screening for the five identified HRSNs, facilities may screen for additional HRSNs that they believe may be impacting their patient population. One resource that facilities could consider is the Accountable Health Communities screening tool, which includes questions for eight supplemental domains, including financial strain. Although the Screening for Social Drivers of Health reporting measure excludes patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf, we would nonetheless encourage facilities to support these patients with resource identification.

Comment: Several commenters expressed concern that the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure would not effectively address poor health outcomes associated with HRSNs. A few of these commenters believed that the measures did not provide sufficient patient or provider support to help empower patients to improve their health outcomes. One commenter noted that the availability of community resources is highly variable depending on location and expressed concern that screening for HRSNs through administering questionnaires may be futile in deprived areas that lack access to such community organizations. One commenter expressed concern that the proposed measures may lead to unintended consequences and further perpetuate health disparities by disincentivizing facilities from providing care to patients with HRSNs or communities with higher rates of HRSNs. One commenter expressed concern that the proposed measures do not distinguish between a patient's social risks and a patient's social needs, noting

that the former is determined by screening instrument and the latter is based on a patient's own priorities and preferences. The commenter recommended that CMS develop a measure that focuses on assessing a patient's self-identified needs and priorities while ensuring that resources are available to provide responsive follow-up care.

Response: We thank commenters for their feedback. During the development of both Social Drivers of Health measures, we gave this topic significant consideration. The intent of the two measures is to incentivize facilities to screen their patients for HRSNs in five core domains, as well as to analyze those data to determine whether there is a relationship between the HRSNs and the outcomes experienced by their patients. Facilities could use those data to develop solutions to improve access to care and clinical outcomes among their patient population. Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected.[316] While broad availability of community-based resources that address patients' health-related social needs would be ideal, we believe that one of the benefits of these measures will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources where feasible. For example, a facility may decide to offer shuttle services for some of its patients if transportation is identified as a barrier to treatment. A facility may also be able to connect patients with local resources to assist with food insecurity, housing instability, or utility difficulties. Beginning to collect the data on patients' HRSNs remains imperative and a crucial step in developing resources for advancing health equity.

We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. Although we believe that the two measures will not lead to unintended consequences because screening would be required for all eligible patients and facilities would not be penalized based on reported

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[316] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

screen positive rates, CMS will monitor measure implementation as part of standard program and measure review and will consider updates to the measures if improvements are identified through this process.

Comment: Several commenters expressed concern that the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure were not ready for inclusion in the ESRD QIP measure set. A few commenters recommended an endorsement review by the CBE to ensure that such measures will drive improved health outcomes and advance health equity, given the significance of addressing social risk factors and the potential administrative burden associated with the inclusion of new measures. One commenter expressed concern with the proposed measures, recommending that more work be done to address potential reporting challenges and potential masking of health disparities before the measures are incorporated into the ESRD QIP. One commenter noted that these are the first measures aimed at HRSNs that would be used in the ESRD QIP, and the impact of their adoption into a payment program is unknown.

Response: Although we recognize the value of measures undergoing review for potential CBE endorsement, given the urgency of improving health equity, we believe it is important to implement this measure as soon as possible while balancing facilities' need for sufficient time to implement screening and data collection processes, which is why we proposed to adopt this measure beginning with the PY 2027 ESRD QIP. We note that the most recent evaluation of the AHC model, which informed the development of these proposed measures, showed that it was effective in screening beneficiaries for HRSNs, identifying eligible beneficiaries, and referring those beneficiaries to HRSN-related navigation services.[317] We believe that the success of the AHC model shows that these measures will have a similar impact. Additionally, we note that, under section 1881(h)(2)(B)(ii) of the Act, the Secretary may specify a measure that is not so

[317] RTI International. (2023). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt.

endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed by a consensus organization, and therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

Comment: Several commenters expressed concern with the potential burden associated with the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure. A few commenters noted that facilities would need additional resources in order to implement and comply with proposed measure requirements. A few of these commenters expressed particular concern regarding staffing constraints. A few commenters expressed concern regarding the administrative burden associated with the data collection and reporting requirements and requested that facilities receive additional resources such as training and funding to support the data collection and reporting efforts associated with the proposed measures. One commenter expressed concern that the administrative burden associated with the proposed measures could divert facility resources from direct patient care and requested an assessment of the administrative burden.

Response: While we understand that implementation of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure are associated with some burden, as discussed in section VI.C.3 of this final rule, we believe the benefits outweigh the burden because screening for and identifying patients' HRSNs is a critical step towards a facility identifying and understanding how the presence of the screened HRSNs might be impacting patient access to ESRD care and outcomes. We intend to monitor the measures for any unintended or adverse outcomes associated with implementation.

We note that screening can occur any time during the patient's treatment at the facility during the performance period prior to discharge and that, for example, the AHC Screening Tool

addresses these 5 HRSNs using a total of 10 questions. Therefore, we believe that facilities will be able to find sufficient time to screen their patients.

Comment: A few commenters expressed concern with the proposed Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure, believing that the goals of the two measures were already effectively covered through other means. One of these commenters noted that facilities are already required to screen their patients for HRSNs as part of ESRD Conditions for Coverage assessments required at 42 CFR § 494.90. One of these commenters stated that dialysis facilities are already required to screen patients for multiple non-clinical conditions, noting that CMS previously proposed revisions to the ESRD Medical Evidence Report form (CMS-2728), which includes seven screening questions related to HRSNs that address the same five core domains as these measures. One of these commenters stated that the clinical measures currently included in the ESRD QIP are more effectively aimed at incentivizing beneficial patient outcomes such as preventing avoidable hospitalizations and reducing mortality.

Response: We recognize that there may be overlap between the HRSN data screened for under the proposed measures and data that facilities are reporting for other purposes. However, we note that some of the data cited by commenters is collected on a one-time basis, whereas the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measures require that the screens be conducted annually. This difference in the frequency of the screens will facilitate the ability of facilities to identify HRSNs that develop or change over time. We agree with the commenter that noted the beneficial impact of clinical measures in the ESRD QIP measure set. Given the link between social risk factors and adverse health outcomes, we believe that incentivizing facilities to screen for and identify a patient's HRSNs will similarly lead to better patient health outcomes.

Comment: A few commenters recommended that the measures use a standardized survey to identify and collect HRSN data. One of these commenters noted that because the measure

does not require facilities to use a standard screening instrument, facility performance on the measure is not comparable and the reported data will not be meaningful to the public. The commenter recommended that CMS only publicly report whether a facility screens for HRSNs and that CMS not publicly report the percentage of patients at a facility that screens positive for each HRSN. One commenter recommended that CMS provide guidance on the role of Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) for screening in dialysis facilities. One commenter suggested that the measure use a standardized survey to identify and collect HRSN data.

Response: We proposed that facilities would be able to choose their own screening tool for purposes of complying with both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure because we think it is important to provide facilities with the flexibility to choose the screening tool that works best for them. We understand that the absence of a standardized screening tool could introduce some inconsistency in the information collected across facilities because different screening tools may vary in terms of the number of screening questions included or the language used in those screening questions. While we acknowledge the potential benefits of requiring all facilities to use the same screening instrument or a prescribed set of standards around the number or types of screening questions used, we also recognize the benefits of providing facilities with flexibility to customize screening and data collection to their patient populations. We encourage facilities to select screening tools that have undergone thorough testing to ensure they are accurate and reliable. We believe that this measure should promote screening practices which, among other things, help to identify unmet HRSNs.

We disagree with commenter's recommendation that CMS publicly report only whether a facility screens for HRSNs and not the percentage of patients at a facility that screens positive for each HRSN. Public reporting provides a means of delivering important healthcare information to facilities, consumers, and patient advocates on the level of unmet HRSNs among a facility's

patient population that might be contributing to the clinical outcomes at the facility. We believe that a facility's ability to identify HRSNs among its patient population should be considered part of the quality of care it provides to its patients. In addition to helping facilities identify these HRSNs among their patient population that could play a factor in clinical outcomes, it also may provide the public with useful information that could be used to improve resources available to patients.

Although the commenter is correct that PRAPARE may be a useful screening tool for engaging patients in assessing and addressing social drivers of health, we are not requiring that facilities use a specific standardized screening tool for purposes of complying with the proposed measures at this time. For selecting a screening tool, we suggest that facilities refer to evidence-based resources for comprehensive information about the most widely used HRSN screening tools. For example, the Social Interventions Research and Evaluation Network (SIREN) website, housed at the Center for Health and Community at the University of California, San Francisco, contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

Comment: One commenter expressed concern with the proposed use of a standardized tool to screen patients for HRSNs, noting that HRSN screening may be accomplished through alternative means such as informal but thorough patient interviewing by a practitioner or predictive modeling using available patient data. The commenter cautioned against penalizing providers for not using a standardized tool to screen for HRSNs, absent evidence showing the superiority of the proposed method.

Response: We did not propose to require facilities to use a standardized screening tool. In the proposed rule, we proposed that facilities would be able to select a screening tool of their choosing for purposes of this measure to give facilities the flexibility to tailor their screen to the needs of their patient population.

Comment: A few commenters requested clarification regarding whether Electronic Data Interchange may be used between systems and the screening tools already in place, including clarification that CMS intends to collect the data through the EQRS. One commenter recommended delaying adoption of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting because dialysis facilities may need more time to update different EMRs.

Response: Facilities will collect and report the measure data through EQRS. Because we are not requiring facilities to adopt a standardized screening tool, we believe that the proposed measures provide facilities with the flexibility to customize screening and data collection to their local community contexts and patient populations, especially in the initial stages of implementing screening protocols. We note that these measures are proposed for inclusion beginning with PY 2027, so we believe that facilities will have ample time to build out their interfaces and test their systems before measure data reporting requirements officially begin.

Comment: A few commenters recommended that CMS align the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure with the requirements of the Comprehensive Kidney Care Contracting (CKCC) option of the KCC Model.

Response: We thank commenters for the recommendations.

Comment: One commenter recommended that facilities should receive full credit for reporting on these measures, cautioning against potentially penalizing facilities by holding them accountable for social disparities beyond their control.

Response: We proposed that the Screening for Social Drivers of Health measure is calculated as the number of eligible patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are screened by the facility for all five HRSNs divided by the total number of patients 18 years or older on the 1st day of the performance period at that dialysis facility. For the Screen Positive Rate for Social

Drivers of Health reporting measure, we proposed that the facility's measure rate would be calculated as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. We note that patients who opt-out or are unable to complete the screening are excluded from the measure denominators, so that facilities are not penalized if a patient refuses to answer certain screening questions. Facilities will be scored on whether they reported the measure data, not the results of the measure data itself. Although we believe that it is important to encourage facilities to screen their patients for HSRNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we will not score a facility based on its screen positive rates, which may reflect circumstances beyond a facility's control. We believe that these scoring policies will encourage facilities to report the measure data accurately without penalizing facilities for the results of such data.

Comment: One commenter expressed strong concern that the two proposed measures were inappropriate for use in the ESRD QIP, noting the risk of exacerbating long-standing mistrust in the healthcare system among certain patient populations. One commenter recommended that resources be offered to all patients to avoid potential stigma associated with a patient's identified HRSNs. One commenter recommended that "screening" be clearly defined to ensure that patients are being actively and directly engaged in these screenings. The commenter expressed strong concern that incentivizing facility performance through data collection and financial penalties would potentially interfere with the autonomy of the facility's patients.

Response: We agree that it is important for the screening for HRSNs to be accomplished in a way that is respectful, person-centered, and engenders trust. We recommend that facilities

consider these factors in their selection of a screening tool or other methodology to use for purposes of implementing these measures. We note that the results of a patient's HRSN screening would become part of the patient's medical record and therefore subject to the same privacy protections as the rest of the patient's medical record. We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. We believe that identifying the HRSNs of ESRD patients will be valuable in helping facilities to identify and understand patients' unmet needs, which may encourage improvements in care coordination with outpatient and community resources, and further support development of patient-centered treatment plans.

Comment: One commenter believed that HRSN screenings should remain voluntary, and clinics should not be penalized if a patient refuses to respond to a question or screening.

Response: Patients who opt-out of a screening or are unable to complete a screening are excluded from the measure denominator, so a facility will not be penalized if a patient declines to respond to a question or opts out of the screening entirely. We encourage facilities to explain to their patients what the purpose of the screening is and that they may opt out.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the Screening for Social Drivers of Health reporting measure as proposed.

3. Adoption of the Screen Positive Rate for Social Drivers of Health Reporting Measure Beginning with PY 2027

a. Background

The impact of social risk factors on health outcomes has been well-established in the

literature.[318,319,320,321,322] The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors such as housing instability and food insecurity would drive health services demand in 2021.[323] Recognizing the need for a more comprehensive approach to closing equity gaps, we have prioritized quality measures that identify social drivers of health among patients served in various care settings and, in turn, support providers in addressing the impact of these drivers on disparities in patient outcomes, healthcare utilization, and costs.[324,325,326] Specifically, in the dialysis facility setting, we aim to encourage systematic identification of patients' HRSNs as part of treatment planning, with the intention of promoting linkages with relevant community-based services that address those needs. We also believe that the identification of HRSNs can help facilities devise strategies that improve the quality of care provided to all of their patients and lead to improved health outcomes following establishment of care at the facility.

While the Screening for Social Drivers of Health reporting measure (discussed in section IV.D.2 of this final rule) enables facilities to identify patients with HRSNs, we stated in the

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[318] Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/18951.
[319] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.
[320] Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/. Accessed November 23, 2021.
[321] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. https://doi.org/10.1037/hea0000268.
[322] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress
[323] The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.
[324] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.
[325] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.
[326] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

CY 2024 ESRD PPS proposed rule (88 FR 42516) that the Screen Positive Rate for Social Drivers of Health measure would allow facilities to capture the magnitude of these needs by reporting the rate of those patients who screen positive for HRSNs and even potentially estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care.[327,328,329] These measures complement each other because they would require facilities to report both the percentage of patients they screened (under the Screening for Social Drivers of Health measure) and the results of that screening (under the Screen Positive Rate for Social Drivers of Health measure) in order to potentially identify gaps and develop sustainable solutions at a facility level and a community level. In the proposed rule, we noted that our proposals to adopt these two separate, complementary measures align with other quality reporting programs (88 FR 42516). These two measures have been finalized for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), and since publication of the CY 2024 ESRD PPS proposed rule, have been finalized for the PPS-Exempt Cancer Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59210 through 59222) and the Inpatient Psychiatric Facility Quality Reporting Program in the FY 2024 IPF PPS final rule (88 FR 51107 through 51121).

In the CY 2024 ESRD PPS proposed rule, we proposed to adopt this measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP (88 FR 42516). The Screen Positive Rate for Social Drivers of Health reporting measure would require facilities to screen all patients who are 18 years or older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal

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[327] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: https://doi.org/10.1377/hlthaff.2020.01742.

[328] CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: https://innovation.cms.gov/innovation-models/ahcm. Accessed November 23, 2021.

[329] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: https://doi.org/10.1161/CIRCOUTCOMES.120.006752.

safety and then report the resulting screen positive rates for each of those domains to CMS. These are the same five core HRSN domains under the Screening for Social Drivers of Health reporting measure, and facilities could use the same screening tool for purposes of both measures. We stated that reporting the screen positive rate for social drivers of health for each domain could inform actionable planning by facilities by helping to enable the development of individual patient action plans for those patients who screen positive (including navigation and referral). Following a positive HRSN screening, facilities could analyze data to understand, for example, whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, this measure has the potential to improve patient outcomes by acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and providing the opportunity for additional support by linking providers with community-based organizations to enhance patient-centered treatment and discharge planning, although such reach out is not required.[330,331,332] This measure may also prove useful to patients by providing data transparency and signifying facilities' familiarity, expertise, and commitment regarding these issues. Finally, we believe this measure has the potential to facilitate data-informed collaboration with community-based services and focused community investments, including the development of pathways and infrastructure to more seamlessly connect patients to local community resources. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it

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[330] The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf.
[331] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69 through 78.
[332] Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et.al, (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. Annals of Family Medicine. 17 (6), 487 through 494. Available at: https://doi.org/10.1370/afm.2470.

identifies would comply with all applicable Federal non-discrimination laws. We also note that the measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a State's civil rights laws.

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure identifies the proportion of patients at the facility who screened positive for each of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We proposed that we would require facilities to report these data as five separate rates.[333] Measure specifications for this measure are currently available on the QualityNet website at: https://qualitynet.cms.gov/esrd/esrdqip.

(1) Cohort

The cohort for the Screen Positive Rate for Social Drivers of Health is patients, aged 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened by the facility for all five HRSNs, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.[334]

(2) Numerator

The numerator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for all five HRSNs, and who screened

[333] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[334] In the CY 2024 ESRD PPS proposed rule, we stated that the cohort consisted of eligible patients "who were screened by the facility for an HRSN, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety." (88 FR 42517). This statement describes the numerator, rather than the measure cohort, and we have revised our descriptions of the measure cohort and the measure numerator in this final rule accordingly.

positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.[335]

(3) Denominator

The denominator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety). The following patients are excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no caregiver able to do so on the patient's behalf.

c. Measure Calculation

We proposed that the facility's measure rate for this measure would be calculated for a payment year as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. The full equation is set forth here:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Reports Screening Results for all Five HSRNs During the Performance Period}}{\text{Total Number of Eligible Patients who were Screened for all Five HSRNs During the Performance Period}}\right] x$$

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However, for purposes of public reporting only, we proposed to display the facility's screen positive rate for each HRSN separately, for a total of five separate rates. Although we would not score facilities on the results of those five separate rates, we believe that making such

[335] In the CY 2024 ESRD PPS proposed rule, we stated that the numerator consisted of eligible patients "who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety." (88 FR 42517). This statement describes the measure cohort, rather than the measure numerator, and we have revised our descriptions of the measure cohort and the measure numerator in this final rule accordingly.

data public may help to better inform patients and their caregivers about a facility. We proposed a 12-month period of performance for the measure, and facilities would be required to report annually.

We believe that these policies would encourage facilities to report the measure data appropriately without scoring facilities based on the results of such data, which may be based on circumstances beyond a facility's control. Although we believe that it is important to encourage facilities to screen their patients for HSRNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we do not want to score a facility based on its patients' given socioeconomic factors, which may be based on circumstances beyond a facility's control.

d. Data Collection, Submission and Reporting

In the CY 2024 ESRD PPS proposed rule, we proposed to require facilities to submit data necessary to calculate the numerator and the denominator for this measure once annually within the ESRD Quality Reporting System (EQRS), beginning with PY 2027 (88 FR 42517). We proposed that facilities would be required to submit data on this measure using the same process we have finalized for the submission of data on other measures in the ESRD QIP within EQRS.

e. Review by the Measure Applications Partnership

We included the Screen Positive Rate for Social Drivers of Health reporting measure for consideration in the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.[336] The CBE-convened MAP Health Equity Advisory Group reviewed the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail and at the same time as the Screening for Social Drivers of Health

[336] Centers for Medicare Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

measure on December 6-7, 2022.[337] The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting and the repetition of asking patients the same questions. In addition, on December 8-9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and was also reviewed by the MAP Hospital Workgroup on December 13-14, 2022.[338] The Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support for the measure for rulemaking pending endorsement by a CBE to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across dialysis facilities).[339] Thereafter, the MAP Coordinating Committee deliberated on January 24-25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.[340]

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area

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[337] Centers for Medicare Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Health Equity Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports

[338] Centers for Medicare Medicaid Services. 2022. MAP Preliminary Recommendations, Rural Health Advisory Group. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[339] Centers for Medicare Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[340] Centers for Medicare Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. We note that the link provided in the CY 2024 ESRD PPS proposed rule has been updated, and is now available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the ESRD QIP score and facility-specific rates for the Screen Positive Rate for Social Drivers of Health measure on an annual basis beginning in PY 2027 through our *Care Compare* website at: https://www.medicare.gov/care-compare/.

We invited public comment on this proposal. The comments we received and our responses are set forth below. We note that we have addressed comments that broadly referred both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in section IV.D.2 of this final rule.

Comment: Several commenters expressed support for the proposed Screen Positive Rate for Social Drivers of Health reporting measure. A few of these commenters noted that the proposed measure would provide facilities with important information regarding a patient's potential HRSNs that often impact patient outcomes. A few commenters expressed support because the measure will help identify patient social risk factors, allowing care providers and community organizations to work together to improve care delivery. One commenter expressed support and noted that the transportation challenges and utility insecurity may be particularly important for dialysis patients.

Response: We thank the commenters for their support. We agree that HRSNs are critical factors that impact patient outcomes, and increased knowledge about patients' HRSNs will help

facilities ensure that all of their patients receive the highest quality ESRD care. Further, we agree that collecting these data will incentivize facilities to better recognize whether any of the HRSNs in the screening tool are impacting their patients and take steps to improve access and outcomes.

Comment: One commenter expressed support for the proposal to include the Screen Positive Rate for Social Drivers of Health measure as a reporting measure so that facilities are not scored based on the results of the data which reflect factors beyond the facility's control.

Response: We thank the commenter for its support.

Comment: Several commenters recommended additional changes to the measure specifications to encourage follow up after a positive screening. A few commenters recommended that CMS require the development of action plans to address HRSNs or otherwise add requirements for facilities to follow up with patients on identified HRSNs where appropriate. A few commenters recommended that CMS update the measure to require referral and delivery of identified needed services. If services are not available, one commenter suggested that facilities should be responsible for reporting this to relevant Federal, State, or local agencies authorities. One commenter recommended that CMS consider potential uses for the data captured by this measure and propose these uses in future rulemaking.

Response: We thank the commenters for their recommendations, and may consider them in future rulemaking. We believe this measure has the potential to improve patient outcomes by acknowledging patients' HSRN needs that can contribute to adverse clinical outcomes.

Comment: A few commenters expressed concern that the Screen Positive Rate for Social Drivers of Health reporting measure would disincentivize caring for socially vulnerable patients because facilities serving patient populations with high rates of HRSNs would be unfairly penalized for poor performance on the proposed measure. One commenter expressed concern that the proposed Screen Positive Rate for Social Drivers of Health reporting measure will disadvantage facilities by penalizing them based on the existence of patients with HRSNs, rather

than the quality of care provided, and recommended that CMS instead offer supplemental payments to facilities that commit to use these supplemental payments to address HRSNs relevant to their patient population.

Response: We believe that identifying the HRSNs of ESRD patients will be valuable in helping facilities to identify and understand patients' unmet needs, which may encourage improvements in care coordination with outpatient and community resources, and further support development of patient-centered treatment plans. We note that identifying and addressing HRSNs is a critical topic for ESRD patients and that there are high levels of health disparities experienced by this patient population. Although we believe that the proposed measure will not lead to unintended consequences because facilities would not be penalized based on reported screen positive rates, CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process. Although we appreciate the commenter's suggestion that CMS offer supplemental payments to facilities to address HRSNs relevant to their patient population, we do not have authority under the ESRD QIP statute to offer the supplemental payments suggested by the commenter.

Comment: A few commenters expressed concern with the proposed Screen Positive Rate for Social Drivers of Health reporting measure, stating that data collected for this measure ultimately would not provide consumers with meaningful information relevant to a facility's quality of care. One commenter noted that publicly reported information would be subject to misinterpretation due to existing biases and preconceptions. A few commenters did not support public reporting because the measure reflects characteristics of the facility's patient population, not the facility's performance or quality of care.

Response: We appreciate the commenters' concerns. The measure provides a means of delivering important healthcare information to facilities, consumers, and patient advocates on the level of unmet HRSNs among a facility's patient population that might be contributing to the

clinical outcomes experienced at the facility. We believe that a facility's ability to identify these HRSNs among its patient population should be considered part of the quality of care it provides to its patients. In addition to helping facilities identify these HRSNs among their patient population that could play a factor in clinical outcomes, it also may provide the public with useful information that could be used to improve resources available to patients. We intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

Comment: A few commenters expressed concern regarding the potential burden associated with the proposed measure. Noting the potential burden to facilities, one commenter recommended that facilities receive adequate support and training to facilitate the data collection efforts associated with such measure prior to the measure's implementation. One commenter expressed concern that the measure adds reporting burden to report data that CMS is already collecting. One commenter expressed concern that the proposed Screen Positive Rate for Social Drivers of Health reporting measure would not benefit small facilities that already have individualized care plans for each of their patients, and that the additional burden from the proposed measure outweighs any potential benefit to patients.

Response: While we understand implementation of HRSN screening processes and reporting of the Screen Positive Rate for Social Drivers of Health reporting measure is associated with some burden, as discussed in section VI.C.3 of this final rule, we believe the benefits outweigh the burden because identifying patients' HRSNs is a critical step towards a facility identifying and understanding how the presence of the screened HRSNs might be impacting patient access to ESRD care and outcomes. We appreciate that facilities may already be collecting relevant data and potentially incorporating it into individualized patient care plans. However, we believe that the proposed Screen Positive Rate for Social Drivers of Health reporting measure is an important step towards health equity by supporting facilities in

leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources.

Comment: One commenter expressed concern with the proposed Screen Positive Rate for Social Drivers of Health reporting measure, recommending that CMS further explore potential reliability and validity concerns associated with the measure before it is included in the ESRD QIP.

Response: We appreciate the commenter's concern. We note that the most recent evaluation of the AHC model, which informed the development of these proposed measures, showed that it was effective in screening beneficiaries for HRSNs, identifying eligible beneficiaries, and referring those beneficiaries to HRSN-related navigation services. Although facilities in the ESRD QIP can use a screening tool of their choice, we note that multiple screening tools exist and are publicly available. Facilities could refer to the SIREN website, for example, for comprehensive information about the most widely used HRSN screening tools, including validity assessments where available.[341] We note that CMS also performs validity assessments as part of its annual EQRS data validation. Additionally, CMS will monitor measure implementation and data reporting as part of standard program and measure review and will consider updates to the measure if improvements are identified through this process.

Comment: One commenter requested that CMS provide additional information regarding how the data will be used. Commenter also questioned the intervals for collecting the data.

Response: We believe that the data may be used by facilities to inform actionable planning by helping to enable the development of individual patient action plans for those patients who screen positive (including navigation and referral). By helping to identify patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes, the data may be used to link providers with community-based organizations to enhance patient-centered

[341] Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison. Accessed October 24, 2023.

treatment and discharge planning, although such reach out is not required. We also note that there are multiple interested parties who will be able to use data regarding facilities' patient populations, including patients and their caregivers, patient advocacy organizations, local community services organizations, and Federal, State, and local policy makers. We also believe that the measure will facilitate systematic gathering of such data in a manner that provides information to facilities on the level of unmet need among their patients that many facilities do not compile currently. Although facilities are reporting the data to CMS for purposes of the measures at this time, CMS at this time does not plan to use the data for any purposes beyond the public reporting being finalized in this final rule.

Comment: One commenter stated that the equation provided does not match the description of the numerator. The commenter also recommended establishing a baseline period for implementation and data validation prior to public reporting.

Response: In the CY 2024 ESRD PPS proposed rule, we stated that the numerator consisted of eligible patients "who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety." (88 FR 42517). However, this statement actually describes the measure cohort, rather than the measure numerator. The measure numerator was correctly described in the equation that we proposed to use for scoring facilities on the measure. Therefore, in this final rule we have updated the description of the numerator to match the equation. The numerator now reads, "The numerator consists of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for all five HRSNs, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety." Regarding the commenter's suggestion to establish a baseline period for implementation and data

validation, we note that we are finalizing an updated definition of mTPS in IV.B.1 of this final rule which applies to new reporting measures for which there is an insufficient quantity of data available prior to the first performance period. Under our finalized policy, if there is an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data, which will account for the possibility that new reporting measures may have different reporting requirements. We believe this policy will allow the timely inclusion of new reporting measures in the ESRD QIP measure set while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting. We also believe that by delaying the implementation of these measures until PY 2027 will give facilities ample time to ensure the validity of their data. CMS also performs validity assessments as part of its annual EQRS data validation.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the Screen Positive Rate for Social Drivers of Health reporting measure.

4. Performance Period for the PY 2027 ESRD QIP

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we will adopt CY 2025 as the performance period and CY 2023 as the baseline period for the PY 2027 ESRD QIP.

We did not propose any changes to this policy. We addressed comments and finalized our proposals to apply this performance period to the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure in sections IV.D.2 and IV.D.3 of this 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 section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (§ 413.178(a)(12)).

a. Performance Standards for Clinical Measures in the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS proposed rule, we erroneously stated that at that time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2022 data, and stated our intention to publish these numerical values, using CY 2022 data, in the CY 2024 ESRD PPS final rule (88 FR 42518). We intended to refer to CY 2023 data in the proposed rule, rather than CY 2022 data. Because we do not have CY 2023 data at this time, we are clarifying in this final rule that we will publish these numerical values, using CY 2023 data, in the CY 2025 ESRD PPS final rule.

b. Performance Standards for the Newly Finalized Reporting Measures Beginning with the PY 2027 ESRD QIP

In this final rule, we are finalizing our proposals to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, which we discuss in IV.D.2 and IV.D.3 of this final rule. We are finalizing a 12-month period of performance for both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health

reporting measure, and facilities will be required to report annually for both measures beginning with the PY 2027 ESRD QIP.

6. Scoring the PY 2027 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e). In the CY 2023 ESRD PPS final rule, we updated our scoring methodology beginning with PY 2025 (87 FR 67251 through 67254).

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e). In section IV.D.2 of this final rule, we are finalizing our proposal to adopt the Screening for Social Drivers of Health reporting measure beginning with PY 2027. We are also finalizing our proposal to adopt the Screen Positive Rate for Social Drivers of Health reporting measure, as discussed in section IV.D.3 of this final rule. As discussed above, we are finalizing in this final rule that a facility will be scored based on the equations described in sections IV.D.2.c and IV.D.3.c of this final rule. We are adopting a 12-month period of performance for the measures, and facilities will be required to report annually. We believe that these scoring policies will encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be impacted by circumstances beyond a facility's control.

7. Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS proposed rule, beginning with PY 2027, we proposed to add the Screening for Social Drivers of Health reporting measure and the Screen Positive for Social Drivers of Health reporting measure to the Reporting Measure Domain (88 FR 42519). To

accommodate the new number of measures in the Reporting Measure Domain, we proposed to update the individual measure weights in this domain. We stated our belief that these proposed updates would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also continuing to further incentivize improvement on clinical measures through those individual measure weights. 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). Since we proposed to add two new measures to the Reporting Measure Domain beginning with PY 2027, we stated that we would weight each measure within that domain equally at approximately 1.43 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We noted that although we proposed to change the number of measures in the Reporting Measure Domain and weights of certain individual measures in that domain, we did not propose to change the weights of the five domains themselves, because we believe the proposed updates to individual measures and measure weights did not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, beginning with PY 2027, were depicted in Table 22 of the proposed rule (88 FR 42520).

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

Comment: One commenter recommended that the ESRD QIP measure set be streamlined to focus more weight on clinically meaningful measures.

Response: We agree with the commenter 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 believe that the measure domains and weights will provide facilities with meaningful incentives to improve their performance on measures that are impactful in terms of both 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.

Comment: One commenter expressed concern that with the large number of program measures, the reporting measures' weight is disproportionately small compared to the effort to operationalize associated processes, and recommended collaboration with the kidney care community to identify appropriate measures and weights.

Response: We note that the weight of a given measure domain takes into account a number of factors, 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. Having taken all of these factors into consideration, we believe that the Reporting Measure Domain weights are appropriate to support high quality health care on all ESRD QIP measures.

Final Rule Action: After considering public comments, we are finalizing our proposals as proposed. As we discussed previously, we are finalizing our proposals to update the measure domains and measure weights beginning with the PY 2027 ESRD QIP as proposed, and therefore provide the updated ESRD QIP measure domains and measure weights in Table 23.

TABLE 23: Newly Finalized ESRD QIP Measure Domains and Weights Beginning with 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 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

*We are finalizing our proposal to convert the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this final rule.
**We are finalizing our proposal to add the Screening for Social Drivers of Health measure beginning with PY 2027, as discussed in section IV.D.2 of this final rule.
***We are finalizing our proposal to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this final rule.
****We are finalizing our proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this final rule.

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 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.[342] CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment under the ETC Model is the 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.

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[342] ZIP code™ is a trademark of the United States Postal Service.

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.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). 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 Measurement Year (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).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the ETC Model

The CY 2024 ESRD PPS proposed rule appeared in the June 30, 2023, version of the **Federal Register**, with a comment period that ended on August 25, 2023. In that proposed rule, we proposed to modify the ETC Model, effective January 1, 2024, to acknowledge the availability of administrative review of targeted review requests. We received five timely public comments on our proposal, including comments from dialysis organizations and national provider and quality improvement organizations. We also received comments related to issues that we did not discuss in the CY 2024 ESRD PPS proposed rule. These include, for example, general expressions of support for the ETC Model, concerns regarding CMS's methodology for ETC Participant selection and aggregation group construction, a recommendation that CMS develop a tool to measure the experience of Beneficiaries using home modalities, and recommendations regarding the format in which CMS posts ETC Model results. While we generally are not addressing those comments in this final rule, we thank commenters for their input and may consider their recommendations in future rulemaking. In this final rule, we provide a summary the proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2024.

In the Specialty Care Models final rule (85 FR 61114), we established our policies for targeted reviews of the calculation of an ETC Participant's Modality Performance Score (MPS). As described in § 512.390(c), targeted reviews are limited to the calculation of the MPS and may not pertain to the methodologies used to calculate the MPS, home dialysis rate, transplant rates, achievement and improvement benchmarks, or the PPA amounts. ETC Participants have 90 days following the availability of the MPS to submit a targeted review request. CMS responds to each targeted review request that is received within the 90-day time period. CMS may solicit additional information from the ETC Participant in support of the request after which a determination is made as to whether there was an error in the calculation of the ETC Participant's MPS that results in an incorrect PPA being applied during the PPA period. In such

a scenario, CMS notifies the ETC Participant and resolves any resulting discrepancy in payment that arises from the application of an incorrect PPA.

In the CY 2024 ESRD PPS proposed rule, we proposed revisions to our regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. In particular, we proposed to add § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

We proposed that within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows: (i) decline to review the targeted review request determination made by CMS, (ii) render a final decision based on the CMS Administrator's review of the targeted review request determination, or (iii) choose to take no action on the request for administrative review. We proposed that targeted review request determinations made by the CMS Administrator are considered final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described.

We also proposed a conforming change to delete the existing provision in § 512.390(c)(5), which states that decisions based on targeted review are final, and there is no further review or appeal.

These changes were proposed to ensure that accountability for the decisions of CMS is vested in a principal officer and to bring the targeted review process to a more similar posture as other CMS appeals entities that provide for CMS Administrator review. These revisions were also proposed to ensure that ETC Participants are aware that administrative review is available to ETC Participants who wish to seek additional review of the results of a targeted review request.

We solicited comment on this proposal.

Comment: We received five in scope comments timely submitted. All five comments were supportive of our proposed administrative review policy. One provider organization wrote that the proposed policy would increase awareness of the availability of administrative review among ETC Participants. A dialysis organization wrote that the proposed policy would increase transparency and accountability for targeted review determinations made by CMS. A kidney care coalition also noted the proposed policy would support awareness, transparency, and accountability.

Response: We thank the commenters for their support of our proposed administrative review policy.

Final Rule Action: We are finalizing our proposed modifications to the ETC Model regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. We are adding § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

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

A. ICRs Regarding the JW and JZ Reporting Requirements; Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS, Section II.B.1.h (OMB control number 0938-0997)

As discussed in section II.B.1.h of this final rule, we are finalizing a requirement that beginning January 1, 2025, ESRD facilities must report information on claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). Additionally, we are finalizing a requirement that ESRD facilities report the JZ modifier for all such drugs and biological products with no discarded amounts beginning no later than January 1, 2025. Based on our analysis of ESRD PPS claims as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we have determined that the JW modifier requirement reflects current practices for ESRD facilities and would not significantly increase burden for ESRD facilities. Additionally, the JZ modifier requirement is not expected to increase burden on ESRD facilities because under the guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single use container or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Additionally, as discussed in section II.B.1.h of this final rule, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would already be subject to the JW and JZ modifier policies under Medicare Part B. Although we recognize that ESRD facilities may need additional time to train staff and update their systems in order to apply existing processes to a broader scope of renal dialysis drugs and biological products, we continue to anticipate that most

ESRD facilities should already be set up to report the JW and JZ modifiers without incurring additional burden.

B. ICRs Regarding the Proposal to Require Time on Machine Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis; Section II.B.1.j (OMB control numbers 0938-0997)

We are finalizing a requirement that ESRD facilities submit data and information on ESRD PPS claims regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility effective January 1, 2025. We have developed monetary estimates of the amount of ESRD facility staff time required to calculate and report on claims the minutes of time on machine for each in-center hemodialysis treatment to estimate the cost associated with the finalized requirement to report time on machine data. We have included those estimates in the Regulatory Impact Analysis in section VII.D.2.a of this final rule. We acknowledge the burden associated with this requirement, but we note that the burden associated with the CMS-1450 institutional claim form already accounts for the variability in the number and type of codes submitted for each claim.

C. Additional Information Collection Requirements

1. ESRD QIP - Wage Estimates (OMB control numbers 0938-1289 and 0938-1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the CDC's NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. In the proposed rule, we stated that the most recently available median hourly wage of a Medical

Records Specialist is $22.43 per hour (88 FR 42522).[343] In this final rule, we are updating the median hourly wage to $22.69 per hour, which reflects the most recently available data.[344] 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. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, in the proposed rule we estimated an hourly labor cost of $44.86 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP (88 FR 42522). In this final rule, we are updating our previously estimated hourly labor cost to $45.38 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2026 that we discussed in the CY 2024 ESRD PPS proposed rule (88 FR 42522 through 42523) and to estimate the total information collection burden in the ESRD QIP for PY 2027. We provide the re-estimated information collection burden associated with the PY 2026 ESRD QIP and the newly estimated information collection burden associated with the PY 2027 ESRD QIP in section VII.C.3 of this final rule.

2. Estimated Burden Associated with the Data Validation Requirements for PY 2026 and PY 2027 (OMB control numbers 0938-1289 and 0938-1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the EQRS (formerly, CROWNWeb) data validation methodology that we previously adopted for the PY 2016 ESRD

[343] https://www.bls.gov/oes/2021/may/oes292072.htm. Accessed on January 3, 2023.
[344] https://www.bls.gov/oes/current/oes292072.htm. Accessed on July 18, 2023.

QIP as the methodology we would use to validate EQRS data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this final rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $34,035 (750 hours x $45.38), or an annual total of approximately $113.45 ($34,035 / 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 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying this policy for NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities x 5 hours). Since we anticipate that Medical

Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $68,070 (1,500 hours × $45.38), or a total of approximately $226.90 ($68,070/300 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).

3. Estimated EQRS Reporting Requirements for PY 2026 and 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 2023 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2026 ESRD QIP was approximately $220 million for approximately 4,908,291 total burden hours (87 FR 67282).

We are finalizing several changes to the ESRD QIP measure set in this final rule that will affect the burden associated with EQRS reporting requirements for PY 2026 or PY 2027. Beginning with PY 2026, we are removing two measures from the ESRD QIP measure set and adding one measure to the ESRD QIP measure set. We note that, although the finalized measure we are adding to the ESRD QIP measure set beginning with PY 2026 is modified from the version of the measure that was proposed, the estimated burden associated with the measure will not change because the modification will not impose additional EQRS reporting requirements on facilities. For PY 2027 and for subsequent years, we are adding two measures to the ESRD QIP

measure set. We have re-calculated the burden estimate for PY 2026 to reflect the impact of these finalized policies, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. In the CY 2024 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 (88 FR 42523). We are further updating these estimates in this final rule. There are 126 data elements for 507,837 patients across 7,833 facilities, for a total of 63,987,462 elements (126 data elements x 507,837 patients). At 2.5 minutes per element, this would yield approximately 340.3 hours per facility. Therefore, the PY 2026 burden would be 2,666,144 hours (340.3 hours x 7,833 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2026 total burden cost is approximately $120.9 million (2,666,144 hours x $45.38).

There would also be an incremental burden change from PY 2026 to PY 2027 because we are adding two new measures beginning with PY 2027. For PY 2027, there are 136 data elements proposed for 507,837 patients across 7,833 facilities. At 2.5 minutes per element, this would yield approximately 367.3 hours per facility. Therefore, the PY 2027 burden would be 2,877,743 hours (367.3 hours x 7,833 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately $130.5 million (2,877,743 hours x $45.38).

We received two comments on the ESRD QIP collection of information discussions. The comments we received and our response is set forth below.

Comment: One commenter stated that because CMS is estimating an increase in facility burden for both PY 2026 and PY 2027, CMS should limit data collection and reporting under the ESRD QIP to those measures that are absolutely necessary to ensure that facilities can spend the

maximum time, effort and resources on caring for patients. A second commenter expressed concern that $131 million dollars of increased burden is not sustainable.

Response: 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. We appreciate the commenter's concern regarding the estimated burden for PY 2027, but note that the net increase in burden from PY 2026 (approximately $120.9 million) to PY 2027 (approximately $130.5 million) is estimated to be less than $10 million. By contrast, the estimated burden for PY 2026 is approximately $100 million less than the estimated burden for PY 2025, which is approximately $220 million (87 FR 67282).

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-1782-F

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the 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 implements updates and policy changes to the CY 2024 ESRD wage index values, the final combined wage index and TPEAPA budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has several policy changes to improve payment stability and adequacy under the ESRD PPS. These include a new transitional add-on payment adjustment for pediatric patients and a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We are also finalizing updates to the administrative process for the LVPA, requiring ESRD facilities to report on claims billing units of any discarded amounts of certain drugs and biological products, and requiring ESRD facilities to report "time on machine" data on ESRD PPS claims for all in-center hemodialysis treatments. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

2. AKI

This final rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B of this final rule, we are also applying to all AKI dialysis payments the updates to the ESRD PPS base rate and wage index. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2024 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 by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This final rule finalizes updates for the ESRD QIP, including removing the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning

with PY 2026, removing the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026, updating the COVID-19 Vaccination Coverage Among HCP beginning with PY 2026, converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026, and adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This final rule also finalizes the adoption of the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

4. ETC Model

We believe it is necessary to make certain changes to the ETC Model to acknowledge the availability of administrative review of targeted review requests. The policy we are finalizing in this rule is necessary to provide transparency to ETC Participants regarding the avenue available to them should they wish to seek additional review of the results of a targeted review request determination.

B. Overall Impact

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 entitled "Modernizing

Regulatory Review" (hereinafter, the Modernizing E.O.) amends section 3(f)(1) 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 (adjusted every 3 years for changes in gross domestic product), 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 or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of Executive Order 12866 ($200 million or more in any 1 year). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this final rule, OMB has determined this rulemaking is significant per section 3(f)(1) economic effect as measured by the $200 million or more in any 1 year threshold, and hence is also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this final rule, and the Department has provided the following assessment of its impact.

C. Impact Analysis

1. ESRD PPS

We estimate that the revisions to the ESRD PPS will result in an increase of approximately $190 million in Medicare payments to ESRD facilities in CY 2024, which

includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the budget-neutral transitional pediatric ESRD add-on payment adjustment, the beginning of the post-TDAPA add-on payment adjustment, and continuation of the approved TDAPA as identified in Table 11. We note that approximately $10 million in projected CY 2024 expenditures for Jesduvroq (daprodustat) are not included in the detailed economic analysis in Table 24 due to the fact that we do not yet have the required claims data for Jesduvroq, and therefore we cannot estimate impacts at the facility level.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2024.

3. ESRD QIP

We estimate that the updates to the ESRD QIP will result in $16 million in estimated payment reductions across all facilities for PY 2026.

4. ETC Model

We estimate that the changes to the ETC Model will not impact the Model's projected direct savings from payment adjustments alone. As described in the CY 2023 ESRD PPS final rule, we estimate that the Model would generate $28 million in direct savings related to payment adjustments over 6.5 years (87 FR 67297 through 67299).

5. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2024 is $190 million based on the estimates of the updates to the ESRD PPS and the AKI payment rates, as well as $10 million in projected new TDAPA spending in CY 2024. We estimate an additional $12 million in costs associated with the final policy to require ESRD facilities to report time on machine data. We estimate the impacts of the ESRD QIP for PY 2026 to be $120.9 million in information collection burden and $16 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for

PY 2027 to be $130.5 million in information collection burden and $13.8 million in estimated payment reductions across all facilities. Finally, we estimate that the changes to the ETC model in this final rule will not impact the Model's projected direct savings from payment adjustments alone.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2024 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 at ESRD facilities by 2.1 percent based on the CY 2024 ESRDB market basket percentage increase reduced by the CY 2024 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.1 percent.

2. Costs

a. ESRD PPS and AKI

As discussed in section II.B.1.j of this final rule, we are finalizing a requirement for ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use will be used to apportion composite rate costs for use in the case-mix adjustment under the ESRD PPS. We estimate that

there will be an increase in costs for ESRD facilities associated with this final reporting requirement; however, as we previously noted in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), we are aware that many ESRD facilities' EHR systems automatically collect this information for every dialysis treatment, minimizing the additional burden of reporting this metric on claims. However, commenters identified that there are additional burdens associated with transmitting that information from the medical records to the billing system, as many ESRD facilities do not have such processes in place. Therefore, we are updating our burden estimate to include the burden associated with this step in the process.

For those ESRD facilities that use EHRs, we estimate that there will be only very minimal additional staff time required to record such time on machine data on the patient's medical records for renal dialysis services. For those ESRD facilities that do not use EHRs, we estimate that additional staff time will be required to take note of the time at which hemodialysis began and the time at which hemodialysis ended and subtract the start time from the end time to determine the total number of minutes of hemodialysis. Conservatively, we estimate this will require no more than 1 minute per treatment.

For all ESRD facilities, we estimate that additional staff time will be required to compile time on machine data for each patient each month and enter it into the billing system to be submitted. Conservatively, we estimate that this will require no more than 5 minutes per patient month.

To calculate the annual additional ESRD facility staff time that will be associated with recording time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per treatment by the number of dialysis treatments. Based on the most recent available CY 2022 ESRD PPS claims for this final rule, we estimate there were approximately 30.6 million treatments. However, as discussed in section II.B.1.j, we proposed to limit this reporting requirement to in-center claims. We estimated that approximately 14.8 percent of claims are for home dialysis, and therefore we reduce our estimate of the total number of

treatments by 14.8 percent. Additionally, we believe it is reasonable to assume that LDOs will utilize existing systems and processes to document treatment duration in the EHR and send that information to the claim. Based on the latest available data as shown in Table 24, approximately 78.4 percent of treatments were furnished by LDOs. Therefore, we estimate that the additional costs associated with this time on machine reporting requirement will be associated with approximately 5.6 million in-center, non-LDO dialysis treatments per year.

Additionally, ESRD facilities already report time on machine data monthly in the EQRS for a single dialysis session. This means that for a patient who receives 156 dialysis treatments per year, the duration of twelve of those sessions would already be reported in the EQRS. We do not believe there will be any additional staff time required to report time on machine data on ESRD PPS claims for the treatments already reported in EQRS. Therefore, we estimate that the additional staff time that will be needed for reporting time on machine will be for 144 out of 156 treatments per year for the typical patient. For our cost estimate, we multiplied our estimate of 5.6 million in-center dialysis treatments by a factor of (144 / 156), which equals approximately 5.2 million treatments per year.

To calculate the annual additional ESRD facility staff time that will be associated with calculating and reporting time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per patient month by the number of dialysis patient months. Based on the most recent available ESRD PPS claims data for this final rule (from CY 2022), we estimate there were approximately 2.2 million patient months for patients receiving in-center hemodialysis. Therefore, we estimate that the additional costs associated with compiling and reporting the data for this time on machine reporting requirement will be associated with approximately 2.2 million in-center dialysis patient months per year.

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates. We believe it is reasonable to assume that Medical Records and Health Information Technicians, who are responsible for

organizing and managing health information data, are the individuals reporting time on machine data. As discussed in the CY 2016 ESRD PPS final rule (80 FR 69069), this is consistent with our assumptions about the types of employees tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available mean hourly wage of a Medical Records and Health Information Technician is $24.42 per hour.[345] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We note that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimate an hourly labor cost of $48.84 as the basis of the wage estimates for the estimate of cost associated with the proposed requirement to report time on machine data on ESRD PPS claims for renal dialysis services.

Based on the figures discussed in the preceding paragraphs, we estimate that total additional staff time each year for ESRD facilities associated with the requirement to record time on machine data is equal to 5.2 million x 1 minute = 5.2 million minutes = 86,667 hours. Additionally, we estimate that the total additional staff time each year for ESRD facilities associated with the calculation and reporting of the time on machine data is equal to 2.2 million x 5 minutes = 11 million minutes = 183,333 hours. We estimate the total annual cost associated with this requirement is equal to (86,667 hours + 183,333 hours) x $47.34 = $12,781,800 per year.

We recognize that some non-LDO ESRD facilities may also choose to adopt an automated process, rather than a manual process. Therefore, the estimate of $12,781,800

[345] https://www.bls.gov/oes/current/oes292099.htm.

represents the upper limit of our burden estimate. For ESRD facilities that choose to utilize existing systems and processes to document treatment duration in the EHR and send that data to the claim, we estimate the burden associated with our requirement to report time on machine data will be minimal.

b. ESRD QIP

For PY 2026 and PY 2027, we have updated 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. 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. We have updated our methodology for calculating the annual burden associated with the information collection requirements for EQRS reporting based on our measure updates for PY 2026, PY 2027, and subsequent years.

We also updated the payment reduction estimates based on our policies that we have finalized in this final rule, using more recent data for the measures in the ESRD QIP measure set. We estimate that as a result of our previously finalized policies and the policies we have finalized in this final rule for PY 2026, there would be approximately $120.9 million in information collection burden and an additional $16 million in estimated payment reductions across all facilities, for a total estimated impact of $136.9 million.

For PY 2027, we estimate that as a result of our previously finalized policies and the policies we have finalized in this final rule for PY 2027, there would be approximately $130.5 million in information collection burden and $13.8 million in estimated payment reductions across all facilities, for a total estimated impact of $144.3 million.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate will result in a total increase of approximately $190 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2024 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $150 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.

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, 256, will be the number of reviewers of this ESRD PPS 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 ESRD PPS proposed rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this final rule. We invited comments on the approach in estimating the number of entities which will review this final rule but did not receive any comments on this topic. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our

estimate we assume that each reviewer reads approximately 50 percent of the rule. We solicited comments on this assumption and none were received.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this final rule is $123.06 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 300 minutes (5.00 hours) for the staff to review half of this final rule, which has a total of approximately 150,000 words. For each entity that reviews the rule, the estimated cost is $615.30 (5.00 hours x $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $157,516.80 ($615.30 x 256).

5. Impact Statement and Table

a. CY 2024 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 2023 to estimated payments in CY 2024. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2023 and CY 2024 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 2022 data from the Medicare Part A and Part B Common Working Files as of August 4, 2023, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 24 shows the impact of the estimated CY 2024 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2023.

TABLE 24: Impacts of the Changes in Medicare Payments to ESRD Facilities for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments[1,2] (E)	Wage Index Changes (F)	Total Percent Change[3] (G)
All Facilities	7,864	30.6	0.0%	0.0%	0.0%	0.0%	2.1%
Type							
Freestanding	7,507	29.4	0.0%	0.0%	0.0%	0.0%	2.1%
Hospital based	357	1.2	0.0%	0.8%	0.1%	0.2%	3.4%
Ownership Type							
Large dialysis organization	6,123	24.0	0.0%	0.0%	0.0%	0.0%	2.0%
Regional chain	913	3.7	0.0%	0.0%	0.0%	-0.1%	1.9%
Independent	462	1.7	0.0%	0.0%	0.1%	0.6%	2.7%
Hospital based	357	1.2	0.0%	0.8%	0.1%	0.2%	3.4%
Unknown	9	0.0	0.0%	0.0%	0.1%	0.4%	2.6%
Geographic Location							
Rural	1,267	4.3	0.0%	0.0%	0.0%	-0.4%	1.6%
Urban	6,597	26.3	0.0%	0.0%	0.0%	0.1%	2.2%
Census Region							
East North Central	1,228	4.1	0.0%	0.0%	0.0%	-0.4%	1.7%
East South Central	617	2.0	0.0%	0.0%	0.0%	-0.3%	1.7%
Middle Atlantic	895	3.8	0.0%	0.0%	0.0%	0.8%	2.9%
Mountain	441	1.7	0.0%	0.0%	0.0%	-0.7%	1.4%
New England	200	1.0	0.0%	0.0%	0.0%	-0.5%	1.6%
Pacific[4]	986	5.2	0.0%	0.0%	0.0%	0.0%	2.1%
Puerto Rico and Virgin Islands	53	0.1	0.0%	0.0%	0.1%	0.0%	2.1%
South Atlantic	1,830	6.8	0.0%	0.0%	0.0%	0.3%	2.4%
West North Central	495	1.7	0.0%	0.0%	0.0%	-0.3%	1.9%
West South Central	1,119	4.1	0.0%	0.1%	0.0%	0.0%	2.1%
Facility Size							
Less than 4,000 treatments	1,245	1.4	0.0%	0.4%	0.0%	-0.1%	2.5%

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments[1,2] (E)	Wage Index Changes (F)	Total Percent Change[3] (G)
4,000 to 9,999 treatments	3,503	10.2	0.0%	0.0%	0.0%	-0.1%	2.0%
10,000 or more treatments	3,116	19.0	0.0%	0.0%	0.0%	0.0%	2.1%
Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients							
Less than 2%	7,761	30.3	0.0%	0.0%	0.0%	0.0%	2.1%
Between 2% and 19%	38	0.2	0.0%	1.5%	0.1%	-0.5%	3.2%
Between 20% and 49%	9	0.0	0.1%	8.4%	0.1%	-1.1%	9.7%
More than 50%	56	0.0	0.1%	25.3%	0.1%	0.0%	28.4%

[1]This column includes the impact of the end of TDAPA payment for Korsuva® and the start of the proposed post-TDAPA payment adjustment for that drug beginning in April, 2024. This change is not budget neutral, but we estimate the overall change in total payments would be an increase of less than 0.1 percent.
[2] Although TDAPA spending for Jesduvroq (January 1, 2024 – December 31, 2024) is projected at approximately $10 million, this amount is not reflected in Table 24, because Jesduvroq utilization was not yet represented in the claims data used for this table.
[3] This column includes the impact of the final updates in columns (C) through (F) in Table 24, and of the ESRDB market basket percentage increase for CY 2024 of 2.4 percent, reduced by 0.3 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.
[4] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2024, 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 less than 0.1 percent.

Column D shows the effect of the TPEAPA as described in section II.B.1.g of this final rule. This adjustment will be implemented in a budget neutral manner, so the total impact of this change would be 0.0 percent. However, there will be distributional impacts of this final change, primarily a 25.3 percent increase to payments to Pediatric ESRD facilities (with more than 50

percent of patients under age 18). This policy change also corresponds to a 0.8 percent increase to hospital-based ESRD facilities. Because the budget neutrality factor for this policy is so small, the impact analysis found no significant decrease to any ESRD facility as the total decrease in payments for ESRD facilities that predominantly serve adults will still be less than 0.05 percent.

Column E shows the effect of year-over-year payment changes related to the post-TDAPA add-on payment adjustment as described in section II.B.1.i of this final rule and current TDAPA payments. The post-TDAPA add-on payment adjustment will not be budget neutral; however, we estimate the difference between total payments in CY 2023 during which time payment is made using the TDAPA under the ESRD PPS and estimated total payments in CY 2024 under the final post-TDAPA add-on payment adjustment would be less than 0.1 percent. Therefore, the total impact of this change as compared to current TDAPA payments is 0.0 percent.

Column F reflects the effect of the update to the ESRD PPS wage index as described in section II.B.1.b 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 would be to mid-Atlantic ESRD facilities that would receive 0.8 percent higher payments because of the final updated ESRD PPS wage index. The largest decrease will be to ESRD facilities with more than 20 percent and less than 50 percent pediatric patients, who will receive 1.1 percent lower payments because of the updated ESRD PPS wage index.

Column G reflects the overall impact, that is, the effects of the final outlier policy changes, the TPEAPA, the post-TDAPA payment adjustment, the updated wage index, and the payment rate update as described in section II.B.1.d of this final rule. The ESRD PPS payment rate update for CY 2024 is 2.1 percent, which reflects the ESRDB market basket percentage increase for CY 2024 of 2.4 percent and the productivity adjustment of 0.3 percent. We expect that overall ESRD facilities will experience a 2.1 percent increase in estimated Medicare

payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from a 1.4 percent increase to a 28.4 percent increase in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2024, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2024 will be approximately $6.7 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 4.3 percent in CY 2024.

(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 2.1 percent overall increase in the CY 2024 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary coinsurance payments of 2.1 percent in CY 2024, which translates to approximately $40 million.

(5) Alternatives Considered

(i) Transitional Pediatric ESRD Add-On Payment Adjustment

As discussed in section II.B.1.g.(4) of this final rule, we proposed and are finalizing to implement a transitional add-on payment adjustment of 30 percent for Pediatric ESRD Patients, which we call the TPEAPA. We also considered, but did not propose, an alternative payment

structure which would phase in the adjustment over 3 years starting at 10 percent for the first year and 20 percent for the second year.

(ii) Add-on Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products after the TDAPA Period Ends

As discussed in section II.B.1.i.(3) of this final rule, we proposed and are finalizing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We also considered, but did not propose, an alternative methodology for calculating this payment adjustment which would incorporate a reconciliation of all the formerly separately billable drugs against the calculated post-TDAPA payment adjustment. Additionally, we considered but did not propose alternative approaches to applying and calculating this add-on payment adjustment for specific patient populations.

(iii) Reporting Time on Machine Data on ESRD PPS Claims for Renal Dialysis Services

As discussed in section II.B.1.j.(3) of this final rule, we proposed and are finalizing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment. We also considered, but did not propose, to use dialysis duration data from EQRS to apportion composite rate costs for this purpose. We discuss why we did not propose this alternative in further detail in section II.B.1.j.(3) of this final rule.

(iv) Allowing ESRD Facilities Impacted by a Disaster or Other Emergency to Apply for an Exception from the Treatment Volume Threshold Requirement for the LVPA

As discussed in section II.B.1.f.(3)(a)(ii), we are finalizing our proposal to allow ESRD facilities to receive exceptions for some of the requirements for the LVPA if they are impacted by a disaster or other emergency. One of these exceptions is for ESRD facilities that exceed the

4000-treatment volume threshold due to treating patients who were displaced from an ESRD facility that closed or experienced an operational disruption due to a disaster or other emergency. To receive this exception, we proposed that the ESRD facility must submit a request for the exception, in writing, to CMS by the annual attestation deadline of November 1st. We are finalizing that the deadline for requesting this exception be either the annual attestation deadline or 30 days after the end of the cost-reporting year for which the ESRD facility is attesting, whichever is later. We also considered, but did not finalize, having a deadline of December 31st for the attestation for ESRD facilities impacted by a disaster or other emergency and, therefore, a deadline of December 31st for requesting the exception. We discuss why we are not finalizing this alternative in further detail in section II.B.1.f.(3)(a)(ii) of this final rule.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2024

(1) Korsuva® (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 and CY 2023 will continue to be eligible for the TDAPA in CY 2024. CMS Transmittal 11295,[346] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Korsuva® (difelikefalin). The TDAPA payment period began on April 1, 2022, and will continue through March 31, 2024. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2024 impacts on the most current 72x claims data; from May 2022, when utilization first appeared on the claims, through July 2023. During that timeframe, the average monthly TDAPA payment amount for Korsuva® was $1,000,000. In applying that average to the 3 remaining months of the TDAPA payment period in CY 2024, we estimate

[346] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: https://www.cms.gov/files/document/r11295CP.pdf.

$3,000,000 in spending ($1,000,000 * 3 = $3,000,000) of which, approximately $600,000 ($3,000,000 * 0.20 = $600,000) would be attributed to beneficiary coinsurance amounts.

(2) Jesduvroq (daprodustat)

On July 27, 2023, CMS Transmittal 12157[347] 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 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.

We based our impact analysis on the most current pricing and manufacturer provided volume estimates at the time of this final rule. Estimates are based on the most current, reasonable assumptions but are subject to change based on any changes to the product's label, indication, recommended dosage, safety profile or changes to applicable law, regulations and/or the standard of care.

Jesduvroq is currently priced at $3.91 per 1 milligram unit.[348] Several factors effect dosing, as described in Jesduvroq's Prescribing Information.[349] However, total volume is estimated at 2,623,860 units in CY 2024. Multiplying the 2,623,860 units by the current pricing of $3.91 would result in approximately $10.3 million in CY 2024 spending (2,623,860 * $3.91 =

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[347] CMS Transmittal 12157, dated July 27, 2023 is available at: https://www.cms.gov/files/document/r12157cp.pdf.
[348] CMS ESRD PPS Transitional Drug Add-on Payment Adjustment web page. Payment Amounts for New Renal Dialysis Drugs and Biological Products Currently Eligible for the TDAPA. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Drugs-and-Biologicals-Eligible-for-TDAPA.pdf. Accessed on September 29, 2023.
[349] Jesduvroq Prescribing Information Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jesduvroq/pdf/JESDUVROQ-PI-MG.PDF. Accessed on September 29, 2023.

$10,259,293), of which, approximately $2.1 million ($10,259,293 * 0.20 = $2,051,859) would be attributed to beneficiary coinsurance amounts.

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

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting 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 2023 to estimated Medicare payments in CY 2024. 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 2023 and CY 2024 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 2022 data from the Medicare Part A and Part B Common Working Files as of August 4, 2023, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule.

Table 25 shows the impact of the estimated CY 2024 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 2023.

TABLE 25: Impacts of the Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
All Facilities	5,110	278.0	-0.1%	2.0%
Type				
Freestanding	4,990	272.6	-0.1%	2.0%
Hospital based	120	5.4	0.1%	2.1%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
Ownership Type				
Large dialysis organization	4,234	229.8	-0.1%	1.9%
Regional chain	576	29.1	-0.1%	1.9%
Independent	179	13.7	0.6%	2.7%
Hospital based[2]	120	5.4	0.1%	2.1%
Unknown	1	0.0	0.2%	2.2%
Geographic Location				
Rural	863	43.0	-0.4%	1.6%
Urban	4,247	235.0	0.0%	2.0%
Census Region				
East North Central	853	44.8	-0.5%	1.6%
East South Central	386	19.5	-0.2%	1.8%
Middle Atlantic	534	32.5	0.7%	2.7%
Mountain	301	19.5	-0.8%	1.2%
New England	146	6.7	-0.3%	1.8%
Pacific[3]	621	42.5	-0.2%	1.8%
Puerto Rico and Virgin Islands	5	0.1	0.0%	2.1%
South Atlantic	1,235	67.4	0.1%	2.2%
West North Central	320	13.2	-0.2%	1.8%
West South Central	709	31.7	0.0%	2.1%
Facility Size				
Less than 4,000 treatments	513	17.3	-0.1%	2.0%
4,000 to 9,999 treatments	2,312	114.1	-0.1%	2.0%
10,000 or more treatments	2,285	146.6	-0.1%	2.0%
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,096	277.4	-0.1%	2.0%
Between 2% and 19%	11	0.6	-1.4%	0.6%
Between 20% and 49%	1	0.1	-1.6%	0.5%
More than 50%	2	0.0	-0.7%	1.4%

[1] This column includes the impact of the updates in columns (C) as well as the impact of the TPEAPA budget-neutrality adjustment factor in Table 25, and of the ESRDB market basket percentage increase for CY 2024 of 2.4 percent, reduced by 0.3 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the CY 2024 wage indices.

Column D shows the overall impact, that is, the effects of the combined wage index and TPEAPA budget-neutrality adjustment factor, wage index updates, and the payment rate update of 2.1 percent, which reflects the ESRDB market basket percentage increase for CY 2024 of 2.4 percent and the productivity adjustment of 0.3 percentage point. We expect that overall ESRD facilities will experience a 2.0 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.5 percent to 2.7 percent in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we proposed to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $70 million will be paid to ESRD facilities in CY 2024 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.

d. ESRD QIP

(1) Effects of the PY 2026 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions 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 2026 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2026, as codified in our regulations at § 413.177.

For the PY 2026 ESRD QIP, we estimate that, of the 7,833 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 30.56 percent or 2,394 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 2,394 facilities that would receive a payment reduction, approximately 64 percent

or 1,544 facilities would receive the smallest payment reduction of 0.5 percent. We are updating the estimated impact of the PY 2026 ESRD QIP that we provided in the CY 2023 ESRD PPS final rule (87 FR 67293 through 67296). Based on our final policies, the updated total estimated payment reductions for all the 2,394 facilities expected to receive a payment reduction in PY 2026 would be approximately $15,990,524. Facilities that do not receive a TPS do not receive a payment reduction.

Table 26 shows the updated overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 26: Updated Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5167	68.34%
0.5%	1544	20.42%
1.0%	628	8.31%
1.5%	194	2.57%
2.0%	28	0.37%

*272 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 27) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 27.

TABLE 27: Data Used to Update the Estimated PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SRR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SHR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
PPPW	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Kt/V Dialysis Adequacy Comprehensive	Jan 2019-Dec 2019	Jan 2022-Dec 2022
VAT		

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
% Catheter	Jan 2019-Dec 2019	Jan 2022-Dec 2022
STrR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
NHSN BSI	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Clinical Depression	Jan 2021-Dec 2021	Jan 2022-Dec 2022

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the final policies outlined in section IV.C of this final rule. Facility reporting measure scores were estimated using available data from CY 2022. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2022 and December 2022 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 28 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. 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 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

TABLE 28: Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,833	29.8	7,561	2,394	-0.23%
Facility Type:					
Freestanding	7,481	28.6	7,232	2,252	-0.22%
Hospital-based	352	1.1	329	142	-0.36%
Ownership Type:					
Large Dialysis	6,068	23.2	5,882	1,622	-0.18%
Regional Chain	901	3.6	877	346	-0.31%
Independent	451	1.7	434	264	-0.60%
Hospital-based (non-chain)	352	1.1	329	142	-0.36%
Unknown	61	0.0	39	20	-0.35%
Facility Size:					
Large Entities	6,969	26.9	6,759	1,968	-0.19%
Small Entities[1]	803	2.9	763	406	-0.50%
Unknown	61	0.0	39	20	-0.35%
Rural Status:					
1) Yes	1,264	4.2	1,211	277	-0.15%
2) No	6,569	25.6	6,350	2,117	-0.24%
Census Region:					
Northeast	1,093	4.7	1,050	333	-0.22%
Midwest	1,718	5.7	1,649	526	-0.23%
South	3,555	12.5	3,439	1,164	-0.25%
West	1,404	6.6	1,362	344	-0.16%
US Territories[2]	63	0.2	61	27	-0.28%
Census Division:					
Unknown	11	0.1	10	5	-0.40%
East North Central	1,223	4.0	1,176	409	-0.25%
East South Central	616	2.0	593	186	-0.22%
Middle Atlantic	893	3.7	854	283	-0.23%
Mountain	438	1.6	429	107	-0.17%
New England	200	1.0	196	50	-0.18%
Pacific	966	5.0	933	237	-0.16%
South Atlantic	1,820	6.5	1,758	643	-0.28%
West North Central	495	1.7	473	117	-0.18%
West South Central	1,119	4.0	1,088	335	-0.22%
US Territories[2]	52	0.1	51	22	-0.26%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,267	1.5	1,100	364	-0.28%
4,000-9,999 treatments	3,294	9.2	3,203	856	-0.19%
Over 10,000 treatments	3,272	19.0	3,258	1,174	-0.24%

[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.

(3) Effects of the PY 2027 ESRD QIP on ESRD Facilities

For the PY 2027 ESRD QIP, we are updating the estimated effect that we presented in the CY 2024 ESRD PPS proposed rule (88 FR 42534 through 42536). In this final rule, we estimate that, of the 7,833 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 28.88 percent or 2,262 of the facilities that have sufficient data to calculate a TPS

would receive a payment reduction for PY 2027. Among an estimated 2,262 facilities that would receive a payment reduction, approximately 70 percent or 1,584 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 2,262 facilities expected to receive a payment reduction is approximately $13,847,479. Facilities that do not receive a TPS do not receive a payment reduction.

Table 29 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 29: Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5362	70.33%
0.5%	1584	20.78%
1.0%	568	7.45%
1.5%	97	1.27%
2.0%	13	0.17%

*Note: 209 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2027, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 30) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 30.

TABLE 30: Data Used to Estimate 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 2019-Dec 2019	Jan 2022-Dec 2022
SRR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
SHR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
PPPW	Jan 2019-Dec 2019	Jan 2022-Dec 2022
Kt/V Dialysis Adequacy Comprehensive	Jan 2019-Dec 2019	Jan 2022-Dec 2022
VAT		
% Catheter	Jan 2019-Dec 2019	Jan 2022-Dec 2022
STrR	Jan 2019-Dec 2019	Jan 2022-Dec 2022
NHSN BSI	Jan 2019-Dec 2019	Jan 2022-Dec 2022

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
Clinical Depression	Jan 2021-Dec 2021	Jan 2022-Dec 2022

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR and SRR measures, 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. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the previously finalized policies and the policies we have finalized in this final rule outlined in section IV.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2022. 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 2022 and December 2022 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 31 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 31: 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	7,833	29.8	7,624	2,262	-0.20%
Facility Type:					
Freestanding	7,481	28.6	7,292	2,127	-0.19%
Hospital-based	352	1.1	332	135	-0.30%
Ownership Type:					
Large Dialysis	6,068	23.2	5,904	1,534	-0.16%
Regional Chain	901	3.6	882	322	-0.26%
Independent	451	1.7	446	254	-0.50%
Hospital-based (non-chain)	352	1.1	332	135	-0.30%
Unknown	61	0.0	60	17	-0.18%
Facility Size:					
Large Entities	6,969	26.9	6,786	1,856	-0.17%
Small Entities[1]	803	2.9	778	389	-0.42%
Unknown	61	0.0	60	17	-0.18%
Rural Status:					
1) Yes	1,264	4.2	1,223	274	-0.14%
2) No	6,569	25.6	6,401	1,988	-0.21%
Census Region:					
Northeast	1,093	4.7	1,066	301	-0.19%
Midwest	1,718	5.7	1,663	507	-0.20%
South	3,555	12.5	3,464	1,118	-0.22%
West	1,404	6.6	1,369	313	-0.15%
US Territories[2]	63	0.2	62	23	-0.20%
Census Division:					
Unknown	11	0.1	11	5	-0.31%
East North Central	1,223	4.0	1,187	397	-0.22%
East South Central	616	2.0	600	176	-0.19%
Middle Atlantic	893	3.7	869	259	-0.20%
Mountain	438	1.6	430	100	-0.16%
New England	200	1.0	197	42	-0.14%
Pacific	966	5.0	939	213	-0.14%
South Atlantic	1,820	6.5	1,771	619	-0.24%
West North Central	495	1.7	476	110	-0.15%
West South Central	1,119	4.0	1,093	323	-0.19%
US Territories[2]	52	0.1	51	18	-0.18%
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,267	1.5	1,163	359	-0.23%
4,000-9,999 treatments	3,294	9.2	3,203	822	-0.17%
Over 10,000 treatments	3,272	19.0	3,258	1,081	-0.21%

[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.

(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions

Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately $13,847,478.73 in Medicare savings. For comparison, Table 32 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2027.

TABLE 32: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	$13,847,479
PY 2026	$15,990,524
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[350] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence 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 are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new

[350] In the CY 2022 ESRD PPS final rule, we adopted a special scoring methodology and payment policy for PY 2022 due to significant impacts related to the COVID-19 public health emergency (86 FR 61918 through 61919). Under this policy, we did not apply any payment reductions to ESRD facilities for PY 2022.

measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.C.5 of this final rule, we are finalizing the removals of the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, beginning with PY 2026. We considered not removing these measures. However, we concluded that removing these two measures was appropriate under our previously finalized measure removal factors. This approach will help to ensure that a facility's performance is assessed based on measures that continue to be meaningful parts of the ESRD QIP measure set.

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), and the CY 2023 ESRD PPS final rule (87 FR 67136) 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. We proposed to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests. 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 33 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). Making administrative review available to ETC Participants who wish to seek additional review of a targeted review determination is not expected to change this estimate.

(3) Medicare Estimate – Primary Specification, Assume Rolling Benchmark

TABLE 33: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

In Table 33, 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 changes in this final rule will not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the 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 changes in this final rule will not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2023 ESRD PPS final rule (87 FR 67136).

(6) Effects on Medicare Beneficiaries

Providing the option for ETC Participants to seek administrative review of targeted review determinations will not impact the findings reported for the effects of ETC Model on Medicare beneficiaries in lieu of the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for 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), the CY 2022 ESRD PPS final rule (86 FR 61874), or the CY 2023 ESRD PPS final rule (87 FR 67136).

(7) Alternatives Considered

In this final rule, we are finalizing the proposal to revise our regulations at § 512.390 to acknowledge the availability of administrative review of targeted review requests. We considered retaining our current process, in which targeted review determinations are final with no further review or appeal; however, we believe that providing for administrative review of targeted review determinations is important to provide ETC Participants with transparency regarding the avenue that is available should they wish to seek review of their targeted review

determination, to vest accountability for the decisions of CMS in a principal officer, and to bring the ETC Model into alignment with other CMS programs.

E. Accounting Statement

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 34 showing the classification of the impact associated with the provisions of this final rule.

TABLE 34: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2024)	
Category	**Transfers**
Annualized Monetized Transfers	$150 million
From Whom to Whom	Federal Government to ESRD facilities
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$40 million
From Whom to Whom	Beneficiaries to ESRD facilities
ESRD PPS (CY 2025)	
Category	**Costs**
Increased Reporting Burden for Time on Machine	$13 million
For Whom	ESRD Facilities
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$16.0 million
From Whom to Whom	Federal Government to ESRD facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-$13.8 million
From Whom to Whom	Federal Government to ESRD facilities
ETC Model for July 1, 2022, through June 30, 2027	
Category	**Transfers**
Annualized Monetized Transfers	$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

F. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (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 $41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $8.1 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 462 facilities that are independent and 357 facilities that are hospital-based, as shown in the ownership category in Table 24, to be small businesses. These facilities represent approximately 10 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 796 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 370 nonprofit ESRD facilities that are also considered small businesses, there are 1,245 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates in this final rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.4 percent increase in Medicare payments for CY 2024. An independent facility (as defined by ownership type) is likewise estimated to receive a 2.7 percent increase in Medicare payments for CY 2024. As

shown in Table 24, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare payments by approximately 2.1 percent.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for $70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 2,394 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2026 ESRD QIP, 406 are ESRD small entity facilities. We present these findings in Table 25 ("Estimated Distribution of PY 2026 ESRD QIP Payment Reductions") and Table 27 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026").

Regarding the ETC Model, in the Specialty Care Models final rule, we described our assumption, for the purposes of the regulatory impact analysis, that the great majority of Managing Clinicians are small entities by nature of meeting the SBA definition of a small business, but that the greater majority of ESRD facilities are not, as they are owned, either partially or entirely, by organizations that do not meet the SBA definition of a small entity. We described the low volume threshold exclusions and aggregation policies used in the ETC Model and our assessment that, in conjunction with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; the ETC Model will not have a significant impact on spending for a substantial number of small entities. For the purposes of this final rule, we have determined that the policy to clarify the ability of the CMS Administrator to review targeted review determinations will not change the assessment that the ETC Model will not have a significant impact on spending for a substantial number of small entities.

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 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities will experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Clarifying the ability of the CMS Administrator to review ETC Model targeted review determinations is not expected to change the Secretary's assessment.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This final rule will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $177 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of

Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal governments.

I. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Files Available to the Public

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-1782-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 24, 2023.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, 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 413 - PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

2. Section 413.178 is amended by revising paragraphs (a)(8) and (c) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

* * * * *

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule*. Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception*. CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications*. CMS uses rulemaking to make substantive updates to the specifications of measures used in the ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (https://qualitynet.cms.gov) and listserv announcements.

(4) *Measure retention*. All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one or more of the following factors:

(A) *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.

(B) *Factor 2.* Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3.* A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4.* A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5.* A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns,

CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure --

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

3. Section 413.198 is amended by revising paragraphs (a) and (b)(3)(iii) and adding paragraphs (b)(5) and (6) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope*. This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

* * * * *

(b) * * *

(3) * * *

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

* * * * *

(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. Beginning January 1, 2025, the data and information must include, but is not limited to the following:

(i) Information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility;

(ii) 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 of this chapter or oral forms of renal dialysis drugs and biological products), of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount (or no discarded amount expected, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), using the JZ modifier (or any successor modifier that includes the same data).

(6) Beginning January 1, 2025, each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

4. Section 413.230 is amended by revising paragraphs (d) and (e) and adding paragraph (f) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

5. Section 413.232 is amended by revising paragraphs (b)(1) and (2) and (g) introductory text and adding paragraphs (g)(5) and (6) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) 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) 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, except as specified in paragraph (g)(6) of this section.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent 3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to one or more displaced patients. For any facility that so attests--

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 days after the end of the cost reporting year, whichever is later, for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests--

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraph (e) of this section and this paragraph (g).

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

* * * * *

6. Section 413.234 is amended by:

a. Adding paragraph (b)(1)(iii);

b. Revising paragraph (c)(1)(i); and

c. Adding paragraphs (c)(1)(ii), (c)(3), and (g).

The additions and revision read as follows:

§ 413.234 Drug designation process.

* * * * *

(b) * * *

(1) * * *

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described in paragraphs (c)(3) and (g) of this section, referred to as the post-transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

* * * * *

(c) * * *

(1) * * *

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

* * * * *

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

* * * * *

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the 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. If the most recent full calendar quarter of ASP data reflects zero or negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in § 413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the latest available forecast of annual growth in the ESRD bundled market basket composite price proxy for pharmaceuticals.

(5) The 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.

7. Section 413.235 is amended by revising paragraph (b) to read as follows:

§ 413.235 Patient-level adjustments.

* * * * *

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

* * * * *

8. Section 413.236 is amended by revising paragraph (b)(2) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

9. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

10. Section 512.390 is amended by removing paragraph (c)(5) and adding paragraph (d). The addition reads as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(d) *Review of targeted review decisions*. The Administrator may review a targeted review request when administrative review is requested by an ETC Participant within 15-calendar days of a targeted review request determination made by CMS.

(1) *Administrative review.* Within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows:

(i) Decline to review a targeted review request determination made by CMS;

(ii) Render a final decision based on the CMS Administrator's review of the targeted review request determination; or

(iii) Choose to take no action on the request for administrative review.

(2) *Administrative review determinations.* The targeted review determination made by the CMS Administrator is final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described in paragraph (d)(1) of this section.CMS-1782-F

Dated: October 25, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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