

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1846–F]

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Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury (AKI) Dialysis Payment, and ESRD Quality Incentive Program

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

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2027. This rule also includes updates to the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates the requirements for the ESRD Quality Incentive Program.

DATES: These regulations are effective on January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Abigail Ryan at (410) 786–4343, for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

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

QNETSUPPORT-ESRD@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

SUPPLEMENTARY INFORMATION:

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

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

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted,

bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates the ESRD PPS for CY 2027, including a routine rebasing and revising of the ESRD Bundled (ESRDB) market basket. This rule also modifies the ESRD PPS base rate to reflect the incorporation of phosphate binders¹ into the ESRD PPS base rate, makes budget neutral changes to certain ESRD PPS payment adjustments, and makes modifications to the transitional drug add-on payment adjustment (TDAPA) and post-TDAPA add-on payment adjustment. The payment adjustments changed budget neutrally include the low-volume payment adjustment (LVPA), the case mix adjusters for pediatric ESRD patients, and the home and self-dialysis add-on payment adjustment.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury

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

¹ We note that all currently available phosphate binders are oral. Throughout this rule, we use the term “oral phosphate binders” when specifically discussing these drugs in certain contexts, such as the TDAPA or historical payment policies. The CY 2027 ESRD PPS base rate increase will encompass all current and future phosphate binders, including a hypothetical future injectable phosphate binder or other form of administration.

under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI dialysis payment rate for CY 2027. The AKI dialysis payment rate update will be indirectly affected by the rebasing and revising of the ESRDB market basket under the ESRD PPS because the AKI dialysis payment rate is the ESRD PPS base rate, which is annually updated by the ESRDB market basket percentage increase factor minus a productivity adjustment, adjusted by the wage index. The change to the ESRD PPS case mix adjusters for pediatric ESRD patients, the expansion of the LVPA, and the technical changes to the TDAPA and post-TDAPA add-on payment adjustment that we are finalizing in this rule will not directly affect the CY 2027 AKI dialysis payment rate update.

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

The 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 includes the following changes to the ESRD QIP measure set beginning with PY 2029: replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients (Hyperphosphatemia) clinical measure, update the National Healthcare Safety Network Bloodstream Infection (NHSN BSI) clinical measure, remove the Medication Reconciliation (MedRec) reporting measure, and remove the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure. Finally, this final rule discusses feedback received on the inclusion of the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) Patient-Reported Outcome Performance Measure (PRO–PM) in the ESRD QIP.

B. Summary of the Major Provisions

1. ESRD PPS

- *Rebasing and revising of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2027:* We are rebasing and revising the ESRDB market basket to a 2024 base year, reflecting the most recent and complete set of Medicare cost report data as well as other publicly available data. In addition, we are updating the labor-related share of the ESRD PPS base rate to reflect the 2024 base year labor-related cost share weights designated in the ESRDB market basket.

• *Update to the ESRD PPS base rate for CY 2027:* The CY 2027 ESRD PPS base rate is \$297.52, an increase from the CY 2026 ESRD PPS base rate of \$281.71. This amount reflects the application of the wage index budget neutrality adjustment factor (1.00260), the addition to the base rate of \$12.85 to include phosphate binders, the budget neutrality factor for the budget neutral changes to several payment adjustments² (0.98864), and an ESRDB market basket update of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $\$297.52 ((\$281.71 + \$12.85) \times 1.00260 \times 0.98864) \times 1.019 = \297.52 .

• *Annual update to the wage index:* We adjust the ESRD PPS wage index on an annual basis using the most current mean hourly wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and occupational mix data from the most recent full CY of freestanding ESRD facility Medicare cost reports. This wage index uses the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. This final rule updates the wage index based on this methodology and the latest available data.

• *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and established methodology. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2027 using the latest available CY 2025 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2025 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2023, CY 2024, and CY 2025. For pediatric beneficiaries, the FDL amount will increase from \$162.43 to \$229.49, and the MAP amount will increase from \$50.19 to \$63.27, as compared to CY 2026 values. For adult beneficiaries, the FDL amount will increase from \$14.80 to \$90.60, and the MAP amount will increase from \$23.68 to \$41.83, as compared to CY 2026 values. The 1.0 percent target for outlier payments was not achieved in CY 2025, as outlier payments represented approximately 0.9 percent of total

Medicare payments. Our current estimates indicate outlier payments will be above the 1.0 percent target for CY 2026, which also reflects the underlying utilization and cost trends that are contributing to increases in the MAP and FDL amounts.

• *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2027:* The CY 2027 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is \$10.63. This offset amount reflects the application of the final ESRDB market basket update of 1.9 percent ($\$10.43 \times 1.019 = \10.63). There are no capital-related assets set to receive the TPNIES in CY 2027 for which this offset will apply.

• *Update to the post-TDAPA add-on payment adjustment amounts:* We calculated the post-TDAPA add-on payment adjustment in accordance with 42 CFR 413.234(g). The final first quarter (Q1) post-TDAPA add-on payment adjustment amount for Korsuva® is \$0.0793 per treatment, which will be included in the calculation of the total post-TDAPA add-on payment adjustment for only the first quarter of CY 2027. The final Q1 post-TDAPA add-on payment adjustment amount for DefenCath® is \$8.3220 per treatment. The post-TDAPA add-on payment adjustment amount for DefenCath® will be included in the calculation for each quarter of CY 2027. The final Q1 post-TDAPA add-on payment adjustment amount for Vafseo® is \$0.9970 per treatment. The post-TDAPA add-on payment adjustment amount for Vafseo® will be included in the calculation for each quarter of CY 2027. We are finalizing the proposal to update the post-TDAPA add-on payment adjustment amounts quarterly. As such, we are only finalizing the post-TDAPA add-on payment adjustment amount for the first quarter of CY 2027 in this final rule and will publish the amounts for the other quarters in CRs published after this final rule, conditional on the continued receipt of Average Sales Price (ASP) data. The final post-TDAPA add-on payment adjustment amount for a given quarter will be added to ESRD PPS payments for all renal dialysis treatments furnished during that quarter and will be adjusted by applicable patient level adjustment factors.

• *Incorporation of phosphate binders into the base rate:* We are incorporating phosphate binders into the ESRD PPS base rate at the end of the TDAPA period for the drugs, for CY 2027 and beyond. The final increase to the ESRD

PPS base rate for phosphate binders is \$12.85. This final amount includes an increase to account for operational costs, as outlined in section II.B.7. of this final rule.

• *Expansion of the LVPA:* We are expanding the LVPA to ESRD facilities which furnish up to 8,000 treatments per year. We are finalizing our proposal to make payments based on 6 tiers of volume. This change will be budget neutral with a budget neutrality factor of 0.98901.

• *Modifications to certain adjustments for pediatric ESRD patients:* We are modifying the case mix adjusters for pediatric ESRD patients. Additionally, we are allowing ESRD facilities to receive the LVPA for pediatric ESRD patients. These changes coincide with the end of the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) as of December 31, 2026. We are finalizing these permanent policies to address payment for pediatric ESRD patients after the temporary increase through TPEAPA is no longer available.

• *Modifications to the home and self-dialysis training add-on:* We are increasing the home and self-dialysis training add-on payment adjustment to \$138.00 from the current amount of \$95.60. We also will allow training sessions during the onset period (the first 120 days of ESRD dialysis). To reduce the potential for duplicative payments during the onset period, we are reducing the onset adjustment factor from 1.327 to 1.311. For the reasons discussed in section II.B.10. of this final rule this change is budget neutral with a budget neutrality factor of 0.99964.

• *Modifications to the TDAPA and post-TDAPA add-on payment adjustment:* We are finalizing that, when ASP data is not usable because ASP is zero or negative, we will use the most recent usable quarter of ASP data, if available, as the basis for the TDAPA and the post-TDAPA add-on payment adjustment.

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

• *Updates to the dialysis payment rate for individuals with AKI:* We are updating the AKI dialysis payment rate for CY 2027. The final CY 2027 payment rate is \$297.52, which is the same as the final CY 2027 ESRD PPS base rate.

3. ESRD QIP

We are replacing the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. Beginning with PY 2029, we are updating the NHSN BSI clinical measure to use the most

² This budget neutrality factor accounts for the budget neutral changes to the LVPA (0.98901), the changes to payment for pediatric ESRD patients (0.99999), and the changes to the home and self-dialysis add-on payment adjustment (0.99964).

recently available national baseline data and to update the risk adjustment methodology. We are removing the MedRec reporting measure and the COVID–19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with

PY 2029. This final rule also includes public comments received in response to an RFI on the potential inclusion of the Dialysis Facility Discussion of Patient Life Goals Patient-Reported Outcome Performance measure (D-PaLS PRO–PM) in the ESRD QIP.

C. Summary of Costs and Transfers
In section VII.C.5. of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. Table 1 summarizes the impacts of each final change in this final rule.

TABLE 1: Summary of Economic Costs and Transfers, By Provision

Changes	Estimated total costs/transfers
CY 2027 ESRD PPS update	The overall economic impact of this final rule is an estimated increase of approximately \$240 million in aggregate Medicare payments to ESRD facilities in CY 2027.
CY 2027 AKI dialysis payment rate update	We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2027 ESRD PPS base rate, will increase by approximately \$5 million.
PY 2029 ESRD QIP updates	We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing, the overall economic impact of the PY 2029 ESRD QIP will be approximately \$133.2 million, which includes \$114.5 million in costs associated with the collection of information requirements and approximately \$18.7 million in payment reductions across all facilities.

1. Impacts of the Updates to the ESRD PPS

The impact table in section VII.C.5.a. of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2027 compared to estimated Medicare payments in CY 2026. The overall impact of the CY 2027 payment changes is projected to be a 2.7 percent increase in Medicare payments. Hospital-based ESRD and freestanding ESRD facilities will both have an estimated 2.7 percent increase in Medicare payments. We estimate that the aggregate Medicare program payments under the ESRD PPS will increase by approximately \$190 million in CY 2027 compared to CY 2026 because of the payment policies in this rule. Because of the projected 2.7 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2027, which translates to approximately \$50 million (20 percent of the overall \$240 million estimated payment increase). This overall \$240 million estimated increase, or 2.7 percent, includes the estimated impact of the final ESRD PPS market basket update of 1.9 percent (\$170 million), as well as the estimated changes in payments associated with several changes that are expected between CY 2026 and 2027. First, as outlined in section II.B.3.b. of this final rule, we estimate that outlier payments in CY 2026 will be approximately 2.6 percent

of total ESRD PPS payments. Accordingly, the increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.6 percent (\$140 million). At the same time, we estimate that approximately \$410 million will be paid through the TDAPA for DefenCath®, Vafseo®, and phosphate binders in CY 2026. The end of the TDAPA periods for these drugs is projected to result in a corresponding decrease to CY 2027 payments of (4.6 percent), which is offset by the final 4.4 percent increase to the ESRD PPS base rate for phosphate binders for a net decrease of \$40 million, and further offset by the estimated 2.9 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027 (\$260 million). The net difference between estimated CY 2026 TDAPA payments and estimated CY 2027 payments under the post-TDAPA add-on payment adjustment and the ESRD PPS base rate, including the final incorporation of phosphate binders, is therefore a 2.5 percent increase in payments to ESRD facilities ($1.044 \times 1.029 \times 0.954 = 1.025$) which equals approximately \$220 million (\$260 million – \$40 million = \$220 million). For CY 2027, we estimate total payments associated with the post-TDAPA add-on payment adjustment will be approximately \$290 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(c) to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products; § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies; and § 413.234(g) to establish the post-TDAPA add-on payment adjustment. The TDAPA, the TPNIES, and the post-TDAPA add-on payment adjustment are not budget neutral. As discussed in section II.D. of this final rule, there are no new or continuing TPNIES payments for CY 2027. As discussed in section II.E. of this final rule, there are no continuing TDAPA payments in CY 2027.

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

The impact table in section VII.C.5.c. of this final rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI for CY 2027 compared to estimated Medicare payments for such services in CY 2026. The overall impact of the CY 2027 changes is projected to be a 5.4 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities will have an estimated 5.2 percent increase in Medicare payments compared with

freestanding ESRD facilities that would have an estimated 5.4 percent increase. The overall impact reflects the effects of the final Medicare ESRD PPS payment rate update and the final CY 2027 ESRD PPS wage index and final labor related share of 63.5 percent. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2027 ESRD PPS base rate, will increase by approximately \$5 million in CY 2027 compared to CY 2026.

3. Impacts of the PY 2029 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing in this final rule, the overall economic impact of the PY 2029 ESRD QIP will be approximately \$133.2 million. The \$133.2 million estimate for PY 2029 includes \$114.5 million in costs associated with the collection of information requirements and approximately \$18.7 million in payment reductions across all facilities.

II. Calendar Year (CY) 2027 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

biologicals³ (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. Effective January 1, 2025, all oral-only renal dialysis drugs and biological products are paid for under the ESRD PPS.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies.

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and 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 dialysis (PD) or hemodialysis (HD) (§ 413.235(a) and (b)(1)).

The ESRD PPS provides four facility-level adjustments. The first payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The second payment adjustment, the low volume payment adjustment (LVPA), accounts for ESRD facilities furnishing a low volume of dialysis treatments, with two tiers such that smaller low-volume facilities receive a higher payment adjustment (§ 413.232). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233(a)). The fourth payment adjustment, the non-contiguous areas payment adjustment (NAPA), accounts for non-labor costs for ESRD facilities in certain non-contiguous areas of the U.S. (§ 413.233(b)).

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3)

³ As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term “biological products” instead of “biologicals” under the ESRD PPS to be consistent with FDA nomenclature. We use the term “biological products” in this final rule except when referencing specific language in the Act or regulations.

a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients for CYs 2024 through 2026 (§ 413.235(b)(2));⁴ and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, in a final rule that appeared in the November 24, 2025, 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” (90 FR 53068 through 53142), referred to herein as the “CY 2026 ESRD PPS final rule,” we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2026. This rule also finalized modifications to the eligibility timeframe for the TDAPA and established a new payment adjustment for ESRD facilities in certain non-contiguous areas, the NAPA. For further detailed information regarding the CY 2026 updates and policy changes, see 90 FR 53068.

B. Summary of the Provisions of the Proposed Rule, Public Comments, and Responses on the CY 2027 ESRD PPS Update

The proposed rule, titled “Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury

Dialysis (AKI) Payment, and ESRD Quality Incentive Program” (91 FR 38784–38875), referred to as the “CY 2027 ESRD PPS proposed rule,” appeared in the June 26, 2026, issue of the **Federal Register**, with a comment period that ended on August 24, 2026. In that proposed rule, we proposed to make several annual updates for CY 2027 including a routine proposal to rebase and revise the ESRD Bundled (ESRDB) market basket. This rule also proposed to modify the ESRD PPS base rate to reflect the incorporation of phosphate binders into the ESRD PPS bundled payment and to make budget neutral changes to certain ESRD PPS payment adjustments, including proposed changes to the case mix adjusters for pediatric ESRD patients, changes to the LVPA, and modifications to the TDAPA and post-TDAPA add-on payment adjustment. The proposed rule also included several requests for information to advance alternative dialysis care, in accordance with E.O. 13879, which were related to payment policy under the ESRD PPS (91 FR 38847 through 38855). The requests for information focused on advancing home dialysis, palliative care to ESRD beneficiaries nationwide, and potential changes to support alternative dialysis schedules.

We received 228 public comments on our proposals, 171 of which were unique comments. These included comments from patients, caregivers, health care providers, ESRD facilities, large dialysis organizations (LDOs), regional chain dialysis organizations, small dialysis organizations, non-profit healthcare organizations, professional organizations, advocacy groups, drug manufacturers, device manufacturers, and two coalitions of kidney care providers. We also received comments from interested parties and health care providers in the skilled nursing facility (SNF) and hospice industries.

We received several comments about ESRD PPS policies for which we did not propose any changes for CY 2027. These comments are briefly summarized in the following paragraphs; however, we are not addressing these comments in this final rule because they are not within the scope for the CY 2027 ESRD PPS proposed rule or final rule. We received approximately 54 timely pieces of correspondence from unique submitters which advocated for the removal of oral drugs which lower serum phosphate from the ESRD PPS bundled payment.

We also received comments that offered suggestions broadly related to improving quality of care for ESRD patients. Two professional organizations and an advocacy group encouraged CMS

to address ESRD facility staffing concerns. One urged CMS to invest in nursing education and raised safety concerns for home dialysis nurses. Similarly, two others called for CMS to address dietitian-to-patient staffing ratios, pointing to high rates of malnutrition among dialysis patients. Several patients and caregivers urged CMS to prioritize patient choice, shared decision-making, and outcomes that matter to patients, like fatigue, recovery time, and ability to work or travel. One professional organization added that therapy interventions improve daily function and quality of life for patients with chronic kidney disease. Industry commenters focused on payment mechanics requesting new payment categories or lengthening the TDAPA payment period with continued coverage for specific products. Comments from trade groups highlighted unique barriers facing rural patients or those in non-contiguous areas of the United States, requesting formal CMS review and payment adjustments to reflect higher operational costs for rural areas or the NAPA. One advocacy group raised concerns about limited transparency in Medicare Advantage (MA) plans covering ESRD beneficiaries, asking CMS to improve data collection on contracting, payment, and home dialysis/transplant referral rates. We also received comments which discussed the impact of ESRD PPS payment policies on MA payment rates. One professional organization requested CMS use “Physician Assistant/Physician Associate” dual terminology in regulatory language to reflect the profession’s evolving title, while another professional organization urged CMS to recognize the professional standard of care that can be provided by physician extenders in policy and regulation.

As we previously stated, we are not providing detailed responses to these comments as they are not within the scope of the CY 2027 ESRD PPS proposed rule or final rule. Nevertheless, we thank the commenters for their input and will consider their recommendations to potentially inform future rulemaking.

1. Rebasing and Revising of the ESRD Bundled (ESRDB) Market Basket; and CY 2027 Market Basket Percentage Increase, Productivity Adjustment, and Labor-Related Share (LRS)

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable

⁴ As the TPEAPA only applies for CYs 2024, 2025, and 2026, it will not apply for the CY 2027 payment year or future years.

Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year effective for CY 2012 (75 FR 49151 through 49162). We subsequently rebased and revised 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), and to a base year of CY 2016 in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964). In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67157), we finalized a rebased ESRDB input price index to reflect a CY 2020 base year. Effective for CY 2027, we proposed to rebase and revise the ESRDB market basket to a 2024 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.

The index itself is constructed in three steps. First, a base period is selected (in the proposed rule, we proposed to use 2024 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage

variable, referred to as a “price proxy.” In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

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

We last rebased the ESRDB market basket cost weights effective for CY 2023 (87 FR 67141 through 67157), with 2020 data used as the base period for the construction of the market basket cost weights. In the CY 2027 ESRD PPS proposed rule, we proposed to rebase the ESRDB market basket to reflect the 2024 cost structure for ESRD facilities and to revise applicable cost categories and price proxies used to determine the ESRDB market basket.

We refer to the market basket as a CY market basket because the base period for all price proxies and weights is set to CY 2024 (that is, the average index level for CY 2024 is equal to 100). The major source data for the ESRDB market basket is the 2024 Medicare cost reports (Form CMS-265–11, OMB No. 0938–0236), supplemented with 2022 data from the United States (U.S.) Census Bureau’s Services Annual Survey (SAS)

inflated to 2024 levels and the Bureau of Economic Analysis’s (BEA) 2017 Benchmark Input-Output (I–O) data, inflated to 2024. The 2022 SAS data and 2017 Benchmark I–O data are the most recent year of detailed cost data published by the Census Bureau and the BEA for North American Industry Classification System (NAICS) Code 6214: Outpatient Care Centers, which is the 4-digit industry code that Kidney Dialysis Centers are classified within. We also proposed to use the May 2024 OEWS data from BLS for NAICS 6214 to further disaggregate the Wages and Salaries and Employee Benefits cost weights into occupational categories. We provide more detail on our methodology in section II.B.1.b. of this final rule.

In the following section, we provide an overview of the ESRDB market basket, describe the methodologies for developing the cost weights, and provide information on the price proxies. Then, we present the proposed CY 2027 market basket update and labor-related share based on the 2024-based ESRDB market basket.

b. Rebasing and Revising of the ESRDB Market Basket

The terms “rebasing” and “revising,” while often used interchangeably, denote different activities. “Rebasing” means moving the base year for the structure of costs of an input price index (for example, in the proposed rule, we proposed to shift the base year cost structure from 2020 to 2024). “Revising” means changing data sources or price proxies used in the input price index. For CY 2027, we proposed to rebase the ESRDB market basket to reflect the 2024 cost structure of ESRD facilities and to revise the index, that is, make changes to cost categories or price proxies used in the index.

(1) Development of Cost Categories and Weights

(a) Use of Medicare Cost Report Data

The major source of cost data for developing the rebased and revised ESRDB market basket cost weights is the 2024 Medicare cost reports. The 2024 Medicare cost reports are for those freestanding ESRD facilities whose cost reporting period began on or after October 1, 2023, and before October 1, 2024 (approximately 95 percent of freestanding ESRD facilities had a begin date on January 1, 2024, approximately 4 percent had a begin date prior to January 1, 2024, and approximately 1 percent had a begin date after January 1, 2024). Using this methodology allowed our sample to include ESRD facilities

with varying cost report years including, but not limited to, the federal fiscal year (FY) or CY. We proposed to use 2024 as the base year because we believe that the 2024 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for ESRD facilities at the time of rulemaking. We proposed to maintain our policy of using data from freestanding ESRD facilities (which account for over 95 percent of total ESRD facilities in CY 2024) because freestanding ESRD facility data reflects only the cost structure faced by the ESRD facility itself. In contrast, cost data for hospital-based ESRD facilities reflect the allocation of overhead from the entire institution.

The current set of instructions and associated forms for the Medicare cost reports for ESRD facilities (Form 265–11, OMB No. 0938–0236) can be found in Chapter 42 of the Provider Reimbursement Manual at the following website (<https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021935>). We reviewed cost data from freestanding ESRD Medicare cost reports (CMS Form 265–11, OMB No. 0938–0236) for 2024 for each ESRD facility that reported costs and payments.

The major types of costs underlying the 2024-based ESRDB market basket are derived from the Medicare cost reports (Form 265–11, OMB No. 0938–0236). Specifically, we proposed to use the Medicare cost reports for eleven specific types of costs: Wages and Salaries; Employee Benefits; Pharmaceuticals (both Erythropoiesis Stimulating Agents (ESAs) and All Other Drugs in the ESRD PPS bundled payment); Supplies; Laboratories; Housekeeping; Operations & Maintenance; Capital-related: Buildings and Fixtures; Capital-related: Moveable Equipment; Professional Liability Insurance; and Administrative & Other. Total Costs are defined as the sum of the eleven cost categories and associated costs identified previously.

To create a market basket that is representative of ESRD facilities and to help ensure the major cost weights accurately reflect the percentage of total costs for furnishing ESRD treatment, we proposed to apply edits to remove reporting errors and outliers. Specifically, edits were applied to include only Medicare cost reports that had total costs greater than zero. Total costs as reported on the Medicare cost report include those costs reimbursable under the ESRD PPS. For example, we excluded costs related to vaccines from total expenditures since these are not

paid for under the ESRD PPS. Next, to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The resulting 2024 data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 6,514 independent ESRD facilities' cost reports from an available pool of 7,297 cost reports (roughly 89 percent of the universe). This sample of ESRD facilities is representative of the national universe of facilities by ownership-type (proprietary, nonprofit, and government) and by urban/rural status.

Since each cost weight is determined independently, that is, the 5 percent trim is applied to each cost category, the resulting weights may not sum to 100.0. We proposed normalizing the results proportionally so that the sum of each of the cost category weights will equal 100.0. A similar methodology was used to derive the major cost weights in the 2020-based ESRDB market basket.

We note that for the 2024 Medicare cost reports, a discrepancy was found with most Medicare cost reports submitted by a major large dialysis organization (LDO) where Medicare cost report field designating the ESRD facility as a chain was completed incorrectly. Worksheet S, Part II, column 1, line 19 states "Are you part of a chain organization? Enter "Y" for yes or "N" for no. If yes, complete lines 20 through 22." Many of these ESRD facilities entered "N"; however, they provided the location of the chain organization in lines Worksheet S, Part II, lines 20 through 22, indicating that the correct response to line 19 should have been "Y". (We note that these ESRD facilities had also indicated being part of a chain organization in their prior year's cost report.) This led to reporting of Administrative & Other net expenses that was inconsistent with the chain designation. Worksheet A–3 provides for the computation of any needed adjustments to costs applicable to services, facilities, and supplies furnished to the ESRD facility by a related organization (by common ownership or control). This worksheet is potentially completed when an ESRD facility answers "Y" to Worksheet S, Part II. These adjustments to costs are transferred to Worksheet A, column 7 (to be reflected in Worksheet A, column 8) and, therefore, would then be

reflected in the Administrative & Other net expenses.

To correct this misreporting, we first checked if the value reported on Worksheet A–3, Part B, column 1, line 1 was missing or 0, and whether the value reported on Worksheet A–3, Part B, column 6, line 1 was greater than zero. If these conditions were satisfied, we added the dollar (\$) value of the related organization adjustment (Worksheet A–3, Part B, column 6, line 1) to the Administrative & Other cost center net expenses reported on Worksheet B, column 9, line 8.01. For any ESRD facility that didn't have a discrepancy, no adjustment was required to the Administrative & Other net expenses.

(i) Wages and Salaries Costs

We proposed to determine Wages and Salaries costs as the sum of (1) direct patient care wages and salaries costs and (2) non-direct patient care wages and salaries costs. Direct patient care wages and salaries for 2024 are equal to the sum of costs from Worksheet B, column 4.01 (salaries for dialysis equipment technicians) and column 5 (direct patient care salaries), lines 8.01 through 17.03 (reimbursable cost centers) of the Medicare cost reports. Non-direct patient care wages and salaries are equal to the sum of all other wages and salaries costs for non-health workers, which we proposed to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the Medicare cost reports. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct groups of cost centers: 'Operations & Maintenance of Plant' combined with 'Capital Related Costs—Renal Dialysis Equipment' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9 and 9.01), Laboratory (line 10), Administrative & General (line 11), and Drugs (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total net costs for each corresponding reimbursable cost center as reported on Worksheet B. The Worksheet B totals are based on the sum of reimbursable costs reported on lines 8.01 through 17.03. For example, the salary percentage for Supplies (as measured by line 9 and 9.01 on Worksheet A) was applied to the total net costs for the

Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8.01 through 17.03). We complete this calculation for each of the seven groups of cost centers listed in step 1.

Step 3: The estimated wages and salaries for each of the non-direct patient cost centers in step 2 were summed and then added to the direct patient care wages and salaries costs to calculate total Wages and Salaries costs.

(ii) Employee Benefits Costs

We proposed to determine the Employee Benefits costs as the sum of direct patient care EH&W benefits (which we will refer to as direct patient care employee benefit costs) and estimated non-direct patient care employee benefit costs. Direct patient care employee benefit costs are reported on Worksheet B, column 6, lines 8.01 through 17.03 of the Medicare cost reports. Non-direct patient care employee benefit costs are not reported separately but are included in Worksheet A, column 3 (“Other”). We proposed to derive the non-direct patient care benefit costs using the following steps:

Step 1: We calculate the ratio of direct patient care employee benefit costs to direct patient care salaries for each ESRD facility. This ratio is calculated as direct patient care employee benefit costs (Worksheet B, column 6, lines 8.01 through 17.03) divided by the direct patient care wages and salaries costs (Worksheet B, columns 4.01 and 5, lines 8.01 through 17.03).

Step 2: We estimate total salaries for all non-direct patient care cost centers except Administrative & Other. This would be the sum of direct patient care salaries plus estimated salaries for the non-direct patient care cost centers: EH&W benefits, pharmaceuticals, supplies, laboratory, housekeeping, and operation and maintenance of plant and equipment.

Step 3: To determine estimated non-direct patient care employee benefit costs for all cost centers other than Administrative & Other we multiply the costs from step 2 by the ratio determined in step 1.

Step 4: To calculate the employee benefit costs for Administrative & Other cost centers, we first estimate adjusted Administrative & Other costs by subtracting Professional Liability Insurance costs, estimated employee benefits costs for all workers except those associated with the Administrative & Other cost center (as derived in step 3), and Administrative & Other costs associated with Non-ESRD related costs or costs that are paid outside the ESRD PPS bundled payment

(Worksheet B, column 9, lines 5 through 7).

Step 5: We estimate the adjusted Administrative & Other salary costs by multiplying the salary percentage for Administrative & Other cost centers (calculated in step 1 of the wages and salaries section) by the adjusted Administrative & Other costs calculated in step 4 of this section.

Step 6: Total salaries are calculated by summing up the salary costs associated with the non-direct patient care cost centers (derived in step 2) and the adjusted Administrative & Other salary costs (derived in step 5).

Step 7: To determine employee benefits costs for all employees, we multiply the total salaries (calculated in step 6) by the ratio of direct patient care benefits to direct patient care salaries (calculated in step 1).

We note that the proposed methodology for deriving total employee benefits costs from the Medicare cost report differs from the methodology we have used in prior ESRDB market baskets. Previously, we derived the Employee Benefits cost weight from Medicare cost report data for direct patient care employee benefits and supplemented with data from the 2012 U.S. Census Bureau’s Services Annual Survey (SAS) for NAICS 621492, Kidney Dialysis Centers, which were inflated to the applicable base year (for example 2020) to account for non-direct patient care employee benefits. The U.S. Census Bureau discontinued publication of the SAS data for NAICS 621492 beginning in 2012 and discontinued publication of the SAS effective after the 2022 data release. For years between 2012 and 2022, the SAS data was only available at the four-digit NAICS level of detail, and we therefore continued to rely on the inflated 2012 data. We believe the proposed methodology is a technical improvement to the prior methodology used to derive the non-direct patient care employee benefits because it relies on more recent Medicare cost report data that are specific to ESRD facilities.

(iii) Pharmaceuticals Costs

The 2024-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and all other renal dialysis drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We proposed to determine the pharmaceuticals costs using data reported on Worksheet B; specifically, the sum of lines 8.01 through 17.03, for the following columns: column 11, “Drugs Included in Composite Rate,” column 12,

“Erythropoiesis stimulating agents (ESAs)” and column 13, “ESRD-Related and AKI-Related Drugs.” We did not include the drug costs for Non-ESRD Related Drugs, Supplies, and Labs as reported on line 5, column 10 or the AKI Non-Renal Related Drugs, Supplies, & Lab as reported on line 5.01 column 10 as these costs are not included in the ESRD PPS bundled payment amount. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, COVID-19, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the vaccine. Since these vaccines are not paid for under the ESRD PPS, we did not include costs reported on Worksheet B, column 9, line 7 in the 2024-based ESRDB market basket. Finally, to avoid double-counting, the pharmaceuticals costs are reduced by the estimated share of non-direct patient care wages and salaries associated with the applicable drug cost centers referenced previously. This results in a 2024-based ESRDB market basket cost weight for Pharmaceuticals of 5.3 percent, with ESA costs accounting for 3.0 percentage points and All Other Drugs accounting for the remaining 2.3 percentage points.

(iv) Supplies Costs

We calculate the Supplies costs using the costs reported in the Supplies cost center (Worksheet B, column 7, lines 8.01 through 17.03) of the Medicare cost report. To avoid double-counting, the Supplies costs are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(v) Laboratory Costs

We calculate the Laboratory costs using the costs reported in the Laboratory cost center (Worksheet B, column 8, lines 8.01 through 17.03) of the Medicare cost report. To avoid double-counting, the Laboratory costs are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

The Medicare cost report data include reported costs for Housekeeping, Operations & Maintenance, Capital-related: Buildings and Fixtures, and Capital-related: Moveable Equipment in a single cost center. We estimated the net costs for each of these four categories using the following steps.

Step 1: We calculate the total net costs for Housekeeping, Operations & Maintenance, and Capital-related as the sum of costs reported on Worksheet B, column 3, lines 8.01 through 17.03).

Step 2: For each of the four subcategories, we estimate the share of the total costs of each subcategory as follows:

- The Housekeeping share is determined based on the total costs for Housekeeping reported on Worksheet A, column 4, line 4 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- The Operations & Maintenance share is determined based on the total costs for Operations & Maintenance costs reported on Worksheet A, column 4, line 3 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- *The Capital-related: Buildings and Fixtures* share is determined based on the total costs for Capital-related buildings and fixtures reported on Worksheet A, column 4, line 1 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.
- *The Capital-related: Moveable Equipment* share is determined based on the total costs for Capital-related moveable equipment reported on Worksheet A, column 4, line 2 divided by the total costs for all four subcategories reported on Worksheet A, column 4, line 5.

(vi) Housekeeping Costs

The Housekeeping costs are estimated by multiplying the housekeeping share determined in step 2 by the total net costs calculated in step 1. To avoid double-counting, the costs for the Housekeeping category are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(vii) Operations & Maintenance Costs

The Operations & Maintenance costs are estimated by multiplying the operations & maintenance share determined in step 2 by the total net costs calculated in step 1. The operations & maintenance costs include the direct costs incurred in the operation and maintenance of the plant and equipment such as heat, light, water (excluding water treatment for dialysis purposes), air conditioning, and air treatment; the maintenance and repair of buildings, parking facilities, and equipment; painting; elevator maintenance; performance of minor renovation of buildings and equipment; and protecting employees, visitors, and facility property. To avoid double counting, the costs for the Operations & Maintenance category are reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(viii) Capital-Related: Buildings and Fixtures Costs

The Capital-related: Buildings and Fixtures costs are estimated by multiplying the capital-related buildings and fixtures share from step 2 by the total net costs calculated in step 1. The capital-related buildings and fixtures costs include depreciation and lease costs for buildings and fixtures, property taxes, insurance costs, and capital improvements.

(ix) Capital-Related: Moveable Equipment Costs

The Capital-related: Moveable Equipment costs are estimated by multiplying the capital-related moveable equipment share from step 2 by the total net costs calculated in step 1. The capital-related moveable equipment costs include depreciation and lease costs for moveable equipment, property taxes, insurance costs, and capital improvements. Next, we sum the costs for capital-related moveable equipment to the Capital-related Renal Dialysis Equipment costs (Worksheet B, column 4, lines 8.01 through 17.03). We believe this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with buildings and fixtures could move differently than those associated with moveable equipment, we continue to believe that two capital-related cost categories are appropriate.

(x) Professional Liability Insurance Costs

We proposed for the 2024-based ESRDB market basket to have a separate category for professional liability insurance (PLI) costs (often referred to as malpractice costs). The PLI costs are equal to the sum of premiums, paid losses, and self-insurance costs reported on Worksheet S, Part II, column 1, lines 15 through 17. For the 2020-based ESRDB market basket we did not create a separate cost category and the PLI costs were included with the Administrative & Other costs.

(xi) Administrative & Other Costs

We proposed to compute the proportion of total Administrative & Other costs using the Administrative & Other cost center data from Worksheet B, the sum of column 9, lines 8.01 through 17.03, less PLI costs and other costs reported in this cost center but paid separately from the ESRDB PPS, which include Non-ESRD Related Drugs, Supplies, & Lab (line 5); AKI Non-renal Related Drugs, Supplies, & Labs (line 5.01); Whole Blood and Packed Red Blood cells (line 6); and

Vaccines (line 7). To avoid double-counting, the costs for the Administrative & Other category are also reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center and the estimated non-direct patient care employee benefits costs.

(b) Final Major Cost Category Computation

After deriving the costs for the major cost categories for each ESRD facility using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps.

First, for each of the major cost weights, we proposed to trim the data to remove outliers (a standard statistical process) by: (step 1) requiring that major costs (such as Wages and Salaries costs) and total costs be greater than zero; (step 2) dividing the costs for each of the eleven categories (calculated as previously described in this section) by total costs to obtain cost weights for each ESRD facility; and (step 3) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2020-based ESRDB market basket.

After the outliers are removed, we sum the costs for each category across all remaining ESRD facilities. We then divide this by the sum of total costs across all remaining ESRD facilities to obtain a cost weight for the 2024-based ESRDB market basket for the given category. This is the same methodology used for the 2020-based ESRDB market basket.

The trimming process is done individually for each cost category so that ESRD facilities excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these trimming methods are the same types of edits performed for the 2020-based ESRDB market basket, as well as other PPS market baskets (including but not limited to Inpatient Prospective Payment System (IPPS) operating market basket, Skilled Nursing Facility (SNF) market basket, and home health market basket). We note that for each of the cost weights, we evaluate the distribution of facilities and costs by ownership-type, and by urban/rural status. For all cost weights, the trimmed sample is nationally representative.

Table 2 presents the 2024-based ESRDB market basket major cost weights as derived directly from the

Medicare cost report data compared to the 2020-based ESRDB market basket

major costs weights derived directly from the Medicare cost report data.

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TABLE 2: ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

	2024	2020	Difference between 2024 weight and 2020 weight
Wages and Salaries	37.4	34.5	2.9
Employee Benefits*	11.3	7.7	3.6
Pharmaceuticals	5.3	10.1	-4.8
ESAs	3.0	6.0	-3.0
All Other Drugs	2.3	4.1	-1.8
Supplies	10.4	11.0	-0.6
Laboratories	1.3	1.3	0.0
Housekeeping	0.5	0.5	0.0
Operations & Maintenance	4.2	3.7	0.5
Capital-related: Buildings and Fixtures	9.0	9.4	-0.4
Capital-related: Moveable Equipment	3.4	4.4	-1.0
Professional Liability Insurance	0.4	n/a	n/a
Administrative & Other	16.8	17.5	-0.7
	100.0	100.0	0.0

Note: Totals may not sum to 100.0 due to rounding.

*The 2020 employee benefits weight, based only on Medicare cost report data, reflects direct-patient care employee benefits costs only while the 2024 employee benefits weight reflects all employee benefits costs.

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From 2020 to 2024, the Wages and Salaries and Employee Benefits cost weights increased by 2.9 percentage points and 3.6 percentage points, respectively. The increase in the 2024-based Wages and Salaries and Employee Benefits cost weights is the result of faster growth in labor costs compared to costs associated with the other market basket cost weights (such as Pharmaceutical costs). This faster growth is consistent with comments received during prior ESRD PPS rulemaking. The Pharmaceuticals cost weight as calculated directly from the Medicare cost reports decreased by 4.8 percentage points, which continues the downward trend in the Pharmaceuticals cost weight observed since the

implementation of the ESRD PPS in 2011. We believe this falling Pharmaceuticals cost weight is attributable to three main inter-related factors: (1) reduced utilization per treatment of certain high-cost drug classes (such as ESAs), (2) a shift to more price-competitive products, including generic drugs or biosimilars, and (3) facility-level cost management and efficiency.

(c) Derivation of the Detailed Cost Weights

There are three instances where the ESRDB market basket costs weights are further adjusted using secondary data sources. The first adjustment is to estimate contract labor costs, which would be reflected in the

Administrative & Other cost weight of 16.8 percent shown in Table 2 derived from the Medicare cost report data. We proposed to estimate the contract labor share of costs and reallocate those from Administrative & Other to Wages and Salaries and Employee Benefits. The second adjustment further disaggregates the Wages and Salaries and Employee Benefits weight, inclusive of contract labor costs, into occupational subcategories. The third adjustment is to further disaggregate the remaining Administrative & Other cost weight (less the contract labor cost weight) into further detail using data from the BEA Benchmark I-O data.

(i) Contract Labor Costs

Contract labor costs are reported in the Medicare cost report; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disaggregated. We proposed the following methodology to derive the contract labor cost weight. Similar to the methodology used in the 2020-based ESRDB market basket, we proposed to use data from the U.S. Census Bureau’s Services Annual Survey (SAS) to estimate these costs for the 2024-based ESRDB market basket. We proposed to use data from the 2022 SAS for NAICS 6214, Outpatient Care Centers, inflated to 2024 to estimate the contract labor weight for the 2024-based ESRDB market basket. Previously, we used the 2012 SAS data for NAICS 621492, Kidney Dialysis Centers inflated to the applicable base year. Since 2012 the SAS data is no longer available from the Census Bureau at the 6-digit NAICS level of detail, we believe our proposal to use the data for NAICS 6214 is a technically appropriate alternative as

ESRD facilities would be included within this NAICS category and the data reflects the more recent experience of this industry’s contract labor usage. We proposed to use the share of the total costs for NAICS 6214 expenses for Temporary staff and leased employee expense from the 2022 SAS. Using this data, the 2024-based ESRDB Contract Labor cost weight is 2.1 percent. To avoid double counting these costs, we proposed to remove the 2.1 percent Contract Labor cost weight from the Administrative & Other cost weight (where we believe most contract labor costs would be reported). The resulting Administrative & Other Residual Cost weight is 14.7 percent, which reflects the 16.8 percent Administrative & Other cost weight from Medicare cost reports less the 2.1 percent Contract Labor cost weight. As we did for the 2020-based ESRDB market basket (87 FR 67143), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract

labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2024 Medicare cost report data, this percentage is 77 percent. Therefore, we proposed to allocate 77 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 23 percent to the Employee Benefits cost weight. The 2020-based ESRDB market basket allocated 80 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 20 percent to the Employee Benefits cost weight. Table 3 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2020-based ESRDB market basket and the 2024-based ESRDB market basket. In aggregate, the Compensation cost weight (calculated using more detailed decimal places) increased from 45.9 percent to 50.9 percent, or 5.0 percentage points.

TABLE 3: Wages and Salaries and Employee Benefits Cost Weights after Contract Labor Allocation

Major Cost Categories	2024-Based ESRDB Market Basket	2020-Based ESRDB Market Basket
Total Compensation	50.9	45.9
Wages and Salaries	39.0	36.5
Employee Benefits	11.9	9.5

Note: Detail may not add to total due to rounding.

(ii) Disaggregation of Compensation Costs Into Occupational Categories

To further disaggregate the “Wages and Salaries” and “Employee Benefits” cost weights into four occupational subgroups (Health-Related, Management, Administrative, and Service), we proposed to use the number of full time equivalents (FTEs) reported on Worksheet S–1, column 3, lines 22 through 35 of the Medicare cost reports and annual mean wages for the occupations within each group from the May 2024 BLS OEWS for NAICS 6214, Outpatient Care Centers.⁵

The ESRD Medicare cost report FTE categories assigned to the Health-Related subgroup include “Physicians,” “Registered Nurses,” “Licensed Practical Nurses,” “Nurses Aides,” “Technicians,” and “Dieticians”; assigned to the Management subgroup is “Management”; assigned to the Administrative subgroup is “Administrative”; and assigned to the Services subgroup are “Social Workers” and “Other”. For each FTE category, we estimate the mean annual wage from the May 2024 BLS OEWS data. We multiply the number of ESRD FTEs in each subgroup by the estimated mean annual

wage. Table 4 shows the share of each FTE group’s compensation (number of FTEs multiplied by the mean annual wage) to total compensation for the 2024-based ESRD market basket and the 2020-based ESRDB market basket. Table 5 shows the Wages and Salaries and Employee Benefits occupational mix for the 2024-based ESRDB market basket compared to the 2020-based occupational mix. The 2024 occupational distribution shows a shift to more health-related FTEs and fewer Management and Administrative Support Occupation FTEs.

⁵ <https://www.bls.gov/oes/>.

TABLE 4: Share of ESRD Compensation by Occupation

Subgroup	Occupation	2024	2020
Health-Related	Physicians and Surgeons	1.5%	3.9%
Health-Related	Registered Nurses	37.9%	36.3%
Health-Related	Licensed Practical and Licensed Vocational Nurses	2.2%	3.2%
Health-Related	Nursing Assistants	1.8%	1.1%
Health-Related	Health Technologists and Technicians, All Other	34.6%	30.9%
Services	Healthcare Social Workers	4.3%	4.0%
Health-Related	Dietitians and Nutritionists	4.4%	4.0%
Administrative	Office and Administrative Support Occupations	4.8%	5.3%
Management	Medical and Health Services Managers	6.1%	9.0%
Services	Healthcare Support Workers, All Other	2.4%	2.3%

TABLE 5: Wages and Salaries and Employee Benefits Occupational Mix (%)

	2024	2020
Health-Related	82.4	79.4
Management	6.1	9.0
Administrative	4.8	5.3
Services	6.7	6.3

We proposed to multiply the occupational mix weights by the Wages and Salaries cost weight and the Employee Benefits cost weight (both inclusive of contract labor) to determine the occupational subgroups' weights for Wages and Salaries and Employee Benefits as shown in Table 6. This is similar to the methodology used in the 2020-based ESRDB market basket to derive these occupational subgroup weights.

(iii) Disaggregation of Administrative & Other Residual Cost Weight

To further divide the “Administrative & Other” residual cost weight estimated from the 2024 Medicare cost report data into more detailed cost categories, we proposed to use the 2017 Benchmark I–O “The Use of Commodities by Industries, Before Redefinitions (Producers' Prices)—Detail” for NAICS 621400, Outpatient care Centers,

published by the BEA.⁶ The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is

⁶ Source: 2017 Benchmark Input-Output “Use of Commodities by Industries, Before Redefinitions (Producers' Prices)—Detail,” NAICS 621400 (Outpatient Care Centers), published by the U.S. Bureau of Economic Analysis (BEA). Available at https://apps.bea.gov/iTable/?reqid=1602&step=2&Categories=Core&isURI=1&gl=1*4ozlmu*ga*MTczMzgWnZcyNC4xNzYxNTk4OTIx*_ga_J4698JNNFT*cze3OTIwMDY0NzMkbzI0JGcxJHQxNzkyMDA3MTkwJGo1MiRsMCRoMA..#eyJhcHBpZCI6MTYwMiwic3RlcHMlOlsxLDIsM10sImRhGEiOltbImNhdGVnb3p3pZXMlLCJDb3JlI0sWYjUYWJsZV9MaXNOIiwVXNlQlJQcm8iXV19.

produced and distributed.⁷ BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the detailed 2017 Benchmark I–O data forward to 2024 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data and calculate the cost shares that each cost category represents using the inflated data. These resulting 2024 cost shares from this I–O based approach are applied to the “Administrative & Other” cost weight to obtain the detailed cost weights for the 2024-based ESRDB market basket. For example, the cost for

⁷ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

Paper & Printing represents 3.9 percent of the sum of the residual “All Other” 2017 Benchmark I–O Outpatient Care Center expenditures inflated to 2024. Therefore, the Paper & Printing cost weight represents 3.9 percent of the 2024-based ESRDB market basket’s “Administrative & Other” cost category (14.7 percent), yielding a Paper & Printing cost weight of 0.6 percent in the 2024-based ESRDB market basket ($3.9 \text{ percent} \times 14.7 \text{ percent} = 0.6 \text{ percent}$). For the 2020-based ESRDB market basket (87 FR 67145), we used a different data source to disaggregate the Administrative & Other residual cost weight. The prior method used data from the 2012 U.S. Census Bureau’s SAS for NAICS 621492, inflated to the 2020 base year of the ESRDB market basket. As mentioned previously, this data is no longer produced or published by the Census Bureau and, therefore we proposed to use an alternative data source.

Using this methodology, we proposed to derive 12 detailed cost categories from the 2024-based ESRDB market basket Administrative & Other cost

weight of 14.7 percent. These categories are: (1) Electricity; (2) Natural Gas; (3) Rubber & Plastics; (4) Paper & Printing; (5) Miscellaneous Products; (6) Telephone and Internet Service; (7) Administrative Services; (8) Financial Services; (9) Professional Fees: Labor-related; (10) Professional Fees: Nonlabor-related; (11) All Other Services: Labor-related; (12) All Other Services: Nonlabor-related.

We noted that the cost category for Professional Fees: Labor-related reflects the proportion of ESRD facilities’ professional fees expenses that we believe vary with local labor market. We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms, and 13 percent are

purchased from businesses located outside of the ESRD’s local labor market. Thus, to derive the Professional Fees: Labor-related weight we proposed to allocate 87 percent of the expenses for Professional Fees for these selected services as labor-related; we note that 87 percent is the same percentage as used in prior years.

This methodology allows for seven additional detailed cost categories than used in the 2020-based ESRDB market basket because the Benchmark I–O data is more comprehensive than the SAS data. The 2020-based ESRDB market basket included categories for Electricity, Natural Gas, Telephone, Professional Fees, and All Other Goods and Services.

Table 6 sets forth the 2024-based ESRDB market basket, including the cost categories and their respective cost weights. For comparison purposes, the corresponding 2020-based ESRDB market basket cost weights also are listed.

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TABLE 6: Comparison of the 2024-based and the 2020-based ESRDB Market Basket Cost Categories and Weights (%)

Cost Category	2024-based ESRDB Market Basket Cost Weight	2020-based ESRDB Market Basket Cost Weight
Total - ESRDB	100.0	100.0
Compensation	50.9	45.9
Wages and Salaries ¹	39.0	36.5
Health-Related Wages and Salaries	32.1	28.9
Management Wages and Salaries	2.4	3.3
Administrative Wages and Salaries	1.9	1.9
Service Wages and Salaries	2.6	2.3
Employee Benefits ¹	11.9	9.5
Health-Related Benefits	9.8	7.5
Management Benefits	0.7	0.9
Administrative Benefits	0.6	0.5
Service Benefits	0.8	0.6
Utilities	1.1	1.4
Electricity	1.0	1.2
Natural Gas	0.1	0.1
Medical Materials and Supplies	16.9	22.4
Pharmaceuticals	5.3	10.1
ESAs	3.0	6.0
All Other Drugs	2.3	4.1
Supplies	10.4	11.0
Laboratories	1.3	1.3
All Other Goods	1.4	n/a
Paper & Printing	0.6	n/a
Rubber & Plastics	0.4	n/a
Miscellaneous Products	0.4	n/a
All Other Services	17.3	16.6
Telephone and Internet Service	0.9	0.5
Housekeeping	0.5	0.5
Operations & Maintenance	4.2	3.7
Administrative Services	0.3	n/a

Cost Category	2024-based ESRDB Market Basket Cost Weight	2020-based ESRDB Market Basket Cost Weight
Financial Services	1.2	n/a
Professional Fees: Labor-related	2.7	0.8
Professional Fees: Nonlabor-related	0.4	n/a
All Other Services: Labor-related	0.7	n/a
All Other Services: Nonlabor-related	6.0	11.1
Professional Liability Insurance	0.4	n/a
Capital Costs	12.4	13.8
Capital-related: Buildings and Fixtures	9.0	9.4
Capital-related: Moveable Equipment	3.4	4.4

Note: The cost weights are calculated using 3 decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

¹ Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

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We received public comments on the proposed methodology for deriving the cost weights of the 2024-based ESRDB market basket. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS's proposal to rebase and revise the ESRDB market basket from a 2020 base year to a 2024 base year, describing this as a routine and methodologically sound update that will better reflect current labor and input costs. However, several commenters noted concerns with the timing of this rebasing relative to the addition of oral-only phosphate binders to the ESRD PPS bundled payment, which they noted did not occur until CY 2025. A few commenters stated that because the 2024 cost report data pre-dates this bundling change, that the resulting cost weights do not reflect the current cost structure created by the phosphate-binder addition in 2027, which would have an impact on the resulting market basket cost weights, and ultimately the labor-related share. The commenters stated that the lack of inclusion of the phosphate binder drug costs results in a lower drug cost weight and higher weights for other cost categories, particularly categories that feed into the labor-related share. A couple of commenters requested the market basket rebasing to be delayed, while another commenter suggested conducting a supplemental revaluation using 2025 data once available. A

commenter disagreed with a delay, arguing that more current data would not be sufficiently complete or validated in time for the CY 2027 final rule.

Response: We appreciate the commenters' support of rebasing and revising the ESRDB market basket to a 2024 base year, consistent with our longstanding practice of periodically rebasing CMS market baskets as more current and complete cost report data become available. We recognize commenters' concern that the 2024 cost report data predate the CY 2025 inclusion of oral-only phosphate binders in the ESRD PPS bundled payment, and that there could be factors that have impacted costs in subsequent years. However, rebasing on a cyclical schedule using the most recently available complete data (which at the time of this rulemaking was CY 2024) is necessary to ensure the market basket is more reflective of ESRD cost structures than the 2020-based ESRDB market basket. We will continue to monitor the cost share weights for potential effects from the incorporation of phosphate binders into the ESRD PPS bundled payment and, if technically appropriate, consider updating the ESRD market basket weights at such time.

Final Rule Action: After consideration of the public comments we received, we are finalizing the methodology for deriving the cost weights of the 2024-based ESRDB market basket as proposed without modification.

(2) Price Proxies for the 2024-Based ESRDB Market Basket

After computing the 2024-based cost weights for the ESRDB market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. Except for the proxy for professional liability insurance (PLI), all price proxies are based on BLS data and are grouped into one of the following BLS categories:

- **Producer Price Indexes—**Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (<https://www.bls.gov/ppi/>).

- **Consumer Price Indexes—**Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (<https://www.bls.gov/cpi/>). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

- **Employment Cost Indexes—**Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly

Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

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

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

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

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

- **Relevance.** Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe the PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best proxy of price changes for the cost categories to which they would be applied.

In the CY 2027 ESRD PPS proposed rule, we presented a detailed explanation of the price proxies that we proposed for each cost category weight.

(a) Health-Related Wages and Salaries

We proposed to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (Hospitals and Health Care and Social Assistance), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62). This is the same price proxy used in the 2020-based ESRDB market basket.

(b) Management Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities. This is the same price proxy used in the 2020-based ESRDB market basket.

(c) Administrative Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities. This is the same price proxy used in the 2020-based ESRDB market basket.

(d) Services Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

BLS does not publish ECI for Benefits price proxies for each wages and salaries ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index. Therefore, we proposed to use these derived ECI benefit price proxies for each of the respective occupational benefit cost categories.

(e) Health-Related Benefits

We proposed to use the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU1016220000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. We believe this constructed ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(f) Management Benefits

We proposed to use the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(g) Administrative Benefits

We proposed to use the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. We believe this constructed ECI series is technically appropriate for the reasons stated in the wages and salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(h) Services Benefits

We proposed to use the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reasons stated in the Wages and Salaries price proxy section. This is the same price proxy used in the 2020-based ESRDB market basket.

(i) Electricity

We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(j) Natural Gas

We proposed to use the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(k) ESAs

We proposed to use the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI-BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI-BPHU measures the price change of prescription biological products, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs and biological products included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI-BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI-BPHU. We did this by comparing the historical price changes in the PPI-BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the 2020 to 2024 timeframe. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI-BPHU is still an appropriate price proxy.

(l) All Other Drugs:

For all other drugs included in the ESRD PPS bundled payment other than ESAs, we proposed to use a blend of 47 percent of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI-VNHP) (BLS series code #WPU063807), and 53 percent of the PPI Commodity for Pharmaceuticals for Human Use, Prescription (which we will abbreviate as PPI-Pharmaceuticals) (BLS series code #WPUSI07003). We continue to believe that the PPI-VNHP is an appropriate price proxy for the iron supplements commonly used in the

treatment of ESRD, and an analysis of claims data indicate that iron supplement costs and Vitamin D analogs account for about 47 percent of the All Other Drugs costs. For the remaining drugs represented in the All Other Drugs category we proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription, which captures the inflationary price pressures for all types of prescription drugs rather than a single therapeutic category of drugs. Though this PPI measure includes a wide variety of prescription drugs, we believe it is technically appropriate to use a broad indicator of prescription drug price trends for three key reasons: (1) the more detailed PPI measure where we believe these types of non-ESA drugs would be captured would more likely reflect price trends not faced by ESRD facilities, such as cancer drugs, (2) there have been notable changes to the types and mix of drugs paid for under the ESRD PPS bundled payment since 2016, such as the inclusion of formerly oral-only drugs and the addition of AKI-related drugs, and (3) the potential for future changes to the types and mix of drugs that may be paid for under the ESRD PPS bundled payment. For these reasons, we believe that a broader drug index representing a larger mix of prescription drugs is technically appropriate to the price proxy for this cost category. We will continue to monitor the relative share of costs for iron supplements and other types of drugs for this cost category to determine if the 47/53 PPI blend warrants an adjustment, and if so, we would propose such an adjustment in future rulemaking. This is similar to the price proxy used in the 2020-based ESRDB market basket, but the composite weight was 50/50.

(m) Supplies

We proposed to use the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

We believe this is a technically appropriate price proxy for this cost category. The Medicare cost report form instructions state that Supplies include the direct cost of total dialysis supplies used in furnishing dialysis services—for example, crit-lines, low volume lines and dialyzers, catheter kits, fistula needles and tape, saline flushes, bandages, chlorhexidine, tego caps for catheters, biopatch for catheter dressing, oxygen, suction, emergency supplies, monitors for vitals, and blood pressure

cuffs. We requested comments on other price indexes that could be applicable to the costs reported in this category, as the instructions may not contain the exhaustive list of supply costs that ESRD facilities include in this category. Examples of potential other price proxies would include, but are not limited to, the PPI Commodity for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI Commodity for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571).

(n) Laboratories

We proposed to use the PPI Industry for Medical and Diagnostic Laboratories (BLS series code #PCU62156215) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(o) Paper & Printing

We proposed to use a 25/75 blend of the PPI Commodity for Publications Printed Matter and Printing Material (BLS Series Code WPU094) and the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to proxy the price growth of this cost category. The 2017 Benchmark I-O data shows that 25 percent of paper and printing costs are for Printing (NAICS 323110) and the remaining costs are for Paper manufacturing (NAICS 322). The 2020-based ESRDB market basket did not have a separate cost category for paper and printing. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(p) Rubber & Plastics

We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for Rubber & Plastics. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(q) Miscellaneous Products

We proposed to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to proxy the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket as these costs

were included in the All Other Goods and Services cost category.

(r) Telephone and Internet Service

We proposed to use the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(s) Housekeeping

We proposed to use the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(t) Operations & Maintenance

We proposed to use the ECI for Total compensation for All Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

(u) Administrative Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to proxy the price growth of this category. The 2020-based ESRDB market basket did not have a separate cost category for Administrative Services. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(v) Financial Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for Financial Services. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less foods and energy.

(w) Professional Fees: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry

Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket; however, the 2012 SAS data did not provide enough detailed information to split the Professional Fees category between labor-related and nonlabor-related services.

(x) Professional Fees: Nonlabor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket; however, the 2012 SAS data did not provide enough detailed information to split the professional fees category between labor-related and nonlabor-related services.

(y) All Other Services: Labor-Related

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to proxy the price growth of this cost category. The 2020-based ESRDB market basket did not have a separate cost category for All Other Services: Labor-related. These costs would have been included in the All Other Goods and Services cost category and proxied by the PPI—Final demand—Finished goods less food and energy.

(z) All Other Services: Nonlabor-Related

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to proxy the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are not included in the ESRD PPS (food) or are already captured elsewhere in the market basket (energy). This is the same price proxy used in other CMS market baskets, such as the IPPS, SNF, Long-term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), and Inpatient Psychiatric Facility (IPF), to proxy the growth in the remaining “All Other Services” cost category. The 2020-based ESRDB market basket did not have a separate cost category for All Other Services: Nonlabor-related, these costs would have been included in the All Other Goods and Services cost category and

proxied by the PPI—Final demand—Finished goods less food and energy.

(aa) Professional Liability Insurance

Unlike the other price proxies that are based on publicly available price indexes from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. We proposed to use the CMS Physician PLI index to measure the price growth of this cost category in the 2024-based ESRDB market basket. This is the same proxy used in the Medicare Economic Index (MEI) and the Home Health market basket. As detailed in the CY 2014 Physician Fee Schedule (PFS) final rule (78 FR 74271), a 2012 MEI Technical Panel expressed that the current index appropriately reflects the price changes in premiums throughout the industry.

(ab) Capital-Related: Buildings and Fixtures

We proposed to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the 2024-based ESRDB market basket. This is the same proxy used in the 2020-based ESRDB market basket.

(ac) Capital-Related: Moveable Equipment

We proposed to use the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category. This is the same price proxy used in the 2020-based ESRDB market basket.

Table 7 shows all the price proxies for the 2024-based ESRDB Market Basket as well as whether the price proxy was used in the 2020-based ESRDB market basket. As outlined in section II.B.1.b.(1)(b)(iii) of the proposed rule, for the 2024-based ESRDB market basket we proposed additional cost categories compared to the 2020-based ESRDB market basket. Therefore, in Table 7, the cost category expenses listed as n/a were included in the All Other Goods and Services cost category of the 2020-based ESRDB market basket and were proxied by the PPI Final demand—Finished goods less foods and energy.

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TABLE 7: Price Proxies for the 2024-based ESRDB Market Basket

<u>Cost Category</u>	<u>2024 Price Proxy</u>	<u>2020 Price Proxy</u>
Total - ESRDB24		
Compensation		
Wages and Salaries		
Health-Related Wages and Salaries	ECI - Wages and salaries for All Civilian workers in Hospitals	same
Management Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Management, Business, and Financial	same
Administrative Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Office and Administrative Support	same
Service Wages and Salaries	ECI - Wages and Salaries for Private Industry workers in Service Occupations	same
Employee Benefits		
Health-Related Benefits	ECI - Total Benefits for All Civilian workers in Hospitals	same
Management Benefits	ECI - Total Benefits for Private Industry workers in Management, Business, and Financial	same
Administrative Benefits	ECI - Total Benefits for Private Industry workers in Office and Administrative Support	same
Service Benefits	ECI - Total Benefits for Private Industry workers in Service Occupations	same
Utilities		
Electricity	PPI - Commodity - Commercial electric power	same
Natural Gas	PPI - Commodity - Commercial natural gas	same
Medical Materials and Supplies		
Pharmaceuticals		
ESAs	PPI - Commodity - Biological products for human use	same
All Other Drugs	Composite: PPI - Commodity - Vitamin, nutrient, and hematinic preparations (47%) and PPI - Commodity - Special Index - Pharmaceuticals for human use, prescription (53%)	same but 50/50 not 47/53
Supplies	PPI - Commodity - Surgical and medical instruments	same
Laboratories	PPI - Industry - Medical and Diagnostic Laboratories	same
All Other Goods		
Paper & Printing	Composite PPI - PPI Commodity for Publications Printed Matter and Printing Material (25%) and PPI - Commodity - Converted paper and paperboard products (75%)	n/a
Rubber & Plastics	PPI - Commodity - Rubber and plastic products	n/a
Miscellaneous Products	PPI - Final demand - Finished goods less foods and energy	same
All Other Services		
Telephone and Internet Service	CPI - Telephone Services	same
Housekeeping	PPI - Commodity - Cleaning and Building Maintenance Services	same
Operations & Maintenance	ECI - Total Compensation for All Civilian workers in Installation, Maintenance, and Repair	same
Administrative Services	ECI Total Compensation Private Industry workers in Office and Administrative Support	n/a
Financial Services	ECI - Total Compensation for Financial Services	n/a
Professional Fees: Labor-related	ECI - Total Compensation for Private industry workers in Professional and related	same

<u>Cost Category</u>	<u>2024 Price Proxy</u>	<u>2020 Price Proxy</u>
Professional Fees: Nonlabor-related	ECI - Total Compensation for Private industry workers in Professional and related	same
All Other Services: Labor-related	ECI - Total Compensation Private Industry workers in Service Occupations	n/a
All Other Services: Nonlabor-related	CPI - All Items less Food and Energy	n/a
Professional Liability Insurance	CMS: Physicians PLI index	n/a
Capital Costs		
Capital-related: Buildings and Fixtures	PPI - Industry - Lessors of nonresidential buildings	same
Capital-related: Moveable Equipment	PPI - Commodity - Electrical machinery and equipment	same

*The cost category expenses listed as n/a for 2020 were included in the All Other Goods and Services cost category and was proxied by the PPI Final demand - Finished goods less foods and energy.

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We invited public comments on our proposed price proxies for the 2024-based ESRDB market basket.

Final Rule Action: We did not receive any comments on the price proxies we proposed to use in the 2024-based ESRD market basket; therefore, we are finalizing the price proxies used in the 2024-based ESRD market basket as proposed.

(3) 2024-Based ESRDB Market Basket Percentage Increase Results

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38802), we compared the yearly increase factors from CY 2021 through CY 2030 for the 2020-based ESRDB market basket and the 2024-based ESRDB market basket. At the time of the proposed rule, based on IGI's first quarter 2026 forecast, this comparison showed that the annual increase factors for individual years sometimes differed between the two indexes; however, on average the two indexes produced identical results across every period we examined: an identical projected CY 2027 update of 2.6 percent, an identical average annual growth of 3.7 percent for CY 2021 through CY 2025, and an identical average annual growth of 2.6 percent for CY 2026 through CY 2030. We did not receive any comments on this

comparison of the proposed 2024-based and 2020-based ESRDB market basket results.

For this final rule, we updated this comparison using IGI's third quarter 2026 forecast, which reflects more recent historical data and a revised economic outlook. Using this updated forecast, the trend identified in the proposed rule no longer holds for CY 2027: the 2024-based ESRDB market basket is now projected to increase 2.9 percent for CY 2027, which is 0.1 percentage point higher than the projected CY 2027 increase under the 2020-based ESRDB market basket of 2.8 percent. For the forecast period CY 2026 through CY 2030, the 2024-based ESRDB market basket percentage is also on average, 0.1 percentage point higher than the 5-year average projected increase of the 2020-based ESRDB market basket. The higher projected increase for the 2024-based market basket is attributable to a relatively higher compensation cost weight compared to the 2020-based market basket, as well as the disaggregation of the All Other Goods and Services cost category into more detailed cost categories in the 2024-based ESRD market basket. This increase is partially offset by the lower pharmaceutical cost weight in the 2024-based ESRD market

basket relative to the 2020-based ESRD market basket.

c. Labor-Related Share for ESRD PPS

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

We proposed to use the 2024-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Therefore, effective for CY 2027, we proposed a labor-related share of 63.5 percent, compared to the current 55.2 percent that was based on the 2020-based ESRDB market basket cost weights, as shown in Table 8. These figures represent the sum of Wages and Salaries, Employee Benefits, Housekeeping, Operations & Maintenance, Administrative Services, Professional Fees: Labor-related, All Other Services: Labor-related and 46 percent of the weight for Capital-related: Buildings and Fixtures (details discussed later in this section). We used a similar methodology to calculate the 2020-based ESRDB market basket labor-related share.

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TABLE 8: Labor-related Share for CY 2027 and CY 2026, based on ESRDB Market Basket Weights

	Labor-Related Share for CY 2027	Labor-Related Share for CY 2026	Difference
Wages and Salaries	39.0	36.5	2.5
Employee Benefits	11.9	9.5	2.4
Housekeeping	0.5	0.5	0.0
Operations & Maintenance	4.2	3.7	0.5
Administrative Services	0.3	n/a	0.3
Professional Fees: Labor-related	2.7	0.7	2.0
All Other Services: Labor-related	0.7	n/a	0.7
Capital-related: Buildings and Fixtures	9.0	9.4	-0.4
Capital-related: Buildings and Fixtures * 0.46	4.2	4.3	-0.1
Total	63.5	55.2	8.3

*Totals may not sum due to rounding

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

We invited public comments on our proposed labor-related share based on the 2024-based ESRDB cost weights. We received public comments on the calculation of the proposed labor-related share based on the 2024-based ESRDB market basket cost weights. The following is a summary of the comments we received and our responses.

Comment: Commenters offered mixed views on the proposed increase to the labor-related share from 55.2 percent to 63.5 percent. Many commenters supported the increase as a more accurate reflection of ESRD facilities'

increasing labor costs and as helpful to staffing and retention efforts. Despite this, some commenters recommended that CMS phase-in the increase in the labor-related share to minimize the impact of this change on ESRD facilities in low-wage index areas. A commenter opposed finalizing the labor-related share as proposed, arguing that it does not reflect the current cost structure faced by ESRD facilities, particularly the impact of the inclusion of the phosphate binder costs. Another commenter noted that they were unable to reach a consensus on the proposed labor-related share given the distributional impacts to their members.

Response: The labor-related share represents the portion of the ESRD PPS base payment rate that is adjusted by the wage index to reflect geographic variation in area wage levels and is derived from the cost weights in the ESRDB market basket that are labor-intensive and vary with, or are influenced by, the local labor market. These categories include Wages and Salaries, Employee Benefits, Housekeeping, Operations & Maintenance, a portion of Professional Fees, and a portion of Capital-Related Building and Fixtures expenses, consistent with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154). We recognize commenters' concern that the 2024 cost report data used to derive the 63.5 percent labor-related share predate the CY 2025 addition of oral-only phosphate binders to the ESRD PPS

bundled payment. However, we believe it is technically appropriate to rebase and revise the labor-related share to 63.5 percent to reflect the most recently available cost report data at the time of CY 2027 rulemaking. We note that in the CY 2026 ESRD PPS final rule (90 FR 53075), several commenters expressed concern regarding the labor-related share of 55.2 percent stating it was outdated.⁸ We will continue to monitor the cost report data and the market basket cost weights and, if appropriate, we will propose changes to the labor-related share during future rulemaking.

We recognize that the increase to the LRS from 55.2 percent to 63.5 percent would reduce relative payments to low-wage index areas in a budget neutral manner and we acknowledge the requests for a policy to phase-in the updated LRS. As noted previously, the updated LRS of 63.5 percent is derived from the updated ESRDB market basket based on CY 2024 cost report data. This updated LRS is based on more recent data, and we believe it is appropriate to use for CY 2027. We note that the LRS is increasing by 8.3 percentage points for CY 2027. For an ESRD facility with the lowest possible wage index value, which is the 0.600 wage index floor, the increase in LRS would result in a decrease in payment of 4.3 percent. So, for the lowest wage index facilities the payment impact of the increase to the LRS is less than 5 percent overall and the impact for most facilities (with

⁸ <https://www.govinfo.gov/content/pkg/FR-2025-11-24/pdf/2025-20681.pdf>.

higher wage index values) would be less. We believe that an across-the-board phase-in of this policy would inappropriately impact other ESRD facilities for which the higher LRS would better align payments with actual costs. As such, we do not believe a phase-in policy would be appropriate at this time.

Final Rule Action: After consideration of public comments received, we are finalizing a labor-related share of 63.5 percent effective for CY 2027, as proposed.

d. CY 2027 ESRD Market Basket Update

Under section 1881(b)(14)(F)(i) of the Act, beginning in CY 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We proposed to use the 2024-based ESRDB market basket as described in section II.B.1.b. of the proposed rule to compute the CY 2027 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 outlined in section II.B.1.d.(3) of the proposed rule, we calculated the proposed ESRDB market basket update for CY 2027 based on the 2024-based ESRDB market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) CY 2027 ESRDB Market Basket Percentage Increase

Using this methodology and IGI's first quarter of 2026 forecast of the 2024-based ESRDB market basket (with historical data through the fourth quarter of 2025), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2027 ESRDB market basket increase factor was projected to be 2.6 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data to determine the CY 2027 ESRDB market basket percentage increase in the final rule, provided such data is appropriate

(meaning methodologically consistent with the proposed approach, sufficiently complete, and available in time to be reasonably evaluated for the final rule). Based on the more recent data available for this CY 2027 ESRD PPS final rule (that is, IGI's third quarter 2026 forecast of the 2024-based ESRDB market basket with historical data through the second quarter of 2026), the CY 2027 ESRDB market basket percentage increase is 2.9 percent.

We invited public comment on the proposed CY 2027 ESRDB market basket percentage increase. The following is a summary of the comments we received and our responses. Several comments discussing the ESRDB market basket percentage increase also discussed the overall ESRD PPS payment level, the ESRD PPS base rate, budget neutrality adjustments, or payment adequacy under the ESRD PPS. These comments are summarized and responded to in section II.B.4. of this final rule.

Comment: Several commenters acknowledged the proposed ESRDB productivity-adjusted market basket increase of 1.6 percent; however, most expressed that this update is insufficient to address the current inflationary environment and workforce shortages. A few commenters pointed to their own experience or broader trends in labor costs as an indication that the update is insufficient. Several commenters noted that most of the \$17.84 proposed increase to the ESRD PPS base rate (to \$299.55) is attributable to the \$15.96 added to account for phosphate-binders, leaving an effective increase of only about \$1.88, or roughly 0.7 to 1.1 percent, once the phosphate binder amount is excluded. Some commenters underscored the importance of accurate payments to ensure ESRD facilities can hire and retain essential clinical staff, mitigate high rates of staff turnover to higher-paying settings, which has had a negative impact on patient experience. A commenter claimed that the proposed ESRDB market basket percentage increase is lower than economy-wide measures of inflation like the CPI and PPI. A couple of commenters noted that the ESRD PPS update has consistently been lower than updates under other Medicare facility-based PPS systems.

Response: We appreciate commenters' concerns regarding the CY 2027 productivity-adjusted market basket update. Section 1881(b)(14)(F)(i)(I) of the Act requires that the ESRD PPS payment rate be increased by the ESRD bundled (ESRDB) market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the phosphate binder

payment amount is a separate, distinct modification to the base rate and is not part of the ESRDB market basket update itself; we clarified that they do not offset one another. Additionally, we note that the application of several budget neutrality factors is decreasing the CY 2027 ESRD PPS base rate. We discuss these budget neutrality factors in greater detail in section II.B.4. of this final rule, however, we want to emphasize that these factors maintain estimated payment at the same amount and do not offset the overall payment impact of the ESRDB market basket update.

The 2024-based ESRDB market basket percent change is equal to the weighted price change of the individual price proxies and their respective cost weights. The cost weights are primarily derived using the freestanding ESRD Medicare cost reports and reflect relative shares of input costs needed to provide medical services to ESRD beneficiaries. Similarly, the other CMS PPS market baskets, such as the 2022-based SNF market basket and 2023-based IPPS market basket, reflect the relative share of input costs needed to provide skilled nursing and hospital care to Medicare beneficiaries based on the data reported on the respective provider cost reports.

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

At the time of the CY 2027 ESRD PPS proposed rule, based on the IHS Global Inc. first quarter 2026 forecast with historical data through the fourth quarter of 2025, the 2024-based ESRDB

market basket update was forecasted to be 2.6 percent for CY 2027, reflecting forecasted compensation price growth of 3.2 percent. In the CY 2027 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 2027 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 includes more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2027. Based on IHS Global Inc.'s third quarter 2026 forecast with historical data through the second quarter of 2026, we are projecting a CY 2027 ESRDB market basket update of 2.9 percent and a final ESRDB productivity-adjusted market basket update of 1.9 percent (2.9 percent reduced by the 1.0 percentage point productivity adjustment) will be applicable, compared to the 1.6 percent productivity-adjusted market basket update that was proposed.

Comment: Many commenters stated that the ESRDB market basket has been consistently under-forecast relative to actual realized inflation, estimating a cumulative error ranging from 6.0 to 7.7 percent that a commenter did not believe were random. Many commenters continued to request that CMS adopt a forecast-error correction policy for the ESRD PPS similar to that used in the SNF PPS, including both a one-time retrospective adjustment to correct the accumulated error and a forward-looking policy triggered when the forecast error exceeds a threshold (most commenters proposed ± 0.5 percentage point). Several commenters requested greater transparency into IHS Global Inc.'s (IGI) forecasting methodology of the price proxies used in the market basket.

Response: We acknowledge commenters' continued concerns regarding market basket forecast error; however, the ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the CY 2027 market basket update in this final rule reflects historical data through the second quarter of CY 2026 and forecasted data through the fourth quarter of CY 2027. While there is no precedent to adjust for market basket forecast error in the ESRD PPS payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year less the forecasted market basket

increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred since the implementation of the ESRD PPS in CY 2011. Over most of this history the forecast errors were smaller in magnitude, with the largest error (in absolute terms) prior to 2021 being an over forecast (the actual market basket increase is less than the forecasted market basket increase) of 0.8 percentage point in 2017. More recently the ESRDB market basket has been under forecast, as noted by the commenters, with larger errors occurring for 2021 through 2024. The cumulative forecast error since ESRD PPS inception (CY 2012 to CY 2025) is 5.5 percent. 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 Public Health Emergency for COVID-19 and the unforeseen rapidly accelerating inflationary environment.

We understand the request for greater transparency into IGI's forecasting methodology of the price proxies used in the CMS market baskets; however, we continue to reiterate that CMS purchases independent forecasts of the price proxies used in the CMS market baskets from IGI, a nationally recognized economic and financial forecasting firm. The rationale for using an independent forecaster is to ensure neutrality in the update while reflecting comprehensive economic and health sector forecasting model capabilities that extend beyond CMS' expertise. As the forecasting models are proprietary in nature, we are not licensed to share information related to the detailed models. More information on the IGI economic forecasts can be found at the following website or by contacting the company directly <https://www.spglobal.com/market-intelligence/en/solutions/products/us-economic-modeling-forecasting-services>.

We recognize that forecast error under the ESRD PPS has been an important concern of commenters in recent years. We did not propose a policy to modify the ESRDB market basket update or ESRD PPS base rate for CY 2027 to address forecast error and are not finalizing any such policy in this final rule.

Final Rule Action: After consideration of the public comments we received, we are finalizing the CY 2027 ESRDB market basket percentage increase of 2.9 percent, based on the more recent data available for this CY 2027 ESRD PPS final rule (that is, IGI's third quarter 2026 forecast of the 2024-based ESRDB

market basket with historical data through the second quarter of 2026).

(2) CY 2027 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 (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), hereafter referred to as the "productivity adjustment".

BLS publishes the official measures of productivity for the United States economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity (TFP) (previously referred to as multifactor productivity).⁹ We refer readers to <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>.

Based on IGI's first quarter 2026 forecast, the proposed productivity adjustment for CY 2027 (the 10-year moving average growth of TFP for the period ending CY 2027) was projected to be 1.0 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 productivity adjustment in the final rule.

We invited public comments on the productivity adjustment. The following is a summary of the comments we received and our responses.

Comment: Several commenters had concerns regarding the application and magnitude of the productivity adjustment. Some commenters requested that CMS use its "special exceptions and adjustments" authority

⁹ <https://www.bls.gov/productivity/notices/2021/mfp-to-tpf-term-change.htm>.

to eliminate or reduce the 1.0 percentage point productivity cut for CY 2027. A commenter stated that the 1.0 percentage point productivity adjustment would be the largest applied in ESRD PPS history and stated that it does not reflect verifiable productivity gains specific to the dialysis sector.

Response: Section 1881(b)(14)(F)(i)(II) of the Act requires the application of the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II), to the ESRD PPS market basket increase factor. The CY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide, private nonfarm business total factor productivity for the period ending CY 2027. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, as we explained in response to similar comments in prior ESRD PPS final rules (90 FR 53076), we are required under section 1881(b)(14)(F)(i)(II) of the Act to apply the specific productivity adjustment described here.

Since 2015, we have provided information on the general method for calculating the productivity adjustment. This information includes providing a link (<http://www.bls.gov/productivity/>) to the most recent BLS historical TFP data, which currently allows interested parties to obtain historical TFP annual index levels for 1987 through 2025. We also provide the IGI projection model (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf), which for this CY 2027 ESRD PPS final rule is used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the CY 2027 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending December 31, 2027, relative to the 40-quarter moving average projected level for the period ending December 31, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the 2027 productivity adjustment reflects BLS

historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.9 percent for 2026 and 2027 based on IGI's third-quarter 2026 forecast. Combining the historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 1.0 percent for CY 2027 (unchanged from the CY 2027 ESRD PPS proposed rule). Interpolation of annual to quarterly data distributes the annual data across quarters by estimating the values between two known annual observations.

Final Rule Action: After consideration of the public comments we received, we are finalizing the CY 2027 productivity adjustment of 1.0 percent based on the IGI third quarter 2026 forecast.

(3) CY 2027 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2027 ESRDB market basket percentage increase on IGI's first quarter 2026 forecast of the 2024-based ESRDB market basket. We proposed to then reduce the ESRDB market basket percentage increase by the proposed productivity adjustment for CY 2027 based on IGI's first quarter 2026 forecast. Therefore, the proposed CY 2027 ESRDB market basket update was equal to 1.6 percent (proposed 2.6 percent ESRDB market basket percentage increase reduced by a proposed 1.0 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ESRDB market basket percentage increase and productivity adjustment in the final rule. Accordingly, the final CY 2027 ESRDB market basket update is calculated using the CY 2027 ESRDB market basket percentage increase, based on IGI's third quarter 2026 forecast of the 2024-based ESRDB market basket, and the final productivity adjustment, based on IGI's third quarter 2026 forecast. Therefore, the final CY 2027 ESRDB market basket update is 1.9 percent (2.9 percent ESRDB market basket percentage

increase reduced by a 1.0 percentage point productivity adjustment).

2. CY 2027 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. As discussed in detail later in this section, we later implemented an ESRD PPS specific wage index methodology in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117). Under current policy, we use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117).¹⁰ OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. We most recently updated the CBSA delineations used for the ESRD PPS wage index in the CY 2025 ESRD PPS final rule (89 FR 89117) to the OMB delineations as described in OMB Bulletin No. 23–01, beginning with the CY 2025 ESRD PPS wage index.¹¹

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

¹⁰ We define urban areas at § 413.231(b) as a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB. Rural areas are defined as any area outside an urban area.

¹¹ <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>.

An ESRD facility’s wage index is applied to the LRS of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a LRS of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we finalized a temporary policy which applied a 5 percent cap on any decrease in an ESRD facility’s wage index from the prior CY. 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. As outlined in section II.B.1.c. of the proposed rule, we proposed that the CY 2027 LRS to which the wage index would be applied is 63.5 percent. This LRS is based on the 2024-based ESRDB market basket as outlined in section II.B.1.b. of the proposed rule.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index

methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). Historically, the ESRD PPS wage index values have been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilized pre-floor hospital data that are not adjusted for occupational mix. In the CY 2025 ESRD PPS final rule (89 FR 89116) we finalized a new ESRD PPS wage index methodology which uses mean hourly wage data from the BLS OEWS. This wage data is then weighted by a national ESRD facility occupational mix (NEFOM) which is derived from FTE data from freestanding ESRD facility cost reports. Treatment data from ESRD facility cost reports is also used to weight the mean hourly wage data when aggregating the wage data at a CBSA level. As set forth in § 413.196(d)(2), we update the ESRD PPS wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from BLS and occupational mix data from the most recent full CY of Medicare cost reports submitted in accordance with § 413.198(b).

For a detailed explanation of the current ESRD PPS wage index methodology, see the discussion in the

CY 2025 ESRD PPS final rule (89 FR 89108 through 89117), and for a detailed explanation of the steps we use to calculate the ESRD PPS wage index according to this methodology see Addendum C of the CY 2025 ESRD PPS proposed rule available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notice/cms-1805-p>.

b. National ESRD Facility Occupational Mix

Table 9 presents the NEFOM alongside the BLS occupation titles and codes for the occupations related to the furnishing of renal dialysis services. We noted in the CY 2027 ESRD PPS proposed rule that we were presenting the NEFOM to aid interested parties in their reconstruction of the proposed ESRD PPS wage index, but the actual ESRD PPS wage index uses the total FTEs for each occupation as described in the calculation in Addendum C of the CY 2025 ESRD PPS proposed rule rather than the rounded percentages presented in Table 9. The data in Table 9 is based on data from CY 2024 freestanding ESRD facility cost reports. We note that the rounded percentages in this table are unchanged from Table 10 of the CY 2027 ESRD PPS proposed rule (91 FR 38805), although the underlying FTE counts may have changed.

**TABLE 9: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports
Occupation Classifications and the CY 2027 ESRD PPS Final Rule NEFOM**

ESRD PPS Colloquial Name	BLS Occupation Title	Occupation Code	ESRD Freestanding Facilities FTE Percentage*
Registered Nurses (RN)	Registered Nurses	29-1141	30.4%
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29-2061	2.7%
Nurse Aides	Nursing Assistants	31-1131	3.2%
Technicians	Health Technologists and Technicians, All Other	29-2099	41.8%
Social Workers	Healthcare Social Workers	21-1022	4.7%
Dietitians	Dietitians and Nutritionists	29-1031	4.6%
Administrative Staff	Medical Secretaries and Administrative Assistants	43-6013	8.5%
Management	Medical and Health Services Managers	11-9111	4.1%

* Totals may not sum to 100.0 percent due to rounding

c. CY 2027 ESRD PPS Wage Index

For CY 2027, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using the ESRD

PPS wage index methodology established in the CY 2025 ESRD PPS final rule (89 FR 89098 through 89107) and specified in § 413.196(d)(2). The ESRD PPS wage index is specific for

ESRD facilities as it uses specific wage data weighted by an ESRD facility occupational mix; this differentiates the ESRD PPS wage index from other Medicare PPSs, several of which utilize

the pre-floor, pre-reclassified IPPS wage index. We proposed to use the most recent available BLS OEWS mean hourly wage data for various occupations related to the furnishing of renal dialysis services weighted by FTE data from CY 2024 freestanding ESRD facility cost reports. 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. For CY 2027, the updated wage data used in the analysis for the proposed rule, and this final rule, are the May 2025 OEWS data released by BLS on May 15 2026, which represents data from six semiannual surveys spanning November 2022 through May 2025.¹²

For CY 2027, we proposed to update the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We proposed that if more recent data became available after the analysis performed for the publication of the proposed rule and before the publication of this final rule (for example, an update to the May 2025 BLS OEWS mean hourly wage data or more complete CY 2024 cost report data), we would use such data, if appropriate, to determine the CY 2027 ESRD PPS wage index in the final rule. For this final rule, we used the most recently available CY 2024 cost report data. No update to the May 2025 BLS OEWS was published at the time of the development of this final rule.

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

Comment: Several commenters expressed concerns about the current ESRD wage index methodology and stated that the legacy ESRD PPS wage index was more appropriate. A commenter expressed support for the wage index floor policy, but urged CMS to increase the floor from 0.6000 to 0.7000. Another commenter urged CMS to use its authority under section 1881(b)(14)(D)(iv) of the Act, which permits CMS to adopt such other payment adjustments as the Secretary determines appropriate, to establish a non-budget neutral wage index floor or supplemental payment adjustment for ESRD facilities in low-wage-index areas.

Response: We appreciate the concerns raised by the commenters regarding the ESRD PPS wage index methodology. We continue to believe that the ESRD facility-specific methodology is most appropriate for the ESRD PPS. We did

not propose any changes to the ESRD PPS wage index methodology for CY 2027, such as a return to the legacy ESRD PPS wage index methodology, and we are not finalizing any such changes in this final rule. We will continue to evaluate the ESRD PPS wage index methodology and consider whether changes may be appropriate through notice-and-comment rulemaking in future years.

Regarding the wage index floor, as we discussed in the CY 2023 ESRD PPS final rule, the 0.6000 wage index floor was based on a statistical analysis (87 FR 67161). We did not propose to change the wage index floor or establish any other supplemental policies to increase payments to ESRD facilities in low-wage-index areas, for CY 2027 and are not finalizing any such changes in this final rule. We will continue to monitor the appropriateness of the current wage index floor and consider whether further changes are warranted through notice-and-comment rulemaking in future years.

Comment: Some commenters expressed concern about the combined impact of the wage index and the increase to the LRS. A commenter urged CMS to consider changes to the wage index, LRS, and other adjusters together as one connected system rather than in silos.

Response: We appreciate the concerns that commenters raised about the impact of the updates to the wage index and the LRS on ESRD facilities in low-wage areas. As we discuss in section II.B.1.c. of this final rule, the increase to the LRS reflects the latest available estimates of the labor-related costs in the ESRDB market basket. We do not believe a delay to the implementation of the increase to the LRS is appropriate as the updated LRS will more accurately reflect labor costs as a percentage of the ESRD PPS bundled payment amount. Overall payment impacts, which take into account all payment changes in this final rule, are discussed in section VII.C.5.a. of this final rule.

Comment: A commenter urged CMS to revisit the ESRD-specific wage index methodology to incorporate wage data drawn specifically from the healthcare sector, or from ESRD facilities directly, rather than an all-industry BLS average, to evaluate whether the current occupational-mix weighting adequately compensates for that underlying data limitation.

Response: As we have previously noted, we recognize the limitations of the data source upon which the ESRD PPS wage index methodology is built. We discussed these limitations in the CY 2025 ESRD PPS proposed rule (89

FR 55769) and, in the CY 2025 ESRD PPS final rule (89 FR 89099, 89116), concluded that, even with these limitations, the methodology represents a significant improvement over the IPPS wage index for use in ESRD facilities. We wish to reiterate that the purpose of the wage index is to estimate the geographic variation in wages, and we believe that this wage index methodology does so appropriately. We note that although we use all-industry wages, the job codes are either for healthcare occupations, such as RNs, or are healthcare-specific occupations, such as Medical Secretaries and Administrative Assistants. Thus, we believe the ESRD PPS wage index is appropriately based on the specific occupations involved in furnishing renal dialysis services. We intend to continue to monitor the ESRD PPS wage index, including the wage data and occupational mix, and may consider future changes through notice and comment rulemaking, if appropriate.

After consideration of public comments, we are finalizing our proposal to update the ESRD PPS wage index following our established methodology. For CY 2027, the final wage index is based on wage estimates from the May 2025 BLS OEWS, which represents data from six semiannual surveys spanning November 2022 through May 2025, and the most recently available CY 2024 cost report data. The final CY 2027 ESRD PPS wage index is set forth in Addendum A and provides a crosswalk between the final CY 2026 wage index and the final CY 2027 wage index. Addendum B provides an ESRD facility level impact analysis. Both Addendum A and Addendum B are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

3. CY 2027 Update to the Outlier Policy a. Background

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

¹² <https://www.bls.gov/news.release/pdf/ocwage.pdf>.

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:

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

- Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

- 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.

- 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.

- 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.¹³

- Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

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, 2011.¹⁴ 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 (CRs), when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term "national adjusted average" in this section of this final rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for ESRD 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 ESRD

outlier services MAP amounts. The ESRD 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 ESRD outlier services MAP amounts for a patient are determined by multiplying the adjusted average ESRD outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the ESRD 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 explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY 2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

Lastly, in the CY 2025 ESRD PPS final rule we finalized several methodological and policy changes to the ESRD PPS outlier policy to address concerns that interested parties have raised in recent years. First, we finalized an expansion of the definition of ESRD outlier services in § 413.237(a)(1) to include drugs and biological products that are Composite Rate Services as defined in § 413.171 (89 FR 89126). Second, we finalized a policy to include the case-mix adjusted post-TDAPA add-on payment adjustment amount in the calculation of the predicted MAP amounts when applicable (89 FR

¹³ 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.

¹⁴ 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 PPS 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>.

89127). Lastly, we finalized changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological products, we use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in average sales price (ASP) prices and utilization for ESRD outlier drugs (89 FR 89127 through 89130). For ESRD outlier laboratory tests and supplies, we use the growth in the Producer Price Index (PPI) Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments, respectively (89 FR 89129 through 89130).

b. CY 2027 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2027, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2025 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2025 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2023, CY 2024, and CY 2025, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174) and the changes finalized in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89130). The latest available CY 2025 claims data show that outlier payments represented approximately 0.9 percent of total Medicare payments. We proposed to update these values with the latest available data, if appropriate, in the final rule.

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

Comment: Several commenters expressed concerns about the proposed increases to the FDL and MAP amounts for CY 2027. Some commenters recommended that CMS use more current 2026 utilization data instead of relying on 2025 projections. Other commenters recommended that CMS phase-in MAP and FDL amount increases more gradually rather than a single large jump.

Response: We appreciate the concerns raised by commenters regarding the projected increase in outlier payments in CY 2026 and corresponding increases in the FDL and MAP amounts for CY 2027. As we noted in the CY 2027 ESRD PPS proposed rule, these increases are primarily attributable to the projected

utilization of drugs currently paid for through the TDAPA in CY 2025, which will be ESRD outlier services in CYs 2026 and 2027. Specifically, we projected that payments under the outlier adjustment would be approximately 3.0 percent of total ESRD PPS payments in CY 2026 based on utilization from the latest available CY 2025 claims. As a result, we proposed to increase the MAP and FDL amounts to better achieve the 1.0 percent outlier target in CY 2027. Although the proposed CY 2027 adult FDL amount was higher than the CY 2026 adult FDL amount, we noted that the retrospective FDL methodology that we finalized in the CY 2023 ESRD PPS final rule accounts for the introduction of these new ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization (87 FR 67174).

Regarding the recommendation to use more recent 2026 utilization data, we note that the latest available full CY of claims data is CY 2025, which is the source of the estimates used in the proposed rule. At the time of final rulemaking, CY 2026 utilization is only available through the end of the second quarter and does not incorporate any information about utilization or pricing patterns in the second half of CY 2026. We will take these comments into consideration to potentially inform future changes to the outlier methodology through notice and comment rulemaking.

We do not agree with the recommendation to phase-in the increases to the FDL and MAP amounts over time. As we have previously noted, we update the outlier FDL and MAP amounts each year to target outlier payments at 1.0 percent of total ESRD PPS payments. If we applied a lower FDL or MAP amount in CY 2027, we estimate that outlier payments would exceed 1.0 percent.

Comment: Several commenters urged CMS to change certain aspects of the ESRD PPS outlier policy. Some commenters stated that a lower target percentage, for example 0.5 percent of total payments, would be more appropriate. These commenters stated that section 1881(b)(14)(D)(ii) of the Act does not require the ESRD PPS outlier percentage to be 1.0 percent. Several commenters also stated that CMS should not include TDAPA and TPNIES payment amounts when calculating total ESRD PPS payments, of which outlier payments are targeted at 1.0 percent.

Response: We appreciate these comments, but we do not agree that either of the suggested revisions to the

outlier methodology would be more appropriate than the current outlier policy. As we have previously stated, while we agree that section 1881(b)(14)(D)(ii) of the Act provides the Secretary with discretion to set an appropriate outlier percentage under the ESRD PPS, we continue to believe the 1.0 percent target is more appropriate than a lower outlier percentage. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients and providing an appropriate level of payment for those patients who do not qualify for outlier payments. We continue to believe the 1.0 percent target strikes the appropriate balance, and as we further noted in the CY 2023 ESRD PPS final rule (87 FR 67171), a reduced outlier percentage may not provide the appropriate level of payment for outlier cases and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payments based on their claims. We did not propose to reduce the outlier percentage for CY 2027, and we are not finalizing any such reduction in this final rule.

Likewise, we do not agree with the suggestion to exclude TDAPA and TPNIES payments from total ESRD PPS payments for the purposes of setting the FDL and MAP amounts for CY 2027. We believe that commenters incorrectly assume that excluding TDAPA and TPNIES payment amounts from this calculation would result in an increase to non-outlier payments (that is, total ESRD PPS payments other than those made as part of the outlier adjustment under the ESRD PPS). To the contrary, this suggested change to our calculations would only reduce the total amount of outlier payments, which would be 1.0 percent of a lower total ESRD PPS payment figure, without increasing other (non-outlier) payments under the ESRD PPS, since the base rate would continue to be reduced by 1.0 percent. This change would require us to increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payments based on their claims.

Comment: Some commenters expressed concerns about the interaction between outlier payments and new drugs. A commenter urged

CMS to develop a predictable, long-term approach for paying for new drugs after they transition out of a TDAPA period, particularly drugs within an existing ESRD PPS functional category. Another commenter encouraged CMS to reserve outlier payments for unusual clinical variation, not as a payment mechanism for new drugs, stating that new drugs are the primary driver for outlier payments in direct contrast to the purpose of the policy. This commenter stated that patients who require unusually higher-cost services are less likely to qualify for outlier payments under the current system.

Response: We agree with commenters that the outlier adjustment is intended to recognize unusual variations in cost due to the use of ESRD outlier services and is not intended as a payment mechanism for new renal dialysis drugs. Rather, the drug designation process under 42 CFR 413.234, which includes the TDAPA and post-TDAPA add-on payment adjustment, is the ESRD PPS mechanism for incorporating new renal dialysis drugs and biological products. As discussed in section II.B.6. of this final rule, we are finalizing our proposal to calculate the post-TDAPA add-on payment adjustment amounts more

frequently to reflect updated information beginning in CY 2027.

Final rule action: After consideration of public comments, we are finalizing our proposal to update the outlier FDL and MAP amounts based on the latest available data. Table 10 outlines the final FDL and MAP amounts for CY 2027. We note that these figures include all changes to the ESRD outlier services for CY 2027, including the incorporation of phosphate binders into the ESRD PPS base rate, which will mean phosphate binders are included as ESRD outlier services in CY 2027 as discussed in section II.B.7. of this final rule.

TABLE 10: Outlier Policy: Impact of Updated Data for the Final Outlier Policy

	Column I Final outlier policy for CY 2026 (based on 2024 data, price inflated to 2026) *		Column II Final outlier policy for CY 2027 (based on 2025 data, price inflated to 2027)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average ESRD outlier services MAP amount per treatment	\$50.64	\$24.83	\$66.33	\$43.71
Adjustments				
Standardization for ESRD outlier services	1.0113	0.9731	0.9734	0.9767
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average ESRD outlier services MAP amount	\$50.19	\$23.68	\$63.27	\$41.83
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$162.43	\$14.80	\$229.49	\$90.60
Patient-month-facilities qualifying for outlier payment	7.58%	14.10%	6.26%	7.51%

*Column I values match the values reported in column II of Table 3 from the CY 2026 ESRD PPS final rule (90 FR 53086).

**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2023, 2024, and 2025.

As demonstrated in Table 10, the FDL amount per treatment that determines the CY 2027 outlier threshold amount for adults (column II; \$90.60) is significantly higher than that used for the CY 2026 outlier policy (column I; \$14.80). The higher threshold amount is accompanied by an increase in the adjusted average MAP amount for ESRD outlier services from \$23.68 to \$41.83. These increases are primarily attributable to the projected utilization

of drugs that were paid for through the TDAPA in CY 2025, which will be ESRD outlier services in CYs 2026 and 2027. Specifically, we project that payments under the outlier adjustment will be approximately 2.6 percent of total ESRD PPS payments in CY 2026 based on utilization from the latest available CY 2025 claims. As a result, we are increasing the MAP and FDL amounts to better achieve the 1.0 percent outlier target in CY 2027.

Although the final CY 2027 adult FDL amount is higher than the CY 2026 adult FDL amount, we note that the retrospective FDL methodology that we finalized in the CY 2023 ESRD PPS final rule accounts for the introduction of these new ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization (87 FR 67174). The retrospective FDL calculations for CYs 2023, 2024, and 2025 are \$116.21,

\$114.06, and \$102.63, respectively. Following the methodology we finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174), we use these retrospective FDL amounts to project a downward trend in the FDL amount for CY 2027, resulting in the final adult FDL amount of \$90.60.

For pediatric patients, there is also an increase in the FDL amount from \$162.43 to \$229.49. There is a corresponding increase in the adjusted average MAP amount for ESRD outlier services among pediatric patients, from \$50.19 to \$63.27. We noted that, as outlined in section II.B.7. of the final rule, we are including phosphate binders in the ESRD PPS base rate. Accordingly, phosphate binders will be eligible as ESRD outlier services for CY 2027, and we have included them in our calculations. Generally, including additional drugs and biological products results in increases to the MAP and FDL amounts, which is contributing to the increases to these figures for CY 2027.

We estimate that the percentage of patient-facility-months qualifying for outlier payments in CY 2027 will be 7.51 percent for adult patients and 6.26 percent for pediatric patients, based on the 2025 claims data.

c. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the CY 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the CY 2025 claims available for this final rule, outlier payments represented approximately 0.88 percent of total payments, which is slightly below the 1.0 percent target.

4. Impacts to the CY 2027 ESRD PPS Base Rate

a. Background

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 included 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-level adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, home and self-dialysis training add-on payment adjustment, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Annual Payment Rate Update for CY 2027

We proposed an ESRD PPS base rate for CY 2027 of \$299.55. As discussed in section II.B.1.d. of this final rule, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ESRDB market basket update in the final rule. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters who discussed ESRD PPS payment policy supported increasing the overall ESRD PPS payment rate. Many commenters, however, expressed an opinion that the proposed ESRD PPS base rate of \$299.55 was insufficient, which added to many commenters' concerns about current payment adequacy under the ESRD PPS. Some commenters noted that this represented an increase of \$17.84 over the CY 2026 base rate, \$15.96 of which is attributable to the increase to the base rate to account for phosphate binders, resulting in an increase to the base rate of only \$1.88 outside of the phosphate binder increase. As discussed in section II.B.7. of this final rule, many commenters supported the base rate increase for phosphate binders. Many commenters acknowledged that the reason why the proposed increase outside of the phosphate binder increase

was low was due to the application of various budget neutrality factors. Many commenters expressed support for implementing certain proposed policy changes non-budget neutrally.

Several comments discussed payment adequacy under the ESRD PPS. Multiple commenters listed figures published by MedPAC listing Original Medicare margins for ESRD facilities, noting that MedPAC has found low and occasionally negative margins in past reports.

Many commenters included current or potential future impacts of lower than appropriate ESRD PPS payments. These impacts included difficulty hiring and maintaining skilled staff, ESRD facility closures, difficulty providing certain expensive drugs and biological products, or other cost reductions. Some commenters provided data on ESRD facility closures, predominantly in rural areas, and attributed this trend to concerns about payment adequacy under the ESRD PPS. Several commenters attributed perceived lower than appropriate payment to historical under-forecasts of the ESRDB market basket, which they stated has resulted in a lower base rate than if forecasts had been accurate.

A few commenters indicated a belief that payment rates under the ESRD PPS were generally adequate. A few commenters raised concerns related to cost sharing under the ESRD PPS and noted that higher payment rates result in increased beneficiary cost sharing. A commenter requested CMS assess and publicly report the beneficiary level impact of ESRD PPS payment changes on cost sharing.

Response: We appreciate support for increasing the ESRD PPS base rate and recognize the concerns over the payment amounts set under the ESRD PPS. The final ESRDB market basket update is 1.9 percent, higher than the proposed value of 1.6 percent, which we believe addresses some of the commenters' concerns about payment adequacy. However, we want to clarify a few points about the proposed CY 2027 ESRD PPS base rate. The proposed ESRD PPS base rate of \$299.55 was derived from the CY 2026 ESRD PPS base rate of \$281.71, the proposed ESRDB market basket update of 1.6 percent, the proposed increase to incorporate phosphate binders of \$15.96, the proposed wage index budget neutrality factor of 1.00267, and the proposed budget neutrality factor of 0.98783 for the proposed policy changes to the LVPA, pediatric payment adjustments and training add-on adjustments. As highlighted by some commenters, the reason why the CY

2027 ESRD PPS base rate is not, excluding the increase of phosphate binders, 1.6 percent higher (or, 1.9 percent higher using the final ESRDB market basket update) than the CY 2026 ESRD PPS base rate is due to the budget neutrality factors applied. We discuss why we believe applying these budget neutrality factors is appropriate in the following comment and response.

We strongly caution commenters against using the ESRD PPS base rate as an estimate of payment adequacy or as a proxy for payment levels under the ESRD PPS. The proposed budget neutrality factor of 0.98783 reduced the proposed ESRD PPS base rate because the proposed policy changes to the LVPA, training add-on, and pediatric payment modifiers result in increases to the payment adjustment factors. If we did not apply this budget neutrality factor, then these policy changes would increase the overall payment rate. The ESRD PPS base rate is not intended to be an average payment amount for ESRD beneficiaries; it is a base unit of payment that is then adjusted by several adjustment factors, almost all of which increase payment. In practice, the ESRD PPS base rate represents the payment provided for an adult patient aged 70–79, with the average BSA of 1.9, has none of the applicable comorbidities, is not in the onset period, and is being treated in an ESRD facility that is neither rural nor low volume and that has a wage index value of 1.000. We acknowledge that the base rate, adjusted by the wage index and other adjustment factors (on a budget neutral basis), represents the payment for beneficiaries with AKI, as required by section 1834(r)(1) of the Act.

We acknowledge the quality concerns that commenters have raised and the data points cited by commenters. We note that in its March 2026 MedPAC Report to Congress¹⁵, MedPAC concluded that payment adequacy indicators for ESRD facilities were generally favorable and recommended that the Congress should eliminate the payment rate update for CY 2027. We agree with MedPAC that payment under the ESRD PPS is appropriate. We share the concerns of commenters regarding ESRD facility closures, especially in rural areas, and note that this was a significant motivator for our changes to the LVPA, which are finalizing, as discussed in section II.B.8. of this final rule.

We agree with the commenters who stated that payments under the ESRD PPS were generally adequate and recognize their concerns related to beneficiary cost sharing. We note that the increase to beneficiary cost sharing associated with the ESRDB market basket update is the result of a statutorily required payment rate update, but we will continue to be mindful of the impact of our payment policies on beneficiary out-of-pocket costs.

Comment: A commenter stated that CMS should reconsider our longstanding philosophy on applying budget neutrality factors. The commenter acknowledged that budget neutrality was appropriate for certain changes, like case mix adjustment factors, but believed it would not be appropriate for others. The commenter highlighted the new ESRD PPS wage index methodology implemented in the CY 2025 ESRD PPS final rule (89 FR 89198 through 89107) as an example of a policy which they believe should not be implemented budget neutrally.

Response: We appreciate the commenter's perspective regarding the application of budget neutrality under the ESRD PPS. Section 1881(b)(14) of the Act establishes the statutory framework for the ESRD PPS. Section 1881(b)(14)(A)(ii) of the Act established the aggregate payment level when the ESRD PPS was implemented in CY 2011, while section 1881(b)(14)(D) of the Act requires or authorizes various adjustments to payments under the ESRD PPS, including adjustments based on case mix, for high-cost outliers, for low-volume facilities, and such other payment adjustments as the Secretary determines appropriate.

Consistent with this statutory framework and our longstanding implementation of the ESRD PPS, we generally believe that it is appropriate to implement changes to payment adjustments in a budget-neutral manner when those changes are intended to redistribute payments to better account for differences in relative resource use for costs that are already reflected in the ESRD PPS base rate. In these circumstances, the purpose of modifying the adjustment is to improve the distribution of payments under the ESRD PPS rather than to increase or decrease the aggregate level of payment for renal dialysis services. This approach is consistent with how we have historically applied budget neutrality to payment adjustments under the ESRD PPS, including case-mix adjustments.

For example, we applied a budget neutrality factor when implementing the

new ESRD PPS wage index methodology in CY 2025 because labor costs are already reflected in the ESRD PPS base rate and the purpose of the wage index is to account for geographic differences in those labor costs (89 FR 89097 through 89116). The new ESRD PPS wage index methodology changed how the labor-related portion of the existing ESRD PPS payment is distributed among ESRD facilities based on geographic differences in wages; it did not add a new category of renal dialysis services or costs to the ESRD PPS bundle. Accordingly, we believe it was appropriate to implement that methodology in a budget-neutral manner so that the change in methodology itself would not increase or decrease aggregate ESRD PPS payments (89 FR 89109).

We believe it is appropriate to implement the modifications to the LVPA in this rule in a budget neutral manner. Section 1881(b)(14)(D)(iii) of the Act requires the ESRD PPS to include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities exceed the costs incurred by other facilities. The costs of furnishing renal dialysis services at low-volume facilities were represented in the data used to establish the ESRD PPS bundled payment (75 FR 49117 through 49125). The purpose of modifying the LVPA therefore is to better align relative payments with relative resource use among ESRD facilities, rather than to recognize a new category of costs or services that is not already reflected in the ESRD PPS base rate. Implementing such modifications without a corresponding budget neutrality adjustment would increase aggregate ESRD PPS payments solely as a result of a policy intended to recalibrate how payments for existing bundled costs are distributed. Our intention in proposing modifications to payment adjustments like the LVPA is generally to make payments that align relative payments with relative resource use, not to increase the ESRD PPS base rate.

By contrast, where a policy accounts for costs that are not already reflected in the ESRD PPS base rate, an increase in aggregate ESRD PPS payments may be appropriate. As discussed elsewhere in this final rule, phosphate binders were not included in the ESRD PPS base rate when the ESRD PPS was established in CY 2011 and were not subsequently incorporated into the base rate. Accordingly, we are increasing the ESRD PPS base rate to account for the costs of phosphate binders rather than offsetting that increase through a budget neutrality adjustment.

¹⁵ Medicare Payment Advisory Commission. March 2026. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. <https://www.medpac.gov/document/march-2026-report-to-the-congress-medicare-payment-policy/>.

We therefore do not believe that all changes to the ESRD PPS necessarily should be treated identically for purposes of budget neutrality. Rather, in determining whether budget neutrality is appropriate for a particular policy, we consider the applicable statutory authority and the nature and purpose of the payment change. In general, where a change to an existing payment adjustment is intended to improve the allocation of payments for costs already reflected in the ESRD PPS base rate, we believe that implementing the change in a budget-neutral manner appropriately preserves the distinction between redistributing payments under the ESRD PPS and increasing the payment amount to account for additional costs or services. Where a policy instead incorporates costs or services that are not already reflected in the ESRD PPS base rate, an increase in aggregate ESRD PPS payments may be appropriate, subject to the applicable statutory authority.

Comment: Commenters expressed concerns over the estimated 1.1 percent increase to overall ESRD PPS payments. Commenters noted that this is lower than the proposed 1.6 percent ESRDB market basket update. Many commenters stated a belief that this 1.1 percent payment increase was insufficient, comparing it to a wide array of estimates for inflation.

Response: We want to clarify why the estimated year-over-year payment increase is less than the proposed 1.6 percent ESRDB market basket update. In our impact analysis, both for the CY 2027 ESRD PPS proposed rule and for this final rule, we simulate claims for CY 2026 and CY 2027 using available CY 2025 claims data. As part of this simulation, we applied the 1.6 percent ESRDB market basket update, as well as simulated the impact of other changes to ESRD PPS payment, including those resulting from policies proposed in the CY 2027 ESRD PPS proposed rule. There are several factors which contribute to the year-over-year estimated increase in payments being lower than the proposed ESRDB market basket update; however, the primary cause driving the lower year over year payment impact for CY 2027 presented in the CY 2027 proposed rule was the impact of the routine changes to the outlier policy as shown in Table 26 in the ESRD PPS CY 2027 proposed rule (91 FR 38860). We estimated and are currently estimating outliers being larger than 1 percent for 2026 and we proposed MAP and FDL amounts to better achieve the 1.0 percent outlier target for CY 2027 (91 FR 38808). So, it is not surprising that the proposed

change to the MAP and FDL amounts are expected to result in a year-over-year decrease in estimated outlier payments.

While we believe that the estimated year-over-year payment increase is an important metric that interested parties may consider when evaluating the impact of the rule, we caution interested parties to interpret it carefully. We include detailed impacts on each of the new policies and many of the routine and established policies in Table 30 in section VII.C.5.a. of this final rule. We note that table indicates that the year-over-year increase in ESRD PPS payments is 2.4 percent, which is higher than the 1.9 percent ESRDB market basket update. These figures are different for the same underlying reasons as the difference the commenters noted.

Comment: A commenter stated CMS should conduct and publish a comprehensive ESRD PPS base rate adequacy analysis using the most current available and representative facility cost-report data.

Response: We continually monitor the adequacy of payment rates under the ESRD PPS, which we have used to inform payment policies. We reiterate that we caution interested parties against using the base rate as a proxy for overall payment amount, as budget neutral increases to payment adjustments reduce the base rate while maintaining the overall payment amount. We note that in proposing the modifications to the LVPA, we published an analysis of payment-to-cost ratios using CY 2024 cost report data and CY 2025 claims data (91 FR 38822). However, in discussing that analysis, we also discussed the limitations of such an analysis in terms of evaluating payment adequacy. We will take into consideration the commenter's suggestion that we publish further analysis on payment rate adequacy.

Comment: A commenter stated that a market basket update cannot fully address payment adequacy since it is designed to measure changes in prices for a fixed mix of inputs. The commenter stated that even a perfectly calibrated market basket update would only preserve the purchasing power of the existing base rate but would not determine whether that original rate was adequate to start with.

Response: We agree with the commenter that the ESRDB market basket update, as required by section 1881(b)(14)(F) of the Act, represents the change in prices of the same mix of goods and services purchased in the base period. It is not intended to capture changes in the types of renal dialysis

services purchased by ESRD facilities. We recognize the extent to which this can create perceived payment adequacy concerns, especially as it pertains to new renal dialysis technologies that may be higher cost than those which were utilized when the base rate was established. Additionally, we recognize that it is not a measure of payment adequacy for the initial CY 2011 ESRD PPS base rate. The CY 2011 ESRD PPS base rate was established in the CY 2011 ESRD PPS final rule based on statutory requirements, which required that overall payments be equal to 98 percent of what they would have been under the composite rate system (75 FR 49071 through 49083). We believe that payments under the ESRD PPS are sufficient for ESRD facilities to furnish renal dialysis services to Medicare beneficiaries. Although the original payment rate from 2011 and the ESRDB market basket increases are based on that fixed bundle of goods and services; by providing a single bundled payment we allow ESRD facilities to provide whichever services are most appropriate for a patient. This gives ESRD facilities the flexibility to provide new technologies to patients when appropriate.

Final Rule Action: After consideration of public comments, we are finalizing a CY 2027 ESRD PPS base rate of \$297.52, which is approximately a 5.6 percent increase from the CY 2026 ESRD PPS base rate of \$281.71. The final CY 2027 ESRD PPS base rate is calculated 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 2027, 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 CY 2027 wage index budget neutrality adjustment factor using treatment counts from the 2025 claims and facility-specific CY 2026 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2026. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2027. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the CY 2027 ESRD PPS wage index and LRS for CY 2027. The total of these payments becomes the new CY 2027 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 2027 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2027 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The final CY 2027 wage index budget neutrality adjustment factor is 1.00260. As we are not finalizing any changes to our established ESRD PPS wage index methodology, this final CY 2027 wage index budget neutrality adjustment factor reflects the impact of all established wage index policies, including the ESRD PPS wage index methodology based on BLS OEWS and freestanding ESRD facility cost report FTE data, the 5 percent cap on year-to-year decreases in wage index values, the 3-year rural phase-out for ESRD facilities in CBSAs which we currently consider urban that were considered rural prior to the new delineations adopted in CY 2025,¹⁶ and the final LRS.

We note that the final CY 2027 wage index budget neutrality factor does not include any impacts associated with the TPEAPA, as was the case with the CY 2024 combined wage index-TPEAPA budget-neutrality factor finalized for CY 2024. Although CY 2026 is the final year of the TPEAPA, as outlined in section II.B.9. of this final rule, we are finalizing budget neutral changes to the payment adjustments that apply for pediatric ESRD patients. Rather than calculating a combined TPEAPA-wage index budget neutrality factor, we are including the effect of the end of TPEAPA in the budget neutrality factor for those pediatric policy changes. This is more consistent with what we have done in past years where there were multiple budget neutral policy changes outside the wage index in a given year, such as in the CY 2016 ESRD PPS final rule (80 FR 69011). This final budget neutrality factor does not incorporate the budget neutrality impact of the end of the TPEAPA effective January 1, 2027. That budget neutrality impact is included in the budget neutrality factor for the

payment adjustments described in this final rule.

Budget Neutrality Factor for Certain Payment Adjustment Changes: As outlined in sections II.B.8., II.B.9., and II.B.10. of this final rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are finalizing changes to the LVPA, payment adjustments for pediatric ESRD patients, and home and self-dialysis training add-on payment adjustment. We are finalizing that the changes to these payment adjustments will be budget neutral and result in a combined budget neutrality factor of 0.98864. This is calculated based on the combined budget neutrality factor of 0.98901 for the LVPA changes, 0.99999 for the pediatric changes, and 0.99964 for the changes to the home and self-dialysis training add-on payment adjustment. As noted previously, this budget neutrality factor also includes the budget neutrality impact associated with the end of the TPEAPA effective January 1, 2027.

Addition of Phosphate Binders to the ESRD PPS Base Rate: As outlined in section II.B.7. of this final rule, for CY 2027 we are finalizing our proposal to modify the ESRD PPS base rate in a non-budget neutral manner, by adding \$12.85 to account for phosphate binders in the ESRD PPS bundled payment. This application would yield a CY 2027 ESRD PPS base rate of \$294.56 (\$281.71 + \$12.85 = \$294.56), prior to the application of the market basket update and budget neutrality factors. We are finalizing the application of the budget neutrality factors to the base rate after the increase to the ESRD PPS base rate, as proposed. As noted in the CY 2027 ESRD PPS proposed rule, this is appropriate because those budget neutrality factors were calculated using estimated payments, which incorporated the increase to the base rate.

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 outlined in section II.B.1.d. of this final rule, the final CY 2027 ESRDB market basket increase based on IGI's third quarter 2026 forecast of the final 2024-based ESRDB market basket is 2.9 percent. For CY 2027, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.d.(2) of this final rule, the final CY 2027 productivity adjustment is 1.0

percentage point based on IGI's third quarter 2026 forecast of the 10-year moving average of TFP for the period ending CY 2027, thus yielding a final CY 2027 ESRDB market basket update of 1.9 percent for CY 2027. Therefore, the final CY 2027 ESRD PPS base rate is \$297.52 ($(\$294.56 \times 1.00260 \times 0.98864) \times 1.019 = \297.52).

5. Updated 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 ESRDB market basket update. 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 two CYs.

There are currently no capital-related assets that are home dialysis machines set to receive the TPNIES for CY 2027, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2027. 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 2027 TPNIES offset amount for capital-related assets that are home dialysis machines of \$10.60, based on the application of the proposed CY 2027 ESRDB market basket update of 1.6 percent (proposed 2.6 percent ESRDB market basket percentage increase reduced by the

¹⁶ We note that the 3-year rural phase-out finalized in the CY 2025 ESRD PPS final rule (89 FR 89117 through 89119) ends December 31, 2026. As discussed in that rule, we will not apply a rural transition adjustment factor in CY 2027 or any future year for ESRD facilities that were rural in CY 2024 but were redesignated as urban for CY 2025. The final wage index budget neutrality factor for CY 2027 reflects the budget neutrality associated with the end of this policy.

proposed 1.0 percentage point productivity adjustment) to the CY 2026 TPNIES offset amount of \$10.43. We requested public comments on our proposal to update the TPNIES offset amount for capital-related assets for CY 2027.

We did not receive any comments on this proposal. We are finalizing an offset amount of \$10.63, based on the application of the final CY 2027 ESRDB market basket update of 1.9 percent (final 2.9 percent ESRDB market basket percentage increase, reduced by the final 1.0 percentage point productivity adjustment). We calculated the CY 2027 TPNIES offset amount using the most recent data available as proposed. The CY 2027 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is \$10.63 (\$10.43 $\times$ 1.019).

6. Post-TDAPA Add-On Payment Adjustment Updates

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjusters and is applied to every ESRD PPS claim. In the CY 2024 ESRD PPS final rule we also clarified that for each year of the post-TDAPA add-on payment adjustment period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. The post-TDAPA add-on payment adjustment amounts are calculated based on the methodology codified at § 413.234(g), which is the total drug expenditure divided by the total ESRD PPS treatments multiplied by the case mix standardization for the time period and the 0.65 risk sharing factor, and the ESRDB pharmaceutical price proxy for the payment year (88 FR 76396). In the CY 2025 ESRD PPS final rule (89 FR 89136) we finalized our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances to ensure that the post-TDAPA add-on payment adjustment amount can be calculated using 12 months of utilization data.

For CY 2026 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment for each of the four calendar quarters and one drug, DefenCath®, included in the calculation for only the third and fourth calendar

quarters. In the CY 2026 ESRD PPS final rule (90 FR 53091 through 53092), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be \$0.1131 for CY 2026 and we finalized a post-TDAPA add-on payment adjustment amount for DefenCath® of \$2.3710 for the third and fourth quarter of 2026.

a. CY 2027 Post-TDAPA Add-On Payment Adjustment Amounts

For CY 2027, there will be four drugs in the 3-year period following the end of their TDAPA period that are potentially eligible to be included in the calculation of the post-TDAPA add-on payment adjustment. Section 413.234(c)(3) states that, should CMS not receive the latest full calendar quarter of ASP data for a drug or biological product during the TDAPA or post-TDAPA add-on payment adjustment period, we will not pay any post-TDAPA add-on payment adjustment for such product in any future year. We refer to this policy at § 413.234(c)(3) as the conditional ASP policy, which was finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76396) and is modeled off the conditional ASP policy for the TDAPA which was finalized in the CY 2020 ESRD PPS final rule (84 FR 60677 through 60681). The intention of these policies is to ensure that the TDAPA and post-TDAPA add-on payment adjustment are always based on the best available data, which we consider to be ASP (when ASP is available). The third quarter of 2026 reflecting the first quarter of 2026 sales would be the latest quarter of ASP data at the time of rulemaking for the proposed rule.¹⁷ As discussed in the CY 2026 ESRD PPS final rule (90 FR 53090), CMS did not receive ASP data for Jesduvroq® for the third quarter of 2025, which reflects sales for the first quarter of 2025. As such, we stated in the CY 2027 ESRD PPS proposed rule that we are not including Jesduvroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2027 (91 FR 38810). Therefore, there are three drugs included in the calculation of the post-TDAPA add-on payment adjustment for CY 2027, conditioned on the continued receipt of the latest full calendar quarter of ASP data for each renal dialysis drug.

The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so Korsuva® would be included in the calculation for the post-TDAPA add-

on payment adjustment for only the first quarter of CY 2027. DefenCath® began its TDAPA period on July 1, 2024, so its post-TDAPA add-on payment adjustment period began on July 1, 2026. Vafseo® began its TDAPA period January 1, 2025, so its post-TDAPA add-on payment adjustment period will begin January 1, 2027. Both drugs would be included in the post-TDAPA add-on payment adjustment calculation for each quarter of CY 2027, conditioned on the continued receipt of ASP data.

In the CY 2027 ESRD PPS proposed rule, we presented the proposed post-TDAPA add-on payment adjustment amounts for each of these drugs based on the most recently available full year of utilization data at the time of rulemaking, which was from January 2025 to December 2025 for the CY 2027 ESRD PPS proposed rule. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we stated that we would update these calculations with the most recent available utilization and pricing data in the final rule. We invited public comments on the estimated CY 2027 post-TDAPA add-on payment adjustment amounts presented in Table 12 of the ESRD PPS CY 2027 proposed rule.

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

Comment: Several commenters expressed concern about our post-TDAPA add-on payment adjustment policy. Commenters expressed concern that lagged ASP data may not be reflective of current prices. Numerous commenters requested we modify our methodology for calculating the post-TDAPA add-on payment adjustment to be based on per-claim utilization and only apply to claims that include the drug or biological product in question and not be time limited. Commenters generally expressed the opinion that such a payment adjustment would better support innovation within the ESRD PPS. A commenter stated the belief that the current post-TDAPA add-on payment adjustment methodology has harmed patients by failing to provide a sustainable pathway for payment for new drugs and biological products and their suggested methodology would better support innovation.

Response: As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76396) we do not agree that a methodology based on per-claim utilization would be appropriate for the post-TDAPA add-on payment adjustment, because it would directly

¹⁷ ASP quarters are based on calendar years, so 3rd quarter ASP reflecting 1st quarter data would reflect data from January to March of the given year.

incentivize utilization of a particular drug or biological product, which we noted can result in overutilization. While the TDAPA and post-TDAPA add-on payment adjustments share the goal of supporting access to new renal dialysis drugs or biological products used to treat or manage a condition in an ESRD PPS functional category, the TDAPA's short-term objectives are more consistent with a methodology that is based on per-claim utilization. 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 business operations 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. The TDAPA for renal dialysis drugs and biological products in existing ESRD PPS functional categories is inherently transitional in nature and therefore not permanent. We later finalized a post-TDAPA add-on payment adjustment beginning in CY 2024 that 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 (88 FR 42460), 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 (75 FR 49162).

We believe that the current post-TDAPA add-on payment adjustment 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. 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. We did not propose any changes to the methodology used to calculate the post-TDAPA add-on payment adjustment, the 3-year timeframe of the adjustment

or the application of the post-TDAPA add-on payment adjustment to all ESRD PPS claims for CY 2027 and are not finalizing any such changes in this final rule.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to maintain the post-TDAPA add-on payment adjustment calculation methodology for CY 2027.

b. Updating the Post-TDAPA Add-On Payment Adjustment Amounts Quarterly

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76393) and codified at 42 CFR 413.234(g), we have finalized a post-TDAPA add-on payment adjustment which is based on the most recent year of utilization data and is calculated annually in each rulemaking cycle. Under § 413.234(g)(1), CMS bases the post-TDAPA add-on payment adjustment calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data.

In the CY 2025 ESRD PPS final rule, we established a policy that, when there is less than a full year's utilization data at the time of rulemaking, we would publish the post-TDAPA add-on payment adjustment amount via Change Request (CR) once we have a full 12 months of data (89 FR 89135). Under this policy, we would still include an estimated post-TDAPA add-on payment adjustment amount in the proposed rule and update that estimated amount in the final rule, but we would note that the estimated amount presented in the final rule is subject to change. In the CY 2025 ESRD PPS final rule, we reiterated that we believe it is important to have a full year's utilization data when determining the post-TDAPA add-on payment adjustment amount so that the post-TDAPA add-on payment adjustment appropriately captures the utilization of the drug or biological product as required by § 413.234(g)(1) (89 FR 89135 through 89136). However, in that final rule, we did not finalize other circumstances where we would update the post-TDAPA add-on payment adjustment amount for a drug or biological product. Specifically, we stated that we did not intend to routinely update the post-TDAPA add-on payment adjustment amount quarterly, as we believed this would make it more difficult for ESRD facilities to estimate payments (89 FR 89136).

In response to the proposed post-TDAPA add-on payment amount published in the CY 2026 ESRD PPS proposed rule, we received a comment

requesting we finalize a policy to publish the post-TDAPA add-on payment adjustment for DefenCath® after the publication of the final rule (90 FR 53091). This commenter stated that publishing the post-TDAPA add-on payment adjustment amount for that drug later, such that data from the third and fourth quarter of 2025 could be included in the calculation, would be more appropriate as it would reflect more recent data that shows increased utilization compared to the third and fourth quarter of 2024. Specifically, they noted that they believed 2024 utilization for DefenCath® was depressed by several factors, which they stated would result in an undervaluing of the drug for the post-TDAPA add-on payment adjustment. The commenter highlighted that the 2024 data would be two years old by the time the post-TDAPA add-on payment adjustment would begin in quarter 3 2026. While we did not finalize any such changes in the CY 2026 ESRD PPS final rule, we noted that we would evaluate whether additional flexibilities may be warranted in the post-TDAPA add-on payment adjustment calculation.

Since the publication of the CY 2026 ESRD PPS final rule, interested parties have repeated their concerns with our established post-TDAPA add-on payment adjustment methodology and stated a belief that it undervalued new drugs and biological products. We understand the concerns raised by interested parties regarding the time delay of the post-TDAPA add-on payment adjustment calculation inherent in calculating the adjustment once per year during rulemaking and we have reevaluated our policy. Although it is important for ESRD facilities to be able to accurately plan for payments, we recognize that rapid changes in price or utilization might not be fully captured by the current methodology.

In the CY 2027 ESRD PPS proposed rule, we proposed to modify the post-TDAPA add-on payment adjustment methodology to routinely calculate the post-TDAPA add-on payment adjustment amounts each quarter. The proposed modification would not change the steps for the calculation of the post-TDAPA add-on payment adjustment, insofar as we would still be using the most recent quarter of ASP data and the most recently available full year of utilization data. We only proposed to perform the calculation more frequently and publish the amounts in CRs quarterly. We acknowledged that, in the past, we have stated that setting the post-TDAPA add-on payment amount once annually would improve ESRD facilities' ability

to estimate payments. However, after further consideration, we stated that we believe that setting the post-TDAPA add-on payment amount more frequently would better align the post-TDAPA add-on payment amounts with the actual utilizations and prices of the renal dialysis drugs and biological products. This would allow for the payment amount to consistently be based on the most recently available data, which we believe would address concerns which interested parties have raised that the post-TDAPA add-on payment adjustment amount was often based on outdated data. Under this proposal, we explained that we would still publish the first quarter post-TDAPA add-on payment adjustment amounts annually in the rule. We stated that we expect that generally the post-TDAPA add-on payment adjustment amounts would not change drastically throughout the year, which would allow ESRD facilities to reasonably estimate payments in advance.

As we proposed calculating the post-TDAPA add-on payment adjustment quarterly, we also proposed modifying the conditional ASP policy such that the post-TDAPA add-on payment adjustment would stop the next quarter after a non-submission of ASP data. We explained in the proposed rule that this is a change from current policy, in which we would wait until the next rulemaking year to discontinue the post-TDAPA add-on payment adjustment for a drug which failed to report ASP. We noted that the amount of time for processing a CR can vary and there are occasionally other factors which create additional lag in the use of claims data, so the time periods utilized in a given quarter could change from year to year. However, we stated that we intend to generally aim to include data from two quarters prior. For example, for the third quarter post-TDAPA add-on payment adjustment, which begins July 1 of a year, we would generally include data through December of the prior year, but depending on the year December data may not be available at the time of processing. We proposed that, if an update to the post-TDAPA add-on payment adjustment amount for a given quarter is not operationally feasible for

some currently unforeseen reason, the post-TDAPA add-on payment adjustment amount for the prior quarter would continue until such a time when updating it is operationally feasible. We stated that we intend to include the months from which the post-TDAPA adjustment was calculated, as well as the quarter of ASP we used for the calculation in the CR. We stated that we would also note any discontinuations of the post-TDAPA add-on payment adjustment due to failure to submit ASP data.

We proposed changes to § 413.234(c)(3) to state that the post-TDAPA add-on payment adjustment would be calculated quarterly and that if we stopped receiving ASP data, we would not calculate the post-TDAPA add-on payment adjustment for any subsequent quarter (rather than any subsequent year, as it currently reads). We also proposed changes to § 413.234(g) to state that we would calculate the post-TDAPA add-on payment adjustment quarterly.

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

Comment: Several commenters expressed concern that quarterly recalculation of post-TDAPA add-on payment amounts would negatively impact payment stability that facilities rely on for long-term planning. One LDO noted that CMS previously recognized, in prior rulemaking, that setting the post-TDAPA add-on payment adjustment amount annually supports ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period, and that facilities have operated under the expectation that a payment amount established for a calendar year remains fixed for that year. This commenter stated this predictability is crucial to ESRD facilities' pharmaceutical operations, which fundamentally rely on the ability to plan and budget over the longer term and expressed concern about the continued post-TDAPA add-on payment adjustment policy.

Some commenters stated that whereas annual updates to post-TDAPA add-on payment adjustment have provided

sufficient information to establish payment amounts and support accurate payment, quarterly recalculations add complexity and uncertainty without a commensurate benefit.

Response: While we agree with commenters that quarterly updates to the post-TDAPA add-on payment adjustment amount may result in more frequent changes to this adjustment; and therefore, would provide less certainty regarding the amount that will apply throughout an entire calendar year, we do not agree that more frequent recalculation necessarily results in greater payment instability. Rather, quarterly recalculation allows changes in price and utilization to be reflected incrementally as more recent data become available, instead of allowing those changes to accumulate until the next annual recalculation. As a result, quarterly calculation may produce smaller, more gradual changes in the post-TDAPA amount from one quarter to the next and reduce the potential for a larger change when the amount is recalculated for a new calendar year.

As we explained in the proposed rule, we proposed to change our policy to calculate the post-TDAPA add-on payment adjustment amount quarterly because rapid changes in price or utilization might not be fully captured by the current annual methodology. Table 11 demonstrates this distinction by comparing the actual post-TDAPA add-on payment adjustment amounts for the second, third, and fourth quarters of 2026 with what the post-TDAPA add-on payment adjustment amounts would have been if they were calculated on a quarterly basis based on the latest available data, as we proposed to do for CY 2027. As shown in this table, if the methodology that we proposed for CY 2027 were applied to CY 2026, it would have resulted in more gradual change in post-TDAPA add-on payment adjustment amounts from one quarter to the next than having a larger change between Q4 2026 and Q1 2027. This results in greater stability and directly addresses the key concerns that commenters raised in response to the CY 2026 post-TDAPA add-on payment adjustment amounts.

TABLE 11: Actual and Hypothetical Recalculated Post-TDAPA Add-on Payment Adjustment Amounts for Q2 2026 through Q1 2027

Quarter	Actual post-TDAPA add-on payment adjustment amount	Recalculated post-TDAPA add-on payment adjustment amount*
Q2 (April – June) 2026	\$0.1131	\$0.0644
Q3 (July – September) 2026	\$2.4841	\$5.6147
Q4 (October – December) 2026	\$2.4841	\$7.3963
Q1 (January – March) 2027	\$9.3983	\$9.3983

*The recalculated post -TDAPA add-on payment adjustment amounts reflect the drugs which were included in the calculation of the post-TDAPA add-on payment adjustment for each quarter. Thus, the Q1 2027 post-TDAPA add-on payment adjustment amount includes the amount calculated for Vafseo®.

We do not believe that the proposed quarterly calculation adds complexity with no commensurate benefit. As we demonstrate in Table 11, the proposed methodology has a clear benefit of capturing ongoing changes in price and utilization resulting in more appropriately adjusted payment. Furthermore, as we explained in the proposed rule, the proposed modification would not change the steps for the calculation of the post-TDAPA add-on payment adjustment, insofar as we would still be using the most recent quarter of ASP data and the most recently available full year of utilization data. We only proposed to perform the calculation more frequently and publish the amounts in CRs quarterly. Therefore, we do not believe that the proposed methodology increases the complexity of the calculation. Rather, we believe this more responsive approach appropriately balances ESRD facilities’ interest in payment predictability with the need for the post-TDAPA add-on payment adjustment amounts to reflect more current price and utilization data.

CMS appreciates commenters’ concerns about payment predictability and the administrative burden of more frequent updates. As we discussed in the CY 2024 ESRD PPS final rule establishing the post-TDAPA add-on payment adjustment, this policy was designed to balance two goals: supporting ESRD facilities’ long-term planning and budgeting for new renal dialysis drugs and biological products and ensuring the payment adjustment accurately reflects the actual prices and utilization of those products (88 FR 76393). We first adopted a policy of calculating post-TDAPA add-on payment adjustment amounts annually, because we believed this would sufficiently address changes in price and utilization over time. However, our

experience implementing the post-TDAPA add-on payment adjustment methodology since CY 2024 has shown that annual calculation, on its own, may not adequately serve the accuracy side of that balance. Specifically, as we noted in the CY 2027 ESRD PPS proposed rule, in response to the CY 2026 ESRD PPS proposed rule, we received a comment requesting that CMS delay publication of the post-TDAPA add-on payment adjustment amount for DefenCath® until later-quarter 2025 data could be incorporated, because the calculation otherwise relied on 2024 utilization data that would have been two years old by the time the adjustment took effect in the third quarter of CY 2026. While we did not finalize a change in response to that comment, we stated in the CY 2026 ESRD PPS final rule that we would evaluate whether additional flexibilities were warranted in the post-TDAPA add-on payment adjustment calculation (90 FR 53091). Since that rule was published, interested parties have continued to raise similar concerns, stating a belief that the post-TDAPA add-on payment adjustment policy’s core purpose of supporting continued access to these products could be better supported by using more recent data to establish the post-TDAPA add-on payment adjustment amounts. The proposed approach of recalculating post-TDAPA add-on payment adjustment amounts quarterly aligns with payment for Part B drugs more broadly, which is more dynamic and responsive to such changes. We believe the proposed post-TDAPA add-on payment adjustment methodology appropriately balances the twin goals of the policy, while allowing the payment amount to track actual drug pricing and utilization more closely than the annual approach has allowed.

Comment: Several commenters expressed concern about the proposed conditional ASP policy. Commenters stated that abruptly ending the post-TDAPA add-on payment adjustment due to a manufacturer’s non-submission of ASP data could create uncertainty around continued coverage and availability of these therapies.

Response: We appreciate the concerns that commenters have raised. As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76393 through 76394), 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 established a policy to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. We continue to believe that our longstanding conditional ASP policy appropriately balances access to new renal dialysis drugs with responsible spending from the Medicare Trust Fund.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to update the post-TDAPA add-on payment adjustment quarterly via CRs. As such, in this final rule we are only finalizing the post-TDAPA add-on payment adjustment amounts for the first quarter of CY 2027, however we note that these amounts also represent our estimate of the post-TDAPA add-on payment adjustment amount for all quarters of CY 2027 based on the best available current data. The cumulative estimated post-TDAPA add-on payment adjustment amount for each quarter is presented in Table 12.

TABLE 12: Estimated Post-TDAPA Add-on Payment Adjustment Amounts for CY 2027 by Quarter

Quarter	Add-on amount for Korsuva®	Add-on amount for DefenCath®	Add-on amount for Vafseo®	Total post-TDAPA add-on payment adjustment amount
Q1 (January – March)*	\$0.0793	\$8.3220	\$0.9970	\$9.3983
Q2 (April – June)	\$0	\$8.3220	\$0.9970	\$9.3190
Q3 (July – September)	\$0	\$8.3220	\$0.9970	\$9.3190
Q4 (October – December)	\$0	\$8.3220	\$0.9970	\$9.3190

*Q1 2027 Post-TDAPA add-on payment adjustment amounts are final.

7. Incorporation of Phosphate Binders Into the ESRD PPS Base Rate

a. Background

(1) Background on Oral-Only Renal Dialysis Drugs

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

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49044), we interpret this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs) and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act, but also all oral drugs and biological products used for the treatment of ESRD and furnished under Title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and issued the payment policies for oral-only renal dialysis service drugs and biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at § 413.171 to include other drugs and biological products furnished to

individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011, under Title XVIII of the Act, including oral-only drugs (75 FR 49044). We further described oral-only drugs as those that have no injectable equivalent or other form of administration (75 FR 49038 through 49039). Although we included oral-only renal dialysis service drugs and biological products in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2014, and codified this delay at § 413.174(f)(6) (75 FR 49042). In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), we noted that the oral-only drugs and biological products that we identified were limited to phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products, including allowing ESRD facilities additional time to make operational changes and logistical arrangements to furnish oral-only renal dialysis drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis drugs and biological products at § 413.174(f)(6) and specified that payment to an ESRD facility for renal dialysis drugs and biological products with only an oral form will be incorporated into the ESRD PPS payment rate on January 1, 2014. Since oral-only drugs were generally not covered under Medicare Part B at this time, the delay of payment under the ESRD PPS allowed these drugs to continue being paid for under Medicare Part D until inclusion in the ESRD PPS, consistent with CMS's discussion at 75 FR 49052 through 49053.

On January 3, 2013, the American Taxpayer Relief Act of 2012 (ATRA) was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this statutory change through revisions of the effective date at § 413.174(f)(6) from January 1, 2014, to January 1, 2016, as discussed in the applicable final rule. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible as ESRD outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014, to January 1, 2016.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this statutory change in the CY 2015 ESRD PPS final rule (79 FR 66262) through revisions by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016, to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2016, to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that, in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must

use data from the most recent year available.

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

(2) ESRD PPS Drug Designation Process and Phosphate Binders

In addition to delaying implementation of the policy for oral-only renal dialysis service drugs and biological products under the ESRD PPS, as discussed in the proposed rule, PAMA included section 217(c), which provided that as part of CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and intravenous (IV) products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount to reflect the costs of furnishing that product.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA (80 FR 69024 through 69027). We defined an oral-only drug at § 413.234(a) to mean a drug or biological product with no injectable equivalent or other form of administration other than an oral form.

Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). In the CY 2016 ESRD PPS

final rule (80 FR 69024), we finalized that the drug designation process is dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the ESRD PPS in 2011, which we discussed in detail in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053). We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated in the CY 2011 ESRD PPS final rule that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

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

We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. We stated that the new injectable or IV product qualifies as an outlier service. We further explained that the ESRDB market basket updates the ESRD PPS base rate annually and accounts for price changes of the drugs and

biological products reflected in the bundled payment.

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

(3) Transitional Drug Add-On Payment Adjustment (TDAPA) Framework

The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products, as codified at § 413.234(c). 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. Furthermore, the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while also focusing Medicare resources on products that are innovative (83 FR 56935 and 84 FR 60654, respectively). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935).

In the CY 2016 ESRD PPS final rule, we finalized a policy at § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than two years (80 FR 69019 through 69025). During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an ESRD outlier service. We established that, following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new

injectable or IV product in the ESRD PPS bundled payment.

(4) Payment Policy for Phosphate Binders and Calcimimetics

In the CY 2016 ESRD PPS final rule (80 FR 69024 through 69027), CMS also established an exception to the drug designation process for calcimimetics and phosphate binders. We noted that in the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), the only oral-only drugs and biological products we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that we defined these oral-only drugs as renal dialysis services in our regulations at § 413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D. We explained in the CY 2016 ESRD PPS final rule that, under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category. Therefore, CMS does not make additional payment to ESRD facilities for these drugs.

However, we recognized the uniqueness of these drugs and stated that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and payment was never included in the ESRD PPS base rate to account for these drugs (80 FR 69025 through 69027). Instead, we finalized a policy that once the injectable or IV phosphate binder or calcimimetic is FDA approved and has a Healthcare Common Procedure Coding System (HCPCS) code, we would issue a CR to pay for all forms of the phosphate binder or calcimimetic using the TDAPA based on the payment methodologies under section 1847A of the Act, which could include average sales price (ASP) + 6 percent (ASP + 6), for a period of at least two years. In the CY 2016 ESRD PPS final rule, we explained that this would allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drugs, as well as payment patterns and beneficiary co-insurance, before we add these drugs to the ESRD PPS bundled payment. We stated that during this period we would not pay outlier payments for these drugs. We further stated that at the end of the two

or more years, we would adopt the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment through notice-and-comment rulemaking (80 FR 69025).

(5) Evolution of TDAPA Policies and Payment for Calcimimetics

In the CY 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we revised the drug designation process regulations at § 413.234(a), (b), and (c) to reflect that the process applies to all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration (83 FR 56932). In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories (83 FR 56942 through 56943). Finally, we revised § 413.234(c) to reflect that the TDAPA would be based on 100 percent of ASP instead of the pricing methodologies available under section 1847A of the Act, which includes ASP + 6. We explained that historically, the six percent add-on to ASP was used to cover administrative and overhead costs. However, the ESRD PPS base rate includes dollars for administrative complexities and overhead costs for drugs and biological products, so we stated that we believe ASP, without + 6, was a reasonable basis for the TDAPA under the ESRD PPS (83 FR 56943 through 56944). In the CY 2020 ESRD PPS final rule, we revised the eligibility criteria for the TDAPA, including defining specific New Drug Application (NDA) categories that are excluded from the TDAPA (84 FR 60659 through 60673).

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule, we issued a CR to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA. CR 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999, issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. The TDAPA for calcimimetics was paid at ASP + 6 for the first two years of the TDAPA period (83 FR 56944) and was paid ASP for the third year of the TDAPA period (84 FR 60676). In the CY 2020 ESRD PPS final rule we stated that after the first two years, sufficient time had passed for ESRD facilities to address any administrative complexities and overhead costs that may have arisen

related to furnishing calcimimetics (84 FR 60673). We then went through notice-and-comment rulemaking to incorporate calcimimetics into the ESRD PPS base rate beginning January 1, 2021, after the TDAPA payment period ended on December 31, 2020, using the methodology codified at § 413.234(f) (85 FR 71404 through 71410).

(6) TDAPA Implementation for Oral Phosphate Binders

In the CY 2025 ESRD PPS final rule, CMS finalized payment for oral phosphate binders under the ESRD PPS using the TDAPA, consistent with § 413.234(c), with incorporation into the ESRD PPS base rate to occur through future rulemaking after sufficient data collection (89 FR 89136 through 89153). This implementation fulfilled existing regulations at § 413.174(f)(6) that required oral-only drugs to be paid for under the ESRD PPS beginning in CY 2025, after multiple legislative delays (ATRA, PAMA, and ABLE) dating back to the original CY 2014 implementation date, as outlined in section II.B.7.a.(1) of the proposed rule.

Since January 1, 2025, oral phosphate binders have been paid under the ESRD PPS through the TDAPA, which is payable under our current regulations for a period of at least two years until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available. The TDAPA amount for phosphate binders currently includes 100 percent of ASP plus a flat rate increase of \$36.41 for monthly ESRD PPS claims to cover the operational costs associated with supplying phosphate binders to ESRD facilities. This \$36.41 figure was based on 6 percent of per-patient phosphate binder spending based on Part D cost and utilization data from before the beginning of the TDAPA period (89 FR 89148). CMS has stated that we would increase the ESRD PPS base rate to account for the average per-treatment phosphate binder spending, consistent with past policy for similar drugs (calcimimetics), after the end of the TDAPA period for phosphate binders (89 FR 89148).

b. Proposed Methodology for Incorporating Phosphate Binders Into the ESRD PPS Base Rate

(1) General Discussion of Claims Data and Intention

As we discussed previously, oral phosphate binders have been paid under the ESRD PPS through the TDAPA since January 1, 2025. In the CY 2016 ESRD PPS final rule, CMS discussed that phosphate binders fall

into the bone and mineral metabolism ESRD PPS functional category but are not accounted for in the base rate. We stated that we will utilize the TDAPA to collect utilization data before incorporating these drugs into the ESRD PPS base rate (80 FR 69025). We explained that this would allow CMS to collect data reflecting current utilization of oral phosphate binders, as well as payment patterns and beneficiary co-insurance, and after a period of at least 2 years, we would adopt the methodology for including these drugs in the ESRD PPS bundled payment through notice-and-comment rulemaking. This would be consistent with section 217(a)(2) of PAMA, which requires the Secretary to use data from the most recent year available when establishing payment for oral-only drugs under the ESRD PPS.

As discussed in the CY 2027 ESRD PPS proposed rule, we have collected sufficient claims data to conduct a rate-setting analysis for phosphate binders (91 FR 38815). Specifically, we have collected robust claims data since January 1, 2025, and analyzed the utilization of various oral phosphate binders, including sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. We monitored the ASP data available during the specific utilization periods. Our overall analysis of ESRD claims data for CYs 2025 and 2026 indicated utilization patterns across the various phosphate binder formulations, with variations in ASP reflecting the different product types and market dynamics within this therapeutic class.

Therefore, we stated in the proposed rule that we believe we are at the step of the ESRD PPS drug designation process (outlined at § 413.234) where we propose the methodology for modifying the ESRD PPS base rate to account for phosphate binders in the ESRD PPS bundled payment for CY 2027. We noted that we believe that a base rate increase is warranted in the case of phosphate binders because, as discussed in the CY 2011 ESRD PPS final rule, oral-only drugs, which included phosphate binders, were not included in the ESRD PPS at the inception of the bundled payment system (75 FR 49043 through 49044) and currently remain unaccounted for within the ESRD PPS base rate. We proposed to add a per-treatment amount to the ESRD PPS base rate to include phosphate binders in the ESRD PPS bundled payment amount for dates of service on or after January 1, 2027.

In developing the proposed methodology for including phosphate

binders into the ESRD PPS base rate, we considered the methodology that we used when we incorporated calcimimetics into the ESRD PPS base rate beginning for CY 2021, as well as the methodology we used when we included Part B drugs and biological products in the ESRD PPS base rate as part of our initial implementation of the ESRD PPS. In the CY 2021 ESRD PPS final rule (85 FR 71404 through 71410), we discussed how we established the methodology for incorporating calcimimetics into the ESRD PPS base rate using utilization data from Medicare claims and applying ASP to establish the price for each drug form.

In addition, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49064), we established a dialysis treatment as the unit of payment. Consistent with the approach we used to include calcimimetics in the ESRD PPS base rate and the ESRD PPS unit of payment, we proposed a similar methodology in the CY 2027 ESRD PPS proposed rule to calculate a one-time modification to the ESRD PPS base rate on a per-treatment basis to account for phosphate binders. The proposed methodology is similar to the calcimimetics approach because we would determine utilization of the drugs, in this case, phosphate binders, along with the payment amounts associated with each phosphate binder product based on ASP, consistent with our established TDAPA pricing policy.

The following sections review each element of our proposed methodology in detail. As an overview, we proposed to calculate a per-treatment amount for phosphate binders that would be added to the ESRD PPS base rate. We proposed to apply 100 percent of the ASP value from the most recent calendar quarter ASP calculations to the utilization data for phosphate binders between April 1, 2025, and December 31, 2025, based on Medicare ESRD claims data, for the proposed rule. For the calculations in this final rule, utilization data is based on ESRD claims from between April 1, 2025, and June 30, 2026. This would provide the phosphate binder expenditure amount. We proposed to then multiply the phosphate binder expenditure amount by 1.06, consistent with the methodology that we used to calculate the flat rate add-on per-monthly claim amount of \$36.41 during the TDAPA period, to yield the adjusted phosphate binder expenditure amount. Next, we proposed to divide the adjusted phosphate binder expenditure amount by the total number of hemodialysis-equivalent dialysis treatments paid between April 1, 2025, and December 31, 2025, under the ESRD PPS (April 1, 2025, and June 30, 2026,

for this final rule). We proposed to reduce this average per-treatment amount by one percent to account for the outlier policy, since phosphate binders would be ESRD outlier services eligible for outlier payments beginning January 1, 2027, under the proposal. We proposed to add the resulting amount to the ESRD PPS base rate, as outlined in section II.B.4. of the proposed rule. We noted that this amount would stay in the base rate and be subject to the annual updates (ESRDB market basket update and application of wage index budget neutrality adjustment factor). Under the proposal, CMS would stop paying for these drugs through the TDAPA for dates of service on or after January 1, 2027.

We stated that, if finalized, this proposal would complete the implementation of § 413.174(f)(6), which provides that oral-only renal dialysis drugs are paid under the ESRD PPS beginning January 1, 2025, and that separate payment for oral-only phosphate binders is no longer provided beginning January 1, 2025. We described that the proposal, if finalized, would establish the methodology for incorporating phosphate binders into the ESRD PPS base rate following the TDAPA period. We proposed revising our drug designation regulation at § 413.234 by adding paragraph (h) to set forth the methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders. The proposed paragraph (h) would include the data sources and the steps we would take to calculate a per-treatment amount. We proposed that, for dates of service on or after January 1, 2027, oral phosphate binders would no longer be paid for under the ESRD PPS through the TDAPA (§ 413.234(c)) and would be paid for through the ESRD PPS base rate and be eligible for outlier payments as ESRD outlier services under § 413.237.

We noted that the methodology proposed in the proposed rule is only for modifying the ESRD PPS base rate to include phosphate binder drugs. This is consistent with our established policy for renal dialysis drugs and biological products that are not considered to be included in the ESRD PPS base rate, and as outlined at § 413.234(c) and (d). This policy states that we would propose and adopt the methodology for modifying the ESRD PPS base rate, if appropriate, to account for the products through notice-and-comment rulemaking after sufficient claims data collection through the TDAPA process.

(2) Determining Utilization of Phosphate Binders

For the CY 2027 ESRD PPS proposed rule calculation, we analyzed the utilization of phosphate binders reported on the ESRD facility claims for CY 2025. For the calculations in this final rule, we analyzed the utilization of phosphate binders reported on the ESRD facility claims between April 1, 2025, and June 30, 2026. ESRD facilities report this information to CMS on Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X. The various phosphate binders are reported using their respective HCPCS codes, including but not limited to codes for sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. For purposes of this rate-setting analysis, we considered utilization of phosphate binders as the units of the products furnished to an ESRD beneficiary.

For purposes of calculating the proposed addition to the ESRD PPS base rate, we proposed to use the latest available claims data with dates of service from April 1, 2025, through December 31, 2025, rather than beginning January 1, 2025 (April 1, 2025, and June 30, 2026, for this final rule). We noted that we believe this approach is appropriate because the first quarter of CY 2025 (January 1, 2025, through March 31, 2025) reflects a transitional period during which oral phosphate binders moved from coverage under Medicare Part D to payment under the ESRD PPS as TDAPA-eligible renal dialysis drugs. Utilization patterns during this initial transition period may not be representative of stable, ongoing utilization under the ESRD PPS, as ESRD facilities were in the process of establishing billing, dispensing, and operational workflows for these products. To ensure that our base rate calculation reflects a more accurate and representative picture of phosphate binder utilization and costs under the ESRD PPS, we proposed to exclude first quarter 2025 data and begin our reference period on April 1, 2025. We stated that we believe this approach would produce a more reliable estimate of the costs that should be incorporated into the ESRD PPS base rate beginning January 1, 2027. We noted that claims which have been received, processed, paid, and passed to the National Claims History (NCH)¹⁸ file are considered “complete” because they have been

adjudicated, and that we proposed to consider only complete claims when calculating the ESRD PPS base rate addition for phosphate binders.

For the CY 2027 ESRD PPS final rule, we proposed to update this calculation with the most recent available claims data, which we anticipated to be claims with dates of service from April 1, 2025, through July 31, 2026 (that is, claims that were received, processed, paid, and passed to the NCH File as of July 2026).

We solicited comments on the proposed use of claims data with dates of service from April 1, 2025, through December 31, 2025, to determine the utilization of phosphate binders and our proposal to omit first quarter 2025 claims data for purposes of calculating the proposed addition to the ESRD PPS base rate to account for phosphate binders at the proposed § 413.234(h).

(3) Methodology for Determining the Price of Phosphate Binders

For use in the proposed calculation, we would set the price for phosphate binders using values from the most recent calendar quarter of ASP calculations available to the public, at 100 percent of ASP. This would be consistent with § 413.234(c)(1), which provides that TDAPA payment is based on 100 percent of ASP. The ASP-based value is a CMS-derived weighted average of all National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the existing HCPCS codes for phosphate binders. For each billing code, CMS calculates a weighted ASP using data submitted by manufacturers, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold, and the ASP for those units. This calculation methodology is consistent with the approach described in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752) and authorized in section 1847A of the Act.

Consistent with the TDAPA basis of payment established for oral phosphate binders in CY 2025, we proposed to use 100 percent of the weighted ASP value. As we explained in the CY 2020 ESRD PPS final rule, the ESRD PPS accounts for storage and administration costs and ESRD facilities do not have acquisition price variation issues when compared to physicians (83 FR 56946). We noted in the CY 2027 ESRD PPS proposed rule that we believe ASP is reasonable for phosphate binders because it reflects manufacturer sales prices net of applicable price concessions specified under section 1847A and provides a standardized measure for valuing phosphate-binder utilization. As we

discussed previously, the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for renal dialysis drugs and biological products. We proposed an increase to the base rate to account for the newfound responsibility and substantial pill volume associated with ESRD facility dispensing of phosphate binders, which we discussed in detail in the proposed rule.

We stated that we believe using a value based on the most recent calendar quarter ASP calculations available to the public for phosphate binders would provide an accurate representation of the price of these drugs for ESRD facilities because it uses manufacturer sales information that includes discounts (that is, rebates, volume discounts, prompt payment, and cash payment specified in section 1847A of the Act).

For the proposed rule, the values from the most recent calendar quarter of ASP calculations available to the public were from the second quarter of 2026, and due to a two-quarter data lag, these ASP calculations reflected manufacturer sales data submitted to CMS for the fourth quarter of 2025. For this CY 2027 ESRD PPS final rule, the most recent calendar quarter of ASP calculations available to the public is the fourth quarter of 2026, which reflects manufacturer sales data submitted into CMS for the second quarter of 2026, and we proposed to use that value for purposes of our final calculation.

We proposed to add § 413.234(h)(2)(ii), under which CMS would use 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for phosphate binders to calculate a price for each product. We solicited comments on the proposed use of the values from the most recent calendar quarter ASP calculations available to the public for phosphate binders for setting the price and the proposed language at § 413.234(h).

(4) Methodology for Calculating the Addition to the ESRD PPS Base Rate To Include Phosphate Binders

To calculate the proposed amount for phosphate binders that would be added to the ESRD PPS base rate, we applied the values from second quarter of 2026 at 100 percent of ASP. We proposed to determine utilization based on the number of units billed during the TDAPA period. For each oral phosphate binder HCPCS code, the short description states what the billing unit is for that drug or biological product and is located in Table 13. Billing units are the standardized quantities used by

¹⁸ The National Claims History (NCH) file is a comprehensive CMS data repository containing all processed Medicare Part A and Part B claims since 1991.

providers and suppliers when submitting Medicare Part B claims and are specific to each HCPCS code. For example, for sevelamer carbonate billed under J0601, one billing unit equals 20 mg/tablet. We noted that billing units differ from revenue units, which are a commercial data construct used to standardize drug volume across dosage strengths for market analysis purposes. We determined that 5,547,594,800 total billing units of oral phosphate binders were used between April 1, 2025, and

December 31, 2025. Table 13 includes a column of billing units reported in claims data for each individual HCPCS code from throughout the study period. Our monitoring indicates that approximately 67 percent of ESRD beneficiaries received oral phosphate binders during the study period.

For the proposed rule, we used the values from the most recent calendar quarter ASP calculations available to the public, which was the second quarter of 2026. This information can be found on

the ESRD Payment website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug>. Table 13 also lists the per unit ASP for the various oral phosphate binder products based on their respective HCPCS codes and unit definitions. (We note that, for the CY 2027 ESRD PPS final rule, we are updating the ASP-based value on the most recent calendar quarter calculations available to the public, which is the fourth quarter of 2026.)

TABLE 13: Phosphate Binder HCPCS Codes and ASP for Proposed Rule

HCPCS	Short Description	ASP	Billing Units
J0601	Sevelamer carbonate 20 mg	\$0.003	2,487,026,286
J0602	Sevelamer carbonate powder 20mg	\$0.008	153,287,238
J0603	Sevelamer hydrochloride 20mg	\$0.011	52,533,278
J0605	Sucroferric oxyhydroxide 5mg	\$0.157	1,261,980,703
J0607	Lanthanum carbonate oral 5mg	\$0.009	304,664,818
J0608	Lanthanum carbonate powder 5mg	\$0.062	5,740,264
J0609	Ferric citrate oral 3 mg iron	\$0.086	666,183,329
J0615	Calcium acetate, oral, 23 mg	\$0.003	616,178,884
Total:			5,547,594,800

Multiplying the utilization of the oral phosphate binders by their respective ASP and then adding the expenditure amount for all forms of phosphate binders together yield the total calculated phosphate binder

expenditure amount. For the period of April 1, 2025, through December 31, 2025, that was evaluated for the proposed rule, CMS calculated the total phosphate binder expenditure amount to be \$269,634,395.87. We proposed to

update this amount in the CY 2027 ESRD PPS final rule using the most recent available data. The updated utilization and ASP is presented in Table 14.

TABLE 14: Final Rule Phosphate Binder Utilization and Price

HCPCS	Short Description	ASP	Billing Units
J0601	Sevelamer carbonate 20 mg	\$0.003	4,210,121,111
J0602	Sevelamer carbonate powder 20mg	\$0.007	273,128,715
J0603	Sevelamer hydrochloride 20mg	\$0.009	88,874,332
J0605	Sucroferric oxyhydroxide 5mg	\$0.122	2,176,776,833
J0607	Lanthanum carbonate oral 5mg	\$0.008	539,600,656
J0608	Lanthanum carbonate powder 5mg	\$0.061	8,293,834
J0609	Ferric citrate oral 3 mg iron	\$0.068	1,023,658,331
J0615	Calcium acetate, oral, 23 mg	\$0.004	999,397,814
Total:			9,319,851,626

For the period of April 1, 2025, through June 30, 2026, that was evaluated for this final rule, CMS calculated the total phosphate binder expenditure amount to be \$359,337,993.84 based on the 9,319,851,626 total billing units of oral phosphate binders used. Table 14 includes a column of billing units reported in claims data for each individual HCPCS code from throughout the final rule study period. Our monitoring indicates that approximately 66 percent of ESRD beneficiaries received oral phosphate binders during the study period.

(5) Accounting for Operational Costs

In addition to including direct drug costs, we proposed to incorporate an additional amount in the base rate to reflect the operational costs associated with supplying phosphate binders to ESRD facilities. During the TDAPA period, we provided a flat rate increase of \$36.41 for monthly ESRD PPS claims to cover these operational costs, which include storage, distribution, staffing, and administrative expenses unique to the high-volume, multi-product nature of phosphate binder therapy. We stated that we expect the ongoing provision of phosphate binders will continue to result in additional operational costs for ESRD facilities. Incorporating these operational costs into the base rate is consistent with our authority under section 1881(b)(14) of the Act to establish a bundled payment that reflects the costs of furnishing renal dialysis services, as CMS considers phosphate binders to be a renal dialysis service as described at § 413.171.

As discussed in the CY 2027 ESRD PPS proposed rule, the ESRD PPS base rate includes general overhead and administrative costs that apply broadly across renal dialysis services. Because of this, CMS did not establish a separate operational cost component for calcimimetics during the TDAPA period for calcimimetics or when calcimimetics were incorporated into the ESRD PPS base rate. However, as discussed in the CY 2025 ESRD PPS final rule, oral phosphate binders present unique, high-volume dispensing and logistical demands that are distinct from and not captured by the general overhead and administrative costs discussed previously (89 FR 89152). For example, in response to the CY 2025 ESRD PPS proposed rule, one interested party commented that phosphate binders represent an exponential increase in the volume of pills that dialysis providers need to acquire, distribute, store, and manage, and that the relative difference between managing 360 pills per year per patient for cinacalcet as compared with 3,240 pills per year per patient for calcium carbonate is 800 percent (89 FR 89141). CMS addressed this comment, among many others, in the CY 2025 ESRD PPS final rule, where we established a flat-rate TDAPA add-on of \$36.41 per monthly claim to address the circumstances¹⁹ associated with

¹⁹ In the CY 2025 ESRD PPS final rule, CMS stated that after consideration of all the comments received, we agree with commenters that there are additional costs associated with ESRD facilities furnishing phosphate binders that are not currently included in the ESRD PPS base rate and that were not addressed when the ESRD PPS base rate was developed in CY 2011. This differentiates

dispensing phosphate binders (89 FR 89152). Specifically, CMS stated that an increase in the payment adjustment amount that approximates 6 percent of ASP would provide the appropriate payment for incremental operational costs associated with ESRD facilities furnishing phosphate binders (89 FR 89152). As discussed previously, CMS expects that the ongoing provision of phosphate binders under Part B will result in a permanent expansion in operational costs for ESRD facilities. Therefore, we stated in the proposed rule, CMS believes proposing to incorporate an equivalent operational cost component into the base rate is not duplicative of existing base rate funds and is necessary to ensure that the base rate accurately reflects the cost of furnishing these renal dialysis services.

Based on our analysis of claims data from April 1, 2025, through June 30, 2026, (April 1, 2025, through December 31, 2025, for the proposed rule), we determined that 1,204,886 (711,875 during the proposed rule study period) monthly claims included phosphate binders. To account for operational costs in the base rate calculation, we considered two approaches: (1) applying the \$36.41 flat rate per monthly claim that was paid during the TDAPA period, and (2) calculating an operational cost component equal to an amount approximately equivalent to 6 percent of

phosphate binders from other drugs and biological products in existing ESRD PPS functional categories, which justifies a change to the TDAPA policy, as phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule due to a lack of data available at the time of rulemaking. (89 FR 89152).

observed ASP-based expenditures, derived from empirical TDAPA-period payment data rather than from the statutory ASP + 6 percent methodology under section 1847A of the Act. We emphasized that this proposed approach is not a methodology for pricing phosphate binders; as we discussed previously, we proposed to address the cost of phosphate binders using a weighted average of 100 percent of ASP for each phosphate binder type and dose.²⁰ Separately, we proposed to address the operational costs associated with ESRD facilities providing phosphate binders due to the large patient population and substantial pill volume. We proposed to estimate this cost by calculating a one-time increase to the ESRD PPS base rate consistent with the approach CMS adopted in the CY 2025 ESRD PPS final rule when establishing the \$36.41 flat-rate TDAPA add-on amount (89 FR 89152). We proposed to base this calculation on the price and utilization data collected during the TDAPA period, where oral phosphate binders were provided by ESRD facilities at scale.

We noted that, as discussed in the CY 2020 ESRD PPS final rule, we continue to believe that 100 percent of ASP is an appropriate basis for pricing renal dialysis drugs within the ESRD PPS because the bundled payment already incorporates general overhead and administrative costs (83 FR 56943 through 56944). However, phosphate binders present unique, high-volume dispensing and logistical demands that were not fully reflected in the historical base rate given that phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule (89 FR 89152).

Accordingly, rather than adopting a pricing methodology that includes an add-on to ASP, we proposed to use the TDAPA-period data to identify and incorporate a distinct, empirically observed operational cost component into the base rate. Multiplying the 1,204,886 (711,875 during the proposed rule study period) monthly claims that included phosphate binders by the \$36.41 flat rate yields a total operational cost amount of \$43,869,899.26 for the final rule reference period (\$25,919,368.75 during the proposed rule study period). As noted previously, the \$36.41 figure was based on 6 percent of the weighted average of Medicare expenditures for phosphate binders per month under Part D, for all phosphate

binders used in a month, based on estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries (89 FR 89152). Alternatively, applying 6 percent to the total ASP-based drug expenditure for oral phosphate binders during the same period yields a total operational cost amount of \$21,560,279.63 (\$16,178,063.75 during the proposed rule study period).

We proposed to base operational costs associated with furnishing phosphate binders on 6 percent of total ASP-based drug expenditure for oral phosphate binders during the TDAPA period. While the flat rate add-on per-monthly claim amount of \$36.41 was administratively straightforward during the TDAPA period, we stated that we believe an operational cost component that scales with drug utilization better reflects the variable, volume-driven nature of phosphate binder dispensing. An operational cost component within the base rate would also be spread across all dialysis treatments, as intended with a PPS, and would ensure that these operational costs are updated annually as part of the ESRD market basket update.

Our analysis indicates that this utilization-based approach yields an amount approximately equivalent to 6 percent of ASP-based expenditures over the reference period.²¹ Therefore, we proposed this approach as a more data-driven and PPS-consistent method for incorporating operational costs into the base rate.

(6) Combined Calculation

In the CY 2027 ESRD PPS proposed rule, we presented a step-by-step calculation for the addition to the base rate for phosphate binders (91 FR 38815). For this final rule, we are updating those calculation steps with the most recent data. The total number of paid hemodialysis-equivalent dialysis treatments furnished to Original Medicare ESRD beneficiaries between April 1, 2025, and December 31, 2025, as mentioned previously, was 17,733,591. This total number of paid treatments reflects all paid dialysis treatments during the proposed rule study period, regardless of whether a phosphate binder was furnished. The updated data available at the time of this final rule displays the total number of paid hemodialysis-equivalent dialysis treatments furnished to Original

Medicare ESRD beneficiaries between April 1, 2025, and June 30, 2026, to be 29,341,805.

As discussed in the CY 2027 ESRD PPS proposed rule, to calculate the combined per-treatment amount, we add the direct drug expenditure amount of \$359,337,993.84 (\$269,634,395.87 during the proposed rule study period), multiplied by 1.06 to account for operational costs, \$21,560,279.63 (\$16,178,063.75 during the proposed rule study period), to get an adjusted phosphate binder expenditure amount of \$380,898,273.47 (\$285,812,459.62 during the proposed rule study period). Dividing this adjusted expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments, 29,341,805 (17,733,591 during the proposed rule study period) provides an average per-treatment payment amount of \$12.98 (\$16.12 during the proposed rule study period).

We proposed to reduce this amount by 1 percent to account for the outlier policy, consistent with the ESRD outlier policy at § 413.237(a)(1)(iv), which provides for budget neutrality adjustments associated with outlier payments, to get a total of \$12.85 ($\$12.98 \times 0.99 = \12.85), which is less than our proposed rule total of \$15.96. Under our proposal, we would apply this 1 percent reduction before increasing the base rate to account for outlier payments that would be paid beginning January 1, 2027, for phosphate binders since they would become eligible ESRD outlier services once the TDAPA period ends.

To determine the estimated costs in CY 2027, we would inflate the outlier-adjusted average per-treatment payment amount for phosphate binders (\$12.85) to 2027 using the CY 2027 ESRDB market basket update. As outlined in section II.B.4. of this final rule, the CY 2027 ESRD PPS base rate is \$297.52. This amount reflects a CY 2027 wage index budget-neutrality adjustment factor of 1.00260, a budget neutrality factor of 0.98864 for the budget neutral policies finalized in sections II.B.8., II.B.9., and II.B.10. of this final rule, a base rate addition of \$12.85 to include phosphate binders (including both direct drug costs and operational expenses), and the CY 2027 ESRDB payment rate update of 1.9 percent. We explained that we believe that using the annual payment rate update would effectively update the prices set for phosphate binders from CY 2026 to CY 2027 because this is consistent with how the other components of the base rate are updated for inflation each year, which includes drugs. We note that in section II.B.1.b. of this final rule, we

²⁰ This refers to the per-treatment spending amount for phosphate binders calculated using the ASP for all oral phosphate binder HCPCS codes weighted by utilization.

²¹ This refers to the per-treatment spending amount for phosphate binders calculated using the ASP for all oral phosphate binder HCPCS codes weighted by utilization.

finalized our proposal to rebase and revise the ESRDB market basket to a CY 2024 base year. The inflation factor used for drugs and biological products for the ESRDB market basket is a composite of various drug-related Producer Price Indexes as outlined in section II.B.1.b.(2) of this final rule.

We proposed to add a new paragraph § 413.234(h) regarding the data sources and methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders and the operational expenses associated with providing phosphate binders in the ESRD PPS bundled payment. This new paragraph would state that, for dates of service on or after January 1, 2027, CMS would determine the utilization of phosphate binders by aggregating total units from Medicare ESRD facility claims (837-institutional form with bill type 072X) for the second, third, and fourth quarters of calendar year 2025 and the first two quarters of calendar year 2026. CMS would price each phosphate binder at 100 percent of the most recent calendar quarter ASP calculations available to the public. CMS would then multiply the utilization of each phosphate binder by its respective price and sum the expenditure amounts across all phosphate binder products to calculate the total oral phosphate binder expenditure amount. CMS would then calculate an adjusted phosphate binder expenditure amount by multiplying the phosphate binder expenditure amount by 1.06 to account for operational expenses. CMS would divide the adjusted total expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments from Medicare ESRD facility claims during the same claims data period to calculate the average per-treatment payment amount. Finally, CMS would reduce the average per-treatment payment amount by 1 percent to account for the outlier policy under § 413.237 to determine the amount added to the ESRD PPS base rate.

Beginning January 1, 2027, phosphate binders would also be eligible ESRD outlier services under § 413.237. The fundamental principle of the ESRD PPS is that the costs of renal dialysis services, including drugs, are incorporated into the base rate and spread across all dialysis treatments rather than assigned only to those treatments for which a particular item or service is furnished (75 FR 49030). We stated that, in keeping with this principle, we believe the cost of phosphate binders should be spread across all dialysis treatments rather than be directed only to the treatments for

patients who are receiving phosphate binders.

We solicited comment on the proposed revisions to add paragraph (h) to § 413.234 to establish the data sources and methodology for modifying the ESRD PPS base rate to account for phosphate binders in the ESRD PPS bundled payment.

We received public comments on numerous aspects of these proposals to include phosphate binders in the ESRD PPS base rate. The following is a summary of the comments we received and our responses.

Comment: Several individual commenters, including registered dietitians, nurses, and other clinical staff, expressed strong support for including phosphate binders in the ESRD PPS bundled payment, citing reduced administrative burden, elimination of prior authorization requirements, and fewer delays related to insurance and pharmacy access. Commenters noted that direct access through the ESRD PPS bundled payment allows for faster response to elevated phosphorus levels, improved medication adherence, and the elimination of out-of-pocket costs that previously led some beneficiaries to ration their medication. Several commenters also noted that home delivery of phosphate binders through the ESRD PPS bundled payment addressed transportation barriers that had previously limited access for some beneficiaries.

Response: We thank the commenters for sharing their experiences with the TDAPA period for oral phosphate binders. We agree that incorporating these drugs into the ESRD PPS base rate should reduce administrative burden for ESRD facilities and improve timely access to phosphate binders for beneficiaries. We continue to believe that incorporating phosphate binders into the ESRD PPS base rate, consistent with the treatment of other oral-only drugs, appropriately reflects the goals of the ESRD PPS bundled payment methodology.

Comment: An interested party representing skilled nursing facility and nursing facility (SNF/NF) interests raised operational and clinical concerns regarding care fragmentation for beneficiaries in congregate care settings. The commenter identified timing gaps during weekend and evening discharges when ESRD facility staff are unavailable, a conflict between SNF federal medication timing requirements and the SNF's lack of direct purchasing authority for bundled phosphate binders, and administrative delays resulting from shifting billing pathways

between Part D, Part A, and ESRD facilities. The commenter recommended that CMS establish a 14- to 30-day "Transitional Care Access" exemption following a hospital discharge to a congregate care setting, during which the SNF or NF could bill directly under Part D or Part A rather than coordinate through the ESRD facility.

Response: We appreciate the commenter identifying these operational challenges for beneficiaries transitioning into SNFs and NFs. We recognize that care coordination between ESRD facilities and congregate care settings presents unique logistical considerations that differ from beneficiaries residing in the community. However, we do not believe it would be appropriate to establish a facility-type-specific exemption from the ESRD PPS bundled payment methodology, as doing so would create a parallel payment pathway that could complicate billing and undermine the consistency of the bundled payment across care settings. We encourage ESRD facilities and SNFs/NFs to work together, along with their contracted pharmacies, to establish protocols that support the timely delivery of phosphate binders around the time of discharge and other transitions of care. We will continue to monitor concerns related to care fragmentation in congregate care settings and will consider whether additional guidance or policy refinements are warranted in future rulemaking.

Comment: One LDO generally supported incorporating phosphate binders into the ESRD PPS bundled payment but emphasized that binder selection should continue to be driven by clinical effectiveness and adherence rather than cost alone. The commenter noted that one sucroferic oxyhydroxide product has a substantial body of real-world evidence demonstrating improved phosphorus control with a lower pill burden compared to alternatives such as sevelamer and calcium acetate. However, the commenter expressed concern that interested parties assuming widespread switching to generic products may be overestimating the ability of providers to achieve equivalent clinical outcomes using lower-cost alternatives. The commenter recommended that CMS finalize the proposed methodology for modifying the ESRD PPS base rate and confirm the policy's applicability to beneficiaries with AKI.

Response: We appreciate the commenter's perspective on the clinical considerations that inform phosphate binder selection. We agree that clinical effectiveness and beneficiary adherence

should remain the primary drivers of treatment decisions and note that our proposal was not intended to restrict a clinician's ability to prescribe the phosphate binder that best meets a beneficiary's clinical needs. We note that phosphate binders would be an eligible ESRD outlier service, which will help support access for unusual variations in the type or amount of medically necessary care. With respect to AKI beneficiaries receiving outpatient dialysis, we address this issue further in our next response to comments.

Comment: Several commenters including an LDO and a non-profit dialysis association requested that CMS clarify the responsibility for furnishing phosphate binders to beneficiaries with AKI who receive outpatient dialysis, noting that once phosphate binders are incorporated into the ESRD PPS base rate, this change will also affect AKI beneficiaries prescribed phosphate binders. The commenter requested that CMS clarify these issues in the CY 2027 ESRD PPS final rule or through subsequent guidance and asked that CMS ensure timely communication reaches MACs, ESRD facilities, nephrologists, Part D plans, Medicare Advantage plans, and beneficiaries prior to implementation.

Response: We thank the commenters for raising this issue and agree that clarity regarding the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis is important to the implementation of this policy. As discussed in section III.B. of this final rule, the AKI dialysis payment rate applies to all renal dialysis services, and ESRD facilities are responsible for furnishing all medically necessary renal dialysis services to beneficiaries with AKI who are receiving dialysis as specified at § 413.374(a). While oral-only renal dialysis drugs and biological products have always met the definition of renal dialysis services, the statutory delays implemented in our regulations at § 413.174(f)(6) postponed their inclusion in the ESRD PPS bundled payment until January 1, 2025. During the TDAPA payment period for phosphate binders, the TDAPA did not apply to renal dialysis services furnished to beneficiaries with AKI, and ESRD facilities were not yet responsible for furnishing phosphate binders to beneficiaries with AKI (89 FR 89172). This is because phosphate binders were not originally included in the ESRD PPS base rate, and therefore were not reflected in the AKI dialysis payment rate that is based on the ESRD PPS base rate. As a result, during the TDAPA period, the AKI dialysis payment rate did not include any amount for

phosphate binders, so ESRD facilities had no payment mechanism through which to furnish them to beneficiaries with AKI.

Now that payment for phosphate binders is being incorporated directly into the ESRD PPS base rate, that payment is included in the AKI dialysis payment rate as well, because the AKI dialysis payment rate is based on the ESRD PPS base rate. As a result, ESRD facilities will be expected to furnish medically necessary phosphate binders to beneficiaries with AKI and receive payment under the AKI dialysis payment rate.

We recognize that the payment rate for renal dialysis services furnished to beneficiaries with AKI is based on the ESRD PPS base rate and that, beginning January 1, 2027, the ESRD PPS base rate will include an amount to account for phosphate binders. We intend to issue subregulatory guidance addressing the implications of this policy for the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis. We will work to ensure that this guidance, along with other operational instructions related to this policy, is disseminated to MACs, ESRD facilities, treating clinicians, Part D plans, MA plans, and beneficiaries in advance of the January 1, 2027, implementation date. For further discussion of CMS policy pertaining to beneficiaries with AKI, please refer to section III.B.1. of this final rule.

Comment: MedPAC supported bundling phosphate binders into the ESRD PPS in principle but raised several methodological concerns. MedPAC recommended that CMS use a more conservative utilization methodology consistent with the approach taken under the MIPPA, specifically recommending that CMS use the lowest per-patient utilization year rather than utilization data from the TDAPA period to minimize the risk of overpayment. MedPAC also questioned whether the entry of generic alternatives, including an authorized generic in March 2025 and a generic version in March 2026, would affect the cost estimates underlying the proposed base rate increase, and noted that one LDO's product, without a generic alternative, accounts for approximately 73 percent of the proposed rate increase. Additionally, MedPAC recommended that CMS remove the proposed 6 percent operational cost multiplier, noting that operational costs associated with furnishing phosphate binders are already partially reflected in the existing ESRD PPS base rate and that including a separate add-on would be duplicative.

Response: We thank MedPAC for its continued support of incorporating phosphate binders into the ESRD PPS base rate and for the commission's detailed methodological feedback. Regarding the utilization methodology, CMS considered the approach used under MIPPA, but we continue to believe that using TDAPA-period utilization data provides the most accurate reflection of current phosphate binder use, as it captures a more recent and complete time period than using the single lowest-utilization year. We note that any claims that include the previously mentioned authorized generic in March 2025 and the generic version in March 2026 would be included in the 2026 fourth quarter ASP data and thus included in the final rule calculations for the base rate increase. We will, however, continue to monitor utilization trends, including the effect of generic alternatives on costs and utilization patterns, and will consider adjustments in future rulemaking if actual experience meaningfully diverges from our projections.

With respect to the proposed operational cost multiplier, we disagree that this adjustment is duplicative of costs already embedded in the base rate. As we discussed in the CY 2027 ESRD PPS proposed rule and previously in this final rule, we believe the additional operational costs associated with ordering, dispensing, and coordinating phosphate binders under the ESRD PPS bundled payment are distinct from the general administrative costs reflected in the existing base rate calculation and warrant additional payment. We note that CMS did not incorporate an equivalent operational cost component when calcimimetics were added to the ESRD PPS base rate, because calcimimetics do not present the same high-volume, multi-product dispensing and logistical demands as phosphate binders, which are typically administered several times daily across six or more distinct products with differing storage and handling requirements. This distinction is consistent with the rationale CMS articulated in the CY 2025 ESRD PPS final rule when establishing the \$36.41 flat-rate TDAPA add-on for phosphate binders, which recognized that dispensing fees and other operational costs were not included in the ESRD PPS base rate for phosphate binders and that every ESRD facility would incur distribution, storage, and staffing expenses not accounted for in ASP data alone (89 FR 55797 through 55829). Moreover, incorporating this operational cost component as a percentage of ASP-

based expenditures embedded in the base rate rather than as a separate flat-rate add-on reflects the same average, empirically observed costs that underlie the ESRD PPS more broadly, and ensures the base rate accurately captures the full cost of furnishing phosphate binders. We appreciate MedPAC's observation regarding the concentration of the proposed rate increase in a single product without a generic alternative and will continue to monitor market entry of generic and authorized generic alternatives as part of our ongoing evaluation of this policy.

Comment: Several commenters, including a regional dialysis organization, an ESRD facility, a coalition of dialysis organizations, and a drug manufacturer, expressed concern regarding CMS's proposal to recalculate the operational cost add-on amount for phosphate binders when converting it from a TDAPA-period flat fee into a permanent component of the ESRD PPS base rate. Commenters noted that the costs of storing, managing, and dispensing phosphate binders have not decreased since CMS established the \$36.41 monthly operational add-on under the TDAPA methodology, and expressed concern that CMS's proposed recalculation would result in a lower operational cost figure. A few commenters recommended that CMS instead maintain the operational add-on amount calculated during the TDAPA period using the ASP+6 percent methodology, rather than recalculate a new amount for CY 2027. A coalition of dialysis organizations similarly urged CMS to add an amount corresponding to the current TDAPA-period operational add-on. A drug manufacturer recommended that CMS adopt this alternative approach and retain the current operational expense add-on to account for distribution, mailing, and storage costs. A non-profit kidney care alliance more generally urged CMS to continue accounting for both drug and operational costs in future methodology updates.

Response: We thank the commenters for their feedback on our proposed approach to calculating the operational cost component of the phosphate binder base-rate addition. We clarify that the 6 percent adjustment is not an add-on to ASP for purposes of pricing phosphate binders. As described in the proposed rule, we proposed to price phosphate binders using 100 percent of ASP and separately account for the operational costs associated with furnishing phosphate binders in calculating the amount incorporated into the ESRD PPS base rate. We understand commenters' preference for maintaining the TDAPA-

period operational add-on amount for consistency and predictability. However, we continue to believe that recalculating the operational cost figure using more recent utilization and cost data provides a more accurate reflection of current operational costs than continuing to rely on the amount established earlier in the TDAPA period. We note that the operational cost add-on, like the drug cost component, is intended to reflect current, rather than static, cost experience, consistent with how we approach other bundled components of the ESRD PPS base rate. We appreciate commenters' support for continuing to account for both drug and operational costs in the base rate and confirm our intention to do so. We recognize the commenters' statement that operational costs associated with ESRD facilities furnishing phosphate binders have not changed since they were first added to the ESRD PPS bundled payment in CY 2025, however we believe that some of the initial costs associated with the transition should decrease over time. For example, we believe that certain costs associated with setting up systems or processes will likely decrease as those processes become standard. We note that the \$36.41 monthly operational add-on was based on part D data, and we believe that recalculating the amount based on actual spending and utilization through the TDAPA is more reflective of these costs under the ESRD PPS.

Comment: A network of dialysis organizations and regional offices and a provider advocacy organization raised concerns regarding whether the operational cost add-on, maintained or recalculated, adequately reflects the real-world costs that ESRD facilities incur in furnishing phosphate binders. The network of dialysis organizations and regional offices supported the proposed \$15.96 base-rate increase and associated 6 percent operational adjustment but urged CMS to revise the adjustment if it does not cover real-world dispensing, shipping, counseling, and adherence-support costs. The provider advocacy organization raised a more specific concern, noting that the \$36.41 monthly operational add-on was derived from 2023 Part D utilization patterns and does not reflect costs specific to small and independent facilities, including specialty pharmacy arrangements, rural and home delivery logistics, and adherence support. The commenter stated that any inadequacy in the original \$36.41 figure has been carried forward, uncorrected, into the

proposed permanent base-rate modification.

Response: We appreciate the commenters' detailed feedback on the real-world costs associated with furnishing phosphate binders. We recognize that ESRD facilities, particularly small and independent facilities, may incur costs related to specialty pharmacy arrangements, rural and home delivery logistics, and beneficiary adherence support that can vary based on facility size, location, and patient population. We do not believe it would be operationally feasible to establish a facility-specific or geographically adjusted operational cost add-on at this time, as doing so would introduce complexity inconsistent with the ESRD PPS's per-treatment bundled payment structure. We will, however, continue to monitor the actual operational costs ESRD facilities incur in furnishing phosphate binders under the base rate and will consider whether adjustments to the operational cost methodology are warranted in future rulemaking. We note that the ESRD PPS base rate is adjusted by several factors, including the wage index, several case-mix adjusters, and facility-level adjusters such as the LVPA. The LVPA is a long-standing policy mechanism through which small, low-volume ESRD facilities receive additional payment under the ESRD PPS. Additional payments made through the LVPA 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, which includes the costs of furnishing phosphate binders.

Comment: A pharmacy-related association raised concerns that incorporating phosphate binders into the ESRD PPS bundled payment would threaten beneficiary access to these therapies through community pharmacies. The commenter stated that, once phosphate binders are furnished exclusively through the ESRD facility under the ESRD PPS, community pharmacies that have historically dispensed these medications under Part D would be effectively excluded from this line of business. The commenter further noted that this shift could increase beneficiaries' out-of-pocket costs in certain circumstances and reduce the pharmacy touchpoints available to support medication counseling and adherence.

Response: We appreciate the commenter's concerns regarding the role of community pharmacies in furnishing phosphate binders to beneficiaries with ESRD. We recognize that incorporating

phosphate binders into the ESRD PPS on January 1, 2025, shifted the responsibility of furnishing these drugs from Part D pharmacy channels to ESRD facilities, consistent with the treatment of other oral-only renal dialysis drugs under the ESRD PPS. We do not believe that this shift increased beneficiaries' out-of-pocket costs, in part because the ASP for phosphate binders has decreased throughout the TDAPA period, and also because the Part D cost-sharing structure (supplemental insurance) no longer applies for these drugs. With respect to medication counseling and adherence support, we expect ESRD facilities, in coordination with their contracted pharmacy arrangements, to continue supporting beneficiaries in managing their phosphate binder regimen. We do not believe that ending the TDAPA period for phosphate binders and incorporating phosphate binders into the ESRD PPS base rate will negatively impact any of the expectations or observations outlined previously, however, we will continue to monitor beneficiary access and adherence outcomes following implementation and will consider whether further guidance is warranted in future rulemaking.

Comment: A provider advocacy organization raised concern regarding the data basis for the proposed \$15.96 base rate addition, arguing that CMS derived this figure from only nine months of TDAPA claims data (April through December 2025) and that this is a thin basis for a permanent, non-adjustable addition to the base rate.

Response: We appreciate the commenters' concern regarding the data period underlying the proposed base rate addition. We confirm that the proposed rule's calculation of \$15.96 relied on phosphate binder utilization data from April 1, 2025, through December 31, 2025, representing only nine months of TDAPA claims following our exclusion of first-quarter 2025 data. CMS notes that for this CY 2027 ESRD PPS final rule, we have updated our utilization calculations using claims data extending through June 30, 2026, expanding the utilization period to approximately fifteen months and significantly expanding the volume of claims data underlying the calculation compared to the proposed rule. We also updated our price calculations using data from the fourth quarter of 2026, consistent with our proposal to use the most recent calendar quarter of ASP data available. We believe this expanded claims period addresses the commenters' concern regarding the adequacy and timeframe of the data and provides a stronger

foundation for this permanent addition to the ESRD PPS base rate. We also note that the one-time amount incorporated into the base rate is not separately repriced each year based on phosphate-binder ASP or utilization, but once incorporated it becomes part of the base rate and is subject to applicable annual ESRD PPS updates.

Final Rule Action: After consideration of public comments, we are finalizing the incorporation of phosphate binders into the ESRD PPS base rate beginning January 1, 2027, with a base rate increase of \$12.85 per treatment, using the utilization methodology and operational cost multiplier alongside the most recent available claims (that is, claims from between April 1, 2025, and June 30, 2026) and fourth quarter 2026 ASP data, as proposed. We are also finalizing our proposal to add a new paragraph § 413.234(h) regarding the final data sources and methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders and the operational expenses associated with providing phosphate binders in the ESRD PPS bundled payment. We are finalizing a slightly modified version of new § 413.234(h)(2)(iv) to more clearly state the proposed methodology for calculating the operational cost component of the base rate increase for phosphate binders. We note that this slight modification is a change in language, not a change in policy. We intend to issue further subregulatory guidance addressing the furnishing of phosphate binders for beneficiaries with AKI receiving outpatient dialysis and will work to ensure timely communication of this guidance to affected interested parties prior to implementation.

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

a. Background on the LVPA

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

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

In addition, under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, "treatments" mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For PD patients, one week of PD is considered equivalent to three HD treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions, unless extraordinary circumstances justify an exception, and specifies exceptions for certain years where the deadline is in December or January. The November 1 attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a payment adjustment factor is applied to the ESRD PPS base rate for all applicable treatments furnished by the ESRD facility (89 FR 89161).

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume facilities based on a treatment threshold. After consideration of public comments, we originally established an 18.9 percent

adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

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

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID-19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we only considered total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. In the CY 2024 ESRD PPS final rule (88 FR 76344), we finalized changes to the LVPA regulation at § 413.232 that allow ESRD facilities affected by disasters and other emergencies to qualify for exceptions to certain eligibility requirements for the LVPA. Facilities may close and reopen if they experience an emergency, or they may temporarily exceed the 4,000-treatment threshold if they take on additional patients displaced by an emergency and still qualify for the LVPA.

In the CY 2025 ESRD PPS final rule (89 FR 89153 through 89162) we finalized a 2-tiered system for the LVPA. This system provided higher payment for ESRD facilities which furnished a median of fewer than 3,000 treatments over the past three years, and a lower amount for those which furnished a median treatment amount between 3,000 and 3,999 treatments. ESRD facilities in the first tier receive a 28.9 percent LVPA, and ESRD facilities in the second tier receive an 18.3 percent LVPA. We did not propose any changes to the LVPA criteria in that rule, as we stated the purpose of that policy was not to expand the LVPA to new ESRD facilities. We implemented this change budget neutrally by scaling the factors

down to maintain the total level of LVPA payments at the same amount. In that rule, we noted that we believed this scheme of budget neutrality was more appropriate because it contained the changes within the LVPA (89 FR 89159). In CY 2025, 342 ESRD facilities received the LVPA.

(1) Current LVPA Issues and Concerns

As discussed in the CY 2025 ESRD PPS final rule, CMS received longstanding input from interested parties, including MedPAC and the Government Accountability Office (GAO),²² recommending 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 (89 FR 89154).²³ These interested parties also expressed concern that the strict treatment count used to determine eligibility introduces a “cliff effect” that may incentivize ESRD facilities to restrict patient volume to remain eligible.²⁴ These recommendations were a significant factor which led us to evaluate the LVPA and propose and finalize the changes in the CY 2025 ESRD PPS rulemaking.

Additionally, at that time, CMS considered several changes to the LVPA eligibility criteria to address the concerns that interested parties, including the GAO and MedPAC, raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. CMS considered incorporating geographic isolation into the LVPA. However, section 1881(b)(14)(D)(iii) of the Act requires that the LVPA 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. CMS analysis did not find that isolated low-volume facilities incur higher costs than other low-volume facilities. Therefore, incorporating a metric for geographic isolation, for example distance to next nearest ESRD facility or number of

ESRD facilities in a geographic area, into the LVPA would not align with statutory requirements.

As discussed in the CY 2027 ESRD PPS proposed rule, CMS has been evaluating alternative approaches under section 1881(b)(14)(D)(iv) of the Act (91 FR 38820). We have been analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, facilities in rural areas, as set forth in § 413.233(a), and facilities in certain non-contiguous areas, as set forth in § 413.233(b). To avoid overlapping with these existing facility-level adjustments, we have been analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

Interested parties have also indicated that LVPA eligibility criteria and the attestation process may be administratively burdensome, particularly for small ESRD facilities (85 FR 71442) and believe it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.²⁵ CMS has been considering whether modification of these requirements could reduce burden, mitigate incentives for gaming, and better align payment for resource use.

As a part of our ongoing efforts to improve the LVPA, we have requested information on improvements to the LVPA in several instances.

(2) Technical Expert Panels and CY 2022 RFI

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.²⁶ During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed

²² https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

²³ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁴ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁵ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

²⁶ https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.²⁷ One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural facility adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a recommendation for a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three LDOs, a non-profit kidney organization, and a provider advocacy coalition commented that the rural facility adjustment should be eliminated and a LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the reliance of the census tract methodology used by the rural facility adjustment upon ‘driving time’ as a data measure, noting this presents legitimate equity issues. ESRD facilities that have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment.²⁸

In the CY 2022 ESRD PPS proposed rule LVPA RFI, we sought input on alternative approaches to the LVPA methodology (86 FR 36398 through 36399). Specifically, we requested input on: (1) whether a distinction other than census tract information should be considered; and (2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility. Additionally, we explored the LVI adjustment that MedPAC recommended in its June 2020 Report to Congress. Under the LVI methodology, a

determination that a facility is low volume and isolated would be based on that facility’s distance from the nearest facility and its total treatment volume. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural facility adjustment should be maintained. As previously discussed, our most recent analysis of cost report data does not support the claim that isolated low-volume ESRD facilities face higher costs than non-isolated ESRD facilities; therefore, the LVI methodology would not adhere to the statutory requirement for the LVPA set forth at section 1881(b)(14)(D)(iii) of the Act.

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

In the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), we issued an RFI regarding several possible modifications to the current LVPA methodology. We provided the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function to commenters. Specifically, we presented four different tiered structures for the LVPA, all of which would expand the LVPA beyond the current threshold of 4,000 treatments per year. These four structures were presented as budget neutral, with two involving a reduction to the base rate and two involving “scaling” down the factors to maintain total LVPA payments.

We received 23 comments in response to the RFI, all of which had differing opinions. Most commenters expressed support for some type of a tiered LVPA, although some commenters expressed further concerns or opposition to such a policy. A coalition of dialysis organizations recommended a 2-tiered approach, while MedPAC reiterated their support for an LVI adjustment. A common theme among a handful of comments was concern about administrative burden and transparency regarding the methodology that is chosen. Most commenters believed that the issue of payment cliffs is substantial, but many did not believe any of the options presented in the RFI could successfully eliminate gaming completely. Several commenters expressed concern with LVPA changes that would impact the base rate. A full summary of responses to the RFI can be found at <https://www.cms.gov/>

medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources.

(4) CY 2025 LVPA Proposal

Informed by the comments on the CY 2024 LVPA RFI, we proposed a simpler, 2-tier methodology in the CY 2025 ESRD PPS proposed rule (89 FR 55797 through 55804) which did not expand the LVPA beyond the current treatment volume limit of fewer than 4,000 treatments per year. One reason why we proposed that option was to maintain the impact of the budget neutrality of that proposal within the LVPA without reducing the base rate. We noted that expanding the LVPA beyond 4,000 treatments would result in the adjustment factor being notably reduced for facilities with fewer than 4,000 treatments, and particularly facilities with fewer than 3,000 treatments (89 FR 55801). When we finalized this 2-tier methodology in the CY 2025 ESRD PPS final rule, some commenters highlighted that while it would reduce the impact of payment cliffs, it would not completely remove them (89 FR 89158 through 89161).

We requested further information in the CY 2025 ESRD PPS proposed rule (89 FR 55803 through 55803) on potential further improvements to the LVPA. These questions focused on administrative processes regarding the LVPA, specifically the attestation process. We did not receive any substantive responses to many of these questions (89 FR 89162).

b. Analysis of Payment Adequacy for ESRD Facilities by Treatment Volume

As discussed in the CY 2027 ESRD PPS proposed rule, CMS routinely evaluates payment adequacy under the ESRD PPS. While we often use outside information, such as public comment letters and MedPAC reports, we also conduct our own analysis of ESRD facility costs and ESRD PPS payments. While the ESRD PPS is not a cost-based system, analyses of Medicare-allowable ESRD facility costs provide insight into whether payments align with resource use. Additionally, the ESRD PPS has a long history of establishing payment adjustment factors based on cost data (occasionally combined with claims data), including the current 2-tiered LVPA (89 FR 89156) and most case-mix adjustment factors, such as adult age and onset of dialysis (80 FR 68973 through 68974 and 68984 through 68994).

CMS analyzed cost report and claims data from 2022 through 2024 to evaluate the ratio of payments to average costs

²⁷ <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

²⁸ The materials from the TEPs and summary reports can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

for ESRD facilities. We note that directly comparing ESRD PPS payments to ESRD facility costs is not a perfect analysis as it disregards other payors, including Medicare Advantage (MA) and private payors, which could be providing higher payments for specific high-cost services. Nonetheless, this analysis indicates that payments exceed costs for higher volume ESRD facilities, while lower-volume ESRD facilities, particularly those furnishing fewer than 10,000 treatments tend to have costs that exceed payments. Notably, ESRD facilities furnishing between 4,000 and 10,000 treatments exhibit costs that exceed payments, suggesting that cost differentials extend beyond the current LVPA threshold of 4,000 treatments.

Informed by this 2022–2024 cost to payment analysis, we conducted a further analysis to account for the ESRD PPS wage index methodology finalized in the CY 2025 ESRD PPS final rule (89

FR 89097 through 89116) and discussed in section II.B.2. of this final rule, as this policy significantly changed relative payments by geographic area. We conducted an additional analysis using available CY 2025 ESRD PPS payments instead, to capture these changes, and compared it to CY 2024 costs projected to CY 2025. We removed the TDAPA amounts from the CY 2025 payments used for this analysis as the TDAPA amounts for phosphate binders represented significant payments in CY 2025 which were not present in the CY 2024 costs to which we are comparing. To account for the fact that, due to the NAPA policy finalized in the CY 2026 ESRD PPS final rule (90 FR 53095 through 53102), ESRD facilities in certain noncontiguous areas receive higher non-labor payments, we further adjusted payments to Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands to account for

the increased non-labor payment. We updated CY 2024 costs to CY 2025 using the most recent forecast of the ESRDB market basket increase for CY 2025 of 1.029. For simplicity, in this analysis we did not reduce this factor by the most recent forecast of the productivity adjustment for CY 2025, which is 0.9 percentage point. However, we adjusted certain cost reports to account for a submission issue from an LDO wherein some costs were not fully reflected. For this analysis we further refined the volume categories from the prior analysis to differentiate between ESRD facilities with 5,000 to 7,999 treatments and 8,000 through 9,999 treatments. We stated that we believe that 8,000 treatments is a good boundary point for this analysis because the median treatment volume is slightly above 8,000. Results from this analysis are presented in Table 15.

TABLE 15: Payment to Projected Cost Analysis for CY 2025

Facility Size	Number of Facilities	Number of Treatments (in millions)	Treatment Weighted Mean Payment to Cost Ratio 2025	Median Payment to Cost Ratio 2025
Less than 3,000 treatments	476	0.42	0.76	0.72
3,000 to 3,999 treatments	391	0.52	0.84	0.82
4,000 to 4,999 treatments	479	0.77	0.88	0.85
5,000 to 7,999 treatments	1,827	3.93	0.93	0.92
8,000 to 9,999 treatments	1,131	3.29	0.99	0.99
10,000 or more treatments	3,062	14.37	1.06	1.05

We noted in the proposed rule that the previously described analysis may not be interpreted directly in the terms of payment adequacy for several reasons. First, the ESRD PPS is not a cost-based system, and we do not make payments based on costs. Consistent with section 1881(b)(14)(A) and 1881(b)(14)(F) of the Act, the ESRD PPS payment amount is based on 98 percent of what would have been paid in 2011 had the ESRD PPS not been implemented, annually updated by an ESRDB market basket update factor. Furthermore, as discussed previously, we had to make several adjustments to both costs and payments for this

analysis, which makes these results less directly applicable to actual costs and payments, although we believe they are a reasonable proxy for our purposes here. Lastly, ESRD facility cost reports include costs for payors other than Original Medicare, which may be higher for several reasons. We noted that we were not proposing to base any changes to the LVPA on this analysis, however, this analysis helped CMS identify ESRD facilities which may be receiving relative payments lower than their resource use and has informed the analysis presented in section II.B.8.c. of this final rule. Specifically, this analysis led us to reconsider our current LVPA

policy to evaluate whether expansion of the LVPA beyond 4,000 treatments would better align payment with resource use.

We also reviewed the patterns of ESRD facility closures over the past few years and found evidence that ESRD facilities which have closed are disproportionately small. We stated that, while we believe that the LVPA tier changes finalized in the CY 2025 ESRD PPS final rule help address this issue by scaling the factors to keep the effect of the policy within the LVPA and maintain budget neutrality, the LVPA factor for ESRD facilities which furnish fewer than 3,000 treatments is not as

large as it would be if we had not scaled the factors. Our payment-to-cost analysis indicates that these 3,000-treatment-and-fewer ESRD facilities have costs which exceed their payments.

c. Updated Expanded Tiered Analysis

To estimate cost differences across treatment volumes, CMS conducted a regression analysis using facility-level cost report data from 2022 through 2024. The dependent variable was cost per treatment, and the primary independent variable was facility size. The regression analysis was conducted at the facility level and controlled for the following characteristics: year, ownership, wage index, rurality, region, Medicare percent, home dialysis percent, pediatric share, and average non-LVPA payment adjustment multiplier.

Facility size was specified using the natural logarithm for total treatments and included both linear and quadratic (squared) terms. This specification is intended to estimate cost differences while reducing the influence of extreme values and capturing non-linear effects.

Cost estimations associated with size as the natural logarithm makes the scale of comparison smaller, which makes the results less subject to variance of high volume facilities, and including a quadratic term allows us to capture more than just a linear relationship, which is preferable in this instance as we believe the marginal cost-per-treatment difference of an additional treatment is likely different between low and high volume facilities.

CMS then calculated the predicted costs at the upper bound of each tier using the mean values for continuous variables and composite values for categorical variables wherein the value for the categorical variable was the proportion of the overall population of ESRD facilities which belong to that category. For example, if 10 percent of ESRD facilities are in rural areas, the value used for the rural term when determining the proxy would be 0.1. This allowed us to create a proxy facility per-treatment cost value for an ESRD facility based on treatment count. We noted in the proposed rule that, for our purposes of deriving LVPA factors, the values to construct the proxies do

not actually impact the final result, so long as the proxies are the same for all calculations; this is because we are using these relative cost values to find the relative difference between proxy values, so the terms cancel in the calculation. As the LVPA is based on the difference in cost between low-volume facilities and other facilities, we then calculated the adjusters by comparing the calculated results to a proxy that represents all non-LVPA facilities, by using the same mean value for continuous control variables and categorical control variables, and the median facility treatment count for non-LVPA facilities. For this non-LVPA proxy, the median facility treatment count was calculated only across non-LVPA facilities and all other values were kept the same. We explained that we are attempting to find the extent to which low-volume facilities faced higher costs than other such facilities; therefore, it is appropriate to have the only difference be the treatment count and it is appropriate for the comparison treatment count to include all non-LVPA facilities. We presented these results in Table 16:

TABLE 16: 6-Tier LVPA Analysis

Treatment Volume	Number of ESRD Facilities Expected to Receive the LVPA	72x Treatments CY 2025	Average EB Multiplier	Average WI Adjusted Base Rate	Updated Adjusters
0-2,999	189	157,407	1.135	\$265.3	1.368
3,000-3,999	223	305,754	1.115	\$265.1	1.249
4,000-4,999	299	495,920	1.118	\$263.5	1.173
5,000-5,999	296	556,387	1.117	\$265.2	1.120
6,000-6,999	307	685,388	1.113	\$265.0	1.080
7,000-7,999	175	416,923	1.113	\$263.8	1.050

As discussed in the proposed rule, the updated adjustment factors in Table 16 are derived from the regression by taking the ratio of the exponentiated outcome for the tier with the exponentiated outcome of the comparison value. That is, we calculated the proxy value for the tier and the comparison value, applied the exponential function for each, and then divided the proxy value for the tier by the comparison value. For example, the proxy per-treatment cost for a facility

with 8,000 treatments in our analysis is \$317.77 and the proxy per-treatment cost for a facility with the median non-LVPA treatment count of 10,332 is \$302.77. We calculated the adjustment factor for the 7,000–7,999-treatment tier by dividing \$317.77 by \$302.77 which equals 1.050. We noted that using these factors in the LVPA would increase payments to current LVPA facilities (those furnishing fewer than 4,000 treatments for each of the past 3 cost reporting years) by

approximately \$17 million and increase payments to facilities not currently eligible for the LVPA by approximately \$67 million. These estimated impacts include the proposed extension of the LVPA to pediatric patients discussed in section II.B.9. of the CY 2027 ESRD PPS proposed rule. We stated that these proposed increased adjustment factors, if finalized, would bring relative payments under the ESRD PPS more in line with relative costs, as demonstrated by our cost-to-payment analysis

discussed in the prior section. We noted that we proposed both policies as budget neutral by reducing the ESRD PPS base rate by a budget neutrality factor, as noted in section II.B.4. of the proposed rule.

d. Proposal for Expanded LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) exceed the costs incurred by other facilities. Under this authority, we proposed to revise the definition of a low-volume facility for purposes of § 413.232 to reflect updated empirical findings demonstrating higher costs among facilities furnishing fewer than 8,000 treatments annually, when controlling for various factors including geographic area, wage index, and average case-mix adjustment factor. This proposal is intended to better align ESRD PPS payments with the observed differences in resource use, and support access to care.

As noted in the CY 2016 ESRD PPS final rule (80 FR 68967 through 69077), we aim to target the benefit of the LVPA

to facilities that serve the access needs of patients in remote locations. CMS analysis indicates higher costs among facilities furnishing between 4,000 and 8,000 treatments per year. Proposing a revised methodology that would increase payment to these ESRD facilities would help protect access to care for ESRD services in areas served by these ESRD facilities. Additionally, we believe that additional tiers would further reduce the incentive for gaming, as the GAO described in its 2013 report.²⁹ This may reduce the incentive for some ESRD facilities to limit access to renal dialysis services to keep their treatment volume below the 4,000-treatment threshold. We would expand access through payments that incrementally align resource use with payment to ESRD facilities that furnish different volumes of treatment.

In the CY 2027 ESRD PPS proposed rule, for CY 2027 and subsequent years, CMS proposed to expand LVPA eligibility and implement a tiered structure based on median treatment volume over the prior three years. This expanded eligibility would apply to ESRD facilities that furnish more than 4,000 treatments per year. As discussed

in the previous section, we have data which demonstrates higher costs for ESRD facilities which furnish fewer than 8,000 treatments. Building on the tiered LVPA finalized in the CY 2025 ESRD PPS final rule, we proposed 6 tiers with decreasing adjustment factors as treatment volume increases. The proposed adjustment factors are presented in Table 17. Consistent with the current tiered LVPA, the tier determination would be based on the median treatment volume from the past three years. CMS proposed to apply this policy in a budget neutral manner by applying a factor of 0.98898 to the ESRD PPS base rate. We noted that ESRD facilities must attest to being eligible for LVPA to receive the payment adjustment, but our data indicates that not all ESRD facilities which are eligible for the LVPA attest for it. Since these ESRD facilities do not attest for the LVPA, they do not receive it. For the impact analysis from which this budget neutrality factor was derived, we used an attestation proxy to estimate attestation patterns so that our total estimated payments considers that not all eligible ESRD facilities would attest for and receive the LVPA.

TABLE 17: Proposed 6-tier LVPA

Treatment Volume Tier	Number of ESRD Facilities Expected to Receive the LVPA	Current Adjustment Factors	Proposed Adjustment Factors
0-2,999 treatments per year	189	1.289	1.368
3,000-3,999 treatments per year	223	1.183	1.249
4,000-4,999 treatments per year	299	1.000	1.173
5,000-5,999 treatments per year	296	1.000	1.120
6,000-6,999 treatments per year	307	1.000	1.080
7,000-7,999 treatments per year	175	1.000	1.050

We proposed to apply this policy as budget neutral outside of the LVPA, and, if finalized, we would apply the previously mentioned 0.98898 factor to the ESRD PPS base rate. When we established the 2-tiered LVPA methodology in the CY 2025 ESRD PPS final rule (89 FR 89161), we did not apply a budget neutrality factor for that methodological change. In the CY 2025 ESRD PPS proposed rule, we stated that we were not proposing to apply a budget neutrality factor because we were making changes only to the LVPA and believed at that time it was most appropriate to keep the impact of the

policy change contained to ESRD facilities that were receiving the LVPA (89 FR 55801). We stated that the purpose of that change was to better allocate relative payments within the LVPA and it was not our intention at that time to expand the LVPA beyond the facilities currently eligible for the LVPA (89 FR 55802). We also discussed that expanding the LVPA beyond 4,000 treatments while scaling the factors to maintain budget neutrality within the LVPA would reduce payments for the lowest volume facilities in a way which was not in alignment with the goals of the LVPA (89 FR 55801). In contrast, as

discussed in the CY 2027 ESRD PPS proposed rule, CMS believes applying budget neutrality to the base rate would be appropriate for this proposal because it would expand LVPA eligibility beyond currently qualifying facilities (that is, to ESRD facilities that furnish more than 4,000 treatments per year). We stated that we believe the proposed tiered structure balances concerns from interested parties regarding payment cliffs while maintaining alignment with statutory requirements.

In constructing this proposal, we carefully considered the responses to

²⁹ Government Accountability Office. 2013. End-stage renal disease: CMS should improve design

and strengthen monitoring of low-volume adjustment. Report 13–287. Washington, DC: GAO.

the CY 2024 RFI on the LVPA.³⁰ In this RFI, most respondents supported some sort of tiered system, although most respondents thought there were some issues with the tiered options presented in the RFI. Many of the respondents who supported a tiered system indicated specific support for a structure that included payments up to 6,000 treatments. Many explicitly supported a methodology that incorporated a metric for geographic isolation into the LVPA; however, as we noted in the CY 2025 ESRD PPS final rule our analysis did not find higher costs associated with low-volume facilities in isolated areas (89 FR 89159). Further analysis does not reveal higher costs associated with isolated low-volume facilities, although we noted that the CY 2026 ESRD PPS final rule contained an unrelated payment adjustment for facilities in certain non-contiguous states and territories, the NAPA. We stated in the CY 2027 ESRD PPS proposed rule that we believe the current NAPA addresses some of the concerns of these commenters (90 FR 53102).

In the CY 2024 RFI, we included two potential LVPA structures which both included up to 8,000 treatments per year, but these were 4-tiered and 8-tiered structures. Some respondents opposed the 8-tier LVPA presented in that RFI, with several raising concerns with the budget neutrality factor and others stating that the adjustment factors for the lower-volume tiers were too high and the factors for the higher-volume tiers were miniscule. We considered these comments when designing the 6-tier LVPA proposed in the CY 2027 ESRD PPS proposed rule. By eliminating the 1,000 and 2,000 treatment tiers, we explained, we have mitigated the overall budget neutrality impact of the proposal. Additionally, this reduces concerns related to the high factors associated with these lowest-volume tiers. We disagreed with those commenters that the higher-volume tiers' adjustment factors are miniscule. Our analysis indicates that a 5.0 percent increase is warranted for the 7,000-treatment count tier, and although the proposed adjustment factor is lower than others, it would still represent a substantial increase in payments to those facilities. Other commenters who supported the tiered approaches in response to that RFI indicated that higher-volume tiers with lower payment adjustments can serve to prevent

facilities that are on the border with the more substantial tiers to exceed the treatment volume threshold in one year and still be eligible for the higher payment adjustment tiers in the next year. Several other commenters raised concerns with the tiered system and indicated a belief that it would not eliminate gaming completely.

We noted that we believe that our proposed 6-tier LVPA strikes a balance between appropriately providing higher payment to these higher cost ESRD facilities and addressing the concerns raised by commenters. We believe that the tiered policy finalized in the CY 2025 ESRD PPS final rule (89 FR 89161) which uses the median treatment volume from the past three years helps to effectively reduce gaming by eliminating the incentive to lower treatment volume in any single year. We believe that our CY 2027 proposal to have 3,000 treatments be the lowest-volume treatment tier also prevents any concerns related to the high adjustment factors associated with potential lower-volume tiers and reduces budget neutrality concerns. We believe that the higher tiers from 6,000 to 7,999 treatments serve to act as a sort of transition phase allowing facilities to exceed the lower treatment tiers, while still receiving a data-supported payment adjustment. Lastly, these proposed payment tiers are evidence-based as they are derived from the analysis described previously to more fully represent the extent to which these low-volume facilities truly face higher costs.

To effectuate this change, we proposed modifications to our LVPA regulation at § 413.232 to update the current maximum LVPA threshold of 4,000 treatments to the proposed new threshold of 8,000 treatments. Specifically, we proposed modifications to § 413.232(b)(1), which contains the treatment volume threshold for the LVPA, and (g)(5), which notes the exceptions to the treatment volume threshold for disasters and other emergencies finalized in the CY 2024 ESRD PPS final rule, to indicate the new treatment threshold of 8,000. We proposed to update the threshold for the exception to the treatment volume threshold for disasters and other emergencies to ensure consistency with the threshold of § 413.232(b)(1). We noted that these proposed modifications would retain the requirements that an ESRD facility be below the treatment volume threshold in each of the prior three cost reporting years, and that the median treatment volume over the past three cost reporting years would only be used for tier determination for eligible ESRD facilities.

We proposed this policy change be effective January 1, 2027. However, we recognized that the LVPA requires an attestation process with which many ESRD facilities that furnish more than 4,000 treatments per year are likely unfamiliar. We solicited comments on how we can accommodate these facilities to allow them to properly attest for the LVPA for CY 2027, including delaying the effective date of this proposal or allowing attestations after the typical November 1, 2026, deadline. We noted that changes to the attestation deadline would require a modification to § 413.232(e), likely in the form of adding a new paragraph. We stated that we were not proposing any of these changes, but we noted that we may finalize them, or other changes to address any administrative challenges associated with this proposal in the CY 2027 ESRD PPS final rule, depending on comments we receive.

We requested comments on all aspects of the proposal, including the proposed expansion of the LVPA above 4,000 treatments per year, the proposal to extend the LVPA to ESRD facilities which furnish fewer than 8,000 treatments per year, the proposed 6-tiered structure and adjustment factors presented in Table 17, the proposed budget neutrality factor, the proposed effective date of January 1, 2027, and the proposed modifications to § 413.232. Additionally, we requested comments on the potential administrative challenges associated with this proposed change and the potential solutions discussed previously.

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

Comment: Most commenters who opined on the policy expressed support for the expanded LVPA. MedPAC supported the policy change but reiterated past suggestions for methodological improvements which are discussed in further detail later in this section. Some commenters highlighted the particular impact on certain patient populations. Several commenters expressed a belief that this policy would have positive impact on quality of care and access for ESRD patients. Some commenters stated a belief that this expanded policy would help mitigate the “cliff” effect for which interested parties had criticized the LVPA in the past. Additionally, some commenters stated that this expanded policy would recognize the financial pressures that exist for facilities which furnish 4,000 or more treatments per year. A commenter cited a MedPAC figure which stated that the lowest

³⁰ <https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources>.

quintile of treatment volumes operated at a –11.6 percent margin.

Response: We appreciate the support for the proposed expansion of the LVPA up to 8,000 treatments and the proposed 6-tier structure. We agree that this policy will have beneficial impacts on many critical populations who are only serviced by a low-volume facility. Likewise, we agree that adding in tiers between 4,000 and 8,000 treatment volume serves both to lower the impact of any “cliff” effect and address the higher costs those facilities face. We acknowledge the citation of MedPAC’s margin analysis; although we did not directly consider this analysis in our calculation of the adjustment factors, we believe that the updated LVPA would better align relative payments with resource use for low-volume facilities.

Comment: Several commenters discussed geographic isolation of ESRD facilities with regard to the LVPA. MedPAC reiterated its support for a low volume and isolated (LVI) methodology which would restrict the LVPA to only facilities in isolated geographic areas and several other commenters expressed support for this LVI methodology. A commenter acknowledged that CMS’s past analysis of cost report data did not show differences in cost between low-volume ESRD facilities in isolated and non-isolated areas but stated that there were different costs for ESRD patients in isolated areas, such as increased transportation costs. A commenter supported the fact that the LVPA does not incorporate geographic isolation and noted that specialized facilities can operate at a low volume even if they are in urban areas. Several commenters, including MedPAC, noted the overlap between the rural adjustment and LVPA and some requested that CMS discontinue the rural adjustment and use that money to fund the LVPA in lieu of, or supplementing, budget neutrality.

Response: We acknowledge the commenters’ array of opinions on whether the LVPA should incorporate geographic isolation. Section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which cost incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing renal dialysis services. As we have noted in the past (88 FR 76370, 89 FR 55800), our analysis has not found a correlation between geographic isolation and higher costs for low-volume facilities. As such we have not proposed to incorporate geographic isolation into our definition of low-volume or our requirements for the LVPA. We continue to acknowledge the suggestion of MedPAC and others, but

we believe that if a facility operates at low volume in an urban or otherwise non-geographically isolated area it is appropriate for it to receive the LVPA. We discuss budget neutrality in greater detail later in this section; however, we note that the relatively small rural adjustment factor of 0.8 percent which applies to approximately 14 percent of ESRD PPS treatments is not enough to counteract the budget neutrality of this proposal, which reduces the base rate for all treatments by greater than 1.0 percent. However, removing the rural factor would lessen the impact of the budget neutrality factor. We did not propose to eliminate the rural factor in the CY 2027 ESRD PPS proposed rule, and we do not believe that such a policy would be appropriate at this time. Although there is overlap between what facilities receive the LVPA and the rural adjustment, not all rural facilities receive the LVPA. The rural factor accounts for any higher costs that both LVPA rural and non-LVPA rural facilities face. In calculating the LVPA adjustment factors for the CY 2027 ESRD PPS proposed rule, we controlled for a facility’s rural status, as discussed in further detail in the next response.

Comment: Some commenters questioned whether CMS accounted for other ESRD PPS payment adjustments, such as the rural adjustment or NAPA, in developing the LVPA proposal. These comments often accompanied concerns that the proposed LVPA may overstate the costs associated with low volume. One of these commenters, an LDO, stated a belief that treatment volume may be serving as a proxy for other underlying factors, such as geographic isolation, and expressed concern that continuing to rely on treatment volume alone would not fully address these underlying factors.

Response: We did control for rurality and being located in a NAPA area in our analysis for the proposed rule. Section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which cost incurred by low volume facilities exceed the costs incurred by other such facilities. We recognize that there are likely other unknown factors which contribute to the LVPA; however, we believe that the analysis upon which the proposed 6-tier LVPA was based is the best available estimate of the extent to which low-volume facilities face higher costs. We acknowledge that it is possible that some other factors are contributing through the LVPA, however, to the extent that those factors result in low-volume facilities facing higher costs than other such facilities, we believe it is reasonable for the LVPA to account for them. While we control

for available factors, like rurality and geographic area, it is impossible for our analysis to control for every single potential covariable. We continue to believe our analysis for calculating the LVPA effectively estimates the extent to which low-volume facilities face higher costs than other such facilities. However, we welcome additional information from interested parties on other potential confounders and covariables which we can control for in a future analysis, as appropriate.

Comment: A commenter recommended that CMS continue to monitor the LVPA and its effectiveness in addressing its goals.

Response: We thank the commenter for the recommendation. We intend to continue to monitor the LVPA and will make further changes, if appropriate, in potential future rulemaking.

Comment: A commenter noted that the analysis we included in the CY 2027 ESRD PPS proposed rule indicated that for the 2022 to 2024 data range most Medicare facilities experienced per-patient costs that exceeded Original Medicare payments for patient care. The commenter emphasized that data point was applicable beyond the context of the LVPA to the broader ESRD PPS.

Response: We appreciate the insight into the data analysis we included in our proposed rule. We agree that considering Medicare cost data is applicable when considering policies outside the LVPA. However, we note that in the analysis we published, which is included earlier in this section in Table 15, we found that the facilities that tend to have costs exceeding payments are those with less than 8,000 treatments, which helped inform our proposal to expand the LVPA up to 8,000 treatments. Although we did not include this result in the CY 2027 ESRD PPS proposed rule, the analysis from which Table 15 was derived also found that the overall treatment weighted facility level mean payment to cost ratio was 1.01 and the median was 0.98. We reiterate that these figures should not be interpreted directly in terms of payment adequacy for the reasons discussed in the context of Table 15, most notably because they reflect costs for payors other than Original Medicare, which may be different. We believe that the overall payment rate under the ESRD PPS is appropriate and that this LVPA policy will better align payments with resource use.

Comment: Several commenters specifically discussed the implementation timeline for the proposed 6-tier LVPA. A few of those commenters recommended delaying the attestation deadline for 2026. A

commenter recommended delaying the implementation of the policy to CY 2028 but also expressed support for delaying the attestation deadline as an alternate recommendation.

Response: We appreciate the insight and recommendation into the operation timeline for this proposed policy change. In the proposed rule we solicited comments on potential changes to the operational timeline for this policy, including the options recommended by the commenters. We believe that extending the attestation deadline would allow for the ESRD facilities to submit attestations for payment year 2027 and for the MACs to process those attestations in time for CY 2027 payments. After considering these comments and evaluating the potential operational difficulties associated with this change, we are finalizing an extension to the attestation deadline for payment year 2026 to December 31, 2026. This is consistent with past extensions to the attestation deadline in 42 CFR 413.232(e) which impacted LVPA attestations for payment years 2015, 2016, and 2021. We are finalizing modifications to § 413.232(e) to add a new paragraph to effectuate this delayed attestation deadline.

Comment: Numerous commenters opined on the proposed budget neutrality of this LVPA proposal. Many commenters requested CMS implement this policy in a non-budget neutral manner. Others requested CMS budget neutralize the policy by removing the rural adjustment factor; some of those requests were combined with requests for an LVI methodology that directly incorporated isolation. A few commenters noted that some high-volume urban facilities treat vulnerable or medically complex patient populations. Many commenters noted the relatively large impact this policy would have on the base rate and stated that such a reduction could have adverse impacts on care. Many commenters highlighted that there is no statutory requirement for budget neutrality for the LVPA.

Response: We understand the concerns raised by commenters regarding the budget neutrality of this LVPA proposal, as the proposed budget neutrality factor of 0.98898 is relatively large compared to the budget neutrality factors of past changes to adjustment factors. However, budget neutrality is appropriate for this proposal. The LVPA is a longstanding, statutorily required part of the ESRD PPS. When the payment system was implemented in 2011, low-volume facilities were considered in creating the base rate. Thus, the higher costs that low-volume

facilities face are included in the ESRD PPS payment rate. The proposed LVPA appropriately recognizes the higher relative costs of low volume facilities, and the application of the budget neutrality factor reduces relative payments to high-volume ESRD facilities.

We considered removing the rural adjustment factor as part of the budget neutrality of this proposal, although we note that it would not be nearly enough to offset the impact of the budget neutrality factor. However, we believe that ensuring access for rural populations is important. While the LVPA addresses some factors which may cause costs to be higher in rural areas, we believe the rural adjustment is still useful in protecting access for higher-volume or otherwise LVPA ineligible ESRD facilities in rural areas.

We likewise recognize that there are some urban facilities with high volume and high costs per treatment. We note that urban areas generally have higher wage index values and receive higher relative payments accordingly. Additionally, the ESRD PPS includes many case-mix adjustment factors which provide higher payment to any ESRD facility which furnishes care to certain medically complex patients as specified at § 413.235. Lastly, for patients whose medical complexity is not addressed by the patient level case-mix adjustment factors, we have an outlier adjustment that can provide increased payment for higher-than-expected use of certain eligible ESRD outlier services as specified at § 413.237. The purpose of the LVPA is to account for the extent to which low-volume facilities face higher costs than other such facilities, and we believe that these other payment adjustments address the concerns of commenters related to high-cost urban ESRD facilities.

The reason this budget neutrality factor is larger than many past budget neutrality factors is because it is reallocating a larger amount of payments. Our analysis indicates that higher volume ESRD facilities have lower costs, and our comparison of Original Medicare payments to costs indicates that payments are notably above costs for these facilities. The purpose of this change is not to increase overall payments, but to better allocate payments within the ESRD PPS. Based on our analysis, this update to the LVPA accomplishes that goal.

We acknowledge and agree with commenters who note that there is no statutory budget neutrality requirement for changes to the LVPA. However, as noted previously, we believe it is most

appropriate to implement this policy change in a budget neutral manner.

Comment: A commenter noted that the payment to cost ratio presented in the proposed rule for facilities with between 8,000 and 10,000 treatments was 0.99 and that a budget neutrality factor would lower payment adequacy for this group of ESRD facilities.

Response: As discussed previously, the analysis presented in the CY 2027 ESRD PPS proposed rule was not a comprehensive margin analysis and should not be interpreted in terms of payment adequacy. The average cost per treatment for that analysis was derived from Medicare cost report data, which reflects costs for payers other than Original Medicare. As MA and private plans may pay higher for renal dialysis services, it is reasonable to believe that beneficiaries may be getting different care. As such, we do not believe that the budget neutrality factor would inappropriately lower payment adequacy for the 8,000–10,000 treatment ESRD facility group. As noted previously, budget neutrality is appropriate for this proposal because it is aligning payments under the ESRD PPS with relative resource use. Our analysis has found that those facilities that furnish more treatments have lower costs-per-treatment, on average. As such, a budget neutrality factor that, when combined with the impact of this policy, reallocates money from higher cost to lower cost facilities is appropriate.

Comment: A commenter stated that it was appropriate for CMS to use an attestation proxy for determining budget neutrality but requested more information and asked if CMS assumed that attestation rates would vary by treatment tier. That commenter noted that higher volume LVPA eligible facilities could be less likely to attest if they determine that the adjustment is not worth the administrative burden. Another commenter recommended that we monitor LVPA participation and make changes in future years if the budget neutrality reduction overestimated LVPA payments.

Response: We appreciate the thoughtful insight into the attestation proxy. We did not account for varying attestation rates for different tiers, as we have no data for the higher volume tiers upon which to base that attestation proxy. Our attestation proxy was by ownership type. We believe that this is the most appropriate as we observe different attestation rates for certain categories of facility ownership and, while we cannot identify specific reasons for why a seemingly eligible ESRD facility does not attest for the

LVPA, we can posit two potential reasons which are both related to ownership. The first potential reason is that an ESRD facility lacks the administrative support or resources to attest. We believe that it is reasonable to assume that administrative support would correlate with ownership type. That is, a facility owned by an LDO would likely have more administrative support than an independent facility, and that hospital-based facilities likely

also have different levels of administrative support and different administrative hurdles. The second potential reason is that our data may not be identifying all instances of common ownership among ESRD facilities, which is relevant as the determination of treatment volume for the LVPA considers nearby facilities with common ownership. While we can plainly identify some instances of common ownership from our data, there are

likely some instances where a seemingly eligible ESRD facility is not attesting for the LVPA because it is not actually eligible due to the common ownership volume aggregation. Using a proxy based on ownership likely catches some of the correlation between an ESRD facility having nearby unidentified commonly owned facilities. The attestation simulation we used for the budget neutrality impacts for this final rule are in Table 18.

TABLE 18: Attestation Proxy Used for Budget Neutrality Calculation

Ownership	Number of Potentially Eligible Low-Volume Facilities*	Observed Attestation Rate
Large Dialysis Organization	230	91.7%
Regional Chain	35	65.7%
Independent Facilities	96	54.2%
Hospital-Based ESRD Facilities	111	45.9%

*This column includes facilities that appear to be eligible for the LVPA based on our data but do not attest. Eligibility for determining the attestation proxy was based on the 4,000-treatment count threshold that applied for the observation period.

We generally do not make retrospective budget neutrality changes as the intention of a budget neutrality factor is to capture the impact attributable to the change itself and not any related or unrelated trends in utilization. For example, if more low-volume ESRD facilities were to open based on this policy, we would not consider that as part of the budget for the proposal, even though overall payment would change. We believe it is appropriate to use the earlier attestation

rates observed for currently eligible LVPA facilities for these newly eligible LVPA facilities. However, we recognize that there is no observed data for attestation rates among these mid-sized 4,000 to 8,000 treatment ESRD facilities, which differentiates this proposal from other past proposals where we have historical data. As such, we intend to monitor the actual attestation rates and actual payments under the LVPA. If attestation patterns differ significantly from our observed historical-rate-

derived attestation rates, we would consider making changes, if appropriate, in potential future rulemaking.

Final Rule Action: After consideration of public comments, we are finalizing the 6-tier LVPA as proposed. We are recalculating the budget neutrality factor with our updated impacts simulation. The updated budget neutrality factor is 0.98901. The final LVPA tiers are presented in Table 19.

TABLE 19: Final 6-tier LVPA

Treatment Volume Tier	Number of ESRD Facilities Expected to Receive the LVPA	Current Adjustment Factors	Final Adjustment Factors
0-2,999 treatments per year	189	1.289	1.368
3,000-3,999 treatments per year	223	1.183	1.249
4,000-4,999 treatments per year	299	1.000	1.173
5,000-5,999 treatments per year	296	1.000	1.120
6,000-6,999 treatments per year	307	1.000	1.080
7,000-7,999 treatments per year	175	1.000	1.050

Additionally, we are finalizing an extension to the attestation deadline to December 31, 2026, for the LVPA for payment year CY 2027. We are finalizing the addition of a new paragraph § 413.232(e)(5) and finalizing conforming edits to paragraphs § 413.232(e)(3) and (e)(4) to effectuate

this change. We note that these modifications to the LVPA and attestation deadline for payment year 2027 also apply to payments for renal dialysis services furnished to pediatric ESRD patients, as discussed in section II.B.9.d.(3) of this final rule.

9. Payment for Pediatric Patients With ESRD Receiving Renal Dialysis Services

a. Background and History of Pediatric ESRD Payment

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. Historically, determining an appropriate payment adjustment for pediatric ESRD patients³¹ has been challenging due to limited data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population; the pediatric ESRD patient population represents approximately 0.16 percent of Original Medicare treatments in 2024 from Common Working File data ending June 27, 2025.

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 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. These policies enabled pediatric ESRD facilities to receive payments recognizing the higher cost associated with furnishing renal dialysis services to pediatric ESRD 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 ESRD 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 ESRD 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 factor of 1.199 for all pediatric ESRD patients receiving renal dialysis services (74 FR 49982 through 49983). 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 (HD, PD) 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” factor, which combined the composite rate factor of 1.199 and the separately billable factors for each of the eight groups (74 FR 44987). These expanded bundle factors were the proposed pediatric ESRD patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS. These factors 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 believed the expanded bundle factor 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 (HD or PD). Additionally, this methodology used the same groups for the expanded bundle and separately billable factors (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 ESRD 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).

b. Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA)

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76375), despite these changes intended to improve payment accuracy for renal dialysis services furnished to pediatric ESRD patients, CMS continued to receive comments and concerns from interested parties that payment amounts for renal dialysis services furnished to pediatric ESRD patients are insufficient. In addition to comments received through the annual ESRD PPS rulemaking, we also solicited comments from interested parties on several occasions. During the Technical Expert Panel (TEP) of December 2020, we queried a panel of experts on how to improve payment for pediatric dialysis care under the ESRD PPS. Panelists 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.³² In the CY 2023

³¹ A “Pediatric ESRD Patient” is defined in § 413.171 as an individual less than 18 years of age who is receiving renal dialysis services. In this section of the final rule, we use the term “pediatric ESRD patient” except when referring to the regulatory language.

³² <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding equitable access for pediatric patients with ESRD. We noted that interested parties have emphasized the higher labor costs, including the need for increased nursing attention and specialized clinical staff. They noted that Medicare payment for pediatric ESRD patients is 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.

We explained that CMS sought to improve payment accuracy for renal dialysis services furnished to pediatric ESRD patients by better aligning payments with observed costs. Ensuring Medicare payments are appropriate and align costs for renal dialysis services furnished to pediatric ESRD patients would support more ESRD facilities in providing quality care to this vulnerable population. The main barrier to aligning payment has been 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 issued changes to the cost reports for hospital-based and freestanding ESRD facilities effective October 1, 2022, and January 1, 2023, respectively (87 FR 26760).^{33 34}

Nevertheless, accurate payment for pediatric ESRD renal dialysis services under the ESRD PPS remains challenging due to small sample sizes and systematic differences between pediatric and adult renal dialysis services. Pediatric renal dialysis treatments often occur in hospitals which have lower volumes and higher costs. This complicates cost estimation. To address these challenges, we conducted an alternative analysis which used propensity score matching (PSM) to estimate costs accurately. Findings presented in the CY 2024 ESRD PPS final rule indicated facilities that only serve pediatric ESRD patients incur 40 percent higher costs per patient than those not serving pediatric ESRD patients (88 FR 76376). Medicare accounted for the current adjustments for higher pediatric costs from established case-mix adjusters, which were about 10 percent higher for pediatric renal dialysis services than adults in 2022.

In the CY 2024 ESRD PPS final rule, CMS finalized the Transitional Pediatric

ESRD Payment Adjustment (TPEAPA) which increased payments for all pediatric ESRD patients under 18 years of age (88 FR 76344). CMS finalized the budget neutral 30 percent add-on payment adjustment in the CY 2024 ESRD PPS final rule effective January 1, 2024, for CYs 2024 through 2026 (88 FR 76380). CMS finalized the TPEAPA as a time-limited payment adjustment, so we could collect more targeted pediatric data. The time-limited 3-year payment adjustment provided enough time to evaluate data from updates to cost reports specific to pediatric treatments. The TPEAPA is codified at § 413.235(b)(2). Beginning January 1, 2024, the ESRD PPS provided 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, as defined in § 413.171, during calendar years 2024, 2025, and 2026. CMS continued to analyze payment and cost data throughout the implementation of TPEAPA to determine whether to extend the TPEAPA past December 31, 2026, or propose an alternative approach after additional data analysis.

c. Analysis of Additional Pediatric ESRD Cost Data

As noted previously, payment accuracy historically has been difficult for pediatric ESRD renal dialysis services because of the small sample size of pediatric ESRD patients receiving renal dialysis services under the ESRD PPS. Pediatric ESRD renal dialysis treatments differ from adult ESRD renal dialysis treatments in several crucial ways. For example, pediatric ESRD facilities³⁵ 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 the treatment site, 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.

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38827), to

better understand these differences, CMS analyzed cost reports from both freestanding (CMS–265–11) and hospital-based (CMS–2552) facilities for 2023 and 2024 following cost report revisions. We found relatively few freestanding facilities reported unique pediatric staff. Additionally, approximately 30 percent of children's hospitals as defined at 42 CFR 412.23(d) reported pediatric ESRD nursing staff and 25 percent reported pediatric ESRD staff other than registered nurses on the cost report. For non-children's hospitals these figures were 1 percent and 0.5 percent, respectively.

CMS observed increased reporting of pediatric-specific supply costs in hospital-based ESRD facilities between 2023 and 2024. In 2023, the mean pediatric ESRD patient supply cost per treatment in hospital-based ESRD facilities was \$138.23; in 2024, it was \$321.22. We noted that this increase in pediatric ESRD patient supply cost per treatment likely reflects increased reporting, rather than increases in pediatric costs of greater than 100 percent. Prior to 2024, the hospital-based (CMS–2552) facilities cost report lacked the specificity to consistently delineate pediatric ESRD patient supply cost from adult ESRD patient supply cost. Additionally, CMS provided interested parties with additional guidance on the completion of cost reports to share with children's hospitals that provide renal dialysis services.

Despite continued limitations in pediatric-specific ESRD reporting, CMS observed statistically significant higher costs associated with the furnishing of renal dialysis services to pediatric ESRD patients. As discussed in the following section, an updated regression analysis of composite rate costs found the incremental cost impact of pediatric ESRD treatment share was approximately 33 percent. Specifically, using data from CYs 2022 and 2023, CMS estimates that the difference in total cost per treatment between facilities with no pediatric ESRD treatments and those furnishing exclusively pediatric ESRD treatments is approximately 33 percent. This does not mean that every pediatric ESRD treatment represents a 33 percent increase in cost.

d. Proposals To Modify Payment for Pediatric ESRD Patients

(1) Updated Regression Analysis for CY 2027

In the CY 2011 ESRD PPS final rule, we established the pediatric ESRD case-mix adjustments based on two age

³³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242>.

³⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i>.

³⁵ The term “pediatric ESRD facility” is used at § 413.170(b) in the context of exceptions to the composite rate prior to 2011. This section specifically refers to § 413.184 for the specification of pediatric patient mix, which includes the qualification at § 413.184(a)(1) that at least 50 percent of the patients are under 18 years of age, alongside other requirements. Consistent with that section, for our proposal and this final rule, we use this term to mean ESRD facilities with at least 50 percent of patients under 18 years of age, but we are not including the other qualifications of § 413.184(a) which were requirements for the exceptions to the composite rate payments.

categories (age <13, 13–17) and two dialysis modalities (PD or HD). We used the resulting four case-mix categories as the basis for classifying pediatric ESRD patients (75 FR 49132). The adjustment factors for each of these case-mix categories were based on the product of two factors representing the cost of composite rate services and another representing the costs of formerly separately billable services. Specifically, the formula used the average payment differential between adults and pediatric ESRD patients (P), the average case-mix multiplier for adults (C), the ratios for composite rate (W_CR) and separately billable services (W_SB), and the separately billable modifiers for each pediatric category (Mult_SB). The expanded bundle payment multiplier established in the CY 2011 ESRD PPS final rule (75 FR 49133) for CR and SB

services for each of the four pediatric classification cells can be calculated as:

$$\text{Mult_EB} = P * C * (W_CR + W_SB * \text{Mult_SB})$$

The pediatric multipliers were most recently recalculated using this established methodology in the CY 2016 ESRD PPS final rule (80 FR 69002). These multipliers are presented in Table 21.

We explained in the CY 2011 ESRD PPS final rule that additional payments currently provided for pediatric ESRD patients under the basic case-mix composite payment system are likely to reflect higher costs for smaller dialysis facilities. Based on that calculation, we noted the application of the low-volume payment adjustment (LVPA) for pediatric ESRD patients would be duplicative. Therefore, the LVPA was

only applicable to adult ESRD patients and was not used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the LVPA which treat both adult and pediatric ESRD patients, have only received the LVPA for adult renal dialysis patients (75 FR 49134).

For the CY 2027 ESRD PPS proposed rule, CMS revised its regression model to evaluate the relationship between cost per treatment and facility characteristics. CMS analyzed a logarithmic regression model using 2022 and 2023 cost report data and controlled for geographical and facility level characteristics (ownership, facility type, rurality, treatment volume, and percentage of home dialysis training treatments) to estimate cost differences based on pediatric share. These results are presented in Table 20.

TABLE 20 Regression Results

Facility Characteristic	Adjustment Factor ⁺	Significance Level ⁺
Pediatric Share	1.3298	**
Ownership - LDO	1.1019	**
Ownership - Regional	1.1400	**
Ownership - Unknown	1.1996	*
Ownership - Independent	1.0000	N/A
Hospital Based	1.6177	**
Rural	0.9589	**
LN (facility size) ³⁶	0.1404	**
LN (facility size) squared	1.1008	**
Training percentage	1.1388	Not statistically significant

⁺ The factors presented in Table 20 are the exponentiated regression coefficients. Significance at p=0.01 is notated with (**) and significance at p=0.05 is notated with (*).

As shown in Table 20 both pediatric ESRD treatment share and ESRD facility treatment volume, are statistically significant predictors of cost. These findings indicate that facilities furnishing a higher share of renal dialysis services to pediatric ESRD patients incur higher per-treatment costs. These increased expenses are

primarily attributable to the need for specialized equipment, dedicated staffing, and unique clinical protocols required for ESRD patients under 18 years of age. However, hospital-based ESRD facilities, which are the primary sites for pediatric dialysis, incur significantly greater operational costs in comparison to freestanding ESRD facilities. Furthermore, this analysis demonstrates that ESRD facilities with lower treatment volume incur higher

costs, independent of their share of pediatric patients. Unlike the payment analysis conducted for the CY 2011 ESRD PPS final rule, this analysis has separately isolated the marginal costs of treating pediatric ESRD patients from the marginal costs associated with low volume. As discussed in the following section, after considering the results of our latest analysis, we proposed revisions to the pediatric ESRD case-mix adjusters and proposed to change our

³⁶ LN denotes the natural logarithm which is to say the logarithm of base (e).

longstanding LVPA policy to appropriately reflect these two main drivers of pediatric ESRD cost.

(2) Revision of Pediatric Adjusters

We proposed to update the pediatric ESRD adjustment factors using the calculation established in the CY 2011 ESRD PPS final rule (75 FR 49133). The updated calculation formula is as follows:

$$\text{Mult}_{EB} = D * C * (W_{CR} + W_{SB} * \text{Mult}_{SB})$$

As discussed in the previous section, the CY 2011 calculation utilized the

estimated separately billable adjustments as well as 4 factors: average payment differential between adults and pediatric ESRD patients (P), the average case mix multiplier for adults (C), the weight for composite rate (W_{CR}) and the weight for separately billable services (W_{SB}). We proposed to update these figures according to the most recent data, as follows. We noted that instead of using the average payment differential P, we proposed to use the average cost differential between adults and pediatric ESRD patients as derived from our regression model, which we refer to as D. As previously discussed,

we conducted an updated regression analysis for the separately billable adjustments using data from CYs 2022 and 2023. These figures are presented in the “Proposed SB Multiplier” column in Table 21. Using the same data, we updated the weights for the CR and SB costs to 0.915 and 0.085, respectively. From CY 2023 claims data, we determined that the average case-mix adjustment factor for adult ESRD beneficiaries is 1.1045. Lastly, as discussed previously, we calculated that the average difference in pediatric to adult ESRD patient costs is 1.3298 (that is, 32.98 percent).

TABLE 21: Proposed Pediatric Payment Multipliers

Category	Current SB Multiplier (2016)	Current EB Multiplier (2016)	Proposed SB Multiplier	Proposed EB Multiplier
Age 12 or under, PD	0.410	1.063	0.523	1.410
Age 12 or under, HD	1.406	1.306	1.269	1.503
Age 13-17, PD	0.569	1.102	0.734	1.436
Age 13-17, HD	1.494	1.327	1.531	1.536

The CMS regression analysis presented previously in this section, using cost report data with fields for more accurate reporting of pediatric costs from 2022 and 2023, indicates 32.98 percent higher costs incurred in treating pediatric ESRD patients compared to adult ESRD patients. These findings suggest that the 30 percent TPEAPA, which was based on a 40 percent cost differential, is approximately the same order of magnitude with observed cost differentials. The current regression analysis verifies the need for establishing more permanent payment adjustments to account for higher pediatric costs on an ongoing treatment basis.

We proposed to update the SB (outlier) and EB (case-mix) multipliers for pediatric patients according to the established methodology as presented in Table 21.³⁷ We noted that these proposed updates would result in functional adjustment factors for pediatric ESRD patients below those established for purposes of the TPEAPA.

We stated that we believe that this is reasonable for two reasons. First, as discussed in the CY 2024 ESRD PPS final rule, the TPEAPA was based on a relatively high variance analysis, and our new 33 percent cost differential falls within the confidence interval of that analysis (88 FR 76376 through 76377). Second, as discussed in the following section, we proposed to extend the LVPA to treatments furnished to pediatric ESRD patients. Taken together, these two proposed modifications, updating the SB (outlier) and EB (case-mix) multipliers for pediatric patients and extending the LVPA to payments for treatments furnished to pediatric ESRD patients, would provide a similar overall level of support while more directly targeting the underlying cost drivers. Under this proposed approach, low-volume facilities would receive higher payments for treatments furnished to pediatric ESRD patients, while high-volume facilities would receive somewhat lower payments relative to current policy.

We received comments from patient and caregiver representatives, patient advocacy organizations, professional associations, dialysis facilities and organizations, and other interested parties regarding the proposed revisions to payment for renal dialysis services furnished to pediatric patients. Commenters generally agreed that

furnishing renal dialysis services to pediatric patients is more resource-intensive than furnishing renal dialysis services to adult patients and supported continued recognition of those additional costs under the ESRD PPS. Commenters differed, however, regarding the appropriate methodology for recognizing those costs, including the proposed pediatric case-mix adjustment factors, the adequacy of the data used to develop the proposed adjustments, continuation of the TPEAPA, and application of budget neutrality. We summarize these comments and provide our responses below.

Comment: Several commenters supported CMS’s recognition that renal dialysis services furnished to pediatric ESRD patients are more resource intensive than renal dialysis services furnished to adult ESRD patients and generally supported establishing a permanent payment methodology following expiration of the TPEAPA. Commenters stated that pediatric dialysis requires specialized pediatric nephrologists, nurses, dietitians, social workers, pharmacists, child life specialists, and other multidisciplinary personnel, as well as pediatric-specific equipment and supplies, specialized clinical protocols, extensive family and caregiver education, psychosocial and nutritional support, care coordination,

³⁷ The EB, or expanded bundle, multipliers are the case-mix adjustment factors that apply to the overall payment. The SB, or separately billable, multipliers are the outlier services multipliers which apply only in the calculation of the outlier payment. As discussed earlier, we use the SB multipliers in the calculation of the EB multipliers, consistent with the calculation established in the CY 2011 ESRD PPS final rule (75 FR 49133).

and infrastructure necessary to care for infants, children, and adolescents with complex medical needs. Some commenters noted that pediatric renal dialysis services also must address growth, nutrition, bone health, development, and preparation for kidney transplantation.

Some commenters specifically supported the proposed permanent pediatric case-mix adjustments and application of the LVPA to qualifying pediatric renal dialysis treatments and urged CMS to finalize these policies. Other commenters agreed that a permanent increase in pediatric payment is necessary but disagreed with the proposed methodology for providing that additional payment.

Response: We appreciate commenters' support for appropriately recognizing the additional resources associated with furnishing renal dialysis services to pediatric ESRD patients. We agree that pediatric renal dialysis patients constitute a small and clinically complex population and that furnishing renal dialysis services to these patients may require specialized staffing, equipment, supplies, clinical expertise, family and caregiver support, and other resources that differ from those required for many adult beneficiaries with ESRD.

The purpose of our pediatric payment policy is to account appropriately for differences in expected resource use within the ESRD PPS while maintaining a methodology that is empirically based, administratively feasible, and consistent with the structure of the ESRD PPS. We appreciate commenters' descriptions of the clinical and operational resources necessary to furnish pediatric renal dialysis services and considered these comments in determining the appropriate payment methodology for CY 2027.

While some commenters disagree with the payment methodology in the CY 2027 proposed rule (91 FR 38826 through 38830) for pediatric ESRD patients, we note that the methodology is based on long-standing policy for calculating the case-mix adjusters for the pediatric ESRD PPS payment. We calculated that the average difference in pediatric to adult ESRD costs is 1.3298 (that is, 32.98 percent). This does not mean that every pediatric renal dialysis service should receive an increased payment as has been the case with the TPEAPA while CMS gathered and analyzed data. We proposed to update the SB (outlier) and EB (case-mix) multipliers for pediatric ESRD patients according to the established methodology as presented in Table 21. We noted that these proposed updates would result in functional adjustment

factors for pediatric ESRD patients below those established for purposes of the TPEAPA. However, extending the LVPA to pediatric renal dialysis services results in a substantially larger payment increase for hospital-based facilities (8.16 percent) than freestanding facilities (2.06 percent). Additionally, ESRD facilities with greater than 50 percent of pediatric ESRD patients saw a 6.54 percent increase in projected payments across all CY 2027 proposed policy changes. According to data analysis these combined policy changes are targeted at hospital-based ESRD facilities that specialize in providing pediatric renal dialysis services.

We believe the regression methodology remains appropriate for the CY pediatric update. As noted previously, the regression methodology targets PD which the pediatric population uses at a higher rate. The pediatric patients 12 and under PD case-mix factor increased by 32.6 percent, and the PD case-mix adjuster for 13–17 increased by 30.3 percent. Hemodialysis for both age groups is less than the increase resulting from the 30 percent TPEAPA based on the propensity score matching (PSM) analyses presented in the CY 2024 ESRD PPS final rule which indicated facilities that only serve pediatric ESRD patients incur 40 percent higher costs per patient than those not serving pediatric patients (88 FR 76376). CMS accounted for the current adjustments for higher pediatric costs from established case-mix adjusters, which were about 10 percent higher for pediatric renal dialysis services than adults in 2022. We continue to believe that it is appropriate to adjust the case-mix for pediatric ESRD patients according to the regression analysis for CY 2027 which is more refined and targeted than the TPEAPA. We note that the decrease in case-mix occurs as the pediatric population moves toward the more traditionally used adult therapy, HD, and as they age. We believe this is a logical progression for payment to follow. While we have not proposed to concurrently update the adult case-mix, we believe this is justified to address the finding that pediatric ESRD patients have higher costs than adult ESRD patients.

Comment: Commenters expressed concern regarding the proposal to replace the TPEAPA with updated pediatric case-mix adjustment factors and to apply the LVPA to treatments furnished to pediatric ESRD patients. Commenters stated that pediatric renal dialysis requires specialized staffing, supplies, and other resources and that these costs are incurred by both low-

and high-volume pediatric ESRD facilities. Commenters noted that treatment volume is not an appropriate proxy for the complexity or cost of pediatric renal dialysis care and noted that higher-volume pediatric ESRD facilities may serve as referral centers for more complex pediatric patients while continuing to incur substantial fixed costs associated with specialized pediatric care. Commenters requested that CMS establish a permanent payment adjustment applicable to pediatric ESRD treatments regardless of facility volume or, alternatively, extend the TPEAPA while collecting additional data.

Response: We appreciate commenters' concerns regarding the unique resource needs associated with furnishing renal dialysis services to pediatric ESRD patients, including the need for specialized clinical staff and supplies. We agree that pediatric ESRD patients have distinct care needs and that furnishing renal dialysis services to pediatric patients is associated with higher costs. Indeed, our updated analysis was specifically intended to quantify those higher costs using more recent cost data and forms the basis for the proposed updates to the permanent pediatric case-mix adjustments.

We clarify, however, that our proposal does not use facility treatment volume as a proxy for the clinical complexity of pediatric ESRD patients or for the additional costs attributable specifically to furnishing pediatric renal dialysis services. Rather, our analysis identifies pediatric ESRD treatment share and facility treatment volume as separate characteristics associated with cost per treatment. As discussed in the proposed rule, after controlling for facility volume and other facility characteristics, we estimated that the difference in total cost per treatment between facilities with no pediatric ESRD treatments and facilities furnishing exclusively pediatric ESRD treatments was approximately 33 percent. This analysis provides the basis for recognizing the additional costs associated with pediatric renal dialysis services through the permanent pediatric case-mix adjustments, independently of the LVPA.

We also conducted additional analysis in response to comments concerning whether the relationship between facility volume and cost observed among ESRD facilities generally is also present among ESRD facilities primarily furnishing pediatric renal dialysis services. For this analysis, we examined facilities with more than 50 percent pediatric ESRD treatment share using cost report and claims data

from CYs 2022 through 2025. The descriptive results demonstrate a clear inverse relationship between facility treatment volume and median cost per treatment within this pediatric ESRD facility sample.

We additionally estimated regression models using the pediatric ESRD facility sample. These models similarly indicate that, within pediatric ESRD facilities, higher facility treatment volume is associated with lower cost per treatment over the range of treatment volumes represented in the data. We recognize that the relatively small number of pediatric ESRD facilities limits the precision of these estimates. Nevertheless, the regression results are consistent with the strong pattern observed in the descriptive data and with our broader analysis of the relationship between facility volume and cost.

We therefore disagree that extending the LVPA for pediatric renal dialysis service assumes that low volume is a proxy for pediatric complexity. The two adjustments address distinct cost relationships. The updated pediatric case-mix adjustments recognize the higher costs associated with furnishing renal dialysis to pediatric ESRD patients, while the LVPA recognizes the higher per-treatment costs associated with lower facility treatment volume. A pediatric ESRD facility may therefore receive the pediatric adjustment for each qualifying pediatric treatment and, if the facility meets the applicable low-volume criteria, also receive the LVPA.

We also recognize commenters' observation that some higher-volume pediatric ESRD facilities may serve as referral centers for medically complex patients and may incur substantial specialized staffing and supply costs. The additional analysis does not establish that every high-volume pediatric ESRD facility has lower costs than every low-volume pediatric ESRD facility, nor does treatment volume measure patient complexity. Rather, the analysis demonstrates an average relationship between facility treatment volume and per-treatment cost among pediatric ESRD facilities. To the extent that pediatric ESRD facilities generally incur additional costs associated with furnishing pediatric renal dialysis services, including at higher-volume facilities, those costs are reflected in the data used to estimate the pediatric cost differential and are recognized through the permanent pediatric payment adjustments.

Finally, we do not believe it is necessary to extend the TPEAPA to recognize these costs. The TPEAPA was established as a temporary adjustment

for CYs 2024 through 2026 while CMS collected and evaluated additional pediatric-specific cost information (88 FR 76377). The TPEAPA's 30 percent add-on was developed using an analysis that CMS previously recognized had substantial statistical uncertainty. The additional data now available permit CMS to establish permanent pediatric payment adjustments based on more recent observed costs while separately recognizing the relationship between low facility volume and higher per-treatment costs through the LVPA. We believe this approach better distinguishes and targets these separate cost drivers than continuing the temporary adjustment.

Comment: Several commenters urged CMS not to replace the TPEAPA with the proposed combination of revised pediatric case-mix adjustment factors and application of the LVPA. These commenters recommended that CMS either make the TPEAPA permanent or extend it while CMS collects additional pediatric-specific cost data and develops and validates a permanent pediatric payment methodology. Some commenters stated that the approximately 30-percent TPEAPA more appropriately reflects CMS's finding that pediatric renal dialysis services costs are approximately 30 to 33 percent higher than adult renal dialysis services costs.

Other commenters recommended using CMS's existing analyses to establish a permanent pediatric adjustment of approximately 30 to 33 percent rather than relying on a combination of case-mix and volume-based adjustments.

Response: We appreciate commenters' support for ensuring adequate payment for pediatric renal dialysis services and their recommendations concerning continuation of the TPEAPA. As discussed when the TPEAPA was established, the TPEAPA was intended to be a temporary payment adjustment while CMS obtained and analyzed additional information concerning the relative costs of furnishing renal dialysis services to pediatric ESRD patients. In the CY 2024 ESRD PPS final rule, we noted that it was possible that a future permanent adjustment could result in a lower adjustment factor for pediatric ESRD patients (88 FR 76377). However, we note that our proposed adjustment factors based on a 33 percent payment differential and the proposed application of the LVPA to pediatric ESRD patients result in approximately the same overall payment level, with distributional changes. We agree with commenters that a permanent methodology should appropriately

reflect the resources associated with pediatric renal dialysis services and should be supported by the best data reasonably available.

We do not believe, however, that an aggregate estimate that pediatric renal dialysis treatment costs are approximately 30 to 33 percent more than adult treatments necessarily demonstrates that every pediatric ESRD treatment or every facility furnishing pediatric renal dialysis services incurs costs that are uniformly 30 to 33 percent higher. A payment methodology must also consider variation in expected resource use among pediatric ESRD patients and facilities.

Comment: Several commenters questioned whether the available data are sufficiently reliable to establish a permanent pediatric ESRD payment methodology. Commenters stated that pediatric-specific cost reporting remains limited, particularly for hospital-based pediatric ESRD facilities, and noted that the 2022 and 2023 data used in CMS's analysis preceded or did not fully reflect more recent cost-reporting guidance. Commenters explained that children's hospitals may have difficulty allocating the costs of personnel who provide services to both dialysis and non-dialysis patients.

Several commenters recommended that CMS revise the hospital cost report to include pediatric-specific staffing, supplies, and other costs. Commenters stated that more granular pediatric cost reporting would improve CMS's ability to measure the costs of specialized personnel, equipment, supplies, and other resources.

Response: We appreciate commenters' concerns regarding the availability and reporting of pediatric-specific cost information, particularly for hospital-based facilities. We recognize the challenges associated with identifying and allocating costs for personnel and resources that may support both renal dialysis services and other hospital services.

In developing the proposed pediatric payment adjustments, we used the most appropriate cost and claims information available to us and considered the limitations of those data. We agree that continued improvement in pediatric-specific cost information could support future refinements to the ESRD PPS. We will consider commenters' recommendations regarding additional pediatric-specific ESRD cost-reporting fields and other mechanisms for improving the accuracy and consistency of pediatric ESRD cost information in future policy development.

We do not believe that the existence of limitations in pediatric cost reporting

necessarily requires CMS to continue a temporary payment adjustment indefinitely where the available data permits us to develop an appropriate permanent methodology. Nevertheless, we agree that continued monitoring and data development are important given the small size and clinical heterogeneity of the pediatric renal dialysis population.

Comment: Several commenters recommended that CMS convene a technical expert panel (TEP) before establishing a permanent pediatric ESRD payment methodology, or if CMS determines that additional data are needed. Commenters recommended that a TEP include pediatric nephrology clinicians and other providers and, in some cases, pediatric ESRD patients and families. They suggested that the TEP identify remaining gaps in pediatric cost and utilization data, recommend improved data-collection strategies, evaluate alternative payment methodologies, and ensure that the ESRD PPS reflects the clinical and operational characteristics of pediatric renal dialysis.

Response: We appreciate commenters' recommendation to convene a TEP and agree that input from clinicians, facilities, patients, families, and other interested parties can provide useful information concerning pediatric renal dialysis resource use and payment. While we believe we have accurate and appropriate data to develop these methodological changes, we will consider whether additional technical expert input would be useful in evaluating future refinements to the pediatric ESRD PPS case-mix adjustments and improving pediatric-specific data collection in future rulemakings.

Comment: A commenter recommended that CMS recalibrate the pediatric and adult ESRD case-mix adjustment factors simultaneously using more recent data. The commenter expressed concern that updating pediatric ESRD adjustment factors using 2022 and 2023 data while retaining adult ESRD adjustment factors based on older data could result in different beneficiary populations being calibrated using different periods of resource use. The commenter also reiterated its recommendation that CMS replace the two-equation regression methodology with a single-equation methodology based on costs for the full ESRD PPS bundled payment.

Other commenters recommended recalibrating the pediatric modifiers using CMS's existing data so that the resulting payment adjustment more directly reflects the approximately 33-

percent difference between pediatric and adult renal dialysis services costs.

Response: We appreciate commenters' recommendations regarding the methodology used to develop the pediatric case-mix adjustment factors. The purpose of the CY 2027 pediatric analysis is to update payment for renal dialysis services furnished to pediatric ESRD patients in light of the expiration of the TPEAPA and the availability of more recent information concerning pediatric renal dialysis resource use. We disagree with the commenter stating that as we are adjusting the pediatric case-mix adjusters we should also adjust the adult case-mix adjusters. Because pediatric case-mix adjusters are scaled to the average adult case-mix adjuster, the impact to pediatric ESRD PPS payments does not depend on the adult case-mix adjusters. We did not propose to update the adult case-mix adjusters, and we are not finalizing a change to those adjusters in this final rule. We recalibrated the pediatric case-mix adjusters for CY 2027 to address the difference in cost for pediatric ESRD patients. We will continue to monitor the adult and pediatric case-mix adjusters for potential refinement in future rulemaking including a potential one-equation cost model.

Comment: Several commenters questioned the proposed case-mix adjustment factors for younger pediatric ESRD patients. Commenters stated that younger and smaller children may require more resources than older pediatric ESRD patients, including substantially greater nursing intensity, educational and behavioral support, caregiver involvement, and specialized equipment. A commenter noted that patients under 10 kilograms may require one-to-one nursing. Commenters therefore requested that CMS reexamine whether the proposed adjustment factors adequately account for the resource intensity associated with the youngest and smallest pediatric ESRD patients.

Response: We appreciate commenters' descriptions of the additional resources that may be required to furnish renal dialysis services to younger and smaller pediatric ESRD patients. We agree that the clinical care of these ESRD patients can involve substantial nursing, caregiver, educational, behavioral, and technical resources.

The proposed pediatric case-mix adjustment factors were derived from the observed relationships in the data using the methodology described in the proposed rule; they were not established based on a policy assumption that older pediatric ESRD patients are inherently more resource intensive than younger

pediatric ESRD patients. Therefore, differences among the proposed factors reflect the results of the empirical analysis rather than a judgment concerning the relative clinical complexity of particular age groups.

Our proposed calculations indicate that revisions to the case-mix adjustment will result in an increase for pediatric ESRD patients 12 and under with PD as a modality of 32.6 percent, those 12 and under with HD as a modality will receive a 15.1 percent increase. Pediatric ESRD patients 13–17 with PD as a modality will receive a 30.3 percent case-mix increase and those 13–17 with HD as a modality will receive a 15.7 percent case-mix increase. Additionally, these changes are driven by the separately billable (SB) multipliers which are also used in calculating the outlier adjustment. The SB multiplier increases 12 and under PD 27.6 percent, 13–17 PD increases 29.0 percent, and 13–17 HD increases 2.5 percent. The only SB multiplier which decreases is the factor for 12 and under HD which decreases by 9.7 percent based on empirically observed spending in the data. Essentially, all case-mix adjustments increased appropriately based on our regression analysis for each age group with the exception of the 12 and under HD group.

We will continue to monitor the relationship between pediatric ESRD patient characteristics and resource use, including whether future data demonstrate that the payment methodology should be refined to better account for the costs associated with younger or smaller pediatric ESRD patients. CMS will consider proposing any changes that may be warranted through future rulemaking.

Final Rule Action: After consideration of public comments CMS is finalizing the proposed pediatric case-mix factors without any modifications, because we believe that the case-mix factors are based on the best available data. These updated factors accurately target most fragile pediatric ESRD patients, those 12 and under, by increasing the PD factor by 32.6 percent. We are allowing the TPEAPA to expire as scheduled. We are confident in the regression analysis that targeted increased payment for PD in both age categories. We will continue to collect and refine data for analysis to ensure the most appropriate payment for pediatric ESRD patients. We do not currently plan to convene a TEP as we believe that the available data and notice-and-comment rulemaking process provided adequate information for the basis of the CY 2027 policy, and

we will continue to listen to the pediatric ESRD community.

(3) Expansion of the LVPA

Historically, the ESRD PPS has not applied the LVPA for treatments furnished to pediatric ESRD patients. Section II.B.8. of this final rule provides background on the LVPA. In the CY 2011 ESRD PPS final rule, we codified the pediatric ESRD patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric ESRD patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality (75 FR 49134). Additionally, we finalized the elimination of several exceptions including the pediatric facility exception, which allowed for higher cost pediatric ESRD facilities to receive additional payments when costs exceeded payment amounts under the composite rate payment system. In other words, the pediatric ESRD facility exceptions terminated for ESRD treatment on or after January 1, 2014 (75 FR 49178). Finally, the LVPA was only applicable to adult ESRD patients and was not directly used in calculating the payment rate per treatment for pediatric dialysis patients. Facilities qualifying for the LVPA that treat both adult and pediatric ESRD patients have only received the LVPA for adult dialysis patients (75 FR 49134). As noted in section II.B.8. of this final rule, small ESRD facilities incur higher costs than larger ESRD facilities, in part because they do not benefit from the same economies of scale as many large ESRD facilities. Due to the low incidents of pediatric ESRD patients most pediatric units are small, which makes accounting for higher costs associated with facility size accurately in payments important; however, the small number of pediatric ESRD patients also makes separate analysis on the costs of treating pediatric ESRD patients difficult. As discussed previously, for the CY 2011 ESRD PPS final rule we finalized an alternative methodology which was based on the average payments for pediatric treatments under the composite rate system (75 FR 49132 through 49134), including those exceptions to the composite rate system for high-cost pediatric facilities. The LVPA was only extended to payments for adult ESRD patients in ESRD facilities because facilities that primarily treat pediatric ESRD patients are typically small, so the higher pediatric payments from which the methodology in the CY 2011 ESRD PPS final rule derived the pediatric case-mix adjusters included any higher costs

associated with low volume. As such, we concluded that extending the LVPA to payments for pediatric ESRD patients would be duplicative with the calculation of the pediatric case-mix adjusters under the methodology used for the CY 2011 final rule (75 FR 49134). However, for this final rule, we included facility size as a separate characteristic in our regression model. As noted in Table 20, the pediatric ESRD share is an independent indicator of cost from the size of the ESRD facility.

As discussed previously, smaller ESRD facilities experience the greatest financial burden, and our latest analysis finds that this holds for pediatric ESRD facilities and adult ESRD facilities. As shown in Table 20, the natural logarithm of facility size (based on the total volume of treatment counts) is associated with a statistically significant reduction in cost. This means that regardless of a facility's share of pediatric ESRD patients, we observe that cost per treatment decreases as the facility's total number of treatments increases and, conversely, the cost per treatment increases as the facility's total number of treatments decreases. Based on this analysis, we believe that expanding the LVPA to include treatments furnished to pediatric ESRD patients would be appropriate.

Therefore, for CY 2027, we proposed to revise § 413.232(f) to state that the LVPA is applicable for renal dialysis treatments furnished to all ESRD patients. As outlined in section II.B.8. of the proposed rule, we proposed to make budget-neutral changes to the LVPA tier structure and adjustment factors, and we proposed that those changes would be applicable to payments for all ESRD patients beginning in CY 2027. We estimated that this change would appropriately increase payments to ESRD facilities that treat a large share of pediatric ESRD patients, which our data demonstrates face higher costs due to low volume status in addition to the specific costs associated with treating pediatric ESRD patients. Our analysis of the distributional impacts associated with the proposed LVPA changes and the proposed expansion of the LVPA to pediatric ESRD patients can be found in section II.B.8. of the proposed rule.

Additionally, we noted that although the LVPA does not currently apply to pediatric ESRD PPS claims, ESRD facilities that provide renal dialysis services to pediatric ESRD beneficiaries are nevertheless permitted to attest to low-volume status and receive the LVPA for any adult ESRD beneficiaries they treat, under current regulation. Among the 32 dedicated children's

hospitals furnishing ESRD treatments, two children's hospitals currently receive LVPA payments. Similarly, four of the 52 ESRD facilities that provide most of their treatments to pediatric ESRD patients are also receiving the LVPA for their adult ESRD patients. As discussed in the proposed rule, we believe that the relatively low rates of low-volume attestation among pediatric ESRD facilities is primarily because the LVPA is not applied to most of the treatments furnished to these ESRD facilities' patients. We estimated that approximately 24 pediatric ESRD facilities could be eligible for the LVPA based on the current 4,000 -treatment threshold. We stated that we expect that if we finalize our proposal to expand the LVPA to pediatric ESRD patients beginning for CY 2027, then additional ESRD facilities like these, which are not currently attesting to low-volume status, would begin to attest and would begin receiving the LVPA in CY 2027.

We also considered that small pediatric ESRD facilities within larger institutions could be small, high-cost centers specializing in care for pediatric ESRD patients. We recognized that in some cases, common ownership with other ESRD facilities that are located 5 road miles or less from the pediatric ESRD facility could create barriers to LVPA eligibility for some pediatric ESRD facilities. Under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, "treatments" mean total HD equivalent treatments (Medicare and non-Medicare). For PD patients, one week of PD is considered equivalent to three HD treatments (80 FR 68994).

We considered the nature of pediatric ESRD facilities, those ESRD facilities with at least a 50 percent pediatric ESRD patient mix, which are uniquely equipped to meet the specialized needs of a small subset of patients that other nearby adult-focused ESRD facilities may not be able to treat, including ESRD facilities under common ownership. We noted that we believe it would be appropriate to allow pediatric ESRD

facilities to request an exemption from the aggregation of volume for ESRD facilities under common ownership. While we did not propose a categorical exemption from these regulations, we proposed that a pediatric ESRD facility that is seeking low-volume status could request an exception from the aggregation of treatment volume for ESRD facilities under common ownership at § 413.232(c) through its MAC. To request such an exception, we proposed that an ESRD facility would need to submit documentation to the MAC demonstrating that: (1) the ESRD facility is either owned and operated by a Medicare-certified children's hospital under § 412.23(d) or the ESRD facility provides at least 50 percent of its total treatments (Medicare and non-Medicare) to ESRD patients who are under the age of 18 and (2) the ESRD facility is under common ownership with an ESRD facility that does not provide at least 50 percent of its total treatments (Medicare and non-Medicare) to ESRD patients who are under the age of 18. If approved, the MAC would not consider the treatment volume of the commonly owned ESRD facility when calculating the treatment volume for the excepted ESRD facility. Once approved, the exception would continue for all future years so long as the ESRD facility continues to either be a Medicare-certified children's hospital or provides at least 50 percent of total treatments to ESRD patients who are under the age of 18.

The excepted ESRD facility would still have to meet all other requirements for the LVPA, including the treatment volume threshold described at § 413.232(b)(1). As this exception is only for the purposes of the aggregation of volume of commonly owned ESRD facilities, it is possible for an ESRD facility to receive this exception and not be eligible for the LVPA if it furnished 8,000 treatments or more (or 4,000 had the change in section II.B.8. of this final rule not been finalized) in one of the past three cost reporting years. The aggregation of volume for ESRD facilities under common ownership would still apply for the excepted ESRD facility and any other commonly owned ESRD facilities within 5 road miles for which an exception has not been approved. An ESRD facility could receive exceptions for multiple commonly owned ESRD facilities, should the requirements for the exception be met for each of them. We proposed the addition of paragraph § 413.232(g)(7) to effectuate this proposed exception and detail the process for requesting the exception.

We solicited comments on our proposed expansion to apply the LVPA to payments for pediatric ESRD patients. We also solicited comments on the proposed exception to the aggregation of volume for ESRD facilities under common ownership, the administrative process required to request such an exception, and whether such an exception is needed. We noted that we believe extending the LVPA to these facilities could alleviate financial pressures. The LVPA is designed to offset the disproportionate costs encountered by low-volume ESRD facilities. Expanding its application would help ensure that pediatric ESRD facilities, which typically operate at lower volumes due to the specialized nature of their ESRD patient populations, receive essential financial support not fully addressed by current payment adjustments under the ESRD PPS.

We received comments from ESRD patient and caregiver representatives, patient advocacy organizations, professional associations, ESRDs facilities and organizations, and other interested parties regarding the proposed revisions to payment for renal dialysis services furnished to pediatric ESRD patients. Commenters generally agreed that furnishing renal dialysis services to pediatric ESRD patients is more resource intensive than furnishing such services to adult ESRD patients and supported continued recognition of those additional costs under the ESRD PPS. Commenters differed, however, regarding the application of the low-volume payment adjustment (LVPA), use of treatment volume as an indicator of resource use, the adequacy of the data used to develop the proposed adjustments, continuation of TPEAPA, and application of budget neutrality. We summarize these comments and provide our responses in the following section.

Comment: One pediatric professional organization provided examples of critically ill pediatric ESRD patients with multiple comorbidities from high-volume pediatric nephrology programs to illustrate that treatment volume is not a proxy for the cost of pediatric renal dialysis services.

Response: We understand the incredible dedication and talent it requires to manage these pediatric ESRD patients. However, the pediatric case-mix does not address comorbidities. The costs for these complicated cases are incorporated into the case-mix that addresses age and modality. We have not removed any money from the case-mix adjustment. The pediatric ESRD case-mix adjustment has increased for every age category. Additionally, these

complicated cases would potentially qualify for the ESRD outlier adjustment. The LVPA is in addition to the ESRD case-mix and outlier adjustments.

Comment: Several commenters expressed concern that the proposed methodology could result in lower payments relative to the TPEAPA for certain higher-volume pediatric ESRD programs. Commenters stated that these ESRD facilities often serve as tertiary referral centers for children with rare genetic or metabolic diseases, cancer, organ transplantation, or other complex conditions and may require broader multidisciplinary teams and subspecialty expertise. Commenters stated that payment reductions could threaten the financial viability of pediatric renal dialysis programs and access to specialized pediatric care.

A commenter reported that its internal comparison suggested that the cost difference between pediatric and adult renal dialysis services was greater than CMS's estimate, although the commenter acknowledged limitations in directly comparing the populations and settings.

Response: We appreciate commenters' concerns regarding payment adequacy and access to specialized pediatric renal dialysis services. We agree that higher treatment volume does not necessarily indicate lower clinical complexity and recognize the important role that tertiary pediatric centers play in caring for children with complex conditions.

The ESRD PPS methodology is intended to establish payment based on expected resource use across categories of ESRD patients and facilities rather than to reimburse each facility's individually reported costs. Nevertheless, we agree that significant payment changes affecting a small number of highly specialized ESRD facilities warrant careful consideration. We intend to monitor pediatric renal dialysis services utilization, facility participation, and access to care following implementation of the final policy and will consider future refinements through rulemaking if the data indicate unintended effects on access to pediatric renal dialysis services.

Comment: Numerous commenters opposed using ESRD facility treatment volume as a basis for determining the amount of additional payment for pediatric renal dialysis services. Commenters stated that pediatric renal dialysis programs incur substantial fixed costs for specialized staff, equipment, supplies, multidisciplinary care, and infrastructure regardless of treatment volume. Commenters also stated that higher-volume pediatric

ESRD centers may serve as regional or national referral centers for the most medically complex children and therefore may have higher, rather than lower, costs.

Commenters expressed concern that the proposed LVPA methodology could reduce payment to larger pediatric ESRD programs, including tertiary children's hospitals, even though those programs furnish highly specialized care. Some commenters also expressed concern about facilities that predominantly treat adults but furnish renal dialysis services to a small number of pediatric ESRD patients, stating that the facility's total treatment volume does not reduce the resources required for its pediatric ESRD patients.

Response: We appreciate commenters' concerns regarding the relationship between treatment volume and pediatric renal dialysis services costs. We agree that treatment volume is not a direct measure of an individual patient's clinical complexity and that high-volume pediatric ESRD programs may treat highly complex patients. We also recognize that pediatric renal dialysis programs may incur certain fixed or semi-fixed costs associated with maintaining specialized staff, equipment, supplies, and infrastructure.

The LVPA, however, is intended to recognize the relationship between ESRD facility treatment volume and per-treatment costs associated with spreading fixed costs across a smaller number of treatments. The proposed application of the LVPA to pediatric renal dialysis treatments was not based on an assumption that low volume captures all differences in pediatric clinical complexity. Rather, the LVPA and the pediatric case-mix adjustment factors address different dimensions of expected resource use. We will continue to monitor whether facility volume appropriately identifies systematic differences in per-treatment costs for pediatric renal dialysis services and whether additional refinements may be warranted as more pediatric-specific data become available.

Comment: Several commenters recommended that, if CMS proceeds with the proposed framework, the agency apply an LVPA to all pediatric renal dialysis services regardless of facility treatment volume. Some commenters recommended applying the LVPA to all pediatric renal dialysis treatments using the adjustment associated with facilities furnishing between 5,000 and 5,999 treatments annually. Commenters stated that pediatric renal dialysis services are inherently a low-volume and highly specialized service and that applying an

adjustment to all pediatric renal dialysis treatments would prevent larger pediatric referral centers from being disadvantaged.

Response: We appreciate commenters' recommendations. Applying the LVPA to all pediatric renal dialysis treatments without regard to facility volume would effectively convert the adjustment, in whole or in part, from a low-volume facility adjustment into a broadly applicable pediatric ESRD patient payment adjustment. Such an approach would not target the adjustment based on the relationship between facility volume and per-treatment costs that the LVPA is designed to recognize. While the pediatric ESRD patient population is inherently small, data analysis has shown that there is a cost difference between pediatric ESRD facilities that provide under 8,000 treatments per year, and those pediatric ESRD facilities that provide over 8,000 treatments per year.

Comment: A commenter expressed concern that ESRD facilities furnishing a high volume of adult renal dialysis treatments but treating only a small number of pediatric ESRD patients may not receive sufficient additional payment for their pediatric ESRD patients under a facility-volume methodology. The commenter stated that efficiencies associated with treating a large number of adult ESRD patients do not eliminate the specialized resources necessary to furnish care to pediatric ESRD patients and that families should not be disadvantaged for obtaining pediatric renal dialysis from a facility that also treats adults.

Response: We appreciate the commenter's concerns. We agree that pediatric ESRD patients may require specialized resources regardless of whether the facility also treats adult patients. This rule increases the case-mix adjusters for all age categories as discussed earlier, which addresses the increased cost of pediatric ESRD patients. At the same time, there are certain facility-level costs and economies of scale may impact costs across treatments, and the ESRD PPS must distinguish between patient-level differences in expected resource use and facility-level differences associated with treatment volume. We will monitor the effects of the policy on ESRD facilities furnishing both adult and pediatric renal dialysis services, including whether the methodology creates unintended access or payment concerns.

Comment: A commenter supported the proposed exception from the common-ownership treatment-volume aggregation requirement for qualifying pediatric ESRD facilities. The

commenter stated that specialized pediatric ESRD programs may be located within larger health systems while continuing to operate as small, high-cost programs serving a clinically distinct population.

Response: We appreciate the commenter's support. We agree that application of common-ownership aggregation requirements without consideration of the circumstances of qualifying pediatric ESRD facilities could cause the volume attributed to a pediatric ESRD program to reflect treatments furnished by other ESRD facilities within a larger organization rather than the operating circumstances of the pediatric ESRD facility itself.

Comment: A commenter supported implementation of the expanded pediatric LVPA beginning in CY 2027 and recommended providing an expanded or later LVPA attestation window rather than delaying implementation until CY 2028. The commenter stated that timely LVPA eligibility would help avoid a payment discontinuity following expiration of the TPEAPA.

Response: We appreciate the comment. We agree that ESRD facilities should have sufficient time to understand applicable eligibility requirements, submit required attestations, and allow MACs sufficient time to process those attestations. We also recognize the importance of avoiding unnecessary disruption as CMS transitions from the temporary pediatric ESRD payment policy to the permanent methodology. As discussed in section II.B.8.d. of this final rule, we are finalizing an extension of the LVPA attestation deadline for payment year 2027 to December 31, 2026. This extension would equally apply for adult and pediatric ESRD patients.

Comment: A commenter requested that CMS monitor whether changes in pediatric renal dialysis services payment affect access to pediatric nephrology expertise, home dialysis training, transplant education, mental health services, nutrition support, and family-centered care. The commenter also recommended monitoring access for children from rural communities, low-income families, racially and ethnically diverse communities, and families whose primary language is not English.

Response: We appreciate the commenter's recommendations regarding access and the range of services needed by pediatric renal dialysis patients and their families. We agree that Medicare payment policy should support continued access to medically necessary renal dialysis

services and that the effects of payment changes on vulnerable and underserved populations are important considerations.

We will consider available claims, enrollment, facility, quality, and other data in monitoring the effects of the pediatric ESRD payment methodology. We also will consider feedback from interested parties concerning access to pediatric renal dialysis services, including services furnished by specialized pediatric ESRD programs and services needed to support home dialysis and transplantation.

Comment: A commenter stated that pediatric home dialysis frequently requires extensive parent or caregiver training, competency validation, and ongoing support and requested that CMS consider whether its analysis adequately captures the additional resources associated with caregiver-dependent pediatric home dialysis relative to adult home dialysis.

Response: We appreciate the comment. We recognize that home dialysis for pediatric ESRD patients may require substantial caregiver involvement and training. The issues raised by the commenter concerning the resources associated with home dialysis training are relevant both to the pediatric payment methodology and to the policies governing payment for home dialysis training. As noted in section II.B.10.e. of this rule, we are adjusting the home and self-dialysis training payment adjustment from \$95.60 to \$138.00. The case-mix adjustments for PD have increased for both age groups. For the 12 years old and under pediatric ESRD patients the case-mix is 32.6 percent and for those pediatric ESRD patients between 13–17 years of age would have a case-mix increase is 30.3 percent.

Comment: A commenter urged CMS to prioritize simplicity and predictability in the pediatric ESRD payment methodology. The commenter stated that changes in pediatric renal dialysis payment policy and associated administrative requirements can create burdens, particularly for pediatric ESRD programs embedded within facilities that predominantly serve adults.

Response: We appreciate the comment. We agree that administrative simplicity and payment predictability are important considerations, particularly for a small patient population and the relatively limited number of ESRD facilities furnishing pediatric renal dialysis services. At the same time, payment accuracy may require adjustments that account for meaningful differences in expected resource use.

In developing the proposal and final policy, we sought to balance payment accuracy with administrative feasibility and to rely, to the extent practicable, on existing ESRD PPS mechanisms rather than creating unnecessary new reporting or billing requirements. There are no new reporting requirements for the pediatric case-mix adjusters and only a yearly attestation for low-volume which many adult ESRD programs are familiar with submitting.

Comment: A commenter requested that CMS more clearly explain the payment effects of ending the TPEAPA, updating the pediatric case-mix and outlier multipliers, and applying the LVPA to pediatric renal dialysis services. The commenter requested information concerning the effects of these policies individually and in combination and their effects on both pediatric and adult beneficiaries, particularly in light of budget neutrality.

Response: We appreciate the request for additional transparency concerning the individual impact and interaction of the pediatric ESRD payment policies. We believe the ESRD PPS payment policy for pediatric ESRD patients and extending the LVPA to pediatric ESRD PPS payments has been explained in detail throughout the CY 2027 ESRD PPS proposed rule and this final rule. Because the expiration of the TPEAPA, revised pediatric adjustment factors, application of the LVPA, and budget-neutrality calculations affect different components of the ESRD PPS bundled payment, we agree that describing their combined effects is useful for understanding the final policy. We refer the commenter to Table 22 of this section that indicates the impacts on pediatric ESRD facilities collectively. ESRD facilities that provide 50 percent or more of their treatments to pediatric ESRD patients can view the individual effects of the ESRD PPS pediatric ESRD payment changes and extension of the LVPA to pediatric ESRD payments in Appendix B to this final rule. The impact to ESRD facilities providing most treatments to adult beneficiaries with ESRD collectively is provided in the final impacts in Table 30 in section VII.C.5.a. of this final rule. ESRD facilities providing most treatments to adult beneficiaries with ESRD can view the individual effects of the ESRD PPS pediatric ESRD payment changes and extension of the LVPA to pediatric ESRD payments in Appendix B to this final rule. We will monitor and report the effect of payment policy revisions such as ending the TPEAPA, updating the pediatric case-mix and outlier multipliers, and applying the LVPA to pediatric renal dialysis services on

pediatric ESRD facilities as warranted in the future.

Comment: Several commenters opposed implementing the pediatric payment changes on a budget-neutral basis. Commenters stated that the higher costs of pediatric renal dialysis services do not imply that the costs of treating adult dialysis patients have decreased and stated that improving payment for pediatric care should not require reductions in payments for other ESRD patients. A commenter noted that pediatric Medicare beneficiaries constitute a small share of ESRD PPS treatments and noted that the cost of financing pediatric payment improvements without budget neutrality, therefore, would be small relative to total ESRD PPS expenditures.

Other commenters supported the substance of the proposed pediatric case-mix and LVPA policies but specifically requested that CMS implement those policies on a non-budget-neutral basis.

Response: We appreciate commenters' concerns regarding the effects of budget neutrality on payments for other ESRD PPS treatments. We agree that the clinical need for additional resources for renal dialysis services furnished to pediatric ESRD patients does not imply that adult dialysis patients require fewer resources.

However, we believe that the application of a budget neutrality factor to the ESRD PPS base rate is appropriate for this payment change as it would ensure that changes in payment adjustments do not result in an unintended change in aggregate ESRD PPS expenditures solely as a result of recalibration. We stated that the TPEAPA applies primarily to costs included in the data used to establish the CY 2011 ESRD PPS bundled payment. Because the methodology attributed pediatric renal dialysis services costs to the general population, the ESRD PPS base rate would be reduced to reflect the reallocation of pediatric renal dialysis services costs. We noted that we believe that future modifications to the pediatric case-mix adjusters must also maintain budget neutrality. We refer the commenter to Table 22 of this section that indicates the impacts on pediatric ESRD facilities. The impact to adult ESRD facilities is provided in the final impacts in Table 30 in section VII.C.5.a. of this final rule. We will continue to monitor the effectiveness of budget-neutral payment adjustments to the impacts of both pediatric and adult ESRD facilities and will potentially revise payment methodologies as warranted in future rulemaking (88 FR 76378). Further

discussion of budget neutrality is noted in section II.B.4. of this final rule.

Comment: Several commenters requested continued data collection and monitoring after implementation of any permanent pediatric ESRD payment methodology. Commenters recommended that CMS evaluate payment adequacy, staffing, specialized resource needs, access to pediatric renal dialysis services, the experience of high-volume tertiary centers, and the resource intensity associated with younger and medically complex ESRD patients. Some commenters requested future changes if experience demonstrates that the finalized methodology does not adequately reflect pediatric renal dialysis services costs.

Response: We agree that continued monitoring is particularly important for pediatric renal dialysis services because the pediatric ESRD population is small and the facilities furnishing these services vary in size, organizational structure, and patient complexity. The relatively small number of pediatric renal dialysis treatments also can make estimates more sensitive to changes in patient mix, facility characteristics, and reporting practices.

We intend to continue evaluating available pediatric cost, claims, utilization, and facility data following implementation of the CY 2027 policy. We will also consider information submitted by pediatric renal dialysis providers, professional organizations, patients, caregivers, and other interested parties. If future data indicate that the pediatric payment methodology does

not appropriately reflect resource use or creates unintended access concerns, we may consider additional refinements to cost reports or action through future notice-and-comment rulemaking.

Final Rule Action: After consideration of public comments, available data and additional feedback from interested parties provided directly to CMS, we are finalizing the pediatric payment changes for CY 2027 as proposed, without modification. Our analysis demonstrates a consistent relationship between facility volume and pediatric per-treatment costs, with higher-volume pediatric referral centers and mixed adult/pediatric facilities incurring distinct resource demands. In response to concerns raised by commenters regarding these centers, CMS has evaluated the impact of volume thresholds and the LVPA methodology. We are maintaining the proposed volume thresholds and tiers for pediatric ESRD facilities, as they accurately reflect observed cost differences and ensure payment aligns with pediatric resource use regardless of facility type. Under the finalized LVPA methodology, pediatric renal dialysis treatments and total facility volume are considered, with the aggregation exception for common ownership ensuring qualifying pediatric ESRD facilities are not disadvantaged.

CMS is finalizing the pediatric exception to the common-ownership aggregation requirement as proposed, without modification. The CY 2027 implementation date will be January 1, 2027. As discussed previously, the

attestation deadline for payment year CY 2027 is extended to December 31, 2026. That is, ESRD facilities, including those that primarily furnish treatment to pediatric ESRD patients, must submit an attestation by December 31, 2026, to receive the LVPA for payments in CY 2027. The extension to the attestation deadline also allows pediatric ESRD facilities to submit any requests for exceptions to the common ownership aggregation by December 31, 2026. Impact analyses indicate expected payment changes for pediatric ESRD facilities based on volume, facility type, and other characteristics, supporting equitable payment. The finalized pediatric case-mix methodology incorporates modality-specific differences, including the home and self-dialysis training add-on payment adjustment, to further refine payments. Attestation, reporting, and billing requirements under the final policy are specified to ensure transparency and accountability. A comprehensive payment-impact Table 22 details the effects of the TPEAPA expiration, revised pediatric case-mix and outlier factors, LVPA eligibility, combined pediatric impact, and applicable budget-neutrality adjustments to the ESRD PPS base rate, is presented in the following table. CMS has determined that budget neutrality is appropriate under section 1881(b)(14)(D)(iv)(I) of the Act and is finalizing these pediatric payment changes on a budget-neutral basis as proposed, with the final budget-neutrality factor and estimated aggregate effects provided in the rule.

TABLE 22: Combined Pediatric Payment Impacts

Age-group and modality	Facility Size	Pre TPEAPA Adjusters*	Payment Under TPEAPA*	Final CY 2027 Adjusters and LVPA Expansion*	Difference Pre-TPEAPA to CY 2027 Final	Difference TPEAPA to CY 2027 Final
<13 PD	<3k	\$316.26	\$411.14	\$573.88	\$257.62	\$162.74
<13 HD	<3k	\$388.56	\$505.13	\$611.73	\$223.17	\$106.60
13-17 HD	<3k	\$394.81	\$513.25	\$625.16	\$230.35	\$111.91
<13 PD	8k or more	\$316.26	\$411.14	\$419.50	\$103.24	\$8.36
13-17 HD	8k or more	\$394.81	\$513.25	\$456.99	\$62.18	-\$56.26

*Calculations are each based on the final CY 2027 ESRD PPS base rate of 297.52 and a wage index value of 1.000

This table demonstrates that all categories of pediatric ESRD patients see their respective payment increase compared to that before the implementation of TPEAPA, and that only those treated at the large ESRD facilities see a payment decrease between payment under TPEAPA and the final CY 2027 factors. As noted previously, the payment changes to the LVPA are based on our most recent analysis of pediatric renal dialysis services costs which indicates that lower-volume ESRD facilities treating pediatric ESRD patients incur higher costs.

(4) Conforming Edits to § 413.232(g) To Specify Calendar Days

As discussed in the CY 2027 ESRD PPS proposed rule, we proposed to create an exception process for ESRD facilities that are Medicare-certified children's hospitals or that furnish more than 50 percent of treatments to pediatric ESRD patients. In the proposed new paragraph § 413.232(g)(7), we specify a timeline based on "calendar days," rather than "days." We believe that specifying "calendar days" avoids confusion between calendar days, working days, business days, or any other type of day. When we finalized the exceptions for disasters or other emergencies in the CY 2024 ESRD PPS final rule (88 FR 76344), we similarly created a timeline but did not specify the type of "days" despite our intention being calendar days. We proposed edits to § 413.232(g)(5) and (6) to specify that the timeline for the exceptions is based on calendar days, consistent with the proposed language of § 413.232(g)(7). We also proposed an edit to § 413.232(g)(6)(iv) to add the word "of" to the first sentence following "30 calendar days," which was omitted in a typographical error. We solicited comments on these proposed changes, including whether we should finalize such changes even if the exception detailed at the proposed new paragraph (g)(7) is not finalized. We also solicited comments on whether another basis for the timeline, for example business days, would be better for ESRD facilities requesting any of these exceptions.

We did not receive any public comments on these proposals. We are finalizing the proposals as proposed.

10. Home and Self-Dialysis Training Add-On Payment Adjustment

a. Background

Under the ESRD PPS, there are three components to payment for home and self-dialysis training: (1) the base rate, (2) a wage-adjusted home and self-

dialysis³⁸ training add-on payment adjustment, and (3) an allowable number of training treatments. The ESRD PPS includes an add-on payment adjustment for home and self-dialysis training, which is described at § 413.235(c). Hereafter, we refer to the home and self-dialysis training add-on payment adjustment as the training add-on.

CMS makes the same training add-on for both HD and PD. We recognize that the costs for home and self-dialysis training for HD and PD are likely not identical, as supported by our analysis of ESRD facility cost report data discussed later in this section. However, the ESRD PPS is a prospective payment system under section 1881(b)(14)(A)(i) of the Act. As such, payments are not intended to reflect the exact costs incurred by individual facilities, but to provide standardized payments that promote efficiency and access.

When the ESRD PPS was implemented in 2011, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930), and therefore, the computation of the base rate included home dialysis training add-on payments made to ESRD facilities as well as all composite rate payments, which account for facility costs associated with equipment, supplies, and staffing. In response to public comments, in the CY 2011 ESRD PPS final rule, we noted that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Accordingly, we finalized the training add-on amount of \$33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either HD or PD training or retraining (75 FR 49063), updated from the previous adjustment amount of \$20. This updated amount of \$33.44 per treatment was based on the national average hourly wage for Registered Nurses (RN) as published by the Occupational Employment Statistics (OES) data compiled by BLS data updated to 2011 (75 FR 49063), and reflected 1 hour of training time by a RN for both HD and PD. This average hourly wage was then inflated to 2011 by the ESRD wages and salaries proxy used in the 2008-based ESRD bundled market basket. In addition, we continued the policy of paying the home dialysis

³⁸ Home dialysis is dialysis performed by a beneficiary or caretaker in their home. Self-dialysis is dialysis performed by a beneficiary in-center.

training add-on payment for 15 training treatments for PD and 25 training treatments for HD.

Section 494.100(a)(2) of the Conditions for Coverage for ESRD Facilities stipulates that the RN must conduct the home or self-dialysis training, and CMS has clarified through interpretive guidance (ESRD Program Interpretive Guidance published October 3, 2008 (<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>)) that other members of the clinical dialysis staff may assist in providing the home training. We also elaborated in this guidance that the qualified home training RN is responsible for ensuring that the training is in accordance with the requirements at § 494.100, with oversight from the ESRD facility's interdisciplinary team.

In the CY 2014 ESRD PPS final rule (78 FR 72185), CMS increased this amount from \$33.44 to \$50.16 to reflect 1.5 hours of training time by an RN in response to concerns from interested parties regarding payment adequacy. The \$50.16 training add-on amount was consistent with average costs based on an analysis of pre-PPS cost report data. In the CY 2017 ESRD PPS final rule (81 FR 77856), CMS further updated the home and self-dialysis training add-on to \$95.60 based on 2.66 hours of RN time using BLS wage data.

In 2025, Medicare paid approximately \$7 million in home and self-dialysis training add-on payment adjustment amounts, which remained relatively stable compared to prior years. This relatively flat trend, in conjunction with feedback from interested parties, may indicate that home dialysis and self-dialysis modalities remain underutilized and that payment adequacy for training may be a contributing factor.

b. Analysis of ESRD Cost Report Data

When we last updated the training add-on amount in the CY 2017 ESRD PPS final rule (81 FR 77848 through 77856), we stated that we made changes to the freestanding ESRD facility cost reports to allow for better collection of training data, and that we would evaluate improved cost report data once available. We stated that we intended to compare the average cost per home dialysis training treatment for PD and HD to the proxy value, and to assess the extent to which the training add-on reflects ESRD facility costs for home dialysis training on average.

As discussed in the CY 2027 ESRD PPS proposed rule (91 FR 38831), we

analyzed the data collected on Worksheets B and C on the average home dialysis training cost per training treatment for freestanding ESRD facilities. Specifically, the following analysis is from Worksheets B and C from the freestanding ESRD facility cost report (CMS-265-11) and Worksheets I-2 and I-4 from the hospital-based ESRD facility cost report (CMS-2552-10).³⁹ We used CY 2024 cost report data, which includes cost reporting periods beginning between January 1, 2024, and December 31, 2024. AKI lines were excluded from this analysis since AKI beneficiaries were not eligible for the training add-on for the entirety of the study period.⁴⁰ Data was evaluated at the facility level, and the top and bottom 1 percent of observations were winsorized.⁴¹

We analyzed CY 2024 ESRD cost report data from freestanding and hospital-based ESRD facilities. The median cost-per-training session was approximately \$712 overall, \$381 for HD, and \$797 for PD. The median labor cost-per-training session was approximately \$283 overall, \$164 for HD, and \$314 for PD. As discussed in the proposed rule, CMS believes that these reported ESRD facility costs include resources associated with routine renal dialysis services in addition to training-specific activities. On average, payment per dialysis treatment was approximately \$300 in 2024. As outlined in section II.B.1. of this final rule, the total compensation in the 2024-based ESRDB market basket is 50.9 percent as presented in Table 3. Applying this to the rough per-treatment payment amount of \$300 gives us a payment amount of approximately \$153. To appropriately determine the extent to which training for home dialysis results in increased labor costs, we can subtract this \$153 amount from the median per-training-treatment labor cost of \$283. This results in a per-treatment labor net cost of about \$130 per training treatment

above that which is included in the per-treatment payment.

Because the ESRD PPS is not a cost-based system, and cost report data may not reliably isolate the marginal cost of training, we noted that CMS does not believe it is appropriate to base the training add-on directly on these data. As discussed in further detail in the next section, CMS proposed to continue to rely on a standardized labor-based methodology reflecting RN time, which is more consistent with the design of the ESRD PPS. However, this \$130 net labor per-training treatment cost demonstrates the effectiveness of the methodology, the results of which we discuss in the following section.

c. Proposed Increase to the Home and Self-Dialysis Training Add-On Payment Adjustment

In the CY 2027 ESRD PPS proposed rule, we proposed to increase the training add-on according to the most recently available BLS OEWS, using the same methodology finalized in the CY 2017 ESRD PPS final rule (81 FR 77856), based on 2.66 hours of RN time and updated wage data. CMS proposed to maintain the 2.66-hour basis as cost report data has indicated it is an appropriate basis for the training payment and is administratively simple to calculate. As discussed in the prior section, cost report data shows a net labor cost of approximately \$130 per training treatment for 2024. While we did not propose to base the training amount on this cost report data, we note that it lines up with the result from our established methodology closely. Specifically, applying this 2.66-hour basis to the estimate of RN wages from the May 2024 BLS OEWS, \$47.32, would give us a training adjustment of \$125.87 for 2024, before the application of any wage index. This demonstrates that our longstanding methodology generally accounts for the net labor costs associated with home dialysis training.⁴² We explained that the training add-on is only intended to cover the labor related costs for home and self-dialysis training, as the ESRD PPS base rate includes payment for all other costs associated with furnishing renal dialysis services, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49063).

We stated that this proposed approach would maintain consistency with prior policy while accounting for wage growth over time and aligning with the prospective principles upon which the

ESRD PPS was established. Under the ESRD PPS, and in accordance with section 1881(b)(14)(A)(i) of the Act, CMS implemented a single base rate that applies to all dialysis treatment modalities. CMS did not propose to differentiate payment amounts between PD and HD training. Although cost report data suggest differences, maintaining a single rate is consistent with the ESRD PPS structure as HD and PD are paid the same for adult beneficiaries, and avoids creating financial incentives that could influence modality selection.

We calculated the updated payment amount using the mean hourly wage for RNs (SOC 29-1141) from the May 2025 BLS OEWS (<http://www.bls.gov/oes/tables.htm>) which was \$48.76 in 2025. We then inflated this 2025 mean hourly wage figure to CY 2027 using the growth in the 2024-based ESRDB market basket Wages and Salaries price proxy. We stated that we believe this proposed increase would improve payment adequacy for training while maintaining the integrity of the PPS. This would result in a new RN hourly wage of \$51.96. For the hours, we proposed to continue to use the 2.66 hours as the amount of time for home dialysis training by an RN that is accounted for by the training add-on. This results in a proposed training add-on payment of \$138.22 (2.66 hours × \$51.96 = \$138.22). We proposed to update the RN hourly wage estimate in the final rule with more recent data, such as an updated estimate in the growth of the price proxy, if appropriate.

This proposal would provide for an increase of \$42.62 per training treatment (that is, \$138.22 – \$95.60 = \$42.62). This approach would provide a significant increase in payment for home and self-dialysis training for CY 2027 while maintaining consistent payment for both PD and HD modalities. After evaluating the cost report data presented previously in the proposed rule, we stated that we believe that this amount is an appropriate proxy for the costs of home dialysis training. We proposed to update this training add-on amount with additional data, for example an update in the growth in the 2024-based ESRDB market basket Wages and Salaries price proxy in the final rule, if appropriate.

CMS proposed to implement this increase for the training add-on in a budget neutral manner through an adjustment to the ESRD PPS base rate. We stated that we believe implementing this budget neutral change, similar to the budget neutral training add-on in the CY 2017 ESRD PPS final rule (81 FR 77856), is appropriate because the ESRD

³⁹ Provider training costs from freestanding ESRD facility worksheet B non-AKI lines between Lines 10-13, columns 3-9 and 11-13 and hospital cost report worksheet I-2 non-AKI lines between Lines 4-7, columns 1-8 and 10. Provider training session count freestanding ESRD facility worksheet C non-AKI lines between Lines 10-13, Column 1 and hospital cost report worksheet I-4 non-AKI lines between Lines 3-6, Column 1.

⁴⁰ The training add-on was extended to AKI dialysis payments in the CY 2025 ESRD PPS final rule (89 FR 89168).

⁴¹ Winsorizing is a statistical data transformation technique that limits extreme values-outliers by replacing them with specific, less extreme percentiles. For this analysis we replaced the top 1 percent of values with the 99th percentile value and the bottom 1 percent of values with the 1st percentile value. Unlike trimming, it keeps the total number of data points unchanged while minimizing the influence of outliers on the analysis.

⁴² May 2024 BLS OEWS estimate for category SOC code 29-1141 (Registered Nurses) can be found at <http://www.bls.gov/oes/tables.htm>.

PPS base rate includes certain training costs. For more information on the history of training add-on changes, we refer readers to a discussion in response to comments in the CY 2017 ESRD PPS final rule (81 FR 77853 through 77854). We noted that CMS would estimate aggregate impacts for this proposal using claims and cost report data.

d. Payment for Training During Dialysis Onset

In the CY 2011 ESRD PPS final rule we finalized a payment adjustment for ESRD patients in their first 4 months on renal dialysis (75 FR 49090 through 49094), which we refer to as the onset adjustment. We stated that as home dialysis training costs represent one-on-one staff time to train a patient for home dialysis, we believed we captured staffing costs for training in the onset adjustment. Since we already accounted for training salary costs in the onset adjustment, we believed that applying the training add-on adjustment in addition to the onset adjustment would have the effect of compounding the composite rate costs and would result in an overpayment of nursing staff costs associated with training renal dialysis patients for home dialysis. Therefore, the rule finalized that ESRD facilities would not receive the training add-on adjustment for ESRD patients who are receiving the onset adjustment. In the CY 2011 final rule we stated that we would continue to study the relationship between costs related to the onset of dialysis and home dialysis training for future refinements of the ESRD PPS (75 FR 49094).

At that time, we stated that we believed that the onset adjustment captured additional labor costs for home dialysis training sessions that occur during the onset period, which is the first four months a patient is on renal dialysis (75 FR 49063). The CY 2011 onset adjustment factor was finalized at 1.510 (75 FR 49094). As the training add-on was \$33.44, the onset adjustment factor was generally much larger than the training add-on for any single patient, so it was reasonable to believe that notable additional labor costs associated with home dialysis training were captured by the analysis from which the onset adjustment was derived.

The current onset adjustment factor is 1.327, as finalized in the CY 2016 ESRD PPS final rule (80 FR 68992 through 68993). The current CY 2026 ESRD PPS base rate is \$281.71 so a 1.327 adjustment factor would be an increase of approximately \$92, which is lower than the current training add-on adjustment. As the onset adjustment is

intended to account for more than just home dialysis training, the lower multiplicative onset adjustment factor, combined with the relatively low utilization of home dialysis training during the onset period, led us to reevaluate our longstanding policy of not applying the training add-on during the onset period.

In the CY 2027 ESRD PPS proposed rule, we proposed to allow ESRD facilities to receive the home and self-dialysis training add-on payment adjustment during the onset period (91 FR 38833). We explained that analysis of 2024 claims data indicates that approximately 7.7 percent of onset claims include training. While this is an improvement from the inception of the ESRD PPS, we believe that patient choice would be improved by increased access to home and self-dialysis training during the onset period. Currently, approximately 44 percent of training sessions occurred during the onset period, which demonstrates that most ESRD patients who receive training are not in the onset period. CMS further believes that the training add-on reflects discrete training labor-related resources that are not fully captured by the onset adjustment and therefore would not result in duplicative payment. Home dialysis was included in the data upon which the ESRD PPS base rate was constructed in the 2011 ESRD PPS final rule (75 FR 49084). However, in that rule, we discussed how the ESRD PPS base payment alone does not address home dialysis training costs, so an additional adjustment was warranted (75 FR 49062). In the regression analysis performed for that rule, we stated that we believed the higher costs associated with the onset period were, in part, due to some training labor costs (75 FR 49063). However, based on our analysis of the training labor cost and the onset adjustment for the CY 2027 ESRD PPS proposed rule, we stated that we no longer believe this is the case. There are training costs, primarily equipment supply costs, included in the ESRD PPS base rate (75 FR 49062) which are likely higher during training which would be captured by the analysis from which the onset adjustment was derived. But, as discussed previously, the ESRD PPS base rate does not contain significant monies for labor related to home dialysis training, so we do not believe that allowing both adjustments would be duplicative now, in large part because the onset adjustment factor has decreased since 2011 (which could have reflected some shifting utilization). Similar to how the training add-on accounts for the extra costs not

accounted for by the ESRD PPS base rate, we stated that we believe that most costs associated with home dialysis training are not reflected in the current onset adjustment. Furthermore, our proposal to implement this policy budget neutrally further mitigates the risk of potential duplicative payment. We proposed to base the budget neutrality of this change on the current utilization of home dialysis training during the onset period.

e. Combined Budget Neutrality Implications and Comment Solicitation

The proposed increase to the training add-on and the proposed allowance of the training add-on for ESRD PPS claims during the onset period would result in a budget neutrality adjustment of 0.99884. We solicited comments on these proposed modifications to the home and self-dialysis training adjustment, as well as the proposed budget neutrality of these proposals and the proposed budget neutrality adjustment factor of 0.99884. Additionally, we solicited comments on other ways in which we could improve both home dialysis and self-dialysis utilization. We also solicited comments on the proposal to continue using the calculation established in the CY 2017 ESRD PPS final rule (81 FR 77856), basing the training add-on on 2.66 hours of RN time. As noted previously, we did not propose to base the training add-on on Medicare cost report data, nor did we propose to set different training payment rates for HD and PD but based on comments received in response to the proposed rule, we stated that we may finalize a different policy, if warranted. Such a policy could involve using cost reports to determine the number of hours of nursing time required for home dialysis training or modifying the training add-on for a modality based on the relative cost of that modality reported on cost reports, and we solicited comments on these potential alternative methodologies. We also solicited comments on alternative ways we could budget neutralize this proposal, and specifically whether it would be more appropriate to make the proposal to allow the training add-on during the onset period budget neutral by reducing the onset adjustment factor.

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

Comment: The majority of commenters, including MedPAC, expressed support for CMS's proposed increase to the training add-on amount. Many commenters noted that labor costs have increased since the last time we

updated the training add-on. Some commenters expressed the importance of adequate training add-on payment for access to home dialysis. Many commenters emphasized the importance of home dialysis as an option for ESRD patients for whom it is appropriate and similarly emphasized the importance of high-quality home dialysis training.

Response: We appreciate the commenters' support. We agree that home dialysis is an important modality option for many ESRD patients.

Comment: Several commenters requested more frequent updates to the training add-on. A commenter stated that annual updates were not necessary but recommended we update the training add-on routinely when we rebase the ESRDB market basket. MedPAC recommended annual updates using publicly available BLS OEWS data. A commenter highlighted how large the increase is from the \$95.60 amount set in CY 2017 to the \$138.22 amount proposed for CY 2027.

Response: We appreciate the suggestions and will consider them for potential future rulemaking. We did not propose a routine methodology to update the training add-on amount and are not finalizing any such methodology in this final rule.

Comment: Some commenters noted that there were other costs associated with home dialysis that the training add-on did not cover, for example utility costs or storage costs for home dialysis patients. The commenter stated that CMS should not assume that an increase in payment to ESRD facilities will eliminate all barriers to home dialysis and requested we consider other mechanisms to support home dialysis uptake.

Response: We agree that there are other costs and barriers associated with uptake of home dialysis. In the CY 2027 ESRD PPS proposed rule we issued an RFI requesting detailed information on such costs and barriers (91 FR 38848). We intend to consider the barriers the commenter listed when considering the responses to that RFI for potential future rulemaking.

Comment: MedPAC generally supported the proposed increase to the home dialysis payment but also offered methodological recommendations. Specifically, MedPAC suggested CMS develop a process to empirically derive the share of treatments that are PD vs home HD and the average length of a training session. MedPAC noted that CMS collects "time on machine" data for hemodialysis treatments which could help this purpose.

Response: We appreciate MedPAC's methodological suggestions. The 2.66-

hour training average that we used for this rule was derived from the following values as described in the CY 2017 ESRD PPS final rule (81 FR 77852): (1) that PD represented 67 percent of all home dialysis training treatments, and (2) that PD training took 2 hours whereas HD training took 4 hours. The values for training time were derived from clinical guidelines on treatment times for both modalities. Analysis of ESRD facility cost report data indicates that the share of PD training treatments has decreased slightly, with PD representing 52 percent of training treatments in 2024. Time on machine data from CY 2025 indicates that the median HD training sessions report approximately 180 minutes, or 3 hours, of time on machine; we note that this is slightly lower than the overall median time on machine for in-center HD treatments, which is approximately 210 minutes, or 3.5 hours. The average time on machine for HD training is 235 minutes, or slightly under 4 hours; we believe the median is probably more representative because there were some implausible outliers for time on machine data, with 5 percent of treatments reporting longer than 7 hours of time on machine. We do not collect time on machine data for PD sessions. Using these updated figures, and maintaining the assumption that PD takes 2 hours, we would get an average training time of 2.48 hours ($3 \times 0.48 + 2 \times 0.52$). Basing the calculation instead on the median HD time on machine would yield an average training time of 2.72 hours ($3.5 \times 0.48 + 2 \times 0.52$). We reiterate that these figures were based on median values for HD time on machines, rather than average, because implausibly high reported values would likely skew the average in a way that is inappropriate. However, in doing so, these figures also do not consider real outlier treatment lengths, which we believe would be appropriate. Nevertheless, our longstanding assumption of 2.66 hours falls in between these two alternative estimates based on median values. We believe that this is empirical evidence that our longstanding assumption is reasonable as a proxy for the average home dialysis training treatment time. However, we intend to evaluate why the time on machine for training treatments is lower than other HD treatments, and whether that was partially driven by the amount of the training add-on. We did not propose to modify the methodology to use 2.66 hours of nursing time as the basis for the training add-on amount and we are not finalizing any such changes in this final rule.

Comment: Several commenters requested CMS reevaluate the use of the 2.66-hour figure in the calculation of the training add-on payment. One healthcare organization which operates ESRD facilities stated that their training sessions last anywhere from 3 to 4 hours. Another commenter indicated that training sessions can last 5 to 8 hours. A commenter stated that both HD and PD training sessions can last 5 to 6 hours. A commenter requested we collect actual data on RN time for home dialysis training and use it to determine whether separate payment amounts for PD and HD were appropriate.

Response: We appreciate the commenters' insight on their experience with home dialysis training. We want to note that the 2.66-hour figure used to calculate the training add-on was derived from an assumption of 4 hours of nursing time for HD and 2 hours of nursing time for PD. Those figures were based on Kidney Disease Outcome Quality Initiative (KDOQI) guidelines for HD and PD treatment length (81 FR 77852). While a commenter did not indicate which modality training they performed, we note that the 3 to 4 hours they stated is consistent with the assumed training time for HD. We recognize that some training sessions may last longer than the typical length of treatment for PD and HD, and that some patients may require more nursing time in training than others. Likewise, we acknowledge that the training costs for PD and HD are likely different on average. We believe that a single bundled training payment, adjusted by the ESRD facility's wage index, is most consistent with the principles of a bundled payment system. As noted previously, we evaluated data from ESRD facility cost reports and we believe that our assumptions on the average HD and PD training treatment length on which our training add-on is based are reasonable. However, we will continue to evaluate the appropriateness of the training add-on and will consider the commenters' suggestions for potential future rulemaking, if appropriate.

Comment: A commenter opined that the proposed training add-on amount of \$138.22 was still too low. The commenter noted that the analysis CMS included in the proposed rule stated that the median labor cost-per-training session was \$283 overall, \$164 for HD, and \$314 for PD.

Response: We want to reiterate that the reported figures to which the commenter pointed are not the best comparison alone for the home dialysis training add-on amount as these figures include all labor costs associated with

furnishing the renal dialysis session. The ESRD PPS base rate includes costs associated with the labor for furnishing renal dialysis services. Dialysis treatments which include home dialysis training, also receive the ESRD PPS base rate which covers the more routine aspects of that dialysis session. Although not every renal dialysis service may be identical between routine maintenance dialysis and dialysis that includes home dialysis training, the nature of a bundled payment allows for ESRD facilities to substitute the specific renal dialysis services as appropriate. In the proposed rule, when we referenced these figures, we then removed a portion of the ESRD PPS payment based on the LRS which resulted in a net increased labor cost-per-training session of approximately \$130 for CY 2024 (91 FR 38831). This is consistent with our proposed training add-on of \$138.22 for CY 2027.

Comment: One professional association stated that home dialysis training was more resource intensive for pediatric ESRD patients and recommended that CMS recognize the difference.

Response: We appreciate the insight into home dialysis training costs for pediatric ESRD patients. We are finalizing changes to the case-mix adjustment factors for pediatric ESRD patients and finalizing an extension of the LVPA to payments for pediatric renal dialysis treatments. We note that the cost analysis upon which the updated case-mix adjustments were based included costs associated with home dialysis training. We are confident that the changes to the payment for renal dialysis services furnished for pediatric ESRD patients, including the increase to the training add-on, will continue to support access to home dialysis training for pediatric ESRD patients, including home dialysis performed by a caregiver. Nevertheless, we will consider the commenter's suggestion for potential future rulemaking. We did not propose, and are not finalizing, different training add-on payments for pediatric ESRD patients.

Comment: Most commenters who opined on the proposal to allow the training add-on during the onset period expressed support for the policy. Many commenters expressed support for this proposal alongside support for the increase to the training add-on and listed the same reasonings for both, including the importance of high-quality home dialysis training. A commenter stated that this would improve patient-centered care. Several commenters highlighted the importance

on home dialysis uptake in the initial months of dialysis, with a commenter especially noting the potential impact on those who "crash" into dialysis.

Response: We appreciate the support of commenters on our proposal to allow the training add-on payment during the onset period. We agree that access to home dialysis training is important to facilitate ESRD beneficiaries' ability to choose the modality best for them. We likewise agree that access to home dialysis training is important for those whose transition to ESRD and dialysis is unexpected.

Comment: One coalition of kidney organizations raised concerns with the proposal to allow the training add-on to be applied during the onset period. The commenter was uncertain whether it was methodologically reasonable and indicated a belief that it may have been appropriate for CMS to make corresponding decreases to the onset adjustment factor.

Response: We acknowledge the concerns of commenters regarding the potential overlap between the onset adjustment and training add-on adjustment, should the training add-on be extended during the onset period. When we finalized the training add-on in the CY 2011 ESRD PPS final rule (75 FR 49062) we stated that we believed the onset adjustment accounts for certain higher costs associated with training patients for home dialysis during the first four months of dialysis treatments. In the CY 2027 ESRD PPS proposed rule, we stated that we believed that most costs associated with home dialysis training are not reflected in the current onset adjustment and that we were accounting for the potential for duplicative payments by reducing the ESRD PPS base rate (91 FR 38833). After consideration of the commenters' concerns, we agree that the onset adjustment captures some of the labor costs associated with home dialysis training and that it would be appropriate to reduce the onset factor to account for the overlap. Additionally, we considered the concerns of several other commenters regarding budget neutrality and recognize that a reduction to the onset factor would mitigate the budget neutrality impact on the ESRD PPS base rate. Thus, after considering all of the comments received, we are finalizing a modification to the onset adjustment to account for the overlap in the payments. Specifically, we are scaling down the onset adjustment factor by the estimated training payments during the onset period. This is an option that we discussed as an alternative in the proposed rule and solicited comments

on (91 FR 38833). This will ensure that the expansion of the training payment to the onset period is done in a budget neutral manner and prevent duplicative payments between the onset adjustment and the training add-on. By reducing the onset adjustment by the estimated overlap spending and maintaining budget neutrality we are functionally targeting the onset adjustment funds towards ESRD treatments that include home dialysis training. The reduced onset factor is 1.311, which is a modest reduction from the current factor of 1.327, which we believe is reasonable given the expansion of the training add-on during the onset period will maintain total estimated spending during the onset period. We note that the budget neutrality for this calculation was based on CY 2025 claims data on training sessions during the onset period; we expect that this policy would also result in a shift of training sessions which are currently occurring after the onset period.

Comment: Several commenters raised concerns with the budget neutrality of the proposal and requested it be implemented in a non-budget neutral manner. Some commenters noted that the original training add-on was established in a non-budget neutral manner and stated a belief that future updates should also be non-budget neutral. A commenter noted that, had the establishment of the training add-on been instead a part of the base rate, it would have been updated by the ESRDB market basket and increased over time. A commenter highlighted that large, infrequent updates to the training add-on concentrate the budget neutrality impact in a single year. MedPAC supported implementing this proposal budget neutrally. Some commenters indicated that they believed lowering the payment rate for budget neutrality would be contrary to the stated goal of supporting home dialysis, as the payment rate for home dialysis would decrease.

Response: We understand the concerns raised by commenters regarding the decrease to the ESRD PPS base rate associated with budget neutrality. We also acknowledge commenters' observations regarding the history of the training add-on payment adjustment, including that the original training add-on was established on a non-budget neutral basis and that certain subsequent changes have been implemented budget neutrally.

We proposed this policy budget neutrally because we believe implementing this budget neutral change is appropriate because the ESRD PPS base rate includes certain training

costs, similar to the budget neutral training add-on in the CY 2017 ESRD PPS final rule (81 FR 77856). We included a detailed history of the training add-on changes, including the choices to implement certain changes budget neutrally, in response to comments in the CY 2017 ESRD PPS final rule (81 FR 77853 through 77854). In that rule we characterized the \$95.60 add-on training amount as a temporary measure stated that we would collect and review cost report and claims data to eventually reevaluate the training add-on amount. As noted previously we have since reviewed the available cost report data and believe those data support our longstanding methodology based on 2.66 hours of RN time as an appropriate proxy for the labor costs associated with home dialysis training.

We do not believe it is appropriate at this time to increase overall expenditures under the ESRD PPS as home dialysis training is also accounted for in the base rate. We view this increase to the training add-on as moving dollars to effectively target this modality based on its relative resource use. We recognize that the training add-on was originally implemented non-budget neutrally and that if it had been added to the base rate it would have been increased by the annual ESRDB market basket update. In the CY 2011 ESRD PPS final rule, we acknowledged that there were dollars in the base rate for home dialysis training (75 FR 49062 through 49064) and we established a policy to implement the additional payment for training through an add-on payment, rather than a base rate increase. Regardless of how the training add-on was originally implemented, we are making this change to better allocate the money that is currently in the ESRD PPS, so budget neutrality is most appropriate at this time.

We acknowledge that this is a single budget neutrality factor reflective of changes since CY 2017 and is larger than if it only reflected typical changes in a single year. The budget neutrality factor is based on the estimated payments under the updated factor, the increase to which was based on the most recently available wage data. As noted previously, we will consider more routine updates to the training add-on in potential future rulemaking.

We disagree with the commenters who stated that a budget neutrality decrease would be contrary to our goal of supporting home dialysis uptake. Although a budget neutrality adjustment would decrease the ESRD PPS base rate, it would not decrease total ESRD PPS payments.

As noted previously, we are finalizing this proposal with a slight modification to decrease the onset adjustment factor based on the estimated training add-on spending during the onset period. This change will maintain budget neutrality for the expansion of the training add-on to the onset period, which reduces the impact of the budget neutrality factor for the base rate.

Final rule Action: After consideration of public comments, we are finalizing our proposals to increase the home and self-dialysis training add-on payment adjustment amount and to allow the training add-on during the onset period. The final home dialysis training amount is \$138.00 ($2.66 \times \$51.88 = \138.00), based on an updated hourly RN wage of 51.88, which reflects an updated estimate of the change in labor compensation of the ESRDB market basket from CY 2025 to CY 2027. Additionally, we are finalizing a reduction to the onset add-on amount by a factor to account for the estimated training add-on spending during the onset period, reducing the factor from 1.327 to 1.311. These changes are being finalized budget neutrally with a budget neutrality factor of 0.99964, driven by the payment impact of increasing the training add-on amount. We note that the change in policy to reduce the onset factor has a lessening impact on the budget neutrality factor, which was proposed as 0.99884.

11. Modification to TDAPA and Post-TDAPA Add-On Payment Adjustment 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 CMS does not receive a full calendar quarter of ASP data within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, or if CMS stops receiving the latest full calendar quarter of ASP data during the applicable TDAPA period specified in § 413.234(c)(1) or (2). 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. 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.

In the CY 2024 ESRD PPS final rule we finalized the post-TDAPA add-on payment adjustment (88 FR 76388 through 76397). When we finalized this payment adjustment, we also finalized a similar conditional ASP policy where if CMS stopped receiving ASP data for a particular drug or biological product, we would no longer apply a post-TDAPA add-on payment adjustment for that drug or biological product.

The CY 2024 ESRD PPS proposed rule (88 FR 42472) discussed that our regulation at § 413.234(c) did not address the application of the TDAPA conditional policy in situations where the manufacturer of the new renal dialysis drug or biological product submitted zero or negative sales ASP data to CMS. 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 Physician Fee Schedule (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.

In the CY 2024 ESRD PPS final rule (88 FR 76410) we clarified that for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted zero or negative sales ASP data 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). We further indicated that, 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. Likewise, we finalized that we would also consider ASP reflecting zero or negative sales during the post-TDAPA add-on payment adjustment period as CMS having received the latest full calendar quarter of ASP data and would not discontinue the post-TDAPA add-on payment adjustment. We finalized that we would

use WAC or, if WAC is not available, invoice pricing, for the post-TDAPA add-on payment adjustment calculation (88 FR 76396).

In the CY 2025 PFS final rule (89 FR 97981 through 97982), we specified that for the purposes of calculating a payment limit for Part B drugs, we will consider positive manufacturer's ASP data "available" and negative or zero manufacturer's ASP data "not available." We further specified that the use of the most recent positive ASP data available for a billing and payment code for a drug is most consistent with the payment limit calculations described in section 1847A(b) and (c) of the Act, including section 1847A(c)(5)(B) of the Act. In the CY 2026 PFS final rule (90 FR 49737) we noted that the published payment limit for a drug with negative or zero ASP data reported after January 1, 2025, could be based on a positive amount that is carried forward from a previous quarter in accordance with § 414.904(i).

In the CY 2027 ESRD PPS proposed rule, we proposed modifications to align the TDAPA and post-TDAPA add-on payment adjustment methodologies with pricing methodologies applicable to separately payable Medicare Part B drugs under section 1847A of the Act, including the use of the most recent available positive ASP data (91 FR 38834). This proposed modification would not change the TDAPA payment for a new renal dialysis drug or biological product that is in the first three quarters of the TDAPA payment period for which ASP data has not been reported. Specifically, for any such product, TDAPA payment would continue to be based on 100 percent of WAC and, if WAC is not available, based on the drug manufacturer's invoice price. Consistent with our policy, if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter following the initiation of the TDAPA, CMS will discontinue the TDAPA for that product beginning no later than 2-calendar quarters after CMS determines that such ASP data is not available. We note that, for purposes of this policy, the submission of zero or negative sales ASP data satisfies the manufacturer's ASP reporting requirement under sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act.

Under this proposal, when ASP data are reported as negative or zero for a renal dialysis drug or biological product and CMS has received positive ASP data for the product in a prior calendar quarter, we would no longer base the TDAPA payment amount on WAC or, if

WAC is not available, invoice pricing for that quarter. Instead, consistent with the approach adopted for separately payable Part B drugs in § 414.904(i), we would base the TDAPA payment amount on the most recent prior calendar quarter, with positive ASP data, which we consider the most recent available ASP for purposes of section 1847A of the Act. We proposed to apply a similar modification to the post-TDAPA add-on payment adjustment methodology. Specifically, when the most recent full calendar quarter of ASP data reflects negative or zero sales, and CMS has received positive ASP data for the product in a prior calendar quarter, we would not base the post-TDAPA add-on payment adjustment on WAC, or invoice pricing. Instead, we would base the post-TDAPA add-on payment adjustment on the most recent prior calendar quarter with positive ASP data.

We explained that, as under current policy, in circumstances where a manufacturer submits ASP data reflecting zero or negative sales, CMS considers the manufacturer to have satisfied its ASP reporting obligation, and such submissions do not trigger the discontinuation of the TDAPA under § 413.234(c). However, if a manufacturer ceases submitting ASP data, and CMS determines that the latest full calendar quarter of ASP data is not available, CMS will discontinue the TDAPA for the product within 2 calendar quarters, consistent with § 413.234(c). For purposes of the TDAPA and post-TDAPA add-on payment adjustment, zero or negative ASP data are treated as not usable for purposes of determining the payment amount but are treated as submitted for purposes of the ASP reporting requirement.

We stated that we believe the proposed approach is consistent with section 1847A of the Act because it relies on the most recent available positive ASP data when current quarter ASP data is not usable for purposes of determining a payment amount. We further believe the proposed policy would improve payment accuracy and consistency across Medicare payment systems by avoiding reliance on WAC or invoice pricing when more representative ASP data are available. This is appropriate for the ESRD PPS as it aligns payment with resource use and promotes efficiency, consistent with the principles of the ESRD PPS.

We proposed modifications to § 413.234(c) and (g)(1) to effectuate this change by amending language to state that when the most recently available quarter of ASP data is not usable because it is zero or negative, we would instead use the most recently available

quarter of positive ASP data, and that we would only resort to WAC or invoice pricing if a prior quarter of positive ASP data is not available.

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

Comment: A commenter supported the proposed technical modifications to ASP pricing. Another commenter supported the technical modifications provided CMS confirms their understanding that the policy would apply for products that have previously reported usable ASP data and have a subsequent quarter where ASP is reported as zero or negative, and in this circumstance, CMS would use the most recently available usable quarter of ASP data as the basis for the adjustments. They requested we differentiate between a product that has previously reported ASP and subsequently reports an unusable ASP and a product which has not yet established ASP.

Response: We appreciate the support for the proposed technical modifications to the ASP pricing policy. The commenter's interpretation is correct. This policy only applies if there is a prior quarter for which the drug has a reported ASP data which could be used for the calculation. If a drug has not yet reported ASP data, for example if it is in its first two quarters of the TDAPA period, we would still base payment on WAC, or invoice pricing if WAC is not available. The intent of this policy is to ensure that the TDAPA and post-TDAPA add-on payment adjustment are based on the best available pricing data, which we believe is ASP, unless ASP reflects zero or negative sales. The intent of this policy is not to make any changes to payment before ASP is established or modify the conditional ASP policy in a way that changes what renal dialysis drugs or biological products would be available for an adjustment in a given quarter. We appreciate the commenter's support for this technical pricing change.

Final Rule Action: After consideration of public comments, we are finalizing our policy to use older ASP data, when available, rather than WAC or invoice pricing when the most recent quarter of ASP data is not usable due to zero or negative ASP.

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

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

(TPNIES) under the ESRD PPS, pursuant to the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new items.

We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES. Under current § 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 a complete application has been submitted to CMS under § 413.236(c) within 3 years of 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 non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines. For additional background on the TPNIES, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2027, we did not include any TPNIES application summaries, CMS analyses, or results in the proposed or final ESRD PPS rules for CY 2027.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2027

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2027. Because no new items were approved for the TPNIES for CY 2026 (90 FR 53102), there are no payments continuing in CY 2027.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2027

In this section of the final rule, we identify any items previously approved for the TDAPA and for which payment is continuing for CY 2027. 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. As described in the CY 2026 ESRD PPS final rule, no new renal dialysis drugs or biological products items were approved for the TDAPA for CY 2026 (90 FR 53102 through 53103). The 2-year TDAPA period for each new renal dialysis drug or biological product previously approved for the TDAPA will conclude on December 31, 2026. As such, there are no items previously approved for the TDAPA for which payment is continuing in CY 2027.

III. CY 2027 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis furnished by ESRD facilities (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 as set forth in § 413.220, updated by the ESRDB market basket percentage increase factor reduced by 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). In the CY 2025 ESRD PPS final rule, we finalized a policy to allow payment for home dialysis for beneficiaries with AKI. Additionally, we extended the payment adjustment for home and self-dialysis training to AKI dialysis payments in a budget neutral manner and calculated a reduction to the AKI dialysis payment rate which rounded to \$0.00 (89 FR 89170).

B. Update of AKI Dialysis Payment

1. CY 2027 AKI Dialysis Payment Rate

The payment rate for AKI dialysis, as set forth in section 1834(r)(1) of the Act, 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 amounts deemed appropriate by the Secretary pursuant to section 1881(b)(14)(D) of the Act, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. Accordingly, in the CY 2027 ESRD PPS proposed rule (91 FR 38835), we proposed that the CY 2027 AKI dialysis payment rate would be equal to the proposed CY 2027 ESRD PPS base rate of \$299.55 ($(\$281.71 + \$15.96) \times 1.00267 \times 0.98783 \times 1.016 = \299.55), as outlined in section II.B.4. of the proposed rule. Additionally, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule, we would use such data, if appropriate, to determine the final CY 2027 ESRD PPS base rate. As discussed in section II.B.4. of this final rule, the final CY 2027 ESRD PPS base rate is \$297.52. As outlined in section II.B.1.b. of this final rule, we are rebasing and revising the ESRDB market basket to reflect a 2024 base year. This change would impact the ESRDB market basket update, which would impact the CY 2027 ESRD PPS base rate and therefore the AKI dialysis payment rate. As outlined in section II.B.1.d. of this final rule, the final CY

2027 ESRDB market basket update is based on IGI's third quarter 2026 forecast of the final 2024-based ESRDB market basket.

We received comments from a small regional dialysis chain, an LDO, and an advocacy group regarding the proposed revisions to payment for renal dialysis services furnished to Medicare beneficiaries with AKI. Commenters generally agreed that increasing the payment rate for renal dialysis services furnished to individuals with AKI to \$299.55 and extending the home dialysis and self-dialysis training (the training add-on) payment adjustments to beneficiaries with AKI is appropriate. Commenters did not oppose the proposed changes to the payment for AKI but did request clarification of some points. We summarize these comments and provide our responses in the following section.

Comment: Several comments supported the application of the proposed ESRD PPS base rate of \$299.55 to payment for renal dialysis services furnished to beneficiaries with AKI. A commenter specifically noted the vulnerability of the AKI patient population and highlighted the importance of adequate payment for renal dialysis services for beneficiaries with AKI.

Response: We appreciate the support for our longstanding policy to apply the ESRD PPS base rate for payments for renal dialysis services furnished to beneficiaries with AKI, which represents a payment increase for CY 2027. We agree that adequate payment for AKI dialysis is important and believe that the final AKI dialysis payment rate for CY 2027 will help continue to support high-quality care for beneficiaries with AKI. We note that the final ESRD PPS base rate is \$297.52.

Comment: A commenter urged CMS to clarify how the phosphate binders and other bundled renal dialysis drugs should be provided and paid for in AKI patient care. The commenter stated that since the AKI dialysis payment rate is tied to the ESRD PPS rate, ESRD facilities need guidance on their responsibilities regarding bundled renal dialysis drugs and services and whether the payment method covers associated costs. Specifically, the commenter requested that CMS confirm in the final rule that ESRD facilities must provide phosphate binders to outpatient dialysis patients with AKI starting CY 2027. Further, the commenter stated that guidance should clarify that this responsibility applies only during outpatient renal dialysis services and not to AKI patients who are hospitalized, have not started outpatient

dialysis, or have discontinued dialysis. The commenter noted that these distinctions will help define ESRD facility responsibilities for clinically complex AKI patients. Additionally, this commenter asked CMS to review the outpatient AKI benefit to ensure payment supports proper dialysis care and focuses on kidney recovery.

Response: The AKI dialysis payment rate applies to all renal dialysis services, and ESRD facilities are responsible for furnishing all medically necessary renal dialysis services to beneficiaries with AKI who are receiving renal dialysis services as specified at § 413.374(a). While oral-only renal dialysis drugs and biological products have always met the definition of renal dialysis services, the statutory delays implemented in our regulations at § 413.174(f)(6) postponed their inclusion in the ESRD PPS bundled payment until January 1, 2025. During the TDAPA payment period for phosphate binders, the TDAPA did not apply to renal dialysis services furnished to beneficiaries with AKI and ESRD facilities were not yet responsible for furnishing them for beneficiaries with AKI (89 FR 89172). This is because phosphate binders were not originally included in the ESRD PPS base rate, and therefore were not reflected in the AKI dialysis payment rate that is based on the ESRD PPS base rate. As a result, during the TDAPA period, the AKI dialysis payment rate did not include any amount for phosphate binders, so ESRD facilities had no payment mechanism through which to furnish them to beneficiaries with AKI. Once the payment amount for phosphate binders is established and incorporated directly into the ESRD PPS base rate, that payment is applied for beneficiaries with AKI. Accordingly, the policies finalized in this rule to incorporate the costs of phosphate binders into the ESRD PPS base rate mean that ESRD facilities must furnish phosphate binders to beneficiaries with AKI. The requirement that ESRD facilities furnish all renal dialysis services to beneficiaries with AKI has not changed.

Starting in CY 2027, ESRD facilities must provide medically necessary phosphate binders to beneficiaries with AKI receiving renal dialysis services. Section 1834(r) of the Act only addresses renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished to a beneficiary with AKI by a renal dialysis facility or provider of services. We do not believe that a renal dialysis facility or provider of services would provide renal dialysis services for AKI patients who are hospitalized, have not started outpatient renal dialysis, or have

discontinued renal dialysis services including phosphate binders.

In the CY 2025 ESRD PPS final rule we included a discussion clarifying how the inclusion of oral-only drugs into the ESRD PPS bundled payment impacted MA plans (89 FR 89152). Now that payment is available under part B for furnishing phosphate binders for beneficiaries with AKI, we believe a similar clarification may be helpful to readers. With respect to MA, per section 1852(a)(1) of the Act and its implementation regulations (42 CFR 422.100 and 422.101(a)), Medicare Advantage organizations (MAOs) must cover items and services, including drugs, for which benefits are available under Parts A and B in the Original Medicare program, subject to limited exclusions. We note that phosphate binders are not subject to the limited exclusions at section 1852(a)(1) of the Act and, therefore, must be covered by MAOs. Specifically, in accordance with section 1852(a)(1) if the Act and 42 CFR 422.100 and 422.101(a), MAOs must provide coverage of, by furnishing, arranging for, or making payment for, generally all services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees. In addition, with respect to coverage of Original Medicare benefits such as Part B drugs, MAOs must comply with applicable Medicare statutes, regulations, national coverage determinations (NCDs) and local coverage determinations (LCDs) of Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan (42 CFR 422.101(b)). In general, an MA plan that offers Part D benefits (MA-PD) must determine whether payment for the drug is allocated under Parts B or D, consistent with Original Medicare and Part D program drug coverage policies (see Appendix C, Attachment II, Question 5 of Chapter 6⁴³ Medicare Prescription Drug Benefit Manual for additional detail). Concerning how Part D sponsors will determine whether a drug is covered under Part B, in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy. A Part D sponsor cannot deny payment for a particular drug on

⁴³ <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>.

the basis that it is covered under Part B in some instances and Part D in others unless there is Part B coverage as the drug is prescribed and dispensed or administered in that particular instance. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug. Regarding new drugs, as decisions are made nationally or by individual A/B MAC contractors, this information will be available on the CMS and contractor websites. MA-PD coordinated care plans must coordinate all benefits administered by the plan with respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D (42 CFR 422.112(b)(7)). As a result of the rules and regulations described here, MAOs must cover oral-only ESRD drugs, including phosphate binders, under their plans for beneficiaries with AKI receiving outpatient renal dialysis services, as these are drugs under Part B and are not subject to the limited exclusions under section 1852(a)(1) of the Act.

Regarding the commenter's suggestion on renal function recovery monitoring, because the ESRD facility Conditions for Coverage (CfCs) apply uniformly across the certified facility's patient population, the same monitoring expectations apply to AKI patients. In addition, any individualized needs specific to a patient's AKI status should be identified through the required patient assessment and reflected in that patient's individualized plan of care, consistent with existing CfC requirements. Facilities should also address these AKI-specific considerations in their facility policies and procedures to ensure staff consistently apply appropriate safeguards for this patient population in accordance with national standards of care.

We will continue to consider comments on dialysis adequacy and kidney recovery and may potentially address these concerns in future rulemaking.

Comment: A commenter requested that CMS ensure AKI patients using home dialysis receive the same safety protections as ESRD beneficiaries, including comprehensive training and access to in-center back-up care. The

commenter stated that sending patients to the hospital or requiring them to find another provider is not acceptable as back-up.

Response: We appreciate the commenters' recommendations regarding patient safety protections for individuals with AKI receiving dialysis in the home. We agree that appropriate patient training, access to necessary support, and monitoring for renal function recovery are important components of furnishing renal dialysis services to patients with AKI. We also agree that sending an AKI home dialysis patient to the hospital or emergency room or discharging the patient and requiring them to find a new ESRD facility or health care provider, does not satisfy the facility's obligation to provide back-up renal dialysis support services. The ESRD Facility CfCs at 42 CFR part 494 apply equally to all patients treated in a Medicare-certified ESRD facility, regardless of whether the patient's underlying diagnosis is ESRD or AKI. Because AKI patients receiving renal dialysis in a Medicare-certified facility are treated under that same facility's conditions for coverage, the existing home dialysis requirements, including comprehensive training on the home modality, and access to back-up renal dialysis support services already apply equally to AKI patients using home modalities. The CfCs do not distinguish between ESRD and AKI patients with respect to these protections; a Medicare certified facility must furnish the same standard of care, training, and support structures to any patient it treats, including AKI patients dialyzing at home.

Final Rule Action: After consideration of public comments, CMS is finalizing the CY 2027 AKI dialysis payment rate of \$297.52, which is equal to the CY 2027 ESRD PPS base rate.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we proposed to apply the same wage index under § 413.231 that is used under the ESRD PPS. As outlined in section II.B.2.a. of this final rule, the ESRD PPS wage index is based on mean hourly wage data from the BLS OEWS weighted by FTE data from freestanding

ESRD facility cost reports. We finalized the methodology for determining the wage index value for an ESRD facility in the CY 2025 ESRD PPS final rule (89 FR 89097 through 89116), and we proposed to continue to apply this methodology to AKI dialysis payments. Consistent with this approach, we proposed to apply the same wage index under § 413.231 that is used under the ESRD PPS to the AKI dialysis payment. We proposed to continue using this methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice. We stated that we believe this approach is appropriate because ESRD facilities utilize substantially similar staff, resources, and cost structures in furnishing renal dialysis services to beneficiaries with AKI and ESRD, and therefore the ESRD PPS wage index reasonably reflects geographic variation in labor costs for both populations. The AKI dialysis payment rate would be adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate would be adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we would apply the wage index to the LRS of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As outlined in section II.B.1.c. of this final rule, we proposed to update the LRS of the ESRD PPS from 55.2 percent to 63.5 percent based on the labor-related cost share weights of the proposed 2024-based ESRDB market basket. We also proposed to continue applying the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. Accordingly, we proposed a CY 2027 AKI dialysis payment rate of \$299.55, adjusted by the ESRD facility's wage index. As outlined in section II.B.2.c. of the proposed rule, we proposed that, if more recent data became available after the publication of the proposed rule and before the publication of this final rule, we would use such data, if appropriate, to update the CY 2027 ESRD PPS wage

index, and we would describe any such changes in this final rule.

We did not receive any substantive comments on our longstanding policy to apply the ESRD PPS wage index value to payment for renal dialysis services furnished to beneficiaries with AKI, although some commenters acknowledged our AKI wage index policy and the underlying statute. We discuss comments on the ESRD PPS wage index more generally in section II.B.2.c. of this final rule.

Final Rule Action: We are finalizing our proposal to continue to apply the ESRD PPS wage index to dialysis payments for beneficiaries with AKI. We note that the CY 2027 ESRD PPS wage index is based on the most recently available data which is the May 2025 BLS OEWS and the most recent available CY 2025 cost report data.

3. Other Adjustments to the AKI Dialysis Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the CY 2025 ESRD PPS final rule, we extended the home and self-dialysis training add-on payment adjustment under the ESRD PPS to AKI dialysis payments in a budget neutral way (89 FR 89170). Under § 413.373(a), CMS applies the wage-adjusted add-on per-treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training. Section 413.235(c) provides for a training add-on payment adjustment for home and self-dialysis modalities, which is wage-adjusted and paid on a per-treatment basis. Therefore, we proposed that any revisions to the ESRD PPS training add-on payment adjustment would be reflected in payments for AKI dialysis. That is, the proposed ESRD PPS training add-on amount of \$138.22 would be applicable to beneficiaries with AKI during the training period. Beneficiaries with AKI do not receive the onset payment adjustment, so they would not be impacted by the proposal to allow training during the onset period. However, we noted that for beneficiaries with AKI that progress to ESRD the proposal to allow training payments during the onset period would allow for

continued access to the training add-on during the onset period for ESRD. We stated that, currently, there are no other adjustments that apply to AKI dialysis payments.

We received a comment specifically on the impact to beneficiaries with AKI of the proposals to modify the training add-on. The following is our summary of the comment and our response.

Comment: The commenter supported extending the home and self-care training add-on to AKI patients, noting that access to home dialysis training is important for patient safety and success. The commenter requested that CMS clarify in the CY 2027 ESRD PPS final rule that the AKI budget-neutrality adjustment for the add-on will remain at zero. The commenter stated that any increase could negatively impact payment rates for AKI patients.

Response: CMS noted in the CY 2025 ESRD PPS final rule when we extended home dialysis and home dialysis training to beneficiaries with AKI (89 FR 89163 through 89167) that incorporation of an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act into AKI dialysis payments must be done on a budget neutral basis for payments under section 1834(r) of the Act. Therefore, we stated that establishing a training add-on payment adjustment for training for home and self-care dialysis could have an impact on the AKI base rate (89 FR 89166). The expansion of the training add-on to dialysis payments for beneficiaries with AKI has already been implemented in a budget neutral manner. As noted in section II.B.10. of this final rule, we are finalizing the modification to the training add-on adjustment in a budget neutral manner. We did not propose, and are not finalizing, a separate budget neutrality factor for the impact of the increase in the training add-on amount for beneficiaries with AKI as the expansion of the training add-on to dialysis payments for the AKI population has already been budget neutralized.

We recognize the commenter's concerns regarding the impact budget neutrality could have on the AKI dialysis payment rate. We reiterate that section 1834(r)(1) of the Act requires the application of any adjustment factor established under section 1881(b)(14)(D) to AKI dialysis payments be budget neutral.

Final Rule Action: As noted in section II.B.10. of this final rule, the final home

and self-dialysis training add-on payment adjustment amount is \$138.00. This reflects a more recent estimate of the change in the ESRDB compensation growth from CY 2025 to CY 2027. We are finalizing our proposal to continue to apply the training add-on to dialysis payments for beneficiaries with AKI at this new amount in a budget neutral manner.

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

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A. of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Updates to Requirements Beginning With the PY 2029 ESRD QIP

1. PY 2029 ESRD QIP Measure Set

In the CY 2027 ESRD PPS proposed rule (91 FR 38836), we proposed to replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients clinical measure, update the National Healthcare Safety Network Bloodstream Infection clinical measure, and remove both the Medication Reconciliation reporting measure and the COVID-19 Vaccination Coverage Among Healthcare Personnel reporting measure beginning with the PY 2029 measure set. Table 19 of the proposed rule summarized the previously finalized measures, proposed new measures, and proposed updated measures that we would include in the PY 2029 ESRD QIP measure set (91 FR 38837). As discussed in sections IV.B.2. through IV.B.5. of this final rule, we are finalizing these updates as proposed. We describe the finalized PY 2029 ESRD QIP measure set in Table 23. Details on the technical specifications for current measures that will remain in the measure set for PY 2029 can be found in the CMS ESRD Measures Manual for the 2026 Performance Period.⁴⁴

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⁴⁴ Centers for Medicare & Medicaid Services (April 2026). CMS ESRD Measures Manual for the 2026 Performance Period: Final Version 11.2.

TABLE 23: Finalized Measures for the PY 2029 ESRD QIP Measure Set

Consensus-Based Entity (CBE) #	Measure Title and Description	Policy Status
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.	Previously finalized
5110*	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.	Previously finalized
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.	Previously finalized
Based on CBE #0323, # 0318**, #1423, and #2706	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures are adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.	Previously finalized
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.	Previously finalized
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Previously finalized
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 the performance period.	Previously finalized
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.	Updated
N/A****	Percentage of Prevalent Patients Waitlisted for Kidney Transplant (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.	Previously finalized
CBE #4650****	Hyperphosphatemia, a clinical measure Percentage of adult dialysis patients with a 6-month rolling average phosphorus value greater than or equal to 6.5 mg/dL.	New

* We note that this measure was endorsed under CBE #5110 in the Spring 2026 endorsement cycle.

** We note that the prior CBE number listed for this measure in last year's rule (#0321) was incorrect.

*** We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

**** We are finalizing our proposal to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this final rule.

***** We note that the Percentage of Prevalent Patients Waitlisted clinical measure name was updated to the Percentage of Prevalent Patients Waitlisted for Kidney Transplant clinical measure in May 2025. For more information on the updated measure specifications please refer to <https://www.cms.gov/files/document/esrd-qip-cy2026-final-technical-specifications.pdf>.

***** We are finalizing our proposal to remove the Hypercalcemia reporting measure, MedRec reporting measure and the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2029, as discussed in sections IV.B.2.a., IV.B.4.a., and IV.B.4.b. of this final rule.

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2. Replacement of the Hypercalcemia Reporting Measure With the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients Clinical Measure

a. Removal of the Hypercalcemia Reporting Measure

Abnormalities of mineral and bone metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease (CKD). Studies have associated disorders of mineral and bone metabolism with mortality, fractures, cardiovascular disease, and other comorbidities.^{45 46} Section 1881(h)(2)(A)(iv)(II) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of mineral and bone metabolism. Therefore, in the CY 2014 ESRD PPS final rule (78 FR 72200 through 72203), we adopted the Hypercalcemia clinical measure as part of the ESRD QIP measure set, which encouraged adequate management of mineral and bone disease in patients with ESRD by monitoring elevated serum calcium levels. In the CY 2023 ESRD PPS final rule, we converted the Hypercalcemia clinical measure to a reporting measure in light of concerns that the measure was close to being topped out and that small differences in measure performance may disproportionately impact a facility's score on the measure (87 FR 67250 through 67251). Given the statutory requirement to include measures of mineral and bone metabolism to the extent feasible, we noted that we would retain the Hypercalcemia reporting measure while we explored possible replacement measures that would be more clinically meaningful for purposes of quality improvement.

Beginning with the PY 2029 ESRD QIP, we proposed to remove the Hypercalcemia reporting measure under measure removal factor 5, a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available (§ 413.178(c)(5)(i)(E)), and replace it

with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients (Hyperphosphatemia) clinical measure. Both calcium and phosphorus are important in mineral and bone metabolism. The Hypercalcemia reporting measure only requires reporting of the calcium value⁴⁷ while the Hyperphosphatemia clinical measure will encourage facilities to identify patients with chronically elevated phosphorus levels who would benefit from additional intervention, a meaningful clinical practice more strongly associated with desired patient outcomes. Studies have demonstrated a consistent association between chronic hyperphosphatemia and adverse outcomes, including cardiovascular complications, bone fractures, and increased mortality.^{48 49} Prospective studies have also reported lower mortality among patients with improved phosphorus control, including treatment with phosphate-binding medications.^{50 51} The Hyperphosphatemia clinical measure will help drive decreases in cardiovascular complications, hospitalizations, and overall mortality by incentivizing additional interventions such as nutritional counseling, phosphorus binding medications, and adjustment of dialysis prescription.^{52 53 54 55} Compared to the

Hypercalcemia reporting measure, the Hyperphosphatemia clinical measure will more directly assess patient-focused clinical outcomes.

b. Adoption of the Hyperphosphatemia Clinical Measure

(1) Measure Overview

The Hyperphosphatemia clinical measure is an outcome measure developed by CMS to assess long-term phosphorus control across the dialysis population by measuring the percentage of adult dialysis patients with a 6-month rolling average serum phosphorus value greater than or equal to 6.5 mg/dL.⁵⁶ The cohort for the Hyperphosphatemia clinical measure will consist of adult patients, aged 18 years and older, with ESRD who are receiving in-center hemodialysis, home hemodialysis, hemodiafiltration, or peritoneal dialysis and have been under the care of the same dialysis facility for the entire reporting month. Eligible patients must have had ESRD for more than 90 days and sufficient laboratory data to calculate a 6-month rolling average serum phosphorus level.⁵⁷

For more information about the testing, feasibility, scientific acceptability, meaningfulness, and validity of the Hyperphosphatemia clinical measure, we refer readers to <https://p4qm.org/prmr-measures/muc2025-064>.

(2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁵³ Rivara, M. B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W. L., Nissenson, A. R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the American Society of Nephrology: JASN*, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁵⁴ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁵⁵ Hall, R., Platt, A., Wilson, J., Ephraim, P. L., Hwang, A. S., Chen, A., Weiner, D. E., Boulware, L. E., Pendergast, J., Scialla, J. J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁵⁶ Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/prmr-measures/muc2025-064>.

⁵⁷ Further details on the proposed Hyperphosphatemia clinical measure are available at <https://p4qm.org/measures/4650>.

⁴⁷ Centers for Medicare & Medicaid Services. (2025). Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Calendar Year (CY) 2026 Measure Technical Specifications. Available at <https://www.cms.gov/files/document/esrd-qip-cy2026-final-technical-specifications.pdf>.

⁴⁸ Kim, J. E., Park, J., Jang, Y., Kang, E., Kim, Y. C., Kim, D. K., Joo, K. W., Kim, Y. S., & Lee, H. (2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁴⁹ Rivara, M. B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W. L., Nissenson, A. R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the American Society of Nephrology: JASN*, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁵⁰ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁵¹ Hall, R., Platt, A., Wilson, J., Ephraim, P. L., Hwang, A. S., Chen, A., Weiner, D. E., Boulware, L. E., Pendergast, J., Scialla, J. J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁵² Kim, J. E., Park, J., Jang, Y., Kang, E., Kim, Y. C., Kim, D. K., Joo, K. W., Kim, Y. S., & Lee, H.

⁴⁵ Salera, D., Merkel, N., Bellasi, A., & de Borst, M. H. (2025). Pathophysiology of chronic kidney disease-mineral bone disorder (CKD-MBD): from adaptive to maladaptive mineral homeostasis. *Clinical kidney journal*, 18(Suppl 1), i3–i14. <https://doi.org/10.1093/ckj/sfae431>.

⁴⁶ Dempster, D. W., Evenepoel, P., Nickolas, T. L., Massy, Z. A., Mazzaferro, S., Harvey, N. C., Miller, P. D., & Pazianas, M. (2026). Osteoporosis and CKD-metabolic bone disease under the same umbrella: Insights from a joint scientific symposium. *Kidney International Reports*. <https://doi.org/10.1016/j.ekir.2026.106362>.

(2) Measure Calculation

The numerator of this measure includes patient reporting months with a 6-month rolling average phosphorus value of 6.5 mg/dL or greater. The number of patient reporting months with a phosphorus average of 6.5 mg/dL or greater will then be divided by the total number of eligible patient reporting months for the facility and multiplied by 100 to calculate the percentage of patient reporting months with hyperphosphatemia. Patient reporting months will be excluded if the patient had a 6-month rolling average albumin level of less than 3.5 g/dL or a body mass index (BMI) of less than 18.5. The measure will be calculated only for facilities with more than 10 eligible patients during the reporting period.

(3) Recommendation From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.^{58 59} The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available “2025 Measures Under Consideration List,” including the Hyperphosphatemia clinical measure (MUC2025–064).⁶⁰

The voting results of the Recommendation Group for the proposed inclusion of the Hyperphosphatemia clinical measure in the ESRD QIP were: 16 members (76 percent) recommended adopting the measure into the ESRD QIP and 5 members (24 percent) voted not to

recommend the measure for adoption.⁶¹ With 76 percent of the votes for recommend, consensus was reached, as the majority of the Recommendation Group expressed support for use of the measure in the ESRD QIP. In expressing support for use of the Hyperphosphatemia clinical measure in the ESRD QIP, Recommendation Group members emphasized its importance given evidence linking chronic hyperphosphatemia to adverse outcomes, including increased mortality, hospitalizations, cardiovascular events, vascular calcification, and bone fractures.⁶² The minority of Recommendation Group members who voted not to recommend the measure for inclusion in the ESRD QIP provided the following rationales: (1) the evidence base does not justify use as a performance measure; (2) the protein restrictions required to achieve the goals of this measure may lead to unintended adverse outcomes; (3) phosphorus control is influenced by multiple clinical and patient-level factors that are not fully captured by this measure; and (4) the measure should undergo additional development before implementation.⁶³

Regarding concerns about the sufficiency of the evidence base supporting use of the Hyperphosphatemia clinical measure, we note that studies have demonstrated a consistent association between chronic hyperphosphatemia and adverse outcomes, including cardiovascular complications, bone fractures, and increased mortality.^{64 65}

Prospective studies have also reported lower mortality among patients with improved phosphorus control, including treatment with phosphate-binding medications.^{66 67} The Hyperphosphatemia clinical measure will incentivize and assess additional interventions such as nutritional counseling, phosphorus binding medications, and adjustment of dialysis prescription.

Regarding concerns about the need for additional measure development, we note that the Hyperphosphatemia clinical measure was developed and refined with input from a technical expert panel (TEP) and underwent extensive feasibility, reliability, and validity testing. The TEP consisted of interested parties, clinicians, subject matter experts, and consumer representatives, including patient advocates who contributed their input through the Hyperphosphatemia clinical measure design process.⁶⁸ There were no concerns regarding feasibility because phosphorus levels are routinely measured as part of standard clinical care in dialysis facilities. Testing demonstrated strong validity at the facility level, with higher rates of hyperphosphatemia associated with increased mortality and hospitalization, consistent with expected clinical relationships. In addition, testing demonstrated high reliability, and the measure was endorsed by the CBE in the Fall 2024 cycle for use in the ESRD QIP.⁶⁹ Please refer to section IV.B.2.b.(4) of this final rule for more information on endorsement of the measure.

Regarding concerns about the potential for unintended adverse outcomes associated with dietary protein restrictions, we note the measure includes exclusions intended to mitigate potential unintended

⁵⁸ Partnership for Quality Measurement. Pre-Rulemaking Measure Review webpage. Available at <https://p4qm.org/prmr/about>.

⁵⁹ In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either “recommend” or “do not recommend” that a measure be added to the intended CMS program(s), thus, removing the “recommend with conditions” voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Recommendation Group members can provide considerations for CMS to review prior to implementation.

⁶⁰ Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

⁶¹ Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

⁶² Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at <https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf>.

⁶³ Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Final Recommendations Report. Available at <https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf>.

⁶⁴ Kim, J.E., Park, J., Jang, Y., Kang, E., Kim, Y.C., Kim, D.K., Joo, K.W., Kim, Y.S., & Lee, H. (2025). Oral phosphate binders and incident osteoporotic fracture in patients on dialysis. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 40(2), 329–340. <https://doi.org/10.1093/ndt/gfae139>.

⁶⁵ Rivara, M.B., Ravel, V., Kalantar-Zadeh, K., Streja, E., Lau, W.L., Nissenon, A.R., Kestenbaum, B., de Boer, I. H., Himmelfarb, J., & Mehrotra, R. (2015). Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. *Journal of the*

American Society of Nephrology: JASN, 26(7), 1671–1681. <https://doi.org/10.1681/ASN.2014050472>.

⁶⁶ Floege J. Phosphate binders in chronic kidney disease: an updated narrative review of recent data. *J Nephrol*. 2020;33(3):497–508. <https://pubmed.ncbi.nlm.nih.gov/31865608>.

⁶⁷ Hall, R., Platt, A., Wilson, J., Ephraim, P.L., Hwang, A.S., Chen, A., Weiner, D.E., Boulware, L.E., Pendergast, J., Scialla, J.J., & Comparative Effectiveness Studies in Dialysis Patients Group (2020). Trends in Mineral Metabolism Treatment Strategies in Patients Receiving Hemodialysis in the United States. *Clinical Journal of the American Society of Nephrology: CJASN*, 15(11), 1603–1613. <https://doi.org/10.2215/CJN.04350420>.

⁶⁸ Centers for Medicare & Medicaid Services. (May 2024). ESRD Mineral and Bone Disorder Measure Development Technical Expert Panel. Available at <https://mmshub.cms.gov/sites/default/files/ESRD-MBD-TEP-Summary-Report.pdf>.

⁶⁹ Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/prmr-measures/muc2025-064>.

consequences, including patients with indicators of poor nutritional status, such as a 6-month rolling average albumin of less than 3.5 g/dL and a BMI under 18.5. We also note that as part of routine measure maintenance we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences.

Regarding concerns that phosphorus control is influenced by multiple clinical and patient-level factors not fully captured by the measure, we note that phosphorus management is addressed through the interdisciplinary care team of a facility, including the prescribing physician and dietitian, who work together with ESRD patients through clinical care, dietary counseling, and treatment decisions. The Hyperphosphatemia clinical measure will capture the extent to which facilities are able to address these multi-layered factors.

(4) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria.⁷⁰ 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. The Hyperphosphatemia clinical measure was submitted to the CBE for endorsement review in the Fall 2024 cycle (CBE #4650), and the CBE endorsed the measure, without conditions, for use in the ESRD QIP on February 12, 2025.⁷¹

(5) Data Submission and Reporting

We proposed to require facilities to submit data needed to calculate the Hyperphosphatemia clinical measure using EQRS beginning with the performance period for PY 2029. Facilities will report the required data through EQRS in accordance with the existing monthly data submission processes used for other ESRD QIP clinical measures. Because the measure

uses a 6-month rolling average of serum phosphorus values, we proposed that facilities will need to submit phosphorus data for the five months preceding the start of the performance period to allow calculation of rolling averages for the first months of the performance year. For example, the rolling average for January 2027 would be calculated using phosphorus values from August 2026 through January 2027. We proposed that data used to calculate the Hyperphosphatemia clinical measure will be based on a 12-month performance period, with data submission consistent with current reporting deadlines for other ESRD QIP measures. For example, for PY 2029, facilities will report the required data through EQRS on a monthly basis during CY 2027, with final data submission due by the end of the December 2027 data reporting month.

Table 26 describes the performance standards we are finalizing for the Hyperphosphatemia clinical measure. Facilities will be required to follow the existing submission and reporting requirements for web-based measures under the ESRD QIP, as described on the QualityNet website at <https://qualitynet.cms.gov/esrd>.

We welcomed public comment on our proposals to remove the Hypercalcemia reporting measure and adopt the Hyperphosphatemia clinical measure beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure, stating that phosphorus management is a clinically meaningful component of dialysis care and that the Hyperphosphatemia measure would more meaningfully assess bone and mineral metabolism management and patient outcomes than the existing Hypercalcemia reporting measure. A few commenters noted that the measure could incentivize and facilitate timely, coordinated interventions such as nutrition counseling, dialysis prescription adjustments, and appropriate use of phosphorus-binding medications rather than simply documenting phosphorus management. A commenter acknowledged that managing phosphorus can be challenging due to the variability associated with diet, dialysis efficiency, residual kidney function, and other factors, but stated that the measure accounts for this variability, focuses on patients at greatest clinical risk, is

consistent with clinical guidelines, actionable, and supported by robust long-term data. A few commenters stated that facilities may be accountable for phosphorus outcomes and for timely, continuous, and equitable access to clinically appropriate care.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure, raising concerns that serum phosphorus is influenced by factors outside a facility's direct control, including patient dietary choices and medication adherence, food insecurity, access to phosphate binders and affordable low-phosphorus foods, pill burden, socioeconomic circumstances, phosphorus additives in processed foods, and the lack of phosphorus content information on food labels. Several commenters expressed concern about holding facilities accountable for phosphorus outcomes when facilities have provided education and support but cannot ensure adherence to dietary recommendations or phosphate binders. A commenter recommended that CMS evaluate the measure threshold, risk adjustment, and potential unintended consequences to avoid penalizing facilities for factors outside of their control or creating inappropriate pressure for patients or additional burden. A few commenters recommended retaining the Hypercalcemia measure, which they stated is more directly manageable by ESRD facilities.

Response: We acknowledge commenters' concerns that phosphorus control may be influenced by multiple clinical and patient-level factors. However, dialysis facilities and their interdisciplinary care teams, including the prescribing physician and dietitian, play an important role in phosphorus management through patient support, clinical care, dietary counseling, treatment decisions, and adjustment of dialysis prescriptions. The Hyperphosphatemia clinical measure would capture the extent to which facilities are able to address these multi-layered factors. We note that the measure includes exclusions intended to mitigate potential unintended consequences for patients with indicators of poor nutritional status, including a 6-month rolling average albumin of less than 3.5 g/dL and a BMI under 18.5. Given the prominent role of phosphorus management as part of ESRD treatment, we continue to believe that the Hyperphosphatemia clinical measure more directly and meaningfully

⁷⁰ Partnership for Quality Management. Pre-Rulemaking Measure Review webpage. Available at <https://p4qm.org/prmr/about>.

⁷¹ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

assesses patient outcomes than the Hypercalcemia reporting measure. We also note that the Hyperphosphatemia clinical measure underwent feasibility, reliability, and validity testing and was endorsed by the CBE in the Fall 2024 endorsement cycle.⁷² Additionally, as part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences.

Comment: A few commenters expressed support for the proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure but recommended initially implementing the Hyperphosphatemia measure as a reporting measure before using it for payment scoring. The commenters stated that a reporting period would allow CMS to establish appropriate data and quality benchmarks, validate data, address initial measurement and technical submission issues, and clarify measure specifications before payment consequences apply. A few commenters that did not support the proposal recommended that CMS withdraw the proposal or, at a minimum, initially implement the measure as a nonpayment reporting or feedback measure while CMS validates the threshold, establishes transparent performance standards, and addresses patient-level factors outside facility control.

Response: We appreciate commenters' recommendations to initially implement the Hyperphosphatemia measure as a reporting measure. However, we believe the measure is sufficiently developed for use as a clinical measure in the ESRD QIP. The measure was developed and refined with input from a TEP and underwent extensive feasibility, reliability, and validity testing. Testing demonstrated strong validity at the facility level and high reliability, and the measure was endorsed by the CBE.⁷³ We also note that the proposed performance standards for the

Hyperphosphatemia clinical measure were published in the CY 2027 ESRD PPS proposed rule (91 FR 38837), providing facilities with information on how performance would be assessed before payment consequences apply. Therefore, we do not believe that initially implementing the measure as a reporting measure is necessary.

Comment: A few commenters questioned or opposed the proposed 6.5 mg/dL threshold. A few commenters stated that there is insufficient evidence supporting a specific biochemical target as a facility-level accountability standard. A commenter stated that the Measures Assessment Tool used as a regulatory compliance guide for CMS surveyors identifies a phosphorus level of 5.5 mg/dL and requested clarification regarding why the proposed measure uses a 6.5 mg/dL threshold. The commenter further recommended that, if CMS adopts the measure, CMS use the exclusion criteria established in the Measures Assessment Tool. A commenter supporting the proposal similarly expressed concern that the proposed threshold is higher than phosphorus targets reflected in other CMS materials and requested clarification regarding how the threshold was selected. Another commenter recommended using a lower threshold, such as 4.4 mg/dL.

A commenter recommended that the 6.5 mg/dL threshold remain a facility-level performance threshold rather than an individual treatment target and that CMS continue to evaluate the threshold, exclusions, case mix, disparities, and unintended consequences. The commenter cautioned that favorable aggregate laboratory results should not mask avoidable delays, interruptions, non-clinical changes in care, excessive treatment burden, or barriers to individualized care plans.

Response: We appreciate commenters' concerns regarding the evidence supporting the proposed 6.5 mg/dL threshold. We wish to clarify that the threshold is not intended to establish a clinical treatment target for individual patients. The threshold was selected for purposes of the facility-level performance measure to identify patients with significant sustained elevations in phosphorus who are at greatest risk of adverse outcomes rather than month-to-month fluctuations. While facilities typically aim for phosphorus below 5.5 mg/dL as part of clinical management, evidence indicates that a 6-month average above 6.5 mg/dL is associated with the highest

cardiovascular risk.⁷⁴ The measure also underwent extensive feasibility, reliability, and validity testing. Testing demonstrated strong validity at the facility level, with higher rates of hyperphosphatemia associated with increased mortality and hospitalization, and high reliability. Regarding the commenter's recommendation to use the exclusion criteria established in the Measures Assessment Tool, we note that the Hyperphosphatemia clinical measure includes exclusion criteria that was established through the measure development process with input from a technical expert panel and underwent extensive testing. We believe the exclusion criteria established are appropriate for purposes of the ESRD QIP.

Regarding commenters' recommendations, we note that the 6.5 mg/dL threshold is intended as a facility-level performance threshold that confers the highest risk of adverse outcomes designed to assess long-term phosphorus control across the dialysis population rather than an individual treatment target. We also note that as part of routine measure maintenance, we conduct ongoing monitoring and evaluation of measure performance and potential unintended consequences. We agree with the commenter that high performance on the measure does not replace the need for individualized clinical assessment and appropriate patient-centered care.

Comment: Several commenters stated that tying facility performance or reimbursement to phosphorus outcomes could disproportionately penalize facilities serving medically complex, low-income, rural, or otherwise underserved patients. A few commenters expressed concern that facilities could be disincentivized from accepting medically complex or otherwise high-need patients. Commenters recommended that CMS account for differences among patients, ensure sufficient risk adjustment for medically and socially complex populations, and monitor for disparities and other unintended consequences. A commenter supporting the proposal similarly recommended that CMS finalize the measure within a balanced accountability framework that holds facilities responsible for outcomes while monitoring patient risk and disparities.

Response: We appreciate commenters' concerns regarding differences among patients and the potential for

⁷² Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷³ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷⁴ Partnership for Quality Management. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Final Recommendations Report. Available at <https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf>.

unintended consequences. During measure development, comorbidities and other factors for potential risk adjustment were evaluated and found that expected factors, such as access to healthy nutrition, did not significantly impact outcomes.⁷⁵ We also acknowledge commenters' concerns regarding potential effects on facilities serving medically or socially complex populations. We do not anticipate unintended consequences with the adoption of the Hyperphosphatemia clinical measure, and we note as part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences and will continue to evaluate measure performance as the measure is implemented.

Comment: A few commenters raised concerns regarding the exclusion for patients with a BMI under 18.5 at ESRD incidence, stating that limiting the exclusion to BMI at ESRD incidence may not align with the CBE-endorsed measure specification, may become inaccurate over time, and may not be known to facilities when patients initiated dialysis elsewhere. The commenters recommended using a more current BMI and suggested that CMS automatically calculate BMI using the height and estimated dry weight information already available in EQRS to avoid duplicative data entry. The commenters recommended changing the exclusion from "BMI at ESRD Incidence" to "Current BMI" or simply "Patients with BMI under 18.5."

Response: We appreciate the commenters' concerns and recommendations regarding the BMI exclusion. We note that, while the CBE-endorsed measure specification identifies the exclusion as "BMI under 18.5" without specifying "at ESRD incidence," the measure documentation indicates that height and weight from the Medical Evidence Form (CMS Form-2728) are used to calculate BMI, which is completed at ESRD incidence. We are currently evaluating the height and weight data available in EQRS to determine if there is acceptable reliability for calculating current BMI rather than relying on the BMI that is calculated from the Medical Evidence Form (CMS Form-2728). If the height

and weight fields in EQRS are found to be sufficiently complete and reliable, we could incorporate this change as part of the annual measure maintenance process.

Comment: A few commenters recommended that CMS consider whether patients may have at least 90 days of dialysis vintage and sufficient time at the facility before being included in the measure so that facilities have a reasonable opportunity to manage the patient's phosphorus.

Response: We appreciate commenters' recommendations. We note that the Hyperphosphatemia clinical measure excludes patients who have been receiving ESRD treatment for fewer than 91 days. In addition, patients are included in a facility's measure calculation only if they remain at the same facility for the full reporting month and the preceding 5 months.⁷⁶

Comment: A few commenters requested clarification regarding which laboratory result would be used for measure calculation, including whether CMS would use a pre-dialysis phosphorus value and whether the first, last, or average phosphorus result during the month would be used. A few commenters noted that the timing of laboratory collection could affect phosphorus results because levels obtained following the two-day interdialytic interval may differ from levels obtained following a one-day interval. A commenter recommended allowing repeat phosphorus measurements following a documented clinical intervention or otherwise recognizing improvement over time rather than relying solely on the initial monthly value. Another commenter recommended using the last phosphorus measurement of the month because an elevated result earlier in the month may prompt initiation or adjustment of phosphate binder therapy and a later result may better reflect the patient's response to treatment.

Response: We appreciate commenters' recommendations. We wish to clarify that the Hyperphosphatemia clinical measure uses phosphorus values that are collected pre-dialysis. Regarding the phosphorus laboratory value used to calculate the measure, the 6-month rolling average is calculated using the first reported pre-dialysis phosphorus value from the current month and up to 5 prior consecutive calendar months. If more than one phosphorus value is collected for a patient during a calendar

month, facilities are expected to report the first phosphorus value of the month. The TEP that informed development of the measure specifically recommended using the first value of the month to avoid potential unintended consequences, such as facilities obtaining multiple repeat measurements during the month for purposes of measure calculation.

Because the Hyperphosphatemia clinical measure assesses long-term phosphorus control using a 6-month rolling average, changes in phosphorus following clinical intervention would be reflected in subsequent monthly values included in the rolling average. We also note that while the phosphorus value obtained after the two-day interdialytic interval may be somewhat higher than values obtained later in the week, the Hyperphosphatemia clinical measure was developed to identify patients with long-term, significantly elevated phosphorus levels that would benefit from further intervention.

Comment: A commenter stated that phosphorus and serum albumin distributions differ between hemodialysis and peritoneal dialysis patients and expressed concern that use of a single threshold could classify a disproportionately higher share of PD patients as having hyperphosphatemia. The commenter also stated that the hypoalbuminemia-related exclusion could exclude a disproportionately higher share of PD patients and potentially destabilize measure performance in PD-only facilities. The commenter recommended that CMS consider differences between HD and PD populations. The commenter also requested clarification regarding which phosphorus laboratory value would apply when a patient changes dialysis modality during a month.

Response: We appreciate the commenter's concerns regarding potential differences in phosphorus and serum albumin distributions between HD and PD patients. The adverse cardiovascular and mortality associations of chronically elevated phosphorus have been reported in both hemodialysis and peritoneal dialysis populations. Differences in phosphate clearance associated with dialysis modality may require individualized management, including nutritional counseling, phosphate binder management, or adjustment of the dialysis prescription. Although albumin values tend to be somewhat lower among patients receiving peritoneal dialysis, the TEP did not recommend a different hypoalbuminemia threshold for PD patients given concerns that doing so could result in unintended

⁷⁵ Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at <https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Fall-2024-Management-Final-Project-Report.pdf>.

⁷⁶ CMS. (July 2026). ESRD QIP CY 2027 Measure Technical Specifications ESRD PPS Proposed Rule. Available at <https://www.cms.gov/files/document/cy-2027-proposed-rule-technical-measure-specifications-072026.pdf>.

consequences, such as excessive nutritional restriction among patients at risk for malnutrition. Therefore, no adjustment in the hypoalbuminemia threshold was recommended for peritoneal dialysis patients. Regarding commenters' request for clarification regarding modality changes, we wish to clarify that the first reported phosphorus value of the month is used for the measure calculation, even if a patient changes modality during the calendar month.

Comment: A few commenters expressed concern about implementing the Hyperphosphatemia measure in conjunction with the incorporation of oral phosphate binders into the ESRD PPS bundled payment, stating that facilities would assume financial responsibility for phosphate binders while also being held accountable under the ESRD QIP for a laboratory outcome affected by patient-level circumstances. A few commenters specifically cited concerns with the timing of the proposal, noting that facilities would be adjusting to the new bundled-payment policy during the measure performance period and that some performance data would reflect a period before phosphate binders were incorporated into the base rate or before facilities had notice that the data could affect QIP payment reductions. Commenters stated these timing issues could affect the establishment of appropriate data and quality benchmarks.

A commenter recommended that CMS monitor whether incorporation of phosphate binders into the ESRD PPS bundle influences prescribing patterns and stated that treatment decisions may reflect individual clinical needs and patient preferences rather than acquisition costs. Another commenter recommended excluding patients who are not eligible for bundled phosphate binders, citing insurance denials, limited insurance-covered medication options, high out-of-pocket costs, and other barriers to obtaining prescribed therapies. A commenter also recommended expanding public reporting on use of oral-only phosphate-lowering therapies to provide additional context for facility performance on the Hyperphosphatemia measure. A commenter stated that CMS policies favoring calcitriol for PTH management may contribute to higher phosphorus levels.

Response: We acknowledge commenters' concerns regarding implementation of the Hyperphosphatemia clinical measure in conjunction with the incorporation of oral phosphate binders into the ESRD PPS bundled payment. The shift in

responsibility for providing phosphate binders to dialysis facilities could improve access to phosphate binders and control of phosphorus levels, and we will monitor trends closely. We also acknowledge commenters' concerns regarding the timing of the measure in relation to the incorporation of phosphate binders into the ESRD PPS and the PY 2029 payment implications. We note that the performance period for the PY 2029 ESRD QIP is CY 2027. We also recognize commenters' concerns regarding the establishment of appropriate performance standards. Consistent with our general methodology, the performance standards, including the benchmark and achievement threshold, for PY 2029 are based on CY 2025 data. This methodology also applies to the Hyperphosphatemia clinical measure. Because the ESRD QIP does not currently calculate this measure, we are using facility-level CY 2025 data to establish the applicable performance standards. The data necessary to calculate this measure have been required elements within EQRS for several years; therefore, we do not anticipate data availability to pose a barrier to implementation. Facilities will continue to report the data needed to calculate the Hyperphosphatemia clinical measure through the existing EQRS submission process. Accordingly, implementation of the measure does not require facilities to establish a new reporting process or submit new data elements. We have published the measure specifications in the CY 2027 Proposed Technical Measure Specifications available at <https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/technical-specifications-esrd-qip-measures>, which provides facilities several months to review the specifications before the start of the performance period. Given these considerations, we are finalizing the measure as proposed.

We agree that treatment decisions must continue to be based on the individual patient's clinical needs and circumstances. Regarding the recommendation to exclude patients who experience barriers to obtaining prescribed phosphate-lowering therapies, we note that the shift in responsibility for the provision of phosphate binders may improve access. We also acknowledge commenters' concerns regarding the potential effects of payment, coverage, or other CMS policies on phosphorus management, including access to phosphate-lowering therapies and prescribing patterns. As

part of routine measure maintenance, we conduct ongoing monitoring and evaluation to identify and act upon any unintended consequences. We appreciate the commenter's recommendation to expand public reporting on the use of oral-only phosphate-lowering therapies. However, the Hyperphosphatemia clinical measure is intended to assess phosphorus management at the facility level, rather than the use of a particular therapy at the individual level. Treatment decisions may vary based on individual patients' clinical needs, and we therefore do not believe that additional therapy-specific public reporting is necessary for purposes of this measure.

Comment: A few commenters recommended that CMS consider a non-punitive process measure focused on actions within the facility's control, such as phosphorus review, dietary education, medication reconciliation, assessment of phosphate binder access, and shared decision-making. A few commenters recommended pairing the Hyperphosphatemia measure with a requirement that facilities document individualized responses to persistently elevated phosphorus, including sustained education, medication review, barrier resolution, individualized nutrition education, and evaluation of the dialysis prescription. A commenter recommended that CMS require education and patient engagement as part of the measure, and another recommended encouraging coordination across interdisciplinary teams to optimize measure performance.

A commenter stated that facilities must not use phosphorus levels to blame patients. Another commenter expressed concern that patients may experience being blamed for their phosphorus levels.

Response: We appreciate commenters' recommendations regarding use of a process measure and documentation of specific facility actions in response to elevated phosphorus. We believe the Hyperphosphatemia clinical measure appropriately encourages facilities to evaluate and respond to persistently elevated phosphorus through the interdisciplinary care team, including through dietary counseling, medication management, patient education, and adjustment of the dialysis prescription. The measure is intended to directly assess and provide useful information regarding facility-level patient outcomes and phosphorus control, allowing for flexibility for facilities to determine the appropriate combination of interventions based on individual patient circumstances. We agree that

patient engagement and individualized care are important components of phosphorus management and do not intend for the measure to be used to attribute elevated phosphorus solely to patient behavior. In fact, the TEP placed a significant focus on patient engagement and non-patient blaming during measure development which drove support for the 6-month rolling average.

Comment: A few commenters recommended that CMS work with other Federal agencies, including the FDA, to improve phosphorus labeling on foods before implementing the measure. A few commenters similarly recommended adding phosphorus content to food labels to help patients better manage dietary phosphorus intake.

Response: We appreciate commenters' recommendations regarding phosphorus content information on food labels and recognize that dietary choices can affect phosphorus levels and management. We agree that access to information about phosphorus content in food may assist patients and clinicians in dietary management and note that dietary counseling and phosphorus education is one of several interventions that facilities may use to address phosphorus management.

Comment: A commenter recommended that CMS assess the pediatric implications of the proposal because the Hyperphosphatemia measure would apply only to adult dialysis patients.

Response: We thank the commenter for this recommendation. The Hyperphosphatemia clinical measure proposed for the ESRD QIP is currently specified for adult dialysis patients age 18 years and older. We note that CMS has subsequently developed an all-patient version of the measure, Percentage of Chronic Hyperphosphatemia in Dialysis Patients, that includes pediatric dialysis patients and was endorsed by the CBE in the Fall 2025 cycle.⁷⁷ We will take the commenter's recommendation into consideration as we evaluate future updates to the ESRD QIP measure set.

Comment: A commenter stated that conventional dialysis treatments do not meaningfully affect phosphorus levels compared with longer or more frequent dialysis treatments.

Response: We appreciate the commenter's concern and recognize that phosphorus management may be influenced by dialysis duration and

frequency which remains an individualized, clinical treatment decision. The Hyperphosphatemia clinical measure uses a 6-month rolling average of phosphorus values, which reflects phosphorus control over time rather than an isolated laboratory result. Phosphorus management may involve multiple interventions, including nutritional counseling, phosphorus-binding medications, and adjustment of the dialysis prescription.

After consideration of public comments, we are finalizing our proposal to remove the Hypercalcemia reporting measure and replace it with the Hyperphosphatemia clinical measure beginning with PY 2029.

3. Update to the National Healthcare Safety Network Bloodstream Infection in Hemodialysis Patients Clinical Measure

In the CY 2014 ESRD PPS final rule, we adopted the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients (hereafter referred to as the NHSN BSI) clinical measure into the ESRD QIP to assess BSIs among patients receiving hemodialysis at outpatient hemodialysis centers (78 FR 72204 through 72207). The NHSN BSI clinical measure is based on infection surveillance data reported by facilities to the Centers for Disease Control and Prevention (CDC) through the NHSN Dialysis Event Surveillance system.⁷⁸ The current measure uses a standardized infection ratio (SIR), which compares the number of observed BSIs to the number of predicted BSIs among facilities. The predicted number of BSIs represents the number expected if a facility had a BSI rate equal to the national rate derived from 2014 NHSN surveillance data. The predicted number is estimated using pooled national BSI rates by patient access type, which are multiplied by facility-level patient-months for each access type.⁷⁹

We proposed to update the baseline and risk adjustment used to calculate the SIR for the NHSN BSI clinical measure beginning with PY 2029 to ensure that national benchmarks better reflect current healthcare practices, surveillance protocols, and infection prevention efforts. To estimate the expected number of BSIs, we proposed

to update the national baseline from 2014 data to 2023 data and revise the risk adjustment model to incorporate additional patient and facility-level characteristics, including vascular access type, facility hospital affiliation, and number of dialysis stations, which were identified as significant predictors of BSI risk among the data reported to NHSN.⁸⁰ Additionally, these factors may reflect differences that are not fully within a facility's direct control. The predicted number of BSIs will be estimated using a regression model developed from the 2023 national baseline data. This model uses parameter estimates associated with the identified risk factors to calculate predicted BSIs for each facility-access type combination and then multiplies these estimates by facility patient-months to determine the predicted number of BSIs. Additionally, this updated risk adjustment model will better account for differences in facility characteristics associated with BSI risk. The proposed 2023 national baseline updates will not change the underlying SIR calculation formula but will instead be used to calculate revised denominators for the SIR by estimating the number of predicted BSIs for a given facility based on the 2023 national baseline data.⁸¹

The proposed 2023 national baseline updates will allow facilities to compare their performance to more recent national data, improve the accuracy of benchmark comparisons, and serve as a new national reference point for measuring progress in BSI prevention. Because the updated 2023 national baseline reflects more recent national data, facilities may observe changes in their SIR values compared to their SIR values calculated using the 2014 national baseline. These changes may reflect differences in national baseline rates rather than changes in facility performance. The number of predicted infections may increase or decrease depending on multiple factors, including vascular access type, location, and number of stations in a facility. The SIRs calculated under the 2014 national baseline will not be directly comparable to the SIRs calculated under the 2023 national baseline because each baseline

⁷⁸ Centers for Medicare & Medicaid Services. (April 2026). CMS ESRD Measures Manual for the 2026 Performance Period: Final Version 11.2. Available at <https://www.cms.gov/files/document/esrd-measures-manual-v11-2.pdf>.

⁷⁹ Centers for Disease Control and Prevention. Guide to the NHSN Dialysis Event Surveillance Bloodstream Infection (BSI) Standardized Infection Ratio (SIR) Measure. Available at <https://www.cdc.gov/nhsn/pdfs/dialysis/understanding-the-de-bsi-sir.pdf>.

⁸⁰ Centers for Disease Control and Prevention. (April 2026). NHSN 2023 Dialysis BSI SIR Rebaseline Guide. Available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/New-SIR-Guide.pdf>.

⁸¹ Centers for Disease Control and Prevention. (2023). Charter the Course: 2023 Dialysis BSI Rebaseline. Available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf>.

⁷⁷ PQM. Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at <https://p4qm.org/measures/5320>.

relies on a distinct national reference dataset and risk adjustment model.

For additional information on the 2023 BSI national baseline process, please refer to the CDC NHSN website at <https://www.cdc.gov/nhsn/bsirebaseline/bsi.html/>.

We welcomed public comment on our proposal to update the NHSN BSI clinical measure beginning with PY 2029.⁸²

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to update the NHSN Bloodstream Infection in Hemodialysis Patients clinical measure to use a more recent 2023 national baseline and revised risk adjustment. Commenters stated that the updates would provide a more current, accurate, and fair assessment of facility performance. A few commenters specifically supported the proposed updates to the revised risk adjustment, noting that incorporating additional facility-level characteristics, including patient access type, hospital affiliation and number of dialysis stations, would help account for factors associated with infection risk that are outside a facility's control. A commenter stated that accounting for these factors could reduce the potential for facilities serving higher-risk patient populations to be unfairly disadvantaged. A few commenters also emphasized that infection prevention remains an important component of high-quality dialysis care and patient safety.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposed updates, but raised continuing concerns regarding the validity and reliability of NHSN BSI data, including potential under-reporting, facilities' reliance on hospitals to report infections, and whether the measure appropriately attributes infections to dialysis facilities. Commenters recommended that CMS continue evaluating measure validity and ensure that differences in facility performance reflect differences in infection prevention rather than differences in reporting practices. A commenter specifically expressed concern that infections originating from non-dialysis sources may be attributed to facilities and recommended limiting

the measure to vascular access-related bloodstream infections or excluding infections with a documented non-dialysis source.

Response: We appreciate commenters' concerns, and agree that accurate and reliable reporting is important to ensure that the measure reflects differences in infection prevention rather than differences in reporting practices. We note that NHSN data validation activities are intended to support the accuracy and completeness of data used for the ESRD QIP. The proposed update to the national baseline and risk adjustment is part of ongoing measure maintenance intended to provide a more current national comparison and account for additional factors associated with BSI risk that are outside a facility's direct control. We will continue to monitor measure performance and consider commenters' concerns regarding validity and reliability.

Regarding the commenter's concern about attribution, facilities are required to report qualifying positive blood cultures regardless of whether a true infection is suspected or whether the infection is thought to be related to hemodialysis. Facilities separately report the suspected source of the positive blood culture, including whether the source is vascular access, another source, contamination, or uncertain. The NHSN Dialysis Event Surveillance Protocol defines a BSI as any positive blood culture event, while an access-related BSI is separately defined as a positive blood culture for which the suspected source is the vascular access or is uncertain.⁸³

Consistent with these definitions, the ESRD QIP NHSN BSI clinical measure numerator includes new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after hospital admission and does not limit the numerator to vascular access-related infections. This enables a standardized approach to collect data for BSIs with a high probability that the infection is associated with hemodialysis. We also note that using a standardized performance measure such as the SIR helps account for possible under- and over-reporting.

Comment: A few commenters requested greater transparency before the revised methodology affects ESRD QIP scoring. Commenters recommended that CMS publish updated technical specifications and the revised risk-

adjustment model, provide facilities an opportunity to preview the changes, and provide sufficient advance notice and baseline performance information to understand how the revised methodology would affect facility performance.

Response: We appreciate commenters' requests for additional transparency regarding the revised methodology. We note that the NHSN has provided email communications and virtual office hours for registered NHSN users regarding updates, trainings, and resources. Additionally, we refer readers to the updated SIR guide, FAQs, and 2023 re-baseline website available at <https://www.cdc.gov/nhsn/pdfs/rebaseline/New-SIR-Guide.pdf>, <https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf>, and <https://www.cdc.gov/nhsn/bsirebaseline/bsi.html>. The ESRD QIP CY 2027 Measure Technical Specifications are also available at <https://www.cms.gov/files/document/cy-2027-proposed-rule-technical-measure-specifications-072026.pdf> for more details.

Comment: A commenter supporting the proposed updates also expressed concern that low event counts or reporting errors may disproportionately affect small facilities and recommended that CMS evaluate measure reliability for these facilities and establish a transparent and timely process for correcting NHSN data-entry errors before the data are used for ESRD QIP scoring. If these refinements cannot be implemented for PY 2029, the commenter recommended delaying payment consequences and initially using the revised methodology for feedback and further testing.

Response: We acknowledge the commenter's concerns regarding measure reliability for small facilities and the potential effect of data entry errors on facility performance. We note that facilities treating fewer than 11 in-center HD patients during the performance period are excluded from the NHSN BSI clinical measure, and facilities treating 11 to 25 in-center HD patients receive the small facility adjustment (SFA).

Regarding data accuracy, facilities are responsible for reporting complete and accurate data and are expected to review their reported data and analysis reports regularly, including at least once before the QIP reporting deadline.⁸⁴ If additional information becomes

⁸² In the proposed rule we stated that this proposed change would be a technical update to the measure specifications, rather than a substantive change. However, we were interested in feedback on this technical update and therefore proposed it in the proposed rule to facilitate public comment.

⁸³ CDC National Healthcare Safety Network. (January 2026). NHSN Dialysis Event Surveillance Protocol. Available at <https://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf>.

⁸⁴ CDC National Healthcare Safety Network. (January 2026). NHSN Dialysis Event Surveillance Protocol. Available at <https://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf>.

available, facilities are expected to report the information retrospectively, which may include reporting additional dialysis events or correcting existing event data. Facilities must submit relevant measure data by the applicable quarterly reporting deadlines and once a reporting deadline has passed, a frozen data file is created for calculating final ESRD QIP scores. Only data reported before the applicable quarterly reporting deadline are used to calculate ESRD QIP scores.

We do not believe that delaying implementation of the revised methodology is necessary. The proposed update would not change the underlying SIR calculation formula, but would update the national baseline from 2014 to 2023 data and revise the risk-adjustment model to provide a more current national baseline and better account for facility characteristics associated with BSI risk that are outside a facility's direct control.

After consideration of public comments, we are finalizing the updates to the NHSN BSI clinical measure beginning with PY 2029.

4. Removal of Two Measures From the ESRD QIP Measure Set

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. Based on that analysis and our evaluation of the ESRD QIP measure set, we proposed to remove the Medication Reconciliation reporting measure and the COVID-19 Vaccination Coverage Among Healthcare Personnel reporting measure, beginning with PY 2029.

a. Removal of the Medication Reconciliation Reporting Measure

To ensure continued impact and effectiveness of our measure set on facility performance, we proposed to remove the Medication Reconciliation (MedRec) reporting measure beginning with PY 2029. When we first adopted the MedRec reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57008 through 57010), we stated that inclusion of the measure in the ESRD QIP measure set would align with national goals for patient safety and the reduction of harm caused by care delivery. The MedRec reporting measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the ESRD patient population because those patients typically see multiple providers and may require numerous medications.

Our proposal to remove the MedRec reporting measure is consistent with

evolving the ESRD QIP to focus on a measure set of high-value, impactful measures that have been developed to drive care improvements for a broader set of ESRD patients. As such, we proposed to remove this measure from the ESRD QIP measure set under measure removal factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program (§ 413.178(c)(5)(i)(H)).

Although recent annual measure analyses have indicated that the MedRec reporting measure may not be fully topped out based on the statistical criteria that we adopted in the CY 2015 ESRD PPS final rule (79 FR 66171 through 66174), available data show consistently high performance and limited variation across facilities. For example, the mean MedRec reporting measure performance in CY 2024 was 97.3 percent and the median MedRec reporting measure score was 10 points, which indicates more than 50 percent of providers achieved perfect scores for the measure. These results suggest that the programmatic benefit of retaining the measure is limited.

One of the goals of the ESRD QIP is to advance the program in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Our priority is a continued focus on measurable clinical outcomes to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency. In light of consistently high performance on the MedRec reporting measure, leaving limited opportunity for further distinctions or improvements in facility performance, and the burden facilities incur in collecting, documenting, and reporting data for the measure, the costs associated with the measure outweigh the benefit of its continued use in the ESRD QIP. Our proposal to remove the MedRec reporting measure from the ESRD QIP is consistent with these priorities.

We welcomed public comment on our proposal to remove the MedRec reporting measure from the ESRD QIP measure set, beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the MedRec reporting measure from the ESRD QIP. A few commenters agreed that performance on the measure is consistently high with limited variation

among facilities, reducing its usefulness for distinguishing differences in facility quality. A few commenters also stated that the administrative burden associated with continued reporting is no longer justified by the measure's value, and supported focusing the ESRD QIP measure set on measures that more meaningfully assess patient outcomes and facility performance.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the proposed measure removal, and emphasized that medication reconciliation remains an important component of high-quality dialysis care and patient safety, particularly for patients with complex medication regimens or who receive medications from multiple providers. A few commenters encouraged CMS to continue working with interested parties to identify ways to account for appropriate medication reconciliation for patients with ESRD. A commenter also recommended replacing the measure with other meaningful and actionable reporting measures.

Response: We agree with commenters that medication reconciliation remains important, particularly for patients with ESRD who receive multiple medications from multiple providers with the potential for medication interactions and dialysis treatment impacts. We thank the commenters for their recommendations and will take these into consideration for future measure development and quality reporting activities in the ESRD QIP.

Comment: A commenter did not support removing the MedRec reporting measure, stating that medication reconciliation can reduce medication discrepancies, improve clinical outcomes, reduce hospital readmissions, and improve quality of life and that continued monitoring is particularly important for patients with ESRD because of the complexity of their medication regimens. The commenter recommended that CMS reconsider the proposed removal despite high current facility performance. Another commenter characterized the measure as topped out, but recommended that CMS continue monitoring whether its removal affects facility medication reconciliation practices and ensure that patients continue to have access to medication safety supports.

Response: We agree with commenters regarding the continued importance of medication reconciliation for patients with ESRD, and note that the removal of the measure is consistent with our goal of evolving the ESRD QIP measure set toward high-value, impactful measures

that more meaningfully drive improvements in care for patients with ESRD. Given the consistently high performance across facilities, the MedRec reporting measure leaves limited opportunity for further distinctions or improvements in facility performance, such that the costs associated with the measure outweigh the benefit of its continued use in the ESRD QIP. Additionally, as part of our usual monitoring and evaluation activities, we monitor for any unintended consequences associated with changes to the ESRD QIP measure set.

After consideration of public comments, we are finalizing our proposal to remove the MedRec reporting measure beginning with PY 2029.

b. Removal of the COVID–19 Vaccination Coverage Among Healthcare Personnel Reporting Measure

We refer readers to the CY 2023 ESRD PPS final rule where we adopted the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure (hereafter referred to as COVID–19 HCP Vaccination measure) into the ESRD QIP (87 FR 67244 through 67248) and the CY 2024 ESRD PPS final rule where we modified the COVID–19 HCP Vaccination measure to account for updated COVID–19 vaccine guidance (88 FR 76446 through 76451). The COVID–19 HCP Vaccination measure requires dialysis facilities to report the COVID–19 vaccination status of HCP through the CDC NHSN. Facilities must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students, and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (88 FR 76448 through 76449).

We proposed to remove the COVID–19 HCP Vaccination measure beginning with the PY 2029 ESRD QIP under removal factor 3, a measure no longer aligns with current clinical guidelines or practice (§ 413.178(c)(5)(i)(C)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID–19 cases and over 965,000 COVID–19 deaths (87 FR 67244). In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID–19 averaged around 1,300.⁸⁵ While preventing the

spread of COVID–19 remains a public health goal, the PHE ended on May 11, 2023,⁸⁶ and the COVID–19 death rate has continued to decrease. The weekly number of deaths attributed to COVID–19 during a recent 6-month period (weeks ending 8/2/25 through 1/31/26) ranged from 188 to 498.⁸⁷

With the end of the PHE, the continued costs and burden to providers of reporting on this measure outweighed the benefit of continued information collection on COVID–19 HCP Vaccination in several settings. We likewise removed this measure from several program measure sets: the Hospital Inpatient Quality Reporting Program (90 FR 37010 through 37012), the Inpatient Psychiatric Facility Quality Reporting Program (90 FR 37657 through 37658), the Inpatient Rehabilitation Facility Quality Reporting Program (90 FR 37701 through 37702), the Ambulatory Surgical Center Quality Reporting Program (90 FR 53917 through 53919), and the Hospital Outpatient Quality Reporting Program (90 FR 53917 through 53919). We did not initially remove this measure from other settings, including ESRD facilities, due to the continuing benefit to higher risk patient populations.

Since the end of the PHE, the CDC's clinical recommendations for COVID–19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.⁸⁸ At the time the COVID–19 HCP Vaccination reporting measure was adopted, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID–19.⁸⁹ There were well-defined parameters for receiving the COVID–19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

Available at <https://www.cdc.gov/covid/php/surveillance/index.html>.

⁸⁶ U.S. Department of Health and Human Services. (2023). COVID–19 Public Health Emergency. Available at <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>.

⁸⁷ Centers for Disease Control and Prevention. Provisional COVID–19 Mortality Surveillance. Available at <https://www.cdc.gov/nchs/nvss/vsrr/covid19/>.

⁸⁸ Dooling, K, McClung, M, et al. "The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020." *Morb. Mortal Wkly Rep.* 2020; 69(49): 1857–1859.

⁸⁹ Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed March 6, 2026 at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

However, these parameters no longer apply, due to evolving circumstances. The latest CDC COVID–19 vaccination recommendations for the 2025 through 2026 season are now based on shared clinical decision-making.⁹⁰ For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.⁹¹ Given that there is no single default recommendation to vaccinate a defined population, both receipt and non-receipt of vaccination may reflect the guidance of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we proposed removing the measure from the ESRD QIP measure set under removal factor 3, a measure does not align with current clinical guidelines or practice.

We stated that, if finalized, facilities would not be required to report COVID–19 HCP Vaccination reporting measure data beginning with the performance period for PY 2029. Any COVID–19 HCP vaccination data received by CMS beginning with the performance period for PY 2029 would not be used for ESRD QIP public reporting.

We welcomed public comment on our proposal to remove the COVID–19 Vaccination Coverage Among Healthcare Personnel measure from the ESRD QIP beginning with PY 2029.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the COVID–19 HCP Vaccination measure from the ESRD QIP. A few commenters stated that the measure no longer aligns with current clinical recommendations and practice. A few commenters also cited consistently high performance, limited value in distinguishing differences in facility quality, reporting burden, and alignment with removal of the measure from other Medicare quality programs. Commenters supported focusing the ESRD QIP measure set on measures that more meaningfully assess patient outcomes and facility performance. A commenter stated that public reporting of COVID–19 healthcare personnel vaccination rates is not an appropriate tool to assess dialysis facility quality.

⁹⁰ Centers for Disease Control and Prevention. (2025). 2025–2026 COVID–19 Vaccination Guidance. Available at <https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html>.

⁹¹ Centers for Disease Control and Prevention. (January 2025). ACIP Shared Clinical Decision-Making Recommendations. Available at <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

⁸⁵ Centers for Disease Control and Prevention. (September 2025). Surveillance and Data Analytics.

Response: We thank the commenters for their support.

Comment: A few commenters supporting removal emphasized that vaccination and infection prevention remain important for patients with ESRD because of their heightened vulnerability to infectious disease. A commenter stated that healthcare personnel may continue to follow current immunization recommendations. A commenter recommended that CMS promptly remove COVID–19 vaccination performance information from Dialysis Facility Compare following removal of the measure to avoid confusion regarding the continued relevance of the information. Another commenter recommended replacing the measure with other meaningful and actionable reporting measures.

Response: We appreciate commenters' feedback on the importance of vaccination and infection prevention for patients with ESRD. We agree that preventing the spread of infectious disease and protecting vulnerable patients remain important goals. We note that removal of the measure is not a reflection of the effectiveness or importance of COVID–19 vaccination.

We also appreciate commenters' recommendations regarding public reporting and future quality measures. As discussed in the proposed rule, COVID–19 HCP vaccination data received beginning with the PY 2029 performance period would no longer be used for ESRD QIP public reporting (91 FR 38842). We will take recommendations regarding future meaningful and actionable measures into consideration as we continue to evaluate the ESRD QIP measure set.

Comment: A commenter did not support removing the COVID–19 HCP Vaccination measure, expressing concern that patients with ESRD remain particularly vulnerable to infectious disease and face repeated exposure in shared dialysis settings. The commenter expressed concern that removing the measure could signal that healthcare personnel vaccination is no longer a priority, potentially reducing vaccination coverage among staff. The commenter recommended that CMS instead update the measure to reflect current vaccination recommendations, align reporting requirements across healthcare settings to reduce burden, and use the measure for monitoring and quality improvement, including identifying facilities with low vaccination rates to target technical assistance.

Another commenter recommended that CMS monitor whether removal of the measure affects facility practices and ensure that patients continue to have access to appropriate vaccination and infection prevention supports.

Response: We acknowledge commenters' concerns regarding the continued importance of vaccination and infection prevention for patients with ESRD and agree that protecting vulnerable patients from COVID–19 remains an important goal. However, removal of the COVID–19 HCP Vaccination measure is based on changes in current clinical guidance and practice, not as a reflection of the effectiveness or importance of COVID–19 vaccination. As discussed in the proposed rule, current COVID–19 vaccination recommendations have shifted toward shared clinical decision-making, for which there is no single default recommendation to vaccinate a defined population (91 FR 38842). Both receipt and non-receipt of vaccination may therefore be consistent with current guidance. Therefore, we continue to believe that removal of the measure is appropriate and consistent with our goal of focusing the ESRD QIP measure set on high-value, impactful measures.

Regarding the commenter's recommendations to update the measure, align reporting requirements across healthcare settings, and use vaccination data for monitoring and quality improvement, we note that we will continue to monitor for unintended consequences associated with changes to the ESRD QIP measure set.

After consideration of public comments, we are finalizing our proposal to remove the COVID–19 HCP Vaccination measure beginning with PY 2029.

5. Updates To Measure Domains and to the Domain and Measure Weights Used To Calculate the Total Performance Score

In the CY 2019 ESRD PPS final rule (83 FR 56991 through 56992), we finalized revisions to the ESRD QIP measure domains. Specifically, in that rule we eliminated the Reporting Domain and reorganized the Clinical Domain into three distinct domains: Patient & Family Engagement Domain, Care Coordination Domain, and Clinical Care Domain. We finalized our proposal to eliminate the Reporting Measure Domain from the ESRD QIP measure set, beginning in PY 2021, because there would no longer be any measures in that domain.

In the CY 2023 ESRD PPS final rule, we finalized our proposal to create a

new Reporting Measure Domain (87 FR 67251 through 67254), which would include the six individual reporting measures in the ESRD QIP measure set at that time. In the CY 2023 ESRD PPS final rule, we stated that a separate Reporting Measure Domain was necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes.

Currently, ESRD QIP measures are weighted and distributed across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. As discussed in section IV.B.2. of the proposed rule, we proposed to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with the PY 2029 ESRD QIP. In sections IV.B.4.a. and IV.B.4.b. of the proposed rule, we also proposed to remove the COVID–19 Vaccination Coverage among HCP reporting measure and the MedRec reporting measure from the ESRD QIP measure set beginning with the PY 2029 ESRD QIP (91 FR 38841 through 38842). We stated that, if these proposals are finalized as proposed, the ESRD QIP measure set would not include any measures under the Reporting Measure Domain. Therefore, we proposed to remove the Reporting Measure Domain and to update the domain weights and individual measure weights in the Care Coordination Domain and the Clinical Care Domain accordingly to reflect the proposed updates to the ESRD QIP measure set. As the ESRD QIP measure set has evolved over the years, we believe that removing the Reporting Measure Domain and updating the Care Coordination Domain and the Clinical Care Domain, both of which contain multiple measures, would help to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score (TPS), while also further incentivizing improvement on clinical measures. Although we proposed to remove the Reporting Measure Domain beginning with PY 2029 because the ESRD QIP measure set would no longer include any reporting measures, we note that in future rulemaking, reporting measures may be proposed for inclusion in the ESRD QIP measure set under the remaining measure domains. For a comparison of current and finalized measure domains and weighting, see Tables 24 and 25.

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TABLE 24: Current ESRD QIP Measure Domains and Weights

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Measure Topic	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
Hypercalcemia reporting measure**	3.33
MedRec reporting measure**	3.33
COVID-19 HCP Vaccination reporting measure**	3.33

*We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

**We are finalizing our proposal to remove the Hypercalcemia reporting measure, the MedRec reporting measure, and the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2029, as discussed in sections IV.B.2.a., IV.B.4.a., and IV.B.4.b. of this final rule.

TABLE 25: Finalized ESRD QIP Measure Domains and Weights beginning with PY 2029

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	35.00
SHR clinical measure	9.00
SRR clinical measure	9.00
PPPW measure	10.00
Clinical Depression Screening and Follow-Up measure	7.00
Clinical Care Measure Domain	40.00
Hyperphosphatemia clinical measure*	7.00
Kt/V Dialysis Adequacy Measure Topic	11.00
Long-Term Catheter Rate clinical measure	11.00
STrR clinical measure	11.00
Safety Measure Domain	10.00
NHSN BSI clinical measure**	10.00

*We are finalizing our proposal to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this final rule.

**We are finalizing our proposal to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this final rule.

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We welcomed public comment on our proposal to remove the Reporting Measure Domain and to update the existing domains and measure weights used to calculate the TPS, beginning with PY 2029.

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

Comment: A few commenters supported removing the Reporting Measure Domain if no reporting

measures remain in the ESRD QIP. A commenter specifically supported the proposed changes to the remaining domains and measure weights.

Response: We thank the commenters for their support.

Comment: A few commenters supporting the updates emphasized that eliminating the Reporting Measure Domain should not preclude future use of reporting measures. Commenters stated that reporting measures may remain useful for data collection, feasibility and reliability testing, baseline development, and evaluation of emerging quality concepts. A commenter also recommended monitoring whether redistribution of the domain weight creates unintended consequences for facilities serving medically complex, high-need, or socially at-risk populations.

Response: We appreciate commenters' recommendations regarding the future use of reporting measures. As discussed in the proposed rule, although we would remove the Reporting Measure Domain beginning with PY 2029 because no reporting measures would remain in the measure set, reporting measures may be proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842). We also note that the proposed changes to the Care Coordination and Clinical Care Domain weights are intended to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score while further incentivizing improvement on clinical measures. As part of our usual monitoring and evaluation activities, we monitor for unintended consequences associated with the ESRD QIP measure set.

Comment: A commenter opposed removing the Reporting Measure Domain and recommended replacing the measures proposed for removal with meaningful and actionable reporting measures rather than eliminating the domain. The commenter recommended that future reporting measures address areas such as patient education and treatment support.

Response: We thank the commenter for their recommendations. As discussed in the proposed rule, although we would remove the Reporting Measure Domain beginning with PY 2029 because no reporting measures would remain in the measure set, reporting measures may be proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842). Regarding the recommendation to address patient education and treatment support, we will take these recommendations into consideration as we continue to evaluate the ESRD QIP measure set.

Comment: A few commenters recommended assigning the full 10 percentage points to the Clinical Care Domain rather than redistributing the Reporting Measure Domain weight as proposed.

Response: Regarding redistribution of the Reporting Measure Domain weight, we intend to redistribute 5 percentage points to the Care Coordination Domain and 5 percentage points to the Clinical Care Domain to address concerns regarding the impact of individual measure performance on a facility's Total Performance Score while further incentivizing improvement on clinical measures. We determined that the proposed weights better reflect the priorities of the ESRD QIP by maintaining a balanced allocation across domains while placing greater emphasis on measures focused on meaningful clinical outcomes and other priority areas of care. For example, within the Care Coordination Domain, the proposed weights place greater emphasis on the PPPW measure to support our priority of increasing transplantation and on the SHR and SRR clinical measures relative to the Clinical Depression Screening and Follow-Up measure to emphasize patient outcomes. We believe the proposed redistribution appropriately balances the impact of individual measures on a facility's TPS while advancing the ESRD QIP's priorities for meaningful clinical measures.

Comment: A few commenters also requested greater transparency regarding the reweighting methodology, including publication of the methodology, examples of effects on facility-level scores, and modeled impacts for different facility types.

Response: The weighting methodology, including the current and updated domain and individual measure weights, is described in Tables 24 and 25 of this final rule. We note that we publish the ESRD QIP scoring methodology in this final rule and also include examples in the ESRD Measures Manual. We also make facility-level ESRD QIP data available to support transparency and allow interested parties to reproduce program calculations. The domain and measure weights reflect CMS priorities and the clinical importance of the measures, including the extent to which measures are associated with meaningful clinical outcomes.

Comment: A commenter recommended retaining the Reporting Measure Domain if the Hyperphosphatemia measure is initially implemented as a reporting measure

and otherwise supported removing the domain if no reporting measures remain. The commenter also requested CMS to ensure that removal of the domain would not preclude use of reporting measures in future years.

Response: We note that the Hyperphosphatemia measure would be implemented as a clinical measure rather than a reporting measure and, therefore, continue to believe it is appropriate to remove the Reporting Measure Domain as no measures would remain in the domain for the proposed PY 2029 measure set. As discussed in the proposed rule, removal of the Reporting Measure Domain would not preclude reporting measures from being proposed for inclusion in the ESRD QIP in future rulemaking under the remaining measure domains (91 FR 38842).

After consideration of public comments, we are finalizing our proposal to update the measure domains and the domain and measure weights used to calculate the Total Performance Score beginning with PY 2029.

6. Performance Standards for the PY 2029 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (77 FR 67500 through 67502), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

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 are finalizing CY 2027 as the performance period and CY 2025 as the baseline period for the PY 2029 ESRD QIP. In the proposed rule, we estimated the performance standards for the PY 2029 clinical measures in Table 22 using data from CY 2024, which were the most recent data available (91 FR 38844). In this final rule, we are updating these performance standards for all measures, using the most recently available data from CY 2025, in Table 26.

TABLE 26: Updated Performance Standards for the ESRD QIP Clinical Measures for PY 2029

Measure	Achievement Threshold (15 th Percentile of National Performance)	Median (50 th Percentile of National Performance)	Benchmark (90 th Percentile of National Performance)
VAT Long-Term Catheter Rate	18.35%*	11.04%*	4.69%*
Kt/V Dialysis Adequacy Measure Topic			
Adult Hemodialysis (HD) Kt/V	96.08%*	98.52%*	99.73%*
Pediatric Hemodialysis (HD) Kt/V	81.25%*	98.29%*	100.00%*
Adult Peritoneal Dialysis (PD) Kt/V	87.37%*	95.20%*	99.04%*
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%*	85.65%	98.91%*
Hyperphosphatemia	34.30%	24.42%	12.94%
Standardized Readmission Ratio ^a	34.27*	26.50*	16.18*
NHSN BSI	2.064	0.688	0.000
Standardized Hospitalization Ratio ^b	166.60*	129.14*	87.98*
Standardized Transfusion Ratio ^b	48.29*	26.19*	8.07*
Percentage of Prevalent Patients Waitlisted for Kidney Transplant	8.12%*	16.73%*	33.90%*
Clinical Depression Screening and Follow-up	93.26%	98.31%	100.00%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	55.82%*	64.90%*	76.18%*
ICH CAHPS: Providing Information to Patients	71.87%	78.53%	85.77%
ICH CAHPS: Overall Rating of Dialysis Center Staff	56.33%	68.77%	82.70%
ICH CAHPS: Overall Rating of the Dialysis Facility	57.42%	70.70%	84.16%

*Values are the same final performance standards for those measures for PY 2028. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2029 because they are higher standards than the PY 2029 numerical values for those measures.

^aRate calculated as a percentage of hospital discharges

^bRate per 100 patient-years

Data sources: VAT measure: 2025 EQRS; SRR, SHR, STTrR: 2025 Medicare claims; Kt/V: 2025 EQRS and 2025 Medicare claims; Hyperphosphatemia measure: 2025 EQRS; NHSN: 2025 CDC; ICH CAHPS: CMS 2025; PPPW: 2025 EQRS and 2025 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2025 EQRS.

7. Eligibility Requirements for the PY 2029 ESRD QIP

In the proposed rule, we proposed to update eligibility requirements as part

of our proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029 (91 FR

38845). Our finalized eligibility requirements are described in Table 27.

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TABLE 27: Finalized Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2029

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hyperphosphatemia (Clinical)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
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 will 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
Clinical Depression Screening and Follow-Up (Clinical)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	11-25 qualifying patients
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

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8. Payment Reduction Scale for the PY 2029 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with

its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined

the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that a facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. In the proposed

rule, for PY 2029, we estimated using available data that a facility must meet or exceed an mTPS of 54 to avoid a payment reduction (91 FR 38846). In the proposed rule, we estimated the mTPS based on data from CY 2024 instead of the PY 2029 baseline period (CY 2025) because CY 2025 data were not yet

available. In this final rule, we are updating the mTPS and associated payment reduction ranges for PY 2029 using the most recently available data, CY 2025. The estimated payment reduction scale for PY 2029 based on the most recently available data is described in Table 28.

TABLE 28: Updated Payment Reduction Scale for PY 2029 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-54	0.0%
53-44	0.5%
43-34	1.0%
33-24	1.5%
23-0	2.0%

C. Request for Information on the Inclusion of the Dialysis Facility Discussion of Patient Life Goals Patient-Reported Outcome Performance Measure in the ESRD QIP

1. Background

We sought feedback related to the potential inclusion of the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) Patient-reported Outcome Performance Measure (PRO-PM) in the ESRD QIP. For people on chronic dialysis, regular discussion of patient life goals with their dialysis facility care team can lead to better understanding by facilities and providers of those life goals, and how patients' goals can be considered as part of initial and ongoing treatment planning and decision-making.^{92 93} Evidence suggests that discussions to identify and incorporate patient life goals into modality and treatment decisions do not consistently

occur in practice among ESRD patients.^{94 95 96} Individuals with ESRD report that they often do not receive adequate information about treatment options or do not regard themselves as the primary decision-maker in their care.⁹⁷ This suggests discussion of life goals as part of treatment planning and

decisions is desired by patients and is not always happening.

Discussions of patient life goals are consistent with the patient plan of care requirements under § 494.90 and the patient rights provisions under § 494.70(a) and with clinical practice guidelines that emphasize integrating patient life goals into kidney replacement therapy decision-making and care planning as established under the ESRD Conditions for Coverage finalized in 2008 (73 FR 20370).⁹⁸ The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guidelines underscore a longitudinal, patient-centered approach to kidney replacement therapy planning that incorporates a patient's medical circumstances, life goals, individual preferences, and social support across the continuum of CKD and end-stage kidney disease (ESKD) care.⁹⁹

⁹² Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbenyikey, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

⁹³ Dahlerus, C., Carlozzi, N. E., Hirth, R. A., Price, K., Sardone, J., Miner, J. A., Segal, J. H., Andress, J., Roach, J., Balovlenkov, E., Clark, S., & Messana, J. M. (2025). Conceptual Development Informing the Kidney Failure Patient Life Goals Survey. *Kidney medicine*, 8(2), 101203. <https://doi.org/10.1016/j.xkme.2025.101203>.

⁹⁴ Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbenyikey, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

⁹⁵ Dahlerus, C., Carlozzi, N. E., Hirth, R. A., Price, K., Sardone, J., Miner, J. A., Segal, J. H., Andress, J., Roach, J., Balovlenkov, E., Clark, S., & Messana, J. M. (2025). Conceptual Development Informing the Kidney Failure Patient Life Goals Survey. *Kidney medicine*, 8(2), 101203. <https://doi.org/10.1016/j.xkme.2025.101203>.

⁹⁶ Ladin, K., Lin, N., Hahn, E., Zhang, G., Koch-Weser, S., & Weiner, D. E. (2017). Engagement in decision-making and patient satisfaction: a qualitative study of older patients' perceptions of dialysis initiation and modality decisions. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 32(8), 1394–1401. Available at <https://doi.org/10.1093/ndt/gfw307>.

⁹⁷ Ladin, K., Lin, N., Hahn, E., Zhang, G., Koch-Weser, S., & Weiner, D. E. (2017). Engagement in decision-making and patient satisfaction: a qualitative study of older patients' perceptions of dialysis initiation and modality decisions. *Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association*, 32(8), 1394–1401. Available at <https://doi.org/10.1093/ndt/gfw307>.

⁹⁸ Chan, C. T., Blankestijn, P. J., Dember, L. M., Gallieni, M., Harris, D. C. H., Lok, C. E., Mehrotra, R., Stevens, P. E., Wang, A. Y., Cheung, M., Wheeler, D. C., Winkelmayer, W. C., Pollock, C. A., & Conference Participants (2019). Dialysis initiation, modality choice, access, and prescription: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney international*, 96(1), 37–47. Available at <https://doi.org/10.1016/j.kint.2019.01.017>.

⁹⁹ Lok, C. E., Huber, T. S., Lee, T., Shenoy, S., Yevzlin, A. S., Abreo, K., Allon, M., Asif, A., Astor, B. C., Glickman, M. H., Graham, J., Moist, L. M., Rajan, D. K., Roberts, C., Vachharajani, T. J., Valentini, R. P., & National Kidney Foundation

Incorporating patient life goals into care planning also aligns with current CMS and HHS priorities to empower beneficiaries, strengthen shared decision-making, and improve health outcomes through person-centered approaches to care delivery.^{100 101}

2. Measure Overview

The D-PaLS PRO-PM assesses patients' satisfaction with whether and how their care team discusses life goals as part of treatment planning.¹⁰² The D-PaLS PRO-PM self-report survey captures patient-reported experiences and allows for facility-level comparison of facility engagement in patient life goals discussions.¹⁰³ The D-PaLS PRO-PM survey contains a total of eight items and takes approximately 2 minutes to complete.¹⁰⁴ The survey includes example life goals that patients may consider when reflecting on their own life goals; however, the list of goals is not intended to be exhaustive and is included only as examples. Selecting or completing these goals is optional as they are not scored or evaluated. There are six Likert-type items¹⁰⁵, including: (1) whether at least one member of the dialysis care team knows about the patient's life goals; (2) whether the patient believes it is important that a

member of the care team discuss life goals with them; (3) whether the patient's treatment plan is consistent with their life goals; (4) whether a member of the care team talks with the patient about their life goals; (5) whether the patient is comfortable discussing changes in life goals with a member of the care team; and (6) whether a member of the care team helps the patient meet their life goals. These six Likert-type items are used to generate a patient-level "quality of facility care team discussion" quality score as described later in this rule. These six items form the quality score, while the final survey item is not scored and is included to provide additional contextual information regarding dialysis care team members with whom the patient reports discussing their life goals. For further information regarding the full survey instrument, including the specific Likert-type items, please refer to <https://p4qm.org/measures/3742>.

The population for this measure is patients on chronic dialysis in the U.S. who are at least 18 years old at the time of the survey and includes all payer types. The survey tool is available to dialysis patients in both U.S. English and in Spanish. Scoring for the D-PaLS PRO-PM is based on responses to the six individual Likert-type items that are used to generate a patient-level t-score. Response options for each item are scored from 1 to 5, with higher scores indicating greater patient agreement that the dialysis care team engages in discussions about the patient's life goals and treatment planning. For each patient at a given facility, the t-score represents a patient's perceptions of their satisfaction with their dialysis care team discussions about life goals, with t-scores greater than 40 indicating average or above average satisfaction with those discussions. The overall D-PaLS PRO-PM is calculated as the percentage of patients at a facility with a t-score greater than 40 (the facility level quality score).

The D-PaLS PRO-PM is not designed to evaluate individual life goals or whether patients achieve those goals; rather, the measure reflects the percentage of patients at a facility who report at least average satisfaction with discussions about life goals with their dialysis care team and the incorporation of those discussions into treatment planning. The intent of the D-PaLS PRO-PM is for the survey tool to be offered to patients for self-administration, with de-identified results and feedback provided to dialysis facilities. For additional details on the measure specifications, please

refer to <https://p4qm.org/prmr-measures/muc2025-011>.

3. Solicitation for Public Comment

We sought public comment on the potential inclusion of the D-PaLS PRO-PM in the ESRD QIP and on the following considerations:

- Would inclusion of the D-PaLS PRO-PM provide valuable information on the extent to which facilities are asking about life goals and incorporating those discussions into treatment planning?
- What concrete approaches could dialysis facilities use to operationalize life-goal discussions on a regular basis into care planning, addressing barriers to care, modality selection including kidney transplantation, vascular access decisions, and other ESRD treatment decisions?
- To what extent can survey burden be minimized for patients while maintaining meaningful patient-reported outcomes around patient life goals discussions?
- What factors may affect patient participation or survey completion rates, and what strategies could CMS consider to encourage meaningful participation and high response rates across patients?

• What strategies could mitigate potential barriers to regular discussions of patient life goals (such as resource constraints, workflow integration, patient engagement and education) and support meaningful integration of these discussions into treatment planning?

• In addition to electronic delivery via email/text directly to patients, are there additional methods of delivery CMS should consider, for example for patients who may not access a computer or cell phone?

• What strategies could CMS use to capture information on patients who may be cognitively impaired or need a proxy to complete the survey?

We received public comments on this RFI. The following is a summary of the comments we received and our responses.

Comment: Many commenters provided feedback in response to our request for public comment on the potential inclusion of the D-PaLS PRO-PM in the ESRD QIP.

Many commenters supported the potential inclusion or continued development of the D-PaLS PRO-PM, emphasizing the importance of incorporating patients' life goals, preferences, and priorities into dialysis care and treatment planning. Commenters stated that the measure should assess meaningful engagement and whether patient priorities are

(2020). KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. American journal of kidney diseases: the official journal of the National Kidney Foundation, 75(4 Suppl 2), S1–S164. Available at <https://doi.org/10.1053/j.ajkd.2019.12.001>.

¹⁰⁰ Centers for Medicare & Medicaid Services. (2025). Strategic Direction: CMS Innovation Center 2025 Strategy to Make America Healthy Again. Available at <https://www.cms.gov/priorities/innovation/about/strategic-direction>.

¹⁰¹ U.S. Department of Health and Human Services. (2025). HHS Priorities. Available at <https://www.hhs.gov/about/priorities/index.html>.

¹⁰² The D-PaLS PRO-PM was included in the 2023 and 2024 Measures Under Consideration (MUC) lists (MUC2023–138 and MUC2025–011, respectively) for inclusion in the ESRD QIP. The 2023 MUC list is available at <https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx>. The 2025 MUC list is available at <https://mmshub.cms.gov/sites/default/files/2025-MUC-List.xlsx>.

¹⁰³ For additional information on the ESRD QIP measure domains and domain weights please refer to section IV.B.5. of this final rule.

¹⁰⁴ Dahlerus, C., Carlozzi, N. E., Price, K., Miner, J. A., Hirth, R. A., Gremel, G., Han, P., Zhang, W., Sardone, J., Roach, J., Agbeniyeky, W., Clark, S. L., Horton, G., Yaldo, A., & Messana, J. M. (2025). Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities. *Kidney medicine*, 7(4), 100972. <https://doi.org/10.1016/j.xkme.2025.100972>.

¹⁰⁵ "Likert-type items" refer to individual survey questions with ordered categorical response options that capture gradations of opinion or experience, such as "strongly disagree," "disagree," "neither agree nor disagree," "agree," and "strongly agree." For further information regarding the full survey instrument, including the specific Likert-type items, please refer to <https://p4qm.org/measures/3742>.

incorporated into care rather than whether a discussion was simply documented. A few commenters emphasized that life-goal discussions should consider patients as whole individuals and may include priorities such as work, family responsibilities, independence, travel, quality of life, treatment burden, and other goals that matter to the patient.

Commenters supporting the measure also recommended that implementation support continuous shared decision-making and meaningful interdisciplinary follow-up on patient-identified goals and barriers. Several commenters recommended minimizing survey burden, providing accessible and non-digital administration options, accommodating language and accessibility needs, involving family members or caregivers when requested, and continuing to involve patients and caregivers in measure testing. A few commenters recommended additional testing and evaluation of feasibility, validity, representative response rates, meaningful use of results, and response disparities before linking payment to the measure.

Many commenters raised concerns about including the D-PaLS PRO-PM in the ESRD QIP at this time. Commenters cited insufficient evidence regarding facility-level validity and reliability, patient and administrative burden, patient readiness, factors outside facilities' control, and uncertainty about whether measure results would be actionable or improve care. Several commenters recommended additional testing and evidence that the measure leads to meaningful improvements in care before considering it for the ESRD QIP. A commenter also stated that the underlying measure previously failed the required evidence criterion during consensus-based review, and that the current version has not been endorsed by a CBE.

A few commenters opposing the measure also noted that patient goals and preferences are already addressed through individualized care planning under the ESRD Conditions for Coverage and questioned the added value of a separate payment-linked measure. A commenter recommended focusing measurement on actionable factors within facility control, such as treatment modality, frequency, scheduling, and time on treatment. A few commenters expressed concern about asking patients to identify goals or barriers that facilities may lack the resources or ability to address and emphasized the importance of patient readiness and flexibility in when and how life-goal discussions occur. A

commenter recommended beginning the patient-reported assessment 45 to 60 days after dialysis initiation to account for patient readiness.

Other commenters offered additional considerations for future measure development. A commenter recommended minimizing administrative burden and preserving flexibility for clinicians so that a scored survey does not make life-goal discussions more rigid or unnecessarily lengthy or take time away from direct patient care. Another commenter supported incorporating patient-defined goals into quality assessment but cautioned that the measure should not influence end-of-life decision-making or use life-expectancy or quality-of-life considerations to affect access to ESRD care.

Response: We appreciate all of the comments and recommendations on this topic. While we are not responding to specific comments submitted in response to this RFI in this final rule, we believe that this input is valuable and will continue to take commenters' concerns, recommendations, and suggestions into account as we consider future implementation of the D-PaLS PRO-PM and development of other patient-centered measure concepts for the ESRD QIP.

V. Requests for Information on Advancing Alternative Dialysis Care in Accordance With Executive Order 13879

A. Background and Overview

On July 10, 2019, President Trump issued Executive Order (E.O.) 13879, *Advancing American Kidney Health*, directing Federal agencies to advance policies that increase patient choice through affordable alternative treatments for ESRD. Despite having a wide range of individual needs and preferences, most dialysis patients in the United States continue to receive their care three times per week in an outpatient renal dialysis facility. E.O. 13879 specifically identifies that greater rates of home dialysis will improve quality of life and care for patients with ESRD.

The ESRD PPS, implemented on January 1, 2011, established a bundled per-treatment payment for outpatient renal dialysis services furnished by ESRD facilities. While this system has served as the foundation of Medicare's ESRD payment framework for over a decade, the landscape of ESRD care delivery has evolved considerably. Advances in clinical practice, such as home dialysis technology, increased attention to the needs of beneficiaries

approaching end-of-life, and growing clinical evidence supporting more flexible dialysis schedules, create opportunities to consider fundamental changes to Medicare's payment and coverage frameworks for ESRD and AKI care that could better support high-quality, patient-centered care across all dialysis modalities, settings, and patient populations.

In this section, we solicited public comment on several interrelated areas where potential payment and coverage policy changes could better align the ESRD PPS and AKI payment frameworks with the goals of E.O. 13879 and the evolving needs of ESRD beneficiaries. Specifically, we sought input on the following: (1) policies to promote greater use of home dialysis among Medicare beneficiaries; (2) approaches to strengthen care continuity and expand beneficiary choice of renal dialysis services that could be considered palliative in nature for beneficiaries approaching end-of-life; and (3) changes to the ESRD PPS to support greater flexibility for patients and nephrologists to use alternative dialysis schedules.

In the CY 2027 ESRD PPS proposed rule, we noted that these RFIs are intended solely to gather information and are not proposals for specific regulatory changes (91 FR 38848). Information received in response to these RFIs will be considered as CMS develops future rulemaking and policy initiatives in furtherance of E.O. 13879 and CMS's broader strategic priorities of aligning payment with value and advancing patient-centered care for Medicare beneficiaries with kidney disease. We noted that the proposals in other sections of the proposed rule are not final policy, and responders may not consider them as such when responding to the RFIs in this section.

B. Request for Information on Increasing Home Dialysis Uptake

1. Background

CMS has statutory authority under section 1881(b)(14) of the Act to implement a PPS for renal dialysis services furnished to individuals with ESRD. Under this authority, CMS established the ESRD PPS, which provides a bundled, per-treatment payment to ESRD facilities for renal dialysis services, as defined at § 413.171, furnished in outpatient settings.

The ESRD PPS base rate is adjusted to account for patient-level characteristics through case-mix adjustments, as well as for geographic differences in area wage levels through the wage index.

The payment system also includes additional adjustments and policies, such as outlier payments for high-cost cases and a training add-on payment under § 413.235(c) for home dialysis modalities. CMS's implementing regulations for the ESRD PPS are codified at 42 CFR part 413, subpart H.

Home dialysis modalities, including PD and home HD, furnish clinically appropriate beneficiaries with the opportunity to receive renal replacement therapy in the home setting. The ESRD Conditions for Coverage at 42 CFR part 494 include requirements related to modality education and patient rights.

According to the most recent United States Renal Data System (USRDS) Annual Data Report, approximately 14 to 15 percent of prevalent (all people currently on renal dialysis in the U.S., not just new starters) dialysis patients nationally are treated with home modalities, with PD accounting for most home treatments and home HD comprising a smaller proportion. CMS ESRD PPS claims and dashboard data for Medicare Fee-For-Service (FFS) beneficiaries reflect similar utilization rates among the FFS population.

Although home dialysis utilization increased between 2019 and 2021, more recent data indicate that growth has moderated. Technique failure, modality switching, workforce constraints, geographic variation, and beneficiary-level factors (lack of education, limited caregiver support, fear of treatment complexity, housing constraints, and insufficient transitional support following hospitalization) may contribute to the observed plateau in prevalence rates. Based on recent Medicare FFS data, approximately 14.5 percent of prevalent FFS dialysis beneficiaries receive dialysis via home modalities. Interested parties have emphasized that increasing home dialysis requires more than provider-facing financial incentives and must address patient experience, education, support systems, operational barriers and infrastructure. They have stated that absent additional policy changes, current growth trends would not significantly increase.

Accordingly, we solicited comment on potential approaches, consistent with our statutory authority under section 1881 of the Act and implementing regulations at 42 CFR part 413, subpart H, that could increase home dialysis utilization among Medicare FFS ESRD beneficiaries. We sought public comment on policy, payment, operational, and regulatory changes within the ESRD PPS, and in coordination with other Medicare

payment systems, when relevant, that could increase the percentage of incident, non-pediatric, non-MA ESRD beneficiaries initiating dialysis on a home modality and remaining on that modality. For purposes of this RFI, we use the term "incident ESRD beneficiaries" to refer to OM beneficiaries who newly initiate maintenance dialysis for ESRD during a given period, consistent with CMS ESRD PPS and United States Renal Data System (USRDS) conventions.

For purposes of this RFI, we considered measuring home dialysis uptake among Medicare FFS ESRD beneficiaries defined as those initiating home dialysis and remaining on that modality for at least 60 days, excluding pediatric ESRD patients, as defined in § 413.171. This continuation threshold is intended to ensure sustained modality selection and prevent short-term initiation from inflating performance measurements.

We note that increasing overall home dialysis prevalence depends largely on influencing modality selection at initiation. Therefore, we were particularly interested in policies that would affect modality choice at or before the start of dialysis.

We did not propose a specific numeric benchmark for the share of Medicare FFS ESRD beneficiaries who receive home dialysis. Instead, we sought comment on actionable policy changes that could measurably increase the number of incidences ESRD PPS beneficiaries select and sustain home dialysis. The RFI noted that commenters may wish to address how incremental increases in initiation rates would translate into additional incident ESRD beneficiaries selecting home modalities annually.

CMS emphasized that modality selection must remain clinically appropriate and consistent with patient choice protections under § 494.70.

2. Medicare FFS Baseline and Illustrative Modeling Framework

For purposes of informing public comment, CMS provided the following illustrative Medicare FFS baseline:

Approximately 220,000 chronic ESRD patients captured under the ESRD PPS receive renal dialysis services annually. At a home dialysis prevalence rate of approximately 14.5 percent, roughly 31,900 Medicare FFS beneficiaries with ESRD currently receive home dialysis.

We sought comment on the feasibility of achieving a significant increase in utilization of the home dialysis modality for ESRD PPS patients.

3. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI on increasing home dialysis uptake. Topics upon which we asked questions included barriers to home dialysis, kidney disease education (KDE), home dialysis training, staff-assisted home dialysis, payment for home dialysis, home dialysis machine installation, in-center self-dialysis, improving access to home dialysis, and interactions with other payment systems and sites of care. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38849).

We received 50 comments in response to the RFI on home dialysis uptake. Commenters included ESRD patients and caregivers; patient and consumer advocacy organizations; ESRD facilities and dialysis organizations, including large dialysis organizations and regional chains; SNF providers and interested parties; professional and trade associations; health systems; device manufacturers; MedPAC; and other parties and experts interested in kidney care. Commenters generally supported efforts to increase appropriate access to and sustained use of home dialysis, while emphasizing that policies must support informed beneficiary choice, clinical appropriateness, and the services needed to initiate and sustain home modalities rather than focus primarily on numerical utilization targets. Commenters frequent recommendations included that CMS: (1) strengthen kidney disease and modality education through earlier, repeated, individualized, unbiased, and culturally and linguistically appropriate education, including opportunities for beneficiaries who initiate dialysis emergently to reconsider home modalities; (2) establish payment or coverage for temporary or ongoing staff-assisted home dialysis, respite and backup support, retraining, and enhanced clinical or technical support to help beneficiaries initiate and remain on home dialysis when health, function, or caregiver availability changes; (3) address financial and practical barriers, including utility and broadband costs, home modifications, housing and storage constraints, supply delivery and disposal, transportation, equipment usability, and caregiver burden; (4) strengthen home dialysis training and workforce capacity and align payment with competency-based training and retraining, qualified staffing, care coordination, practitioner involvement, remote monitoring, and program infrastructure; and (5) align payment, regulatory, and quality policies to

support home dialysis capacity, access, and retention, including appropriate access in SNFs and transitional settings, while preserving modality neutrality and beneficiary choice.

Commenters also raised recurring concerns about policies intended to increase home dialysis utilization. These include concerns related to: (1) numerical targets or incentives tied primarily to home dialysis uptake could steer ESRD beneficiaries toward a modality that is not clinically appropriate or preferred and could disadvantage ESRD facilities serving medically or socially complex patients; (2) expansion without adequate support could shift treatment, financial, technical, and caregiving burdens to ESRD beneficiaries and unpaid caregivers; (3) workforce flexibility that weakens qualification, competency, or supervision standards could create patient-safety risks, with several commenters emphasizing continued qualified nephrology RN oversight; (4) budget-neutral financing or redistribution within the ESRD PPS could reduce resources for existing renal dialysis services or weaken investment in home dialysis capacity; and (5) staff-assisted home dialysis and other new supports could create cost, workforce, safety, duplicative-payment, or overutilization risks without clear eligibility criteria, clinical safeguards, accountability, and evaluation.

We thank the commenters for their thoughtful responses to our RFI on increasing home dialysis uptake and will consider them when developing any potential future policy. Any change in policy would be proposed in future notice and comment rulemaking.

C. Request for Information To Advance Palliative Care for Dialysis Patients

1. Background

a. Statutory and Regulatory Framework

Section 1881 of the Act establishes Medicare coverage and payment for renal dialysis services furnished to individuals with ESRD. CMS implemented the ESRD PPS beginning January 1, 2011 (75 FR 49030), which provides a bundled, per-treatment payment for renal dialysis services, including certain drugs, biologicals, laboratory services, and supplies.

The hospice benefit, established under section 1814(i) of the Act, provides a per diem payment to hospice providers for all items and services related to the palliation and management of the terminal illness and related conditions. Under current policy, services related to the terminal

condition are not separately payable outside the hospice benefit.

b. ESRD PPS and Current Payment Policy

Under the ESRD PPS, Medicare pays a single bundled amount for dialysis treatments furnished in-center or at home. This payment is intended to cover all renal dialysis services as defined in regulation at § 413.171.

Dialysis is life-sustaining but not curative. While it may be furnished consistent with palliative goals of care, current Medicare policy does not distinguish between maintenance dialysis and dialysis furnished in a comfort-focused context. As a result, payment policy does not explicitly account for palliative care objectives within ESRD treatment.

c. Interaction With the Hospice Benefit

When ESRD is the terminal condition, hospice providers are responsible for furnishing dialysis services within the hospice per diem payment. Because dialysis is a high-cost service, it is rarely furnished under the hospice benefit in practice.¹⁰⁶ As a result, beneficiaries with ESRD often delay or forgo hospice services to continue receiving renal dialysis services under the ESRD PPS.

MedPAC reported relatively low rates of hospice utilization among ESRD beneficiaries and noted that dialysis costs may represent a substantial share of hospice payments if furnished within the hospice benefit.¹⁰⁷ MedPAC also highlighted the potential for improved care coordination and reduced end-of-life spending when ESRD beneficiaries receive hospice services.

d. Home Dialysis and Structural Barriers

Current policy requires that home dialysis be performed independently by the ESRD beneficiary or with the assistance of an unpaid caregiver. Medicare does not routinely pay for ongoing staff assistance in the home for dialysis treatments. This may create access barriers for beneficiaries with functional impairments, frailty, or lack of caregiver support.

These barriers may be particularly relevant for ESRD beneficiaries with palliative care goals who may benefit from receiving renal dialysis services in a home-based, lower-burden setting.

¹⁰⁶ Schell JO, Johnson DS. Challenges with Providing Hospice Care for Patients Undergoing Long-Term Dialysis. *Clin J Am Soc Nephrol*. 2021 Mar 8;16(3):473–475. doi: 10.2215/CJN.10710720. Epub 2020 Oct 9. PMID: 33037019; PMCID: PMC8011021.

¹⁰⁷ <https://www.medpac.gov/wp-content/uploads/2025/09/Tab-F-Hospice-ESRD-cancer-Sept-2025-SEC.pdf>.

e. Policy Considerations and Prior Rulemaking Context

In prior ESRD PPS rulemaking (see, for example, 84 FR 60648 through 60652), CMS emphasized goals of promoting home dialysis, improving patient experience, and supporting high-quality, patient-centered care. CMS also sought to maintain the integrity of prospective payment systems and avoid duplicative payment.

Consistent with these goals, CMS is exploring whether refinements to payment policy could improve access to palliative dialysis while maintaining the following: ESRD PPS bundled payment integrity; Hospice per diem integrity; and appropriate safeguards against duplicative payment and program integrity risks.

3. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI to advance palliative care for dialysis patients. Topics upon which we asked questions included the definition of palliative dialysis, eligibility, care delivery, payment considerations, program integrity, and potential policy approaches. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38852).

CMS received 29 comments on the RFI on palliative care for dialysis patients. Commenters included patient advocates, hospice and palliative-care organizations, professional associations, dialysis organizations, health systems, MedPAC, and other interested parties. Commenters generally supported improving access to goal-concordant dialysis, that is, dialysis provided in a way that reflects the patient's needs, goals, and wishes, including goals related to comfort and quality of life, and reducing barriers to hospice, but differed on eligibility, treatment limits, payment, and terminology.

Areas of greatest agreement were an intent-based definition, shared decision-making and documented goals, clear provider roles, payment that does not place the full cost of dialysis on the hospice per diem, and quality policies aligned with palliative goals. Key areas of disagreement were terminology, prognosis and eligibility thresholds, treatment or time limits, payment methodology, and whether policy should proceed through demonstrations or broader national changes.

Some of the specific recommendations we received included: (1) that CMS should define palliative dialysis by treatment intent and patient goals as commenters generally favored a definition centered on symptom relief,

comfort, quality of life, function, treatment burden, and documented goals rather than modality, frequency, or duration; (2) that CMS should permit concurrent hospice and renal dialysis services without requiring hospices to absorb dialysis costs as many commenters identified the hospice per diem as the primary access barrier when ESRD is the terminal condition and favored separate or direct payment to the ESRD facility; (3) that CMS should base eligibility and safeguards on shared decision-making and a documented care plan focusing on documenting patient goals, expected benefits and burdens, provider roles, and reassessment, with clinical, functional, frailty, and prognostic factors generally serving as screening tools; (4) that commenters generally favored ESRD facilities retaining dialysis-specific responsibilities and hospices retaining responsibility for the hospice plan of care, supported by shared care plans, designated contacts, information exchange, and cross-provider education; (5) that maintenance-dialysis measures and payment incentives may conflict with individualized palliative care and recommended protections or measures focused on symptoms, treatment burden, goal concordance, patient experience, and avoidable acute care.

Commenters also noted several concerns, which include: (1) that ESRD beneficiaries may postpone or decline hospice to preserve access to renal dialysis services, resulting in shorter hospice stays and potentially greater distress and acute-care use; (2) that the hospice per diem generally cannot absorb dialysis costs, while emphasizing the need for clear payment boundaries across the ESRD, hospice, and home health benefits; (3) differing opinions on the appropriate role of hospice eligibility, prognosis, frailty, and functional decline, with many cautioning against criteria that are either too restrictive or too broad; (4) that there were several barriers including separate care plans and records, contracting, transportation, scheduling, vascular-access management, medication responsibility, and differing regulatory requirements; and (5) that maintenance-oriented quality measures may discourage palliative treatment changes, while some payment models could create undertreatment risk.

We thank the commenters for their thoughtful responses to our RFI on palliative care for dialysis patients and will consider them when developing any potential future policy. Any change in policy would be proposed in future notice and comment rulemaking.

D. Requests for Information on Potential Payment Changes To Support Alternative Dialysis Schedules

1. Background

Section 1881(b)(14)(C) of the Social Security Act (the Act) authorizes payment under the ESRD PPS based on renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. When we implemented the ESRD PPS beginning January 1, 2011, we established payment on a per-treatment basis (75 FR 49064). In developing that policy, we considered other units of payment, including a monthly ESRD PPS, which would provide ESRD facilities more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis services. However, given the difficulties of implementing a monthly ESRD PPS during the transition period in which a per-treatment methodology applied, we chose to continue the per-treatment payment methodology that had been in effect under the composite rate system prior to the ESRD PPS (75 FR 49064). That transition period concluded on December 31, 2013.

In the CY 2011 ESRD PPS final rule, we noted that MedPAC recommended that we reconsider the unit of payment once a strengthened dialysis quality monitoring system is implemented, to ensure that quality of care does not decline (75 FR 49064). In its comments on the CY 2011 ESRD PPS proposed rule, MedPAC noted that a larger unit of payment would be consistent with several aspects of dialysis care, pointing out that a weekly unit of payment corresponds to the typical weekly interval for PD. MedPAC also noted that Medicare pays nephrologists a monthly capitated payment for caring for dialysis beneficiaries (75 FR 49064). Since that time, the ESRD Quality Incentive Program (QIP) and the Five-Star Quality Rating System for ESRD facilities have been established and are well-functioning, addressing the quality monitoring concern MedPAC identified.

2. Current ESRD PPS Payment Methodology and Considerations for Potential Changes to the ESRD PPS Unit of Payment

Although the ESRD PPS unit of payment is a treatment, renal dialysis services are billed monthly. In addition, the ESRD PPS currently makes a daily rate payment, which is effectively a prorated monthly payment, for certain renal dialysis services. Specifically,

home Continuous Ambulatory PD (CAPD) and Continuous Cycling PD (CCPD) are paid daily for the number of PD days billed in the month, following the payment approach for this modality that has been in place since the inception of the composite rate payment system in 1983. For home ESRD patients undergoing PD, the number of days of PD, regardless of the number of dialysate exchanges performed each day, is converted to home HD-equivalent sessions by dividing the number of PD days by 7 and multiplying the result by 3 (see Medicare Benefit Policy Manual, Chapter 11). For example, a patient receiving 30 days of home CAPD would be paid an amount equal to 12.857 home HD-equivalent treatments ($30 \div 7 \times 3 = 12.857$). This approach creates a per-treatment amount that is paid for each day of PD treatment and that complies with the monthly treatment payment limit of 13 treatments in a 30-day month and 14 treatments in a 31-day month (81 FR 42809).

This existing methodology demonstrates that a daily rate structure is operationally feasible within the current ESRD PPS framework and has been successfully administered by MACs for over 4 decades. When considering alternative units of payment for the ESRD PPS, a daily payment rate is effectively the same as a prorated monthly payment rate, which functions identically to a monthly payment rate in the case that an ESRD facility bills for a full month, but also offers additional flexibility. Importantly, the daily rate payment allows for more flexible payment for renal dialysis services during service interruptions such as hospitalizations. A daily rate payment could also provide flexibility when a patient temporarily receives renal dialysis services at a different ESRD facility than their usual ESRD facility.

In recent public comments, interested parties have further noted that some renal dialysis services do not directly correspond to a dialysis treatment. For example, oral phosphate binders, which were incorporated into the ESRD PPS bundled payment beginning January 1, 2025, through the TDAPA, and which we are including in the ESRD PPS base rate beginning in CY 2027, are typically taken daily with meals and often follow irregular dosing schedules. Other oral drugs, as well as clinical interventions such as patient education, access management, and nutrition management, may occur outside the boundaries of a dialysis session. Furthermore, alternative treatment options—such as in-center self-dialysis, nocturnal dialysis, and more frequent

home HD, or more conservative approaches for renal care which may not focus on dialysis—may involve treatment schedules that align more naturally with a monthly unit of payment than with the current per-treatment payment structure.

These considerations lead us to examine whether a change to the unit of payment for the ESRD PPS could more appropriately recognize patient-specific needs and better align payment with overall resource use, while continuing to advance the principles of prospective payment and the goals of Executive Order 13879, *Advancing American Kidney Health*. A monthly (or daily rate) unit of payment could offer meaningful administrative simplification for ESRD facilities. Under the current system, facilities must obtain and document additional medical justification when an ESRD patient's clinical needs require more than 3 treatments per week. These requirements impose administrative burden on ESRD facilities of all sizes, and may be particularly challenging for smaller, independent ESRD providers with limited billing infrastructure. A daily rate structure would eliminate the need for the $\frac{3}{7}$ conversion, reduce the complexity of tracking monthly treatment limits (13 or 14 per month depending on month length), and simplify billing for ESRD patients who receive care at multiple ESRD facilities or experience service interruptions. ESRD facilities would bill for actual days of service provided, creating a more direct and transparent relationship between care delivery and payment.

Beyond administrative simplification, a daily rate structure could better support patient-centered care by reducing financial disincentives associated with alternative dialysis schedules. Under the current per-treatment payment structure, the ESRD PPS was designed around a conventional thrice-weekly home HD schedule. As noted in the CY 2011 ESRD PPS final rule, CMS recognized that a monthly unit of payment would provide ESRD facilities with more flexibility in alternative treatment requirements, such as increased frequency nocturnal dialysis, home HD using compact portable dialysis machines, and shorter but more frequent dialysis services (75 FR 49064). A daily rate structure could reduce the rigidity of the current payment framework and better support individualized treatment plans developed collaboratively by patients and their nephrologists, without creating financial incentives to adhere to a fixed treatment schedule when a patient's clinical needs call for a different approach. For patients who

would benefit from more frequent renal dialysis services—such as those with fluid management challenges, cardiovascular comorbidities, or a preference for shorter, more frequent sessions—a daily payment structure could remove a structural barrier to accessing those options.

At the same time, we recognize that such a change would represent a significant operational shift for ESRD facilities, MACs, and CMS systems, and would require careful consideration of how to maintain budget neutrality, preserve payment equity across modalities, protect beneficiary access to care, and ensure that payment incentives continue to support high-quality, appropriate care. We are mindful that any change to the unit of payment must be designed to ensure that patients receive all medically necessary services and that ESRD providers are not inadvertently incentivized to reduce the frequency or intensity of care. We sought public input on how a daily payment structure could be designed and monitored to achieve these goals.

4. Request for Information

In the CY 2027 ESRD PPS proposed rule we issued an RFI on potential payment changes to support alternative dialysis schedules. Topics upon which we asked questions included the appropriateness and calibration of a daily payment rate, administrative burden and operational impacts on facilities, safeguards to prevent underutilization of medically necessary care, and how a new payment structure could affect billing, budget neutrality, and outlier policy. For a full list of questions included in the RFI we invite readers to see the proposed rule (91 FR 38854).

CMS received 16 comments on the RFI on potential payment changes to support alternative dialysis schedules. Commenters expressed a wide range of views in response to this RFI. Some commenters wrote that they did not support the change at all, arguing that a monthly system could lead facilities to reduce services to the minimum necessary to receive full payment, and that it would introduce new complications, such as accounting for partial months of service in the event of travel or hospitalization. Other commenters questioned whether the change was necessary in the first place, writing that it was not clear how modifying the payment cadence would meaningfully improve patient outcomes or support innovation, and separately noted that revising the payment structure to address a comparatively

small group of ESRD patients who need less-frequent renal dialysis services could risk health outcomes for the larger population that requires thrice-weekly treatment.

Other commenters took a more conditional stance. Some wrote in support of exploring payment approaches that could better accommodate individualized and alternative dialysis schedules, while stipulating that any change must include explicit safeguards ensuring ESRD patients retain timely access to medically necessary extra in-center treatments. A commenter stated that a per-treatment unit may be a reasonable fit for conventional, episodic dialysis care but could become a less natural fit for future therapies prescribed for longer, more frequent, nocturnal, portable, or continuous use. This commenter suggested that Medicare evaluate future authorized therapies based on their prescribed use, safety, outcomes, and total cost of care rather than requiring them to conform to a facility-based billing schedule. Another commenter wrote that, since medical justification is already required for a facility to receive payment for additional treatments, changing to a daily rate calculated as three-sevenths of the per-treatment base rate would have limited practical impact, and separately observed that the current per-treatment system already discourages clinically appropriate twice-weekly dialysis schedules due to lost revenue on unfilled treatment slots and potential risk of penalties under the IPFQR program. A commenter noted that nephrologists often set thrice-weekly dialysis as an early expectation for patients, in part to avoid the more difficult conversation of persuading patients to increase treatment frequency later as residual kidney function declines.

A subset of commenters called for more extensive analysis, such as a Technical Expert Panel or a similar formal review process before any further action, citing the methodological complexity and significance of a potential change to the payment unit.

We thank the commenters for their thoughtful responses to our RFI on potential payment changes to support alternative dialysis schedules. We will take these comments into consideration when developing any potential future policy through notice and comment rulemaking.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we

are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

A. ESRD QIP—Wage Estimates

We refer readers to the CY 2026 ESRD PPS final rule for information regarding previously used wage estimates and resulting information collection burden calculations used in this final rule (90 FR 53121 through 53122). To derive wage estimates, we used data from the United States Bureau of Labor Statistics' May 2025 National Occupational Employment and Wage Estimates for Medical Records Specialists, who are responsible for organizing and managing health information data, and are tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist (SOC 29–2072) was \$24.59 per hour.¹⁰⁸ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance

on estimating the cost of fringe benefits and overhead. Using these assumptions, we estimated an hourly labor cost of \$49.18 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimates for the total information collection burden in the ESRD QIP for PY 2029. We provide the re-estimated information collection burden to reflect updated facility and patient counts in this final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2029

We refer readers to the CY 2026 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2028 (90 FR 53122).

1. Estimated Burden Associated With EQRS Data Validation Requirements for PY 2029

In this final rule, using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2029 will be approximately \$36,885 (750 hours × \$49.18), or an annual total of approximately \$122.95 (\$36,885/300 facilities) per facility in the sample. We include the updated aggregate cost of EQRS data validation to reflect updated wage estimates in this final rule. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289).

2. Estimated Burden Associated With NHSN Data Validation Requirements for PY 2029

In this final rule, we estimate that the aggregate cost of the NHSN data validation for PY 2029 will be approximately \$73,770 (1,500 hours × \$49.18), or a total of approximately \$245.90 (\$73,770/300 facilities) per facility in the sample. We included the updated aggregate cost of NHSN data validation to reflect updated wage estimates in this final rule. The burden cost updates associated with these requirements will be submitted to OMB as a revision of the information collection request currently approved under OMB control number 0938–1340.

C. Estimated EQRS Reporting Requirements for PY 2029

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 will 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 2026 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2028 ESRD QIP was approximately \$125 million for approximately 2,588,770 total burden hours (90 FR 53122).

We are finalizing measure updates in this final rule that will affect the burden associated with EQRS reporting requirements beginning with PY 2029. We are finalizing two measure removals and one measure adoption that will affect the burden associated with EQRS reporting requirements beginning with PY 2029. We provide the burden estimate for PY 2029 in this final rule to reflect the impact of these policies and include the updated information collection burden to reflect updated facility and patient counts in this final rule. In this final rule, we estimate that the amount of time required to submit measure data to EQRS will be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 109 data elements for 512,458 patients across 7,551 facilities, for a total of 55,857,922 elements across all patients (109 data elements × 512,458 patients). At 2.5 minutes per element, the changes will yield approximately 308 hours per facility for a total PY 2029 burden of 2,327,413 hours. Using the Medical Records Specialist wage estimates available at this time, we estimate that the PY 2029 total burden cost will be approximately \$114.5 million (2,327,413 hours × \$49.18). The estimated reduction in burden associated with the measure updates is described in Table 29.

¹⁰⁸ Bureau of Labor Statistics. (May 2026). U.S. Department of Labor, Occupational Outlook Handbook, Medical Records Specialists. Available at <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.

**TABLE 29: Updated Estimated Reduction in Burden Associated with Measure Updates
Beginning with the PY 2029 ESRD QIP**

Requirement	Per Facility		All Facilities	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Adoption of the Hyperphosphatemia Clinical Measure	135.73	\$6,675.32	1,024,916	\$50,405,369
Removal of the Hypercalcemia Reporting Measure	-67.87	-\$3,337.66	-512,458	-\$25,202,684
Removal of the MedRec Reporting Measure	-101.80	-\$5,006.49	-768,687	-\$37,804,027
Total Change in Information Collection Burden Hours: -256,229				
Total Cost Estimate: Updated Hourly Wage (\$49.18) x Change in Burden Hours (-256,229) = - \$12,601,342				

The information collection request currently approved under the OMB control number 0938-1289 will be revised and submitted to OMB for approval.

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 ESRDB market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule finalizes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and rebases and revises the ESRDB market basket and labor-related share. This rule also finalizes policy changes to the ESRD PPS for CY 2027, including updates to our ESRD PPS wage index, outlier threshold, TPNIES offset amount, and post-TDAPA add-on payment adjustment amounts to reflect the latest available data for Korsuva®, DefenCath®, and Vafseo®. We are also finalizing changes to increase the ESRD PPS base rate to account for the addition of phosphate binders into the ESRD PPS bundled payment, changes to payment for pediatric ESRD patients, changes to the LVPA, changes to the home and self-dialysis training add-on, and changes to

our ASP policy for the TDAPA and post-TDAPA payment adjustment. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2027 for renal dialysis services furnished to ESRD beneficiaries.

2. AKI

This rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2027 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to 2 percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule finalizes updates for the ESRD QIP, which will replace the Hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients clinical measure. This rule also finalizes updates to the NHSN BSI clinical measure. Additionally, this rule finalizes the removal of the MedRec reporting measure and the COVID-19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with PY 2029.

B. Overall Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism,” Executive Order 13563,

“Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); 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 those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more 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, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our analysis, OMB’s Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant pursuant to section 3(f)(1) of

Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately \$190 million in ESRD PPS payments to ESRD facilities in CY 2027. This includes the estimated impact of the final ESRD PPS market basket update of 1.9 percent (\$170 million), as well as the estimated changes in payments associated with several changes that are expected between CYs 2026 and 2027. The net effect of the offsetting increases and decreases to payments, as discussed in the following paragraph, results in the estimated \$240 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

First, as discussed in section II.B.3.b. of this final rule, we estimate that outlier payments in CY 2026 will be approximately 2.6 percent of total ESRD PPS payments. Accordingly, the final increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.6 percent (\$140 million). At the same time, we estimate that approximately \$413 million will be paid through the TDAPA for DefenCath®, Vafseo®, and phosphate binders in CY 2026. The end of the TDAPA periods for these drugs is projected to result in a corresponding decrease to CY 2027 payments of 4.6 percent, which is offset by the final 4.4 percent increase to the ESRD PPS base rate for phosphate binders for a net decrease of \$40 million, and further offset by the estimated 2.9 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027 (\$260 million). The net difference between estimated CY 2026 TDAPA payments and estimated CY 2027 payments under the post-TDAPA add-on payment adjustment and the ESRD PPS base rate, including the final incorporation of phosphate binders, is therefore a 2.5 percent increase in payments to ESRD facilities ($1.044 \times 1.029 \times 0.954 = 1.025$) which equals approximately \$220 million (\$260 million – \$40 million = \$220 million). In addition, this amount includes, but is not impacted by, any budget neutral changes for CY 2027 such as the routine updates to the ESRD PPS wage index, labor-related share, and the changes to the LVPA. In addition, for public awareness, we estimate that the updated CY 2027 post-TDAPA add-on payment adjustments will total approximately \$290 million, an increase from around

\$34 million in CY 2026. These amounts are included in the estimated \$240 million overall increase in ESRD PPS payments for CY 2027, because as we previously noted the net effect of the offsetting increases and decreases to payments, as discussed in the prior paragraph, results in the estimated \$240 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

2. AKI

We estimate that the final updates to the AKI dialysis payment rate will result in an increase of approximately \$5 million in Medicare payments to ESRD facilities in CY 2027.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are finalizing in this final rule, the updated ESRD QIP will result in \$18.7 million in estimated payment reductions across all facilities for PY 2029.

4. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2027 is approximately \$245 million based on the combined estimates of the updated ESRD PPS and the AKI dialysis payment rates.¹⁰⁹ We estimate the impacts of the ESRD QIP for PY 2029 to be \$114.5 million in information collection burden and \$18.7 million in estimated payment reductions across all facilities.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the final CY 2027 ESRD PPS and AKI dialysis 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 dialysis treatments furnished by ESRD facilities by 5.6 percent based on the final CY 2027 ESRDB market basket percentage increase of 2.9 percent reduced by the

¹⁰⁹ Note: The combined estimated payment increase for the rule may not align with the sum of ESRD PPS and AKI payment estimates due to rounding.

final CY 2027 productivity adjustment of 1.0 percentage point, as well as the final increase to the ESRD PPS base rate from the inclusion of phosphate binders into the base rate, will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.7 percent and payments under the AKI payment system will increase by 5.3 percent because of the final policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rate-setting will create additional costs or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the updates in this final rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2029, we have included the updated estimated costs associated with the information collection requirements under the ESRD QIP in this final rule, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI dialysis payment rates will result in a total increase of approximately \$245 million in Medicare payments to ESRD facilities in CY 2027, which includes the amount associated with the final inclusion of phosphate binders to the base rate, the final updates to the outlier threshold amounts, and final updates to the ESRD wage index. This estimate includes an increase of approximately \$5 million in Medicare payments to ESRD facilities in CY 2027 due to the final updates to the AKI dialysis payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately \$195 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately \$50 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, which was 171 for the CY 2027 ESRD PPS proposed rule, is equal to the number of individual reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters will review this year's final rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2027 ESRD PPS proposed rule. For these reasons, we determined that the number of past commenters will be a fair estimate of the number of reviewers of this final rule. We used a similar methodology for calculating the regulatory review costs in the CY 2027 ESRD PPS proposed rule. We solicited comments on this approach.

We also recognized 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 assumed that each reviewer reads approximately 50 percent of this final rule. We sought comments on this assumption.

We did not receive public comments on this provision, and therefore, we are using our established methodology for estimating the regulatory review costs of this rule.

Using the BLS OEWS May 2025 National, cross-industry median hourly wage information for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is \$119.10 (\$59.55 * 2) per hour, including overhead and fringe benefits¹¹⁰ (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 240 minutes (4 hours) for the staff to review half of this final rule, which has a total of approximately 120,000 words. For each entity that reviews the rule, the estimated cost is \$476.40 (4 hours × \$119.10). Therefore, we estimate that the total cost of reviewing this regulation is \$81,464.40 (\$476.40 × 171 reviewers).

¹¹⁰ Calculated by multiplying the mean hourly wage for medical and health service managers (SOC 11–9111) by 2 to account for overhead and fringe benefits.

5. Impact Statement and Table

a. CY 2027 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 2026 to estimated payments in CY 2027. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2026 and CY 2027 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 use CY 2025 data from the Medicare Part A and Part B Common Working Files as of July 31, 2026, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2025 claims to 2026 and 2027 using various updates. The final updates to the ESRD PPS base rate are described in section II.B.4. of this final rule. Table 30 shows the impact of the estimated CY 2027 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2026.

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TABLE 30: Impacts of the Final Changes in Medicare Payments to ESRD Facilities for CY 2027

Facility Type	Number of Facilities (A)	Treatments (in millions) (B)	Routine Outlier Update (C)	TDAPA and Post-TDAPA (incl phosphate binder incorporation) (D)	Pediatric Changes (incl LVPA) (E)	Adult LVPA Changes (F)	Training Add-on Changes (G)	Wage Index and LRS (H)	All Changes (I)
All Facilities	7,570	24.0	-1.6%	2.5%	0.0%	0.0%	0.0%	0.0%	2.7%
Type									
Freestanding	7,238	23.1	-1.5%	2.4%	0.0%	0.0%	0.0%	0.0%	2.7%
Hospital-based	332	0.9	-4.0%	5.1%	0.1%	0.1%	-0.1%	-0.1%	2.7%
Ownership Type									
Large dialysis organization	5,841	18.6	-1.4%	3.1%	0.0%	0.0%	0.0%	-0.1%	3.5%
Regional chain	890	3.0	-2.2%	-2.6%	0.0%	-0.3%	0.0%	0.4%	-2.9%
Independent	500	1.5	-1.8%	5.9%	0.0%	0.0%	-0.1%	0.3%	6.2%
Hospital-based ¹	332	0.9	-4.0%	5.1%	0.1%	0.1%	-0.1%	-0.1%	2.7%
Unknown	7	0.0	-1.8%	6.2%	0.0%	3.9%	-0.1%	1.8%	12.1%
Geographic Location									
Rural	1,224	3.3	-1.7%	2.7%	0.0%	2.0%	0.0%	-1.1%	3.7%
Urban	6,346	20.7	-1.6%	2.5%	0.0%	-0.3%	0.0%	0.2%	2.6%
Census Region									
East North Central	1,161	3.1	-1.7%	3.0%	0.0%	0.7%	0.0%	-0.3%	3.6%
East South Central	592	1.4	-1.6%	1.9%	0.0%	0.8%	0.0%	-1.5%	1.3%
Middle Atlantic	845	3.0	-1.9%	3.3%	0.0%	-0.2%	0.0%	-0.1%	2.9%
Mountain	425	1.4	-1.2%	3.1%	0.0%	0.1%	0.0%	-0.8%	3.1%
New England	198	0.9	-1.7%	2.9%	0.0%	-0.3%	0.0%	0.6%	3.4%
Pacific ²	974	4.6	-1.3%	2.2%	0.0%	-0.7%	0.0%	1.8%	3.8%
Puerto Rico and Virgin Islands	54	0.1	-1.7%	5.9%	-0.1%	-0.9%	0.1%	0.5%	5.5%
South Atlantic	1,779	5.0	-1.7%	2.3%	0.0%	0.0%	0.0%	-0.7%	1.6%
West North Central	468	1.4	-1.7%	3.5%	0.0%	1.5%	0.0%	-0.3%	4.8%
West South Central	1,074	3.1	-1.6%	1.5%	0.0%	-0.2%	0.0%	-0.5%	0.9%
Facility Size									
Less than 3,000 treatments	556	0.4	-1.7%	4.3%	0.3%	2.6%	0.0%	-0.1%	7.4%
3,000 to 3,999 treatments	432	0.6	-1.5%	3.3%	0.0%	5.3%	0.0%	-0.4%	8.6%
4,000 to 4,999 treatments	516	0.8	-1.6%	3.1%	0.0%	6.5%	0.0%	-0.3%	9.6%
5,000 to 5,999 treatments	567	1.1	-1.7%	2.7%	0.0%	4.6%	0.0%	-0.5%	6.9%

Facility Type	Number of Facilities (A)	Treatments (in millions) (B)	Routine Outlier Update (C)	TDAPA and Post-TDAPA (incl phosphate binder incorporation) (D)	Pediatric Changes (incl LVPA) (E)	Adult LVPA Changes (F)	Training Add-on Changes (G)	Wage Index and LRS (H)	All Changes (I)
6,000 to 6,999 treatments	644	1.4	-1.6%	2.7%	0.0%	2.7%	-0.1%	-0.4%	5.2%
7,000 to 7,999 treatments	641	1.6	-1.7%	2.4%	0.0%	0.3%	0.0%	-0.3%	2.4%
8,000 or more treatments	4,214	18.1	-1.6%	2.4%	0.0%	-1.0%	0.0%	0.1%	1.8%
Percentage of Pediatric Patients									
Less than 2%	7,469	23.8	-1.6%	2.5%	0.0%	0.0%	0.0%	0.0%	2.7%
Between 2% and 49%	48	0.2	-1.3%	3.4%	-0.3%	-0.9%	0.1%	-0.5%	2.3%
More than 50%	53	0.0	-4.0%	7.2%	2.0%	-1.2%	0.0%	0.4%	6.1%

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category.

Column B indicates the number of dialysis treatments (in millions).

Column C represents the change in payment to each ESRD facility type based on the changes to the outlier FDL and MAP amounts finalized in section II.B.3. of this final rule. As we previously discussed, we estimate a 1.6 percent reduction in ESRD PPS

payments to reduce outlier payments to better align with the 1.0 percent outlier target in CY 2027. The largest projected decrease will be approximately 4.0 percent for hospital-based ESRD facilities.

Column D represents the changes in simulated payments between CY 2026 and CY 2027 due to routine changes in TDAPA eligibility for Vafseo®, which will become outlier eligible and be included in the post-TDAPA add-on payment adjustment calculation

beginning January 1, 2027, at the end of its TDAPA period, and DefenCath®, which is paid for through the TDAPA until July 1, 2026, and is included in the post-TDAPA add-on payment adjustment calculation for the third and fourth quarters of CY 2026. DefenCath® will continue to be outlier eligible and included in the post-TDAPA add-on payment adjustment in CY 2027. This column also represents the difference between simulated TDAPA payments for phosphate binders in CY 2026 and

simulated payments under the ESRD PPS base rate for these drugs in CY 2027.

Column E represents the impact of final budget neutral changes to payments for pediatric ESRD patients, including the final revisions to the pediatric case-mix adjusters as well as the final expansion of the LVPA to treatments for pediatric ESRD patients. Table 30 shows that these final policies will increase payments by 2.0 percent to ESRD facilities with 50 percent or more pediatric patients, while the largest decrease will be -0.3 percent for ESRD facilities with between 2 and 49 percent pediatric patients.

Column F represents the impact of final budget neutral changes to the LVPA. The largest estimated increase would be 6.5 percent for ESRD facilities, furnishing between 4,000 and 4,999 treatments per year. Conversely, we estimate that payments to ESRD facilities furnishing more than 8,000 treatments per year will decrease approximately 1.0 percent.

Column G represents the impact of final budget neutral changes to the home and self-dialysis training add-on, which includes the impact of the policy change to allow payment of the home and self-dialysis training add-on during the onset period and the corresponding reduction to the onset adjustment factor. We estimate these changes will have distributional impacts of 0.1 percentage point or less for nearly all categories of ESRD facilities.

Column H represents the effect of the final updates to the ESRD PPS wage index for CY 2027, including the continued application of the 5 percent cap on wage index decreases. This column also shows the effect of the update the LRS from 55.2 percent to 63.5 percent in CY 2027. These final updates will be budget neutral, so the total impact of these policy changes is 0.0 percent. However, we estimate there will be distributional impacts because of these updates. The largest increase will be to ESRD facilities in the Pacific Census region, which will receive 1.8 percent higher payments because of the updated ESRD PPS wage index and LRS. The largest decrease will be for ESRD facilities in the East South Central Census region, which will receive 1.5 percent lower payments because of the updated ESRD PPS wage index and LRS.

Column I reflects the overall impact of the policies discussed in this final rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA add-on payment adjustment amounts as well as the inclusion of phosphate binders into the

base rate, the changes to payments for pediatric ESRD patients, the LVPA changes, and the changes to the home and self-dialysis training add-on payment adjustment. This column also reflects the final ESRD PPS payment rate update for CY 2027 of 1.9 percent, which reflects the final ESRDB market basket percentage increase for CY 2027 of 2.9 percent reduced by the final productivity adjustment of 1.0 percentage point. We expect that overall ESRD facilities will experience a 2.7 percent increase in estimated Medicare payments in CY 2027. The categories of types of ESRD facilities in the impact table show impacts ranging from a 2.9 percent decrease in CY 2027 estimated Medicare payments for regional chain ESRD facilities to a 9.6 percent increase in estimated payments for ESRD facilities which furnish between 4,000 and 4,999 treatments.

(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 or suppliers (for example, laboratories, and durable medical equipment suppliers) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2027, 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 2027 will be approximately \$9.3 billion. This estimate considers a projected increase in FFS Medicare ESRD beneficiary enrollment of 1.0 percent in CY 2027.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.7 percent overall increase in the CY 2027 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2027, which translates to approximately \$50 million.

(5) Alternatives Considered

(a) Incorporation of Phosphate Binders Into the ESRD PPS Base Rate

In section II.B.7. of this final rule, we discuss our proposal to incorporate phosphate binders into the ESRD PPS base rate and our final policy. We considered, but are not finalizing, a delay of the incorporation of phosphate binders in the ESRDB market basket and

continuing TDAPA for another year. We are not finalizing the continuation of TDAPA for a third year after we evaluated utilization data during the first year of TDAPA and met with several interested parties through public meetings where they recommended incorporation this year.

We also considered alternative ways to account for operational costs when proposing the incorporation of phosphate binders. We considered basing the increased amount on the \$36.41 paid during TDAPA. We also considered not including an increased amount as some operational costs associated with furnishing oral drugs are already included in the ESRD PPS base rate. As discussed in section II.B.7. of this final rule, we are finalizing a recalculation of the operational increase based on more recent utilization and price data. We believe that this final policy strikes the appropriate balance by capturing the operational costs not already included in the ESRD PPS base rate while accounting for the efficiency of the ESRD PPS.

We note that our final base rate modification will cause a relatively uniform and significant increase in payments across all provider types, including small entities. As we have previously discussed, this increase in payments is partially offset by the projected decrease in TDAPA payments from CY 2026 to CY 2027. For small entities, including independent ESRD facilities, hospital-based ESRD facilities, and ESRD facilities furnishing fewer than 3,000 treatments per year, we estimate a net increase of between 4.3 and 4.5 percent in payments as a result of these changes. We believe this final significant increase will appropriately align payment with resource use for these small entities and therefore, we did not consider alternatives to minimize this final increase.

(b) Modifications to the LVPA

As discussed in section II.B.8. of this final rule, we are finalizing extending the LVPA beyond the current treatment volume threshold of 4,000 treatments per year in a budget neutral manner. We considered finalizing this policy non-budget neutrally but did not do so because budget neutrality for this policy is more consistent with our well-established methodologies. As discussed in section II.B.8. of this final rule, we finalized the 6-tier methodology based on our analysis of cost report data, consideration of responses to comments on our CY 2024 RFI on the LVPA, and consideration of comments we received on the CY 2027 ESRD PPS proposed rule.

We are finalizing an extension of the LVPA attestation deadline for payment year 2027 from November 1, 2026, to December 31, 2026. We considered, but are not finalizing, a delay in the implementation of the policy until CY 2028. These approaches both would have provided additional time for ESRD facilities to attest for the LVPA, however we believe that implementing the policy as soon as reasonably feasible is appropriate given our analyses, which indicate that certain ESRD facilities are receiving payments which may not align with relative resource use. Additionally, the estimates on the impact of the proposed payment modifications to the case-mix adjusters for pediatric ESRD patients included the impact of the expanded LVPA. We are concerned that delaying the expansion of the LVPA until CY 2028 could have negative impacts on the payments to pediatric ESRD patients which may not have been fully clear to commenters who evaluated that alternative. In making this decision, we considered the comments of commenters who supported both options.

We note that this final policy will have a positive impact on smaller ESRD facilities that furnish fewer than 8,000 treatments per year. For the smallest ESRD facilities that furnish fewer than 3,000 treatments per year, this increase is estimated to be approximately 2.6 percent. For independent and hospital-based ESRD facilities, we estimate an impact of 0.1 percentage point or less. We believe this final change to the LVPA will appropriately align payment with resource use for small entities and therefore, we did not consider alternatives to minimize the impact of the final increases for those categories of small entities that will be significantly impacted.

(c) Payment for Pediatric ESRD Patients

As discussed in section II.B.9. of this final rule, we are finalizing the recalculation of the case-mix adjustment factors for pediatric ESRD patients. We considered, but are not finalizing, an extension of the TPEAPA for a year

rather than establishing permanently increased adjustment factors effective for CY 2027. We considered this in concert with the previously mentioned delay to the effective date of the LVPA to CY 2028 so that the policy changes would become effective at the same time. Furthermore, we discussed in the proposed rule that we considered a TPEAPA extension so that we could have more time to collect and evaluate pediatric-specific cost report data. However, as noted in section II.B.9. of this final rule, we believe that we have enough information to establish permanent adjusters for CY 2027, and our evaluation of cost report data indicates that the final adjusters are appropriate.

For small entities, including independent ESRD facilities and hospital-based ESRD facilities, we note that the impact of these finalized policies is estimated to be 0.1 percentage point or less. For ESRD facilities furnishing fewer than 3,000 treatments per year, we estimate a 0.3 percentage point increase in payment. Therefore, we did not consider alternatives to mitigate the impact of this final increase on small entities.

(d) Modifications to the Home and Self-Dialysis Training Add-On

As discussed in section II.B.10. of this final rule, we are finalizing a reduction to the onset adjustment factor to account for the estimated training add-on payment adjustment during the onset period. This change will prevent duplicative payments during the onset period while maintaining budget neutrality for the expansion of the training add-on payment adjustment during the onset period. We considered not finalizing this reduction and instead finalizing a reduction to the base rate, which is what we proposed. However, after reviewing comments which raised concerns on the impact of the budget neutrality factor on the base rate and comments which raised methodological concerns with expanding the training add-on during the onset period without corresponding decreases to the onset

adjustment factor, we decided that a reduction to the onset factor was most appropriate.

For small entities, including independent ESRD facilities, hospital-based ESRD facilities, and ESRD facilities furnishing fewer than 3,000 treatments per year, we note that the impact of these finalized policies is estimated to be 0.1 percentage point or less and therefore, we did not consider alternatives to mitigate the impact of this final change on small entities.

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

(1) Effects on ESRD Facilities

To understand the impact of the final 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 2026 to estimated Medicare payments in CY 2027. 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 2026 and CY 2027 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 2025 data from the Medicare Part A and Part B Common Working Files as of July 31, 2026, as a basis for Medicare renal dialysis services furnished to individuals with AKI. We updated the 2025 claims to 2026 and 2027 using various updates. The final updates to the AKI dialysis payment amount are described in section III.C. of this final rule. Table 27 shows the impact of the estimated CY 2027 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 2026.

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TABLE 31: Impacts of the Final Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2027

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Phosphate Binder Incorporation (C)	Combined Impact of Budget Neutral Proposals (Pediatrics and LVPA) (D)	Training Add-On (E)	Wage Index and LRS (F)	All Changes (G)
All Facilities	5,229	321.7	4.6%	-1.1%	0.0%	0.0%	5.3%
Type							
Freestanding	5,119	315.8	4.6%	-1.1%	0.0%	0.0%	5.3%
Hospital-based	110	5.9	4.6%	-1.1%	0.0%	-0.2%	5.2%
Ownership Type							
Large dialysis organization	4,279	245.3	4.6%	-1.1%	0.0%	-0.1%	5.3%
Regional chain	620	35.9	4.6%	-1.1%	0.0%	0.3%	5.7%
Independent	217	34.4	4.6%	-1.1%	0.0%	-0.1%	5.2%
Hospital-based ¹	110	5.9	4.6%	-1.1%	0.0%	-0.2%	5.2%
Unknown	3	0.2	4.6%	-1.1%	0.0%	1.6%	7.0%
Geographic Location							
Rural	858	45.4	4.6%	-1.1%	0.0%	-1.1%	4.2%
Urban	4,371	276.4	4.6%	-1.1%	0.0%	0.1%	5.5%
Census Region							
East North Central	829	56.5	4.6%	-1.1%	0.0%	-0.5%	4.9%
East South Central	385	18.3	4.6%	-1.1%	0.0%	-1.4%	3.9%
Middle Atlantic	571	40.9	4.6%	-1.1%	0.0%	0.1%	5.5%
Mountain	319	23.0	4.6%	-1.1%	0.0%	-0.9%	4.4%
New England	152	7.7	4.6%	-1.1%	0.0%	0.5%	5.9%
Pacific ²	690	50.6	4.6%	-1.1%	0.0%	2.3%	7.8%
Puerto Rico and Virgin Islands	6	0.1	4.6%	-1.1%	0.0%	-4.0%	1.1%
South Atlantic	1,253	73.4	4.6%	-1.1%	0.0%	-0.8%	4.6%
West North Central	328	16.5	4.6%	-1.1%	0.0%	-0.4%	4.9%
West South Central	696	34.7	4.6%	-1.1%	0.0%	-0.7%	4.6%
Facility Size							
Less than 3,000 treatments	178	5.9	4.6%	-1.1%	0.0%	-0.4%	5.0%
3,000 to 3,999 treatments	231	9.1	4.6%	-1.1%	0.0%	-0.4%	5.0%
4,000 to 4,999 treatments	309	14.2	4.6%	-1.1%	0.0%	-0.6%	4.7%
5,000 to 5,999 treatments	366	16.9	4.6%	-1.1%	0.0%	-0.7%	4.7%
6,000 to 6,999 treatments	463	23.0	4.6%	-1.1%	0.0%	-0.6%	4.8%
7,000 to 7,999 treatments	469	23.6	4.6%	-1.1%	0.0%	-0.4%	5.0%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Phosphate Binder Incorporation (C)	Combined Impact of Budget Neutral Proposals (Pediatrics and LVPA) (D)	Training Add-On (E)	Wage Index and LRS (F)	All Changes (G)
8,000 or more treatments	3,213	229.1	4.6%	-1.1%	0.0%	0.1%	5.5%
Percentage of Pediatric Patients							
Less than 2%	5,207	320.9	4.6%	-1.1%	0.0%	0.0%	5.3%
Between 2% and 49%	21	0.8	4.6%	-1.1%	0.0%	-0.5%	4.9%
More than 50%	1	0.0	4.6%	-1.1%	0.0%	-1.5%	3.8%

¹ Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

² Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the final policy to increase the ESRD PPS base rate to incorporate payment for phosphate binders, which directly increases the AKI dialysis payment rate by approximately 4.6 percent. Column D shows the combined budget neutral impact associated with the final pediatric adjustment and LVPA changes, which do not apply to AKI dialysis payments, but which reduce the ESRD PPS base rate and by extension the AKI dialysis payment rate by approximately 1.1 percent. The main driver of this estimated decrease is the application of the budget neutrality factor of 0.98901 associated with the final changes to the LVPA. As we noted earlier in this rule, the final changes to pediatric payments result in a budget neutrality factor of 0.99999.

Column E shows the impact from the changes to the home dialysis training adjustment add-on, which have a 0.0 percentage point reduction to total payments and have small distributional impacts for the small number of AKI dialysis claims that include home dialysis training sessions. We note that the onset adjustment does not apply for AKI beneficiaries, so the change to allow home dialysis training payments during the onset period does not have any impact on this population, nor does the corresponding decrease to the onset adjustment factor. Column F shows the effect of the final CY 2027 wage index described in section II.B.2. of this final

rule as well as the increase to the LRS for CY 2027.

Column G shows the overall impact of all policies discussed in this final rule, including the final 1.9 percent ESRDB market basket update, which reflects the final ESRDB market basket percentage increase for CY 2027 of 2.9 percent reduced by the final productivity adjustment of 1.0 percentage point as well as the final incorporation of phosphate binders into the ESRD PPS base rate. We expect that overall ESRD facilities will experience a 5.4 percent increase in estimated Medicare payments in CY 2027 for treatment of AKI beneficiaries. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 1.1 percent for ESRD facilities in Puerto Rico and the U.S. Virgin Islands to an increase of 7.8 percent for ESRD facilities in the Pacific Census Region in CY 2027 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are finalizing updates to the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two types of Medicare providers and suppliers authorized to furnish 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 final change will have zero impact on other types of Medicare providers.

(3) Effects on the Medicare Program

We estimate that approximately \$95 million in total payments will be paid to ESRD facilities in CY 2027 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 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 dialysis 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. Similarly, we considered applying other facility-level or case-mix adjustment factors, for example the LVPA with the changes finalized in this rule. As with past adjustments, we ultimately determined that treatment for AKI is substantially different from

treatment for ESRD, and the case-mix and facility-level 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 2029 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD

dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's Total Performance Score (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 2029 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2029, consistent with our regulations at § 413.177.

For the PY 2029 ESRD QIP, we estimate that, of the 7,551 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 37.1 percent or 2,802 of the facilities

will receive a payment reduction for PY 2029. Among an estimated 2,802 facilities that will receive a payment reduction, approximately 57.2 percent or 1,603 facilities will receive the smallest payment reduction of 0.5 percent. Based on our proposals finalized in this rule, the total estimated payment reductions for all the 2,802 facilities expected to receive a payment reduction in PY 2029 will be approximately \$18,726,589. Facilities that do not receive a TPS do not receive a payment reduction.

Table 32 shows the overall estimated distribution of payment reductions resulting from the PY 2029 ESRD QIP.

TABLE 32: Estimated Distribution of PY 2029 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4609	62.2%
0.5%	1603	21.6%
1.0%	839	11.3%
1.5%	283	3.8%
2.0%	77	1.0%

* 140 facilities not scored due to insufficient data

To estimate whether a facility will receive a payment reduction for PY 2029, we scored each facility on achievement and improvement on several clinical measures for which

there were available data from EQRS and Medicare claims. Payment reduction estimates (specified in Table 32) were calculated using the most recent data available in accordance with

the proposals finalized in this final rule. Measures and time periods used for the simulation are shown in Table 33.

TABLE 33: Data Used to Update the Estimate of the PY 2029 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 2024-Dec 2024	Jan 2025-Dec 2025
SRR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
SHR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
PPPW	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Pediatric HD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Adult PD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Pediatric PD Kt/V	Jan 2024-Dec 2024	Jan 2025-Dec 2025
VAT Long-term Catheter Rate	Jan 2024-Dec 2024	Jan 2025-Dec 2025
STrR	Jan 2024-Dec 2024	Jan 2025-Dec 2025
NHSN BSI	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Clinical Depression	Jan 2024-Dec 2024	Jan 2025-Dec 2025
Hyperphosphatemia	Jan 2024-Dec 2024	Jan 2025-Dec 2025

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility’s TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility’s TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility’s TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the

facility’s TPS. Each facility’s TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the finalized policies outlined in section IV.B. of this final rule. 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 2029 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2025 and December 2025 by the facility’s estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 34 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2029. 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 2029 ESRD QIP, the actual impact of the PY 2029 ESRD QIP may vary significantly from the values provided here.

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TABLE 34: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029

	Number of Facilities	Number of Medicare Treatments 2025 (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	7551	23.6	7411	2802	-0.30%
Facility Type:					
Freestanding	7225	22.8	7132	2704	-0.30%
Hospital-based	326	0.8	279	98	-0.28%
Ownership Type:					
Large Dialysis	5817	18.4	5777	2111	-0.27%
Regional Chain	883	2.9	870	290	-0.27%
Independent	484	1.5	457	293	-0.70%
Hospital-based (non-chain)	326	0.8	279	98	-0.28%
Unknown	41	0.0	28	10	-0.27%
Facility Size:					
Large Entities	6700	21.3	6647	2401	-0.27%
Small Entities ¹	810	2.3	736	391	-0.54%
Unknown	41	0.0	28	10	-0.27%
Rural Status:					
1) Yes	1222	3.2	1190	428	-0.27%
2) No	6329	20.4	6221	2374	-0.31%
Census Region:					
Northeast	1042	3.9	1017	346	-0.26%
Midwest	1628	4.4	1587	636	-0.33%
South	3432	9.3	3382	1402	-0.33%
West	1386	5.8	1363	392	-0.21%
US Territories ²	63	0.2	62	26	-0.25%
Census Division:					
East North Central	1161	3.1	1131	480	-0.35%
East South Central	592	1.4	585	214	-0.29%
Middle Atlantic	844	3.0	823	294	-0.29%
Mountain	425	1.4	421	125	-0.21%
New England	198	0.9	194	52	-0.17%
Pacific	961	4.4	942	267	-0.21%
South Atlantic	1773	4.9	1742	770	-0.36%
West North Central	467	1.3	456	156	-0.28%
West South Central	1067	3.0	1055	418	-0.32%
US Territories ²	63	0.2	62	26	-0.25%
Facility Size (# of total treatments)					
Less than 3,000 treatments	655	0.6	550	151	-0.25%
3,000-3,999 treatments	440	0.7	434	132	-0.26%
4,000-4,999 treatments	493	0.8	483	176	-0.29%
5,000-5,999 treatments	586	1.1	581	200	-0.28%
6,000-6,999 treatments	625	1.4	621	206	-0.28%
7,000-7,999 treatments	609	1.5	607	253	-0.33%
8,000 or more treatments	4143	17.5	4135	1684	-0.31%

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.

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(2) Effects on the Medicare Program
For PY 2029, we estimate that the ESRD QIP will contribute approximately \$18,726,589 in Medicare savings. For comparison, Table 35 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2029.

TABLE 35: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2029

Payment Year	Estimated Payment Reductions
PY 2029	\$18,726,589
PY 2028	\$20,624,345 (90 FR 53134)
PY 2027	\$21,652,956 (90 FR 53134)
PY 2026	\$15,990,524 (88 FR 76500)
PY 2025	\$32,457,693 (87 FR 67297)
PY 2024	\$17,104,031 (86 FR 62011)
PY 2023	\$5,548,653 (87 FR 67297)
PY 2022	\$0 (86 FR 62011)
PY 2021	\$32,196,724 (83 FR 57062)
PY 2020	\$31,581,441 (81 FR 77960)
PY 2019	\$15,470,309 (80 FR 69074)
PY 2018	\$11,576,214 (79 FR 66257)

(3) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program’s inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost

of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(4) Alternatives Considered

In section IV.B.2. of this final rule, we are finalizing replacing the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. We considered retaining the Hypercalcemia measure in the ESRD QIP. However, we believe removal is appropriate because the Hyperphosphatemia clinical measure captures a related clinical

concept while reducing reporting burden and improving alignment with clinical care priorities. We believe adoption of the Hyperphosphatemia measure in its place is appropriate because it addresses an important clinical outcome associated with dialysis care and aligns the ESRD QIP with current clinical priorities related to mineral and bone disease management among dialysis patients.

D. Accounting Statement

Consistent with OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table 36 showing the classification of the impact associated with the provisions of this final rule.

TABLE 36: Accounting Statement: Classification of Estimated Transfers, and Costs

ESRD PPS and AKI (CY 2027)	
Category	Primary Estimate
Annualized Monetized Transfers	\$195 million
From Whom To Whom	Federal Government To ESRD Facilities
Category	Primary Estimate
Increased Beneficiary Co-insurance Payments	\$50 million
From Whom To Whom	Beneficiaries To ESRD Facilities
ESRD QIP for PY 2029	
Category	Primary Estimate
Annualized Monetized Transfers	-\$18.7 million
From Whom To Whom	Federal Government To ESRD Facilities
Category	Primary Estimate
Annualized Monetized Costs (Reduction in Burden Associated with Measure Updates	-\$12.6 million

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to evaluate alternatives that may reduce regulatory burden on small entities when a rule is expected to have a significant impact on a substantial number of small entities. This section presents a detailed analysis of the anticipated effects of this final rule on small entities. Overall, this final rule includes final updates to the ESRD QIP, as well as final revisions to payment rates and policies applicable to the ESRD PPS and AKI dialysis payment. These final changes are expected to have a significant positive impact on small entities. The anticipated benefits are primarily attributable to projected cost savings and increases in payments, as discussed in the sections that follow.

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This final rule will likely impact ESRD facilities, which are classified under NAICS category 621492, Kidney Dialysis Centers. There could also be impacts to hospitals that operate a hospital-based ESRD facility, including NAICS category 622110, hospitals, and NAICS category 622310, specialty hospitals (which can include children's hospitals). We focused our analysis on Kidney Dialysis Centers (NAICS category 621492), because we generally believe that hospital-based ESRD facilities make up

only a portion of a hospital's revenues and therefore payment updates finalized in this rule will not have significant impact on hospitals overall.

Furthermore, as shown in Table 30, we estimate that payments to hospital-based ESRD facilities will increase by approximately 2.7 percent overall, and payments to ESRD facilities with more than 50 percent pediatric patients, which are more likely to be owned by children's hospitals, will increase by approximately 6.1 percent.

We also 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) March 2023 size standards, an ESRD facility (NAICS code 621492) is classified as a small business if it has average revenues of less than \$47 million across the past 5 years.¹¹¹ The U.S. Census Statistics of U.S. Businesses (SUSB) data shows there are 459 firms below this threshold.

As shown in Table 37, approximately 459 ESRD facilities, at the firm level, can be considered small according to

the SBA. As we stated earlier, the SBA defines small ESRD facilities (firms) as businesses having less than \$47 million in total annual revenue. According to the U.S. Census, a firm is a legal entity or parent company that owns and operates the business, or ESRD facility, in this case. Therefore, Table 37 only reflects data at the firm level and not at the establishment level, where multiple establishments could be owned by a firm. However, we note that according to the SUSB data, the 459 firms identified as small kidney dialysis centers in Table 37 account for 589 establishments, and no firm under \$2.5 million in annual revenue has more than 1 establishment.

HHS uses a change in revenue of more than 3 to 5 percent as its measure of significant economic impact on small entities. The agency considers the rule to have a significant impact on a substantial number of small businesses when more than 5 percent of impacted small entities meet the significant impact threshold defined previously.

As shown in Table 37, the impact of the finalized QIP measure changes in this rule will result in a cost savings impact of 3.5 percent for the smallest category of ESRD facilities, which comprise approximately 7.8 percent of small firms. For all other categories the changes have an impact that falls below the 3 to 5 percent threshold.

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¹¹¹ <https://legacy.sba.gov/document/support-table-size-standards>.

TABLE 37: (NAICS 621492) ESRD Facilities Impacts On Small Entities

Firm Size (by Receipts)	Avg. Annual Revenue	Firm Count	Annualized Cost Savings per Firm	% of Small Firms	Revenue Test
All Kidney Dialysis Centers	\$57,952,874	507	\$1,636	N/A	0.0%
Large Kidney Dialysis Centers	\$579,653,354	48	\$1,636	N/A	0.0%
Small Kidney Dialysis Centers	\$3,395,961	459	\$1,636	100%	0.0%
<100,000	\$46,055	36	\$1,636	7.8%	3.5%
100,000- 499,999	\$309,604	91	\$1,636	19.8%	0.5%
500,000- 999,999	\$770,338	65	\$1,636	14.2%	0.2%
1,000,000- 2,499,999	\$1,635,250	112	\$1,636	24.4 %	0.1%
2,500,000- 4,999,999	\$3,709,628	70	\$1,636	15.3 %	0.0%
5,000,000- 7,499,999	\$6,270,675	37	\$1,636	8.1%	0.0%
7,500,000- 9,999,999	\$8,409,545	11	\$1,636	2.4%	0.0%
10,000,000- 14,999,999	\$11,228,363	11	\$1,636	2.4%	0.0%
15,000,000- 19,999,999	\$16,243,333	9	\$1,636	2.0%	0.0%
20,000,000- 24,999,999	\$15,160,250	4	\$1,636	0.9%	0.0%
25,000,000- 29,999,999	\$27,083,333	3	\$1,636	0.7%	0.0%
30,000,000- 34,999,999	\$22,241,000	4	\$1,636	0.9%	0.0%
35,000,000- 39,999,999	\$35,356,333	3	\$1,636	0.7%	0.0%
40,000,000- 49,999,999	\$34,958,000	4	\$1,636	0.9%	0.0%

Source: US Census 2022 SUBS.

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We also considered the impacts of changes in transfers due to final payment policy changes in this final rule. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains, which will have total revenues of more than \$6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because

we lack data on individual ESRD facilities' receipts, we applied a different analytic framework to identify ESRD facilities that are likely small businesses and to assess the impact of payment policy changes on those entities. Accordingly, we consider the 500 ESRD facilities that are independent and 332 ESRD facilities that are hospital-based, as shown in the ownership category in Table 30, to be small businesses. These ESRD facilities

represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 766 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 353 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.

As we noted earlier in this final rule, HHS's practice in interpreting the RFA is to consider effects economically "significant" on a "substantial" number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As shown in Table 30, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.7 percent. For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.7 percent increase in Medicare FFS payments for CY 2027. An independent facility (as defined by ownership type) is likewise estimated to receive a 6.2 percent increase in Medicare FFS payments for CY 2027. Although not displayed in Table 30, we have found that among the 832 ESRD facilities that are small businesses, approximately 28.7 percent (239 out of 832) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive a 7.8 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 4.7 percent increase in Medicare FFS payments. Additionally, among the 766 nonprofit ESRD facilities, approximately 18.4 percent (141 out of 766) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive an 8.5 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 2.7 percent increase in Medicare FFS payments. For AKI dialysis, we are unable to estimate whether patients will go to certain types of ESRD facilities, however, we have estimated there is a potential for \$95 million in total CY 2027 payments for AKI dialysis treatments that could potentially be furnished in ESRD facilities that are small businesses or nonprofits.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this final rule. This analysis is based on the assumptions described earlier in section VII.C of this final rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 2,802 ESRD facilities expected to receive a payment reduction as a result

of their performance on the PY 2029 ESRD QIP, 391 are ESRD small entity facilities. As shown in Table 32 ("Estimated Distribution of PY 2029 ESRD QIP Payment Reductions"), the maximum ESRD QIP payment reduction is 2.0 percent. Therefore, none of the 391 small entity facilities expected to receive a PY 2029 ESRD QIP payment reduction would experience a reduction attributable to the ESRD QIP that reaches the 3 to 5 percent threshold HHS uses to assess significant economic impact. Table 34 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029") shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2029 and also details the distribution of ESRD facilities by size, geography, and facility type.

Therefore, the Secretary has determined that the final policies in this rule are expected to have a significant positive economic impact on a substantial number of small entities, primarily through increased revenues associated with the final ESRD PPS base rate increase. In addition, the final updates to the ESRD QIP are expected to generate cost savings for small entities. As discussed in section VII.C.5.a.(5) of this CY 2027 ESRD PPS final rule, CMS considered alternative policy approaches to minimize the impact of this final rule on small entities. However, CMS did not finalize these alternatives, because the final policies are expected to more appropriately align payments with resource utilization in CY 2027. This RFA section, together with the RIA, constitutes our Initial Regulatory Flexibility Analysis. We did not receive any comments from small business interests in response to the analysis presented in the proposed rule.

In addition, section 1102(b) of the Act requires the preparation of a regulatory impact analysis for any rule that 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 anticipate that this final rule will have a significant adverse impact on a substantial number of small rural hospitals, as the majority of dialysis facilities operate as freestanding entities. Although there are 111 rural hospital-based ESRD facilities, we do not have sufficient information to determine how many of these ESRD facilities are affiliated with hospitals

that have fewer than 100 beds. Nevertheless, the 111 rural hospital-based ESRD facilities are projected to experience an average payment increase of 4.7 percent under this final rule. Accordingly, the Secretary has determined that the final rule is expected to have a significant positive impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal. Therefore, this final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal government.

H. Executive Order 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, entitled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025. The Executive Order requires that, to the extent permitted by law, "any new incremental costs associated with new regulations shall be offset by the elimination of existing costs associated with at least 10 prior regulations." This final rule is expected to constitute a deregulatory action under Executive Order 14192. We estimate that the rule will result in approximately \$8.74 million in annualized cost savings, calculated

using a 7 percent discount rate and discounted to 2024, over a perpetual time horizon.

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-1846-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.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2026.

List of Subjects in Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 413 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 1395www.

- 2. Section 413.232 is amended by—

- a. Revising paragraphs (b)(1), (c) introductory text, (e)(3), and (4);
- b. Adding paragraph (e)(5);
- c. Revising paragraphs (f), (g)(5), and (g)(6)(i), (ii), and (iv); and
- d. Adding paragraph (g)(7).

The revisions and additions read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished fewer than 8,000 total 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

* * * * *

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, except as specified at paragraph (g)(7) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

* * * * *

(e) * * *

(3) For payment year 2016, the attestation must be provided by December 31, 2015;

(4) For payment year 2021, the attestation must be provided by December 31, 2020; and

(5) For payment year 2027, the attestation must be provided by December 31, 2026.

(f) The low-volume adjustment applies for dialysis treatments provided to all ESRD patients.

(g) * * *

(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 8,000 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 8,000 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 calendar 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 8,000 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 calendar 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 8,000 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 8,000 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) * * *

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 calendar days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) Within 30 calendar 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

* * * * *

(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 calendar days of reopening and providing renal dialysis services. Within 30 calendar 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.

* * * * *

(7) ESRD facilities that are children's hospitals, as defined at § 412.23(d), or that furnish more than 50 percent of treatments (Medicare and non-Medicare) to Pediatric ESRD Patients, may request an exception to the aggregation of number of treatments in paragraph (c) of this section.

(i) The ESRD facility must attest that it is either owned and operated by a Medicare-certified children's hospital, as defined at § 412.23(d), or the ESRD facility provides at least 50 percent of its total treatments (Medicare and non-Medicare) to Pediatric ESRD Patients and that it is under common ownership, as defined in paragraph (d) of this section, with one or more ESRD facilities that do not furnish at least 50 percent of its total treatments to Pediatric ESRD Patients;

(ii) The facility must request an exception under this paragraph (g)(7) 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 calendar days after the end of the cost reporting year, whichever is later;

(iii) Within 60 calendar days of CMS's receipt of the facility's request, CMS will review the request and either

approve or deny the request based on a determination of whether the ESRD facility meets the requirements of paragraph (g)(7)(i) of this section, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility's number of treatments, for the purposes of the low-volume adjustment, would not be aggregated with the number of treatments of the commonly-owned facility for which the exception has been granted, on the basis of the exception in this paragraph (g)(7), for all future payment years, so long as the ESRD facility remains a children's hospital or furnishes more than 50 percent of treatments to Pediatric ESRD Patients. To receive the low-volume adjustment the ESRD facility must continue to satisfy all other requirements. Approval of an exception under this paragraph (g)(7) applies only to the ESRD facility for which the exception is granted and does not affect the aggregation of treatment volume for any other commonly-owned ESRD facility; and

(v) The facility must maintain documentation of the number of total treatments and pediatric treatments which it provides and must provide such supporting documentation to CMS and the MAC upon request.

* * * * *

■ 3. Section 413.234 is amended by—

■ a. Revising paragraphs (c) introductory text, (c)(3), and (g)(1) and (2); and

■ b. Adding paragraph (h).

The revisions and addition read as follows:

§ 413.234 Drug designation process.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP), except as provided in paragraph (c)(4) of this section. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of the wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. If CMS receives negative or zero ASP data for a new renal dialysis drug or biological product after receiving positive ASP data in a previous quarter, the transitional drug add-on payment adjustment would be based on the most recent positive ASP amount carried forward from a previous quarter. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this

section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraphs (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(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 quarter.

* * * * *

(g) * * *

(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 the most recent positive ASP amount from a previous quarter; if there is no

previous quarter of positive ASP data, then the calculation is based on 100 percent of WAC; and, if WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment quarterly 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.

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(h) *Methodology for modifying the ESRD PPS base rate to account for the costs of phosphate binders in the ESRD PPS bundled payment.* For dates of service on or after January 1, 2027, payment for phosphate binders is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (h)(2) of this section for determining the average per treatment payment amount for phosphate binders that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of phosphate binders and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims (the 837-institutional form with bill type 072X) for the second, third, and fourth

quarters of calendar year 2025 and for the first and second quarters of calendar year 2026.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for phosphate binders that is added to the ESRD PPS base rate:

(i) Determines utilization of each phosphate binder by aggregating the total units of phosphate binders from the claims data described in paragraph (h)(1)(i) of this section.

(ii) Determines a price for each phosphate binder by calculating 100 percent of the value from the most recent calendar quarter ASP calculations available to the public for each HCPCS code describing phosphate binders.

(iii) Calculates the total phosphate binder expenditure amount by multiplying the utilization of each phosphate binder determined in paragraph (h)(2)(i) of this section by their respective prices determined in paragraph (h)(2)(ii) of this section and summing the expenditure amounts across all phosphate binder products.

(iv) Calculates an adjusted phosphate binder expenditure amount that

accounts for operational cost expenditures associated with furnishing phosphate binders by increasing the total phosphate binder expenditure amount determined in paragraph (h)(2)(iii) of this section by 6 percent of the total phosphate binder expenditure amount.

(v) Calculates the average per treatment payment amount by dividing the adjusted phosphate binder expenditure amount determined in paragraph (h)(2)(iv) of this section by the total number of paid hemodialysis-equivalent dialysis treatments during the same period described in paragraph (h)(1)(i) of this section.

(vi) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (h)(2)(v) of this section by 1 percent to account for the outlier policy under § 413.237.

(3) Phosphate binders will be eligible ESRD outlier services under § 413.237 beginning January 1, 2027.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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