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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS-1846-P]

RIN 0938-AV81

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

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

ACTION: Proposed rule.

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

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 60 days after date of filing for public inspection at the Federal Register].

ADDRESSES: In commenting, please refer to file code CMS-1846-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to https://www.regulations.gov/docket/CMS-2026-2245. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1846-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1846-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: ESRDPayment@cms.hhs.gov or Abigail Ryan (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:

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

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

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I. Executive Summary

A. Purpose

This rule proposes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI). This rule also proposes to update requirements for 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 proposes updates to the ESRD PPS for CY 2027, including a routine proposal to rebase and revise the ESRD Bundled (ESRDB) market basket. This rule also proposes to modify the ESRD PPS base rate to reflect the incorporation of phosphate binders[1] 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 low-volume payment adjustment (LVPA), and modifications to the TDAPA and post-TDAPA add-on payment adjustment.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an

[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 proposed CY 2027 ESRD PPS base rate increase would encompass all current and future phosphate binders, including a hypothetical future injectable phosphate binder or other form of administration.

individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule proposes updates to the AKI dialysis payment rate for CY 2027. The AKI dialysis payment rate update would be indirectly affected by the proposed rebasing and revision 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 proposed change to the ESRD PPS case mix adjusters for pediatric ESRD patients, the proposed expansion of the LVPA, and the proposed technical changes to the TDAPA and post-TDAPA add-on payment adjustment would 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 proposed rule proposes 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 proposed rule requests public comment 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.

4. Requests for Information (RFIs) on Advancing Dialysis Care

This proposed rule includes RFIs to solicit public input to inform potential future policy

development related to increasing home dialysis uptake, improving palliative dialysis, and supporting alternative dialysis schedules. We seek to better understand how Medicare payment policy may support care for ESRD beneficiaries while maintaining the integrity of existing prospective payment systems, including the ESRD PPS, AKI dialysis payment, the Hospice benefit (section 1814(i) of the Act), and the Home Health PPS (section 1895 of the Act).

B. Summary of the Major Provisions

1. ESRD PPS

- *Proposed rebasing and revising of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2027*: We are proposing to rebase and revise 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 proposing to update the labor-related share of the ESRD PPS base rate to reflect the proposed 2024 base year labor-related cost share weights designated in the ESRDB market basket.

- *Proposed update to the ESRD PPS base rate for CY 2027*: The proposed CY 2027 ESRD PPS base rate is $299.55, an increase from the CY 2026 ESRD PPS base rate of $281.71. This proposed amount reflects the application of the proposed wage index budget neutrality adjustment factor (1.00267), the proposed addition to the base rate of $15.96 to include phosphate binders, the budget neutrality factor for the proposed budget neutral changes to several payment adjustments (0.98783), and a proposed ESRDB market basket update of 1.6 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $299.55 ((($281.71 + $15.96) × 1.00267 × 0.98783) × 1.016 = $299.55).

- *Proposed 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. For CY 2027, we are proposing to update the wage index based on this methodology and the latest available data.

- *Proposed annual update to the outlier policy*: We are proposing to update the outlier policy based on the most current data and established methodology. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2027 using the latest available CY 2025 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2025 claims data and update 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 would increase from $162.43 to $206.43, and the MAP amount would increase from $50.19 to $60.86, as compared to CY 2026 values. For adult beneficiaries, the FDL amount would increase from $14.80 to $114.98, and the MAP amount would increase from $23.68 to $41.28, 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 are 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.

- *Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2027*: The proposed CY 2027 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.60. This proposed offset amount reflects the application of the proposed ESRDB market basket update of 1.6 percent ($10.43 × 1.016 = $10.60). There are no capital-related assets set to receive the TPNIES in CY 2027 for which this offset would apply.

- *Proposed update to the post-TDAPA add-on payment adjustment amounts*: We calculate the post-TDAPA add-on payment adjustment in accordance with 42 CFR 413.234(g).

We are proposing modifications to the post-TDAPA add-on payment adjustment to calculate the adjustment quarterly and publish the post-TDAPA add-on payment adjustment amount via Change Request (CR). The estimated post-TDAPA add-on payment adjustment amount for Korsuva® is $0.1068 per treatment, which would be included in the calculation of the total post-TDAPA add-on payment adjustment for only the first quarter of CY 2027. Accordingly, for the first quarter of CY 2027, this amount would be incorporated into ESRD PPS payments for all dialysis treatments and adjusted by applicable patient-level adjustment factors. The estimated post-TDAPA add-on payment adjustment amount for DefenCath® is $5.5951 per treatment, which would be included in the calculation for each quarter of CY 2027. The estimated post-TDAPA add-on payment adjustment amount for Vafseo® is $0.9437 per treatment, which would be included in the calculation for each quarter of CY 2027. We would finalize the post-TDAPA add-on payment adjustment amounts for each of these drugs, conditional on the continued receipt of ASP data, in the final rule. Should the proposal to update the post-TDAPA add-on payment adjustment amounts quarterly be finalized, we would only finalize the post-TDAPA add-on payment adjustment amount for the first quarter of CY 2027 in that final rule and would publish the amounts for the other quarters in CRs published after that final rule. The final post-TDAPA add-on payment adjustment amount for a given quarter would be added to ESRD PPS payments for all dialysis treatments furnished during that quarter and would be adjusted by applicable patient level adjustment factors.

- *Proposed incorporation of phosphate binders into the base rate*: We are proposing to incorporate phosphate binders into the ESRD PPS base rate at the end of the TDAPA period for the drugs, for CY 2027 and beyond. We are proposing to increase the ESRD PPS base rate by $15.96. This proposed amount would include an increase to account for operational costs, as discussed in section II.B.7. of this proposed rule.

- *Proposed expansion of the LVPA*: We are proposing to expand the LVPA to ESRD facilities which furnish up to 8,000 treatments per year. We are proposing to make payments

based on 6 tiers of volume. We are proposing that this change be budget neutral with a budget neutrality factor of 0.98898.

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

- *Proposed modifications to the home and self-dialysis training add-on*: We are proposing to increase the home and self-dialysis training add-on payment adjustment to $138.22 from the current amount of $95.60. We are also proposing to allow training sessions during the onset period (the first 120 days of ESRD dialysis). For the reasons discussed in section II.B.10. of this proposed rule, we are proposing that this change be budget neutral with a budget neutrality factor of 0.99884.

- *Proposed modifications to the TDAPA and post-TDAPA add-on payment adjustment*: We are proposing that, when Average Sales Price (ASP) data is not usable because ASP is zero or negative, we would 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

- *Proposed update to the dialysis payment rate for individuals with AKI*: We are proposing to update the AKI dialysis payment rate for CY 2027. The proposed CY 2027 payment rate is $299.55, which is the same as the proposed CY 2027 ESRD PPS base rate.

3. ESRD QIP

We are proposing to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. Beginning with PY 2029, we are proposing to update the NHSN BSI clinical measure to use the most recently available national

baseline data and to update the risk adjustment methodology. We are proposing to remove the MedRec reporting measure and the COVID–19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with PY 2029. We are also including 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.

4. RFIs on Advancing Dialysis Care

These RFIs solicit comments on increasing home dialysis uptake, improving palliative dialysis care, and supporting alternative dialysis schedules.

C. Summary of Costs and Transfers

In section VIII.C.5. of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. Table 1 summarizes the impacts of each proposed change in this proposed rule.

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

Proposed Changes	Estimated total costs/transfers
Proposed CY 2027 ESRD PPS update	The overall economic impact of this proposed rule is an estimated increase of approximately $90 million in aggregate payments to ESRD facilities in CY 2027.
Proposed 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 proposed CY 2027 ESRD PPS base rate, would increase by approximately $5 million.
Proposed PY 2029 ESRD QIP updates	We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2029 ESRD QIP would be approximately $125.4 million, which includes $102.1 million in costs associated with the collection of information requirements and approximately $23.3 million in payment reductions across all facilities.
RFIs on Advancing Dialysis Care	We do not estimate any costs or transfers based on these RFIs.

1. Impacts of the Proposed Updates to the ESRD PPS

The impact table in section VIII.C.5.a. of this proposed 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 proposed CY 2027 payment changes is projected to be a 1.1 percent increase in Medicare payments. Hospital-based ESRD facilities would have an estimated 2.0 percent increase in Medicare payments compared with freestanding

ESRD facilities with an estimated 1.1 percent increase. We estimate that the aggregate Medicare program payments under the ESRD PPS would increase by approximately $70 million in CY 2027 compared to CY 2026 because of the proposed payment policies in this rule. Because of the projected 1.1 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.1 percent in CY 2027, which translates to approximately $20 million. This overall $90 million estimated increase, or 1.1 percent, includes the estimated impact of the proposed ESRD PPS market basket update of 1.6 percent ($130 million), as well as the estimated changes in payments associated with several proposed changes that are expected between CY 2026 and 2027. First, as discussed in section II.B.3.b. of this proposed rule, we estimate that outlier payments in CY 2026 will be approximately 3.0 percent of total ESRD PPS payments. Accordingly, the proposed increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.9 percent ($150 million). At the same time, we estimate that approximately $430 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 $430 million (5.5 percent), which is offset by the proposed 5.3 percent increase to the ESRD PPS base rate for phosphate binders and the estimated 2.0 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027. The net difference between estimated CY 2026 TDAPA payments and estimated CY 2027 payments through the post-TDAPA add-on payment adjustment and the ESRD PPS base rate, including the incorporation of phosphate binders, is a 1.5 percent increase in payments to ESRD facilities. For CY 2027, we estimate total payments associated with the post-TDAPA add-on payment adjustment would be approximately $170 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 proposed rule, there will be no new or continuing TPNIES payments for CY 2027. As discussed in section II.E. of this proposed rule, there are currently no continuing TDAPA payments in CY 2027.

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

The impact table in section VIII.C.5.c. of this proposed 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 proposed CY 2027 changes is projected to be a 6.0 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 5.9 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 6.0 percent increase. The overall impact reflects the effects of the proposed Medicare ESRD PPS payment rate update and the proposed CY 2027 ESRD PPS wage index and proposed 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 proposed CY 2027 ESRD PPS base rate, would 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 proposing, the overall economic impact of the PY 2029 ESRD QIP would be approximately $125.4 million. The $125.4 million estimate for PY 2029 includes

$102.1 million in costs associated with the collection of information requirements and approximately $23.3 million in payment reductions across all facilities.

4. RFIs on Advancing Dialysis Care

These RFIs do not propose any policy changes and therefore do not have a direct economic impact under Executive Order 12866.

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 biologicals[2] (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

[2] 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 proposed rule except when referencing specific language in the Act or regulations.

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) 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))[3]; and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

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

Most recently, we published a final rule, which appeared in the November 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," referred to herein as the "CY 2026 ESRD PPS final rule." In that rule (90 FR 53068 through 53142), 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-

[3] As the TPEAPA only applies for CYs 2024, 2025, and 2026, it will not apply for the CY 2027 payment year.

contiguous areas, the NAPA. For further detailed information regarding the CY 2026 updates and policy changes, see 90 FR 53068.

B. Proposed Provisions of the CY 2027 ESRD PPS Update

1. Proposed Rebasing and Revising of the ESRD Bundled (ESRDB) Market Basket; and Proposed 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 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 are proposing to rebase and revise the ESRDB market basket to a 2024 base year.

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 this proposed rule, we propose 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. For this CY 2027 ESRD PPS proposed rule, we propose 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, as discussed in this proposed rule.

We refer to the proposed 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 proposed 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 are proposing to use 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 proposed methodology in section II.B.1.b. of this proposed rule.

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

b. Proposed 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 this proposed rule, we propose 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 are proposing 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.

We invite public comments on our proposed methodology for deriving the proposed 2024-based ESRDB market basket discussed in this section of the proposed rule.

(1) Development of Cost Categories and Weights

(a) Use of Medicare Cost Report Data

The major source of cost data for developing the proposed 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 propose 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 are proposing 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 facility that reported costs and payments.

The major types of costs underlying the proposed 2024-based ESRDB market basket are derived from the Medicare cost reports (Form 265–11, OMB No. 0938–0236). Specifically, we propose 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 ESRDB 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 ESRDB facilities and to help ensure the major cost weights accurately reflect the percentage of total costs for furnishing ESRD treatment, we propose 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 providers 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 propose 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 the Medicare cost report field designating the 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 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 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 facility by a related organization (by common ownership or control). This worksheet is potentially completed when a 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 facility that didn't have a discrepancy, no adjustment was required to the Administrative & Other net expenses.

(i) Wages and Salaries Costs

We propose 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 are proposing to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the 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 propose 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 propose to derive the non-direct patient care benefit costs using the following steps:

Step 1: We calculated the ratio of direct patient care employee benefit costs to direct patient care salaries for each 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 bundle (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 this 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 proposed 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 propose 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 drug. 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 proposed 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 resulted in a proposed 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 calculated the proposed 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 were reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(v) Laboratory Costs

We calculated the proposed 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 were 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 proposed 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 were reduced to exclude the estimated share of non-direct patient care wages and salaries associated with this cost center.

(vii) Operations & Maintenance Costs

The proposed 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 were 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 proposed 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 fixture costs include depreciation and lease costs for buildings and fixtures, property taxes, insurance costs, and capital improvements.

(ix) *Capital-related: Moveable Equipment Costs*

The proposed 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 reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with buildings and fixtures could move differently than those associated with moveable equipment, we continue to believe that two capital-related cost categories are appropriate.

(x) Professional Liability Insurance Costs

We propose 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 computed 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 were 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 we derived costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to address data outliers using the following steps.

First, for each of the major cost weights, we propose 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 have been removed, we sum the costs for each category across all remaining providers. We then divide this by the sum of total costs across all remaining providers to obtain a cost weight for the proposed 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 facilities excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these proposed 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 evaluated the distribution of providers and costs by ownership-type, and by urban/rural status. For all cost weights, the trimmed sample was nationally representative.

Table 2 presents the proposed 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.

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

	Proposed 2024	2020	Difference between proposed 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 proposed 2024 employee benefits weight reflects all employee benefits costs.

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 proposed 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 proposed 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 propose 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 Bureau of Economic Analysis Benchmark Input-Output 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 propose the following methodology to derive the contract labor cost weight. Similar to the methodology used in the 2020-based ESRDB market basket, we are proposing 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 propose 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 that proposing 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 propose 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 proposed 2024-based

ESRDB Contract Labor cost weight is 2.1 percent. To avoid double counting these costs we are proposing 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 propose 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 propose 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 proposed 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: Proposed Wages and Salaries and Employee Benefits Cost Weights after Contract Labor Allocation

Major Cost Categories	Proposed 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 propose 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[4].

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 proposed 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 proposed 2024-based ESRDB market basket compared to the 2020-based occupational mix. The proposed 2024 occupational distribution shows a shift to more health-related FTEs and fewer Management and Administrative Support Occupation FTEs.

TABLE 4: Share of ESRD Compensation by Occupation

Subgroup	Occupation	Proposed 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%

[4] https://www.bls.gov/oes/.

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 (%)

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

We propose to multiply the proposed occupational mix weights by the Wages and Salaries proposed cost weight and the Employee Benefits proposed 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 propose to use the 2017 Benchmark I-O "The Use Table (Supply-Use Framework)" for NAICS 621400, Outpatient care Centers, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following website: https://www.bea.gov/industry/input-output-accounts-data. 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 produced and distributed.[5] 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 propose 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 were applied to the "Administrative & Other" cost weight to obtain the detailed cost weights for the proposed 2024-based ESRDB market basket. For example, the cost for 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 proposed 2024-based ESRDB market basket's "Administrative & Other" cost category (14.7 percent), yielding a Paper & Printing proposed cost weight of 0.6 percent in the proposed 2024-based ESRDB market basket (3.9 percent x 14.7 percent = 0.6 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 are proposing to use an alternative data source.

Using this methodology, we propose to derive 12 detailed cost categories from the proposed 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;

[5] http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

(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 note that the proposed 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 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 proposed 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 proposed 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.

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

Cost Category	Proposed 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

Cost Category	Proposed 2024-based ESRDB Market Basket Cost Weight	2020-based ESRDB Market Basket Cost Weight
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
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.

We invite public comments on our proposed methodology for deriving the proposed 2024-based ESRDB cost categories and weights.

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

After computing the proposed 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 proposed 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 proposed 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 this proposed rule, we present a detailed explanation of the price proxies that we propose for each cost category weight.

(a) Health-Related Wages and Salaries

We propose 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 propose 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 propose 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 propose 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 propose to use these derived ECI benefit price proxies for each of the respective occupational benefit cost categories.

(e) Health-Related Benefits

We propose 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 #CIU10162200000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. We believe this constructed ECI series is technically appropriate for the 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 propose 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 #CIU20100001100000I) 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 propose 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 #CIU20100002200000I) 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 propose to use the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU20300003000000I) 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 propose 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 propose 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 propose 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 biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/ biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI– BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the 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 propose 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 propose 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 proposed 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 proposed 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 propose 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 are requesting 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 propose to use the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose to use the CMS Physician PLI index to measure the price growth of this cost category in the proposed 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 propose to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the proposed 2024-based ESRDB market basket. This is the same proxy used in the 2020-based ESRDB market basket.

(ac) Capital-related: Moveable Equipment

We propose 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 proposed price proxies for the proposed 2024-based ESRDB Market Basket as well as whether the price proxy was used in the 2020-based ESRDB market basket. As discussed in section II.B.1.b.(1)(b)(iii) of this proposed rule, for the proposed 2024-based ESRDB market basket we are proposing 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.

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

Cost Category	2024 Proposed Price Proxy	2020 Price Proxy
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		

Cost Category	2024 Proposed Price Proxy	2020 Price Proxy
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 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
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.

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

(3) Proposed 2024-based ESRDB Market Basket Percentage Increase Results

A comparison of the yearly differences of increase factors from CY 2021 to CY 2030 for the 2020-based ESRDB market basket and the proposed 2024-based ESRDB market basket is shown in Table 8. The proposed CY 2027 ESRDB market basket increase factor would be the same if we continued to use the 2020-based ESRDB market basket.

TABLE 8: Historical and Projected CY Market Basket Increase Factors under the Proposed 2024-based ESRDB Market Basket and 2020-based ESRDB Market Basket

Calendar Year (CY)	Proposed 2024-based ESRDB Market Basket Percent Change	2020-Based ESRDB Market Basket Percent Change
Historical data:		
CY 2021	2.8	2.9
CY 2022	4.9	5.1
CY 2023	4.2	4.1
CY 2024	3.6	3.3
CY 2025	3.0	2.9
Average CYs 2021-2025	**3.7**	**3.7**
Forecast:		
CY 2026	3.1	3.2
CY 2027	2.6	2.6
CY 2028	2.5	2.4
CY 2029	2.4	2.4
CY 2030	2.4	2.4
Average CYs 2026-2030	**2.6**	**2.6**

Source: IHS Global, Inc., 1st Quarter 2026 forecast

Over the CY 2021 through CY 2025 timeframe, the average percent change of the proposed 2024-based ESRDB market basket is 3.7 percent, the same as the average percent change of the 2020-based ESRDB market basket. For CY 2027, the proposed 2024-based ESRDB market basket is projected to increase 2.6 percent, which is the same projected increase as the CY 2027 projected increase of the 2020-based ESRDB market basket. For the forecast period, CY 2026 through CY 2030, the proposed 2024-based ESRDB market basket percentage increase is on average the same 5-year average projected increase as the 2020-based ESRDB market basket.

c. Proposed Labor-related Share for ESRD PPS

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

We propose to use the proposed 2024-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Therefore, effective for CY 2027, we are proposing 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 9. 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.

TABLE 9: Labor-related Share of Current and Proposed ESRDB Market Baskets

	Proposed Labor-Related Share for CY 27	Labor-Related Share for CY 26	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

The proposed labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related: 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 facilities, and skilled nursing facilities (66 FR 39585).

We invite public comments on our proposed labor-related share based on the proposed 2024-based ESRDB cost weights.

d. Proposed 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 propose to use the proposed 2024-based ESRDB market basket as described in section II.B.1.b. of this proposed rule to compute the CY 2027 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.d.(3) of this proposed rule, we are calculating the proposed ESRDB market basket update for CY 2027 based on the proposed ESRDB market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) Proposed CY 2027 ESRDB Market Basket Percentage Increase

Using this methodology and IGI's first quarter of 2026 forecast of the proposed 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 is 2.6 percent. We also propose that if more recent data becomes 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).

(2) Proposed 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).[6] 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.

[6] https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.

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) is 1.0 percentage point. Furthermore, we propose that if more recent data becomes available after the publication of this proposed rule and before the publication of the 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.

(3) Proposed CY 2027 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we propose to base the CY 2027 ESRDB market basket percentage increase on IGI's first quarter 2026 forecast of the proposed 2024-based ESRDB market basket. We propose 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 is 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 propose that if more recent data becomes available after the publication of this 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 ESRD market basket percentage increase and productivity adjustment in the final rule.

We invite public comment on our proposals for the CY 2027 ESRDB market basket percentage increase and productivity adjustment.

2. Proposed 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 OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117)[7]. OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. We most recently updated the CBSA delineations 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.[8]

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).

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

[7] 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.

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

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. 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 discussed in section II.B.1.c. of this proposed rule, we are proposing that the CY 2027 LRS to which the wage index would be applied is 63.5 percent. This proposed LRS is based on the proposed 2024-based ESRDB market basket as discussed in section II.B.1.b. of this 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 report data. Treatment data from ESRD facility cost reports is also used to weigh 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-notices/cms-1805-p.

b. National ESRD Facility Occupational Mix

Table 10 presents the NEFOM alongside the BLS occupation titles and codes for the occupations related to the furnishing of renal dialysis services. In this proposed rule we present 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 10. The data in Table 10 is based on data from CY 2024 freestanding ESRD facility cost reports.

TABLE 10: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports Occupation Classifications and the CY 2027 ESRD PPS Proposed 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. Proposed CY 2027 ESRD PPS Wage Index

For CY 2027, we propose 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-reclassification IPPS wage index. We propose 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 this proposed rule are from the May 2026 release of the BLS OEWS, which represents data from six semiannual surveys spanning November 2022 through May 2025.[9]

For CY 2027, we propose to update the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We are proposing that if more recent data becomes available after the analysis performed for the publication of this proposed rule and before the publication of the 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.

The proposed 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 proposed 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. Proposed CY 2027 Update to the Outlier Policy

a. Background

[9] https://www.bls.gov/news.release/pdf/ocwage.pdf.

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 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.[10]

[10] 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.

- 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.[11] 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

[11] 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.

claim. We use the term "national adjusted average" in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

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 CY2023 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 FR89127). 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. Proposed CY 2027 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2027, we propose to update the MAP amounts for adult and pediatric patients using the latest available CY 2025 claims data. We propose 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 propose to update these values with the latest available data, if appropriate, in the final rule.

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

	Column I Final outlier policy for CY 2026 (based on 2024 data, price inflated to 2026) *		**Column II Proposed outlier policy for CY 2027 (based on 2025 data, price inflated to 2027)****	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$50.64	$24.83	$63.06	$43.07
Adjustments				
Standardization for outlier services	1.0113	0.9731	0.9847	0.9780
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$50.19	$23.68	$60.86	$41.28
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$162.43	$14.80	$206.43	$114.98
Patient-month-facilities qualifying for outlier payment	7.58%	14.10%	8.91%	6.42%

*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 11, the proposed FDL amount per treatment that determines the CY 2027 outlier threshold amount for adults (column II; $114.98) 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 outlier services from $23.68 to $41.28. 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 project 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 are proposing 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 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 $134.81, $132.36, and $124.44, 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 proposed adult FDL amount of $114.98.

For pediatric patients, there is also a proposed increase in the FDL amount from $162.43 to $206.43. There is a corresponding proposed increase in the adjusted average MAP amount for outlier services among pediatric patients, from $50.19 to $60.86. We note that, as discussed in section II.B.7. of this proposed rule, we are proposing to include phosphate binders in the ESRD PPS base rate. Accordingly, phosphate binders would be eligible as ESRD outlier services for CY 2027, and we have included them in our calculations.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2027 would be 6.42 percent for adult patients and 8.91 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 proposed rule, outlier payments represented approximately 0.9 percent of total payments, which is slightly below the 1.0 percent target.

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

b. Proposed Annual Payment Rate Update for CY 2027

We propose an ESRD PPS base rate for CY 2027 of $299.55, which is approximately a 6.3 percent increase from the CY 2026 ESRD PPS base rate of $281.71. As outlined in section II.B.1.d. of this proposed rule, we are proposing that if more recent data becomes 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. The proposed 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 are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 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 proposed CY 2027 ESRD PPS wage index and proposed 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 proposed CY 2027 wage index budget neutrality adjustment factor is 1.00267. As we are not proposing any changes to our established ESRD

PPS wage index policy, this proposed 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[12], and the proposed LRS.

We note that the proposed CY 2027 wage index budget neutrality factor does not include any impacts associated with the TPEAPA, as was the case with the 2024 combined wage index-TPEAPA budget neutrality finalized factor for CY 2024. Although CY 2026 is the final year of the TPEAPA, as discussed in section II.B.9. of this proposed rule, we are proposing 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 proposed budget neutrality factor for those pediatric proposals. 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 proposed 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 proposed budget neutrality factor for the payment adjustments described in this proposal.

Proposed Budget Neutrality Factor for Certain Payment Adjustment Changes: As outlined in sections II.B.8., II.B.9., and II.B.10. of this proposed rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are proposing changes to the LVPA, payment adjustments for pediatric ESRD patients, and home and self-dialysis training add-on payment

[12] We note that the 3-year rural phase-out finalized in the CY 2025 ESRD PPS final rule (89 FR 89117 through 89119) ends January 1, 2027. 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 proposed wage index budget neutrality factor for CY 2027 reflects the budget neutrality associated with the end of this policy.

adjustment. We are proposing that the changes to these payment adjustments would be budget neutral and would result in a proposed combined budget neutrality factor of 0.98783. This is calculated based on the combined budget neutrality factor of 0.98898 for the proposed LVPA changes, 0.99999 for the proposed pediatric changes, and 0.99884 for the proposed changes to the home and self-dialysis training add-on payment adjustment. As noted previously, this proposed budget neutrality factor also includes the budget neutrality impact associated with the end of the TPEAPA effective January 1, 2027.

Proposed Addition of Phosphate Binders to the ESRD PPS Base Rate: As discussed in section II.B.7. of this proposed rule, for CY 2027 we are proposing to modify the ESRD PPS in a non-budget neutral manner base rate by adding $15.96 to account for phosphate binders in the ESRD PPS bundled payment. This application would yield a CY 2027 ESRD PPS base rate of $297.67 ($281.71 + $15.96 = $297.67), prior to the application of the proposed market basket update and budget neutrality factors. We propose to apply the budget neutrality factors to the base rate after the addition of the $15.96. This is appropriate because those budget neutrality factors were calculated using estimated payments, which incorporated the proposed 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 proposed rule, the proposed CY 2027 ESRDB market basket increase based on IGI's first quarter 2026 forecast of the proposed 2024-based ESRDB market basket is 2.6 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 proposed rule, the proposed CY 2027 productivity adjustment is 1.0 percentage point based on IGI's first quarter 2026 forecast of the 10-year moving average of TFP for the period ending CY 2027, thus yielding a proposed CY 2027 ESRDB market basket update

of 1.6 percent for CY 2027. Therefore, the proposed CY 2027 ESRD PPS base rate is $299.55(($297.67 × 1.00267× 0.98783) × 1.016 = $299.55).

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

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

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

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 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 2019 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[13]. As discussed in the CY 2026 ESRD PPS proposed 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 are not proposing to include Jesduvroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2027. Therefore, conditional on the continued receipt of the latest full calendar quarter of ASP data for the renal dialysis drugs discussed later in this document, there are three drugs included in the calculation of the post-TDAPA add-on payment adjustment for CY 2027.

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

[13] 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.

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

We are presenting 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 this time. Utilization for this proposed rule is from January 2025 to December 2025. The estimated post-TDAPA add-on payment adjustment amount for Korsuva® is $0.1068, the estimated post-TDAPA add-on payment adjustment amount for DefenCath® is $5.5951, and the estimated post-TDAPA add-on payment adjustment for Vafseo® is $0.9437. The cumulative estimated post-TDAPA add-on payment adjustment amount for each quarter is presented in Table 12. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we intend to update these calculations with the most recent available utilization and pricing data in the final rule. If the proposal in section II.B.6.b. is finalized, we would update the post-TDAPA add-on payment adjustment amounts quarterly via change requests (CRs). We invite public comments on the estimated CY 2027 post-TDAPA add-on payment adjustment amounts 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)	$0.1068	$5.5951	$0.9437	$6.6456
Q2 (April – June)	$0	$5.5951	$0.9437	$6.5388
Q3 (July – September)	$0	$5.5951	$0.9437	$6.5388

Q4 (October – December)	$0	$5.5951	$0.9437	$6.5388

b. Proposal to Update 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, stakeholders 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 stakeholders 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.

We propose to modify the post-TDAPA add-on payment adjustment methodology to routinely calculate the post-TDAPA add-on payment adjustment amounts each quarter. This 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 are only proposing to perform the calculation more frequently and publish the amounts in CRs quarterly. We acknowledge 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 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 stakeholders have raised that the post-TDAPA add-on payment adjustment amount was often based on outdated data. Under this proposal, we would still publish the first quarter post-TDAPA add-on payment adjustment amounts annually in the rule. 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 are proposing to calculate the post-TDAPA add-on payment adjustment quarterly, we are also proposing to modify 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. 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 note 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 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. Under this proposed policy, 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. CMS intends 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 would also note any discontinuations of the post-TDAPA add-on payment adjustment due to failure to submit ASP data.

We are proposing 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 are also proposing changes to § 413.234(g) to state that we would calculate the post-TDAPA add-on payment adjustment quarterly.

7. Proposal to Incorporate 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 promulgated 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 for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014, to January 1, 2016.

On April 1, 2014, 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 made under the ESRD PPS from January 1, 2016, to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that, in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available.

On December 19, 2014, 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, discussed previously in this 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 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 (80 FR 69013 through 69015). We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 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 biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule (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 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 discussed in section II.B.7.a.(1) of this 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 using 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 two 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.

We have collected sufficient claims data to conduct a rate-setting analysis for phosphate binders. 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 believe that 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. CMS believes 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 (CY 75 FR 49043 through 49044) and currently remain unaccounted for within the ESRD PPS base rate. We propose 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 are proposing a similar methodology in this 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 discuss each element of our proposed methodology in detail. As an overview, we propose to calculate a per-treatment amount for phosphate binders that would

be added to the ESRD PPS base rate. We would 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. This would provide the phosphate binder expenditure amount. We would 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 would 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. We would 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 this proposal. We propose to add the resulting amount to the ESRD PPS base rate, as discussed in section II.B.4. of this proposed rule. We note 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 this proposal, CMS would stop paying for these drugs using the TDAPA for dates of service on or after January 1, 2027.

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. This proposal, if finalized, would establish the methodology for incorporating phosphate binders into the ESRD PPS base rate following the TDAPA period. We propose 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. This proposed paragraph (h) would include the data sources and the steps we would take to calculate a per-treatment amount. We propose that, for dates of service on or after January 1, 2027, oral phosphate binders would no longer be paid for under the ESRD PPS using

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 note that the methodology proposed in this 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 use in the proposed calculation, we analyzed the utilization of phosphate binders reported on the ESRD facility claims for CY 2025. 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 propose 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. 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 propose to exclude first quarter 2025 data and begin our reference period on April 1, 2025. 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 note that claims which have been received, processed, paid, and passed to the National Claims History (NCH)[14] file are considered "complete" because they have been adjudicated, and that we propose 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 propose to update this calculation with the most recent available claims data, which we anticipate 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 are soliciting 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

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

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 propose 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 believe ASP is reasonable for phosphate binders because it reflects the average amount that ESRD facilities spend to obtain the phosphate binders. As we discussed earlier in this section of this proposed rule, the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for renal dialysis drugs and biological products. We are proposing 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 discuss in detail later in this proposed rule.

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 this proposed rule, the values from the most recent calendar quarter of ASP calculations available to the public are from the second quarter of 2026, and due to a two-quarter data lag, these ASP calculations reflect manufacturer sales data submitted to CMS for the fourth quarter of 2025. For the CY 2027 ESRD PPS final rule, the most recent calendar quarter of ASP

calculations available to the public would be the fourth quarter of 2026, which reflects manufacturer sales data submitted into CMS for the second quarter of 2026, and we propose to use that value for purposes of our final calculation.

We propose 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 are soliciting 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 propose 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 providers and suppliers when submitting Medicare Part B claims and are specific to each HCPCS code. For example, for sevelamer carbonate billed under J0602, one billing unit equals 20 mg/tablet. We note 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 this proposed rule, we used the values from the most recent calendar quarter ASP calculations available to the public, which is 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 would update the ASP-based value on the most recent calendar quarter calculations available to the public, which we anticipate being the fourth quarter of 2026.)

TABLE 13: Phosphate Binder HCPCS Codes and ASP

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

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 this proposed rule, CMS calculated the total phosphate binder expenditure amount to be $269,634,395.87. We propose to update this amount in the CY 2027 ESRD PPS final rule using the most recent available data.

(5) Accounting for Operational Costs

In addition to including direct drug costs, we are proposing 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 expect that 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 earlier in this 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 circumstances[15] associated with dispensing oral 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

[15] 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 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).

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 oral phosphate binders under Part B will result in a permanent expansion in operational costs for ESRD facilities. Therefore, CMS believes that 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 December 31, 2025, we determined that 711,875 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 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 emphasize that this proposed approach is not a methodology for pricing phosphate binders; as we discussed earlier, we propose to address the cost of phosphate binders using a weighted average of 100 percent of ASP for each phosphate binder type and dose.[16] Separately, we propose to address the operational costs associated with ESRD facilities providing phosphate binders due to the large patient population and substantial pill volume. We propose 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 propose 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.

[16] 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.

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, oral 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 propose to use the TDAPA-period data to identify and incorporate a distinct, empirically observed operational cost component into the base rate. Multiplying the 711,875 monthly claims that included phosphate binders by the $36.41 flat rate yields a total operational cost amount of $25,919,368.75 for the reference period. As noted previously in this rule, 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 $16,178,063.75.

We are proposing 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 believe that 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.[17] Therefore, we propose this approach as a more data-driven and PPS-consistent method for incorporating operational costs into the base rate.

(6) Combined Calculation

The total number of paid hemodialysis-equivalent dialysis treatments furnished to 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 regardless of whether a phosphate binder was furnished.

To calculate the combined per-treatment amount, we add the direct drug expenditure amount ($269,634,395.87) multiplied by 1.06 to account for operational costs ($16,178,063.75) to get an adjusted phosphate binder expenditure amount of $285,812,459.62. Dividing this adjusted expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments (17,733,591) provides an average per-treatment payment amount of $16.12.

We propose 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 $15.96 ($16.12 × 0.99 = $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 oral 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 ($15.96) to 2027 using the proposed CY 2027 ESRD PPS base rate update. As discussed in section II.B.4. of this proposed

[17] 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.

rule, the proposed CY 2027 ESRD PPS base rate is $299.55. This amount reflects a proposed CY 2027 wage index budget-neutrality adjustment factor of 1.00267, a proposed budget neutrality factor of 0.98783 for the budget neutral policies proposed in sections II.B.8., II.B.9., and II.B.10. of this proposed rule, a proposed base rate addition of $15.96 to include phosphate binders (including both direct drug costs and operational expenses), and the proposed CY 2027 ESRDB payment rate update of 1.6 percent. 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 proposed rule we are proposing to rebase and revise the ESRDB market basket to a CY 2024 base year. The proposed inflation factor used for drugs and biological products for the ESRDB market basket is a composite of various drug-related Producer Price Indexes as discussed in section II.B.1.b.(2) of this proposed rule.

We propose 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 oral 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). 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 are soliciting 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.

8. Proposed 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 4,000 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 stakeholders, including MedPAC and the Government Accountability Office (GAO),[18] 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).[19] These stakeholders 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.[20] 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

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

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

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

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.

CMS is evaluating alternative approaches under section 1881(b)(14)(D)(iv) of the Act. Currently, we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, 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 are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

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.[21] CMS is considering whether modification of these requirements could reduce burden, mitigate incentives for gaming, and better align payment for resource use.

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

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.[22] During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.[23] 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

[22] https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.
[23] https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.

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.[24]

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

[24] 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 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 cap of 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

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 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 proposed 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 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 14.

TABLE 14: 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 note that the previously described analysis should 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 (OM), which may be higher for several reasons. We note that we are not proposing to base any changes to the LVPA on this analysis, however, this analysis has 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 proposed rule. Specifically, this analysis has 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 have also reviewed the patterns of ESRD facility closures over the past few years and have found evidence that ESRD facilities which have closed are disproportionately small. 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-treatments-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 think 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 note 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 calculate 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 because we are attempting to find the extent to which low-volume facilities faced higher costs than other such facilities, so 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 present these results in Table 15:

TABLE 15: 6-Tier LVPA Analysis

Treatment Volume	Number of Eligible ESRD facilities	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

The updated adjustment factors in Table 15 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 $304.77 which equals 1.050.

We note 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 payment 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 this proposed rule. 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 note that we are proposing 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 this 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, CMS proposes 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[25]. This should 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.

For CY 2027 and beyond, CMS proposes 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 are proposing 6 tiers with decreasing adjustment factors as treatment volume increases. The proposed adjustment factors are presented in Table 16. Consistent with the current tiered LVPA, the tier determination would be based on the median treatment volume from the past three years. CMS proposes to apply this policy in a budget neutral manner by applying a factor of 0.98898 to the ESRD PPS base rate. We note 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 impacts analysis from which this budget neutrality factor was derived, we use 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 16: Proposed 6-tier LVPA

[25] 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.

Treatment Volume Tier	Number of eligible ESRD facilities	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 propose 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, CMS believes applying budget neutrality to the base rate would be appropriate now because this proposal would expand LVPA eligibility beyond currently qualifying facilities (that is, to ESRD facilities that furnish more than 4,000 treatments per year). CMS believes the proposed tiered structure balances stakeholder concerns regarding payment cliffs while maintaining alignment with statutory requirements.

In constructing this proposal, we carefully considered the responses to the CY 2024 RFI on the LVPA.[26] 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 note 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 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 this rule. By eliminating the 1,000 and 2,000 treatment tiers, 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 disagree 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 this proposed adjustment factor is lower than others, it would still represent a substantial increase in payments to those facilities. Other commenters

[26] https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources.

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 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 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 are proposing 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 are proposing 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 are proposing 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 note 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 are proposing this policy change be effective January 1, 2027. However, we recognize 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 are soliciting 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 note that changes to the attestation deadline would require a modification to § 413.232(e), likely in the form of adding a new paragraph. We are not proposing any of these changes, but we note 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 request comments on all aspects of this 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 16, the proposed budget neutrality factor, the proposed effective date of January 1, 2027, and the proposed modifications to § 413.232. Additionally, we are requesting comments on the potential administrative challenges associated with this proposed change and the potential solutions discussed previously.

9. Proposed 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 patients[27] 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 OM 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

[27] 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 proposed rule, we use the term "pediatric ESRD patient" except when referring to the regulatory language.

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 dialysis (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 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[28]. In the CY 2023 ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding equitable access for pediatric patients with ESRD. We noted that stakeholders have emphasized the higher labor costs, including the need for increased nursing attention and specialized clinical staff. They asserted 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)[29, 30].

Nevertheless, accurate payment for pediatric ESRD dialysis under the ESRD PPS remains challenging due to small sample sizes and systematic differences between pediatric and

[28] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.
[29] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242.
[30] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i.

adult renal dialysis services. Pediatric 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 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 dialysis 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 dialysis because of the small sample size of pediatric ESRD patients receiving renal dialysis services under the ESRD PPS. Pediatric ESRD dialysis treatments differ from adult ESRD

dialysis treatments in several crucial ways. For example, pediatric ESRD facilities[31] 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.

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 423(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 supply cost per treatment in hospital-based ESRD facilities was $138.23; in 2024, it was $321.22. We note that this increase in pediatric ESRD 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 supply cost from adult ESRD 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

[31] 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 this proposal 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 for the composite rate payments.

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.

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 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:

Mult_*EB* = P * C * (W_*CR* + W_*SB* * 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 18.

We explained in the CY ESRD PPS 2011 final rule that to the extent the 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 otherwise qualifying for the low-volume adjustment under the ESRD PPS, 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 dialysis patients (75 FR 49134).

For this 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 17.

TABLE 17: 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)[32]	0.1404	**
LN(facility size) squared	1.1008	**
Training percentage	1.1388	Not statistically significant

[+] The factors presented in Table 17 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 17 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

[32] LN denotes the natural logarithm which is to say the logarithm of base (e).

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 are proposing revisions to the pediatric ESRD case-mix adjusters and proposing to change our longstanding LVPA policy to appropriately reflect these two main drivers of pediatric ESRD cost.

(2) Proposed Revision of Pediatric Adjusters

We propose 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 are proposing to update these figures according to the most recent data, as follows. We note that instead of using the average payment differential P, we propose 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 18. 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 costs is 1.3298 (that is, 32.98 percent).

TABLE 18: 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 propose to update the SB (outlier) and EB (case-mix) multipliers for pediatric patients according to the established methodology as presented in Table 18.[33] We note that these proposed updates would result in functional adjustment factors for pediatric ESRD patients below those established for purposes of the TPEAPA. 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

[33] 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).

following section, we are proposing 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.

(3) Proposed 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 proposed 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 payment pediatric ESRD facilities to receive additional payments when costs exceeded payment amounts under the composite rate payment system. In other words, the pediatric 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 proposed 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 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 proposed rule, we included facility size as a separate characteristic in our regression model. As noted in Table 17, the pediatric share is an independent indicator of cost from the size of the 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 17, 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 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 propose to revise § 413.232(f) to state that the LVPA is applicable for dialysis treatments furnished to all ESRD patients. As discussed in section II.B.8.

of this proposed rule, we are proposing to make budget-neutral changes to the LVPA tier structure and adjustment factors, and we propose that those changes would be applicable to payments for all ESRD patients beginning in CY 2027. We estimate that this change would appropriately increase payments to ESRD facilities that treat a large share of pediatric 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 this proposed rule.

Additionally, we note that although the LVPA does not currently apply to pediatric ESRD PPS claims, ESRD facilities that provide renal dialysis 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. 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 facilities' patients. We estimate that approximately 24 pediatric ESRD facilities could be eligible for the LVPA based on the current 4,000 -treatment threshold. We expect that if we finalize our proposal to expand the LVPA to pediatric 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 recognize 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 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 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 are not proposing a categorical exemption from these regulations, we are proposing that a pediatric ESRD facility that is seeking low-volume status could request an exception from its MAC from the aggregation of treatment volume for ESRD facilities under common ownership at § 413.232(c). To request such an exception, we propose 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 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 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 provide at least 50 percent of total treatments to 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 should the proposal in section II.B.8. of this proposed rule, not be 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 are proposing the addition of paragraph § 413.232(g)(7) to effectuate this proposed exception and detail the process for requesting the exception.

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

(4) Conforming edits to § 413.232(g) to specify calendar days

As discussed, we are proposing 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 are proposing 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 are also proposing 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 solicit 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 solicit comments on whether another basis for the timeline, for example business days, would be better for ESRD facilities requesting any of these exceptions.

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-dialysis[34] 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.

[34] Home dialysis is dialysis performed by a beneficiary or caretaker in their home. Self-dialysis is dialysis performed by a beneficiary in-center.

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 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 elaborate 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 stakeholder concerns 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 stakeholder feedback, 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.

For this proposed rule, 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).[35] 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.[36] Data was evaluated at the facility level, and the top and bottom 1 percent of observations were winsorized.[37]

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. 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 discussed in section II.B.1. of this proposed rule, the total compensation in the proposed 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

[35] 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.

[36] The training add-on was extended to AKI dialysis payments in the CY 2025 ESRD PPS final rule (89 FR 89168).

[37] 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.

$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, 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 is proposing 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

We propose 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 is proposing 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 are not proposing 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[38]. 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

[38] May 2024 BLS OEWS estimate for category SOC code 29-1141 (Registered Nurses) can be found at http://www.bls.gov/oes/tables.htm.

all other costs associated with furnishing renal dialysis services, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49063).

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 is not proposing 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 proposed 2024-based ESRDB market basket Wages and Salaries price proxy. 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 propose 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 propose 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 this section of

the proposed rule, we believe that this amount is an appropriate proxy for the costs of home dialysis training. We propose to update this training add-on amount with additional data, for example an update in the growth in the proposed 2024-based ESRDB market basket Wages and Salaries price proxy in the final rule, if appropriate.

CMS proposes to implement this increase for the training add-on in a budget neutral manner through an adjustment to the ESRD PPS base rate. 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 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). CMS will 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 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 dialysis patients for home dialysis. Therefore, the rule finalized that ESRD facilities would not receive the training add-on adjustment for 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 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 dialysis training add-on during the onset period.

We propose to allow ESRD facilities to receive the home and self-dialysis training add-on payment adjustment during the onset period. 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 patients which 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 this proposed rule, 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 in this section of the proposed rule, 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 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 propose 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 are soliciting 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 are soliciting comments on other ways in which we could improve both home dialysis and self-dialysis utilization. We are also soliciting comments on the proposal to continue to use 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 this proposed rule, 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 solicit comments on these potential alternative methodologies. We are also soliciting 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.

11. Proposed Modification to TDAPA and post-TDAPA Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on the wholesale acquisition cost (WAC) or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if 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 period as CMS having received the latest full calendar quarter of ASP data and would not discontinue the post-TDAPA payment. 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).

We propose 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. 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 propose 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.

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 believe this 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 this 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 propose modifications to § 413.234(c) and § 413.234(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.

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 this proposed rule.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and

Innovative Equipment and Supplies for CY 2027

In this section of the proposed 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 proposed rule, we identify any items previously approved for the TDAPA 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. Proposed 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. Proposed Update of AKI Dialysis Payment

1. Proposed 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, we propose 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) × 1.00267 × 0.98783) × 1.016 = $299.55), as discussed in section II.B.4. of this proposed rule. Additionally, we propose that if more recent data becomes available after the publication of this proposed rule and before the publication of the 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.1.b. of this proposed rule, we are proposing to rebase and revise the ESRDB market basket to reflect a 2024 base year. This proposal would impact the ESRDB market basket update, which would impact the CY 2027 ESRD PPS base rate and therefore the AKI dialysis payment 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 propose to apply the same wage index under § 413.231 that is used under the ESRD PPS. As discussed in section II.B.2.a. of this proposed 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 propose to continue to apply this methodology to AKI dialysis payments. Consistent with this approach, we propose to apply the same wage index under § 413.231 that is used under the ESRD PPS to the AKI dialysis payment. We propose to continue using this methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice. 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 discussed in section II.B.1.c. of this proposed rule, we are proposing 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 propose 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 propose a CY 2027 AKI dialysis payment rate of $299.55, adjusted by the ESRD facility's wage index. As discussed in section II.B.2.c. of this proposed rule, we propose that, if more recent data becomes available after the publication of this proposed rule and before the publication of the 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 the final rule.

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 are proposing 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 AKI beneficiaries during the training period. AKI beneficiaries 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 note that for AKI beneficiaries 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. Currently there are no other adjustments that apply to AKI dialysis payments.

IV. Proposed 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. Proposed Updates to Requirements Beginning with the PY 2029 ESRD QIP

1. PY 2029 ESRD QIP Measure Set

We propose 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 summarizes the previously finalized measures, proposed new measures, and proposed updated measures that we would include in the PY 2029 ESRD QIP measure set. The technical specifications for current measures that would remain in the measure set for PY 2029 can be found in the CMS ESRD Measures Manual for the 2026 Performance Period.[39]

TABLE 19: Previously Finalized Measures, Proposed New Measures, and Proposed Updated 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
NA*	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

[39] Centers for Medicare & Medicaid Services. (November 2025). CMS ESRD QIP CY 2026 Measure Technical Specifications. Available at https://www.cms.gov/files/document/cy-2025-final-technical-specifications.pdf.

Consensus-Based Entity (CBE) #	Measure Title and Description	Policy Status
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 would 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 proposal

* We note that this measure is being submitted for endorsement under CBE #5110 in this upcoming spring endorsement cycle.
** We note that the prior CBE number listed for this measure in last year's rule (#0321) was incorrect.
*** We are proposing to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this proposed rule.
**** We are proposing to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this proposed 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 proposing 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 proposed rule.

2. Proposed Replacement of the Hypercalcemia Reporting Measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients Clinical Measure

a. Proposed 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 morbidities.[40,41] 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 bone mineral 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. 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 bone mineral 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 are proposing 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 value[42] while the Hyperphosphatemia clinical measure would encourage facilities to

[40] 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.

[41] 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.

[42] 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.

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.[43,44] Prospective studies have also reported lower mortality among patients with improved phosphorus control or treatment with phosphate-binding medications.[45,46] The Hyperphosphatemia clinical measure would help drive decreases in cardiovascular complications, hospitalizations, and overall mortality by incentivizing additional interventions such as nutritional counseling, phosphorus binding medications, or adjustment of dialysis prescription.[47,48,49,50] Compared to the Hypercalcemia reporting measure, the Hyperphosphatemia clinical measure would more directly assess patient-focused clinical outcomes.

b. Proposed Adoption of the Hyperphosphatemia Clinical Measure

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[43] 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.

[44] 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.

[45] 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.

[46] 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.

[47] 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.

[48] 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.

[49] 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.

[50] 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.

(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.[51] The cohort for the Hyperphosphatemia clinical measure would 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.[52]

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.

(2) Measure Calculation

The numerator of this measure includes patient reporting months with a six-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 would then be divided by the total number of patient reporting months for the facility and multiplied by 100 to calculate the percentage of patient reporting months with hyperphosphatemia. Patient reporting months would 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 proposed measure would be calculated only for facilities with more than 10 eligible patients during the reporting period.

(3) Recommendation from the Pre-Rulemaking Measure Review Process

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[51] Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at https://p4qm.org/prmr-measures/muc2025-064.

[52] Further details on the proposed Hyperphosphatemia clinical measure are available at https://p4qm.org/measures/4650.

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.[53,54] 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).[55]

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.[56] 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.[57] The minority of Recommendation Group members who voted not to recommend the measure for inclusion in

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[53] Partnership for Quality Management. Pre-Rulemaking Measure Review webpage. Available at https://p4qm.org/prmr/about.

[54] 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.

[55] 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.

[56] 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.

[57] 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.

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.[58]

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.[59,60] Prospective studies have also reported lower mortality among patients with improved phosphorus control or treatment with phosphate-binding medications.[61,62] The Hyperphosphatemia clinical measure would incentivize and assess additional interventions such as nutritional counseling, phosphorus binding medications, or 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, experts, and consumer advocates who contributed their input

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[58] 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.

[59] 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.

[60] 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.

[61] 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.

[62] 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.

through the Hyperphosphatemia clinical measure design process.[63] 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.[64] Please refer to section IV.B.2.b.(4) of this proposed 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 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 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 would 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

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[63] 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.

[64] Partnership for Quality Measurement. Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients. Available at https://p4qm.org/prmr-measures/muc2025-064.

Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria.[65] 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.[66]

(5) Data Submission and Reporting

We are proposing to require facilities to submit data needed to calculate the Hyperphosphatemia clinical measure using EQRS beginning with the performance period for PY 2029. Facilities would 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 are proposing that facilities would 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 are proposing that data used to calculate the Hyperphosphatemia clinical measure would 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 would 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.

As described in Table 19 of this proposed rule, we are proposing performance standards for the Hyperphosphatemia clinical measure. Facilities would be required to follow the existing

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[65] Partnership for Quality Management. Pre-Rulemaking Measure Review webpage. Available at https://p4qm.org/prmr/about.

[66] 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.

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 welcome public comment on our proposals to remove the Hypercalcemia reporting measure and adopt the Hyperphosphatemia clinical measure beginning with PY 2029.

3. Proposed 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.[67] 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.[68]

We are proposing 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 are proposing to update the national baseline from 2014 data to 2023 data and revise the risk adjustment model to incorporate

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[67] Centers for Medicare & Medicaid Services. (November 2025). CMS ESRD Measures Manual for the 2026 Performance Period: Final Version 11.1. Available at https://www.cms.gov/files/document/esrd-measures-manual-v11-1.pdf.

[68] Centers for Disease Control and Prevention. (March 2024). The NHSN Standardized Infection Ratio (SIR). Available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf.

additional facility-level characteristics, including patient 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. Additionally, these factors identified are not modifiable by the facility and are outside a facility's direct control. The predicted number of BSIs would 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 would better account for differences in facility characteristics associated with BSI risk and cannot be modified by the facility. The proposed 2023 national baseline updates would not change the underlying SIR calculation formula but would 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 and facility characteristics.[69]

The proposed 2023 national baseline updates would allow facilities to compare their performance to more recent national data, improve the accuracy and fairness of external 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 calculated in comparison with their SIR values calculated using the 2014 national baseline. These changes would reflect differences in national baseline rates rather than changes in facility performance. Additionally, the SIRs calculated under the 2014 national baseline would not be directly comparable to the SIRs calculated under the 2023 national baseline because each baseline relies on a distinct national reference dataset and risk adjustment model.

[69] 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.

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 welcome public comment on our proposal to update the NHSN BSI clinical measure beginning with PY 2029.[70]

4. Proposed 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 are proposing to remove the Medication Reconciliation reporting measure and the COVID–19 Vaccination Coverage Among Healthcare Personnel reporting measure, beginning with PY 2029.

a. Proposed Removal of the Medication Reconciliation Reporting Measure

To ensure continued impact and effectiveness of our measure set on facility performance, we are proposing 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 are proposing to remove this measure from the ESRD QIP measure set under measure removal

[70] This proposed change would be a technical update to the measure specifications, rather than a substantive change. However, we are interested in feedback on this technical update and are therefore proposing it in this rule to facilitate public comment.

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 welcome public comment on our proposal to remove the MedRec reporting measure from the ESRD QIP measure set, beginning with PY 2029.

b. Proposed 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 propose 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.[71] While preventing the spread of COVID–19 remains a public health goal, the PHE ended on May 11, 2023,[72] 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.[73]

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

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[71] Centers for Disease Control and Prevention. (September 2025). Surveillance and Data Analytics. Available at https://www.cdc.gov/covid/php/surveillance/index.html.
[72] 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.
[73] Centers for Disease Control and Prevention. Provisional COVID–19 Mortality Surveillance. Available at https://www.cdc.gov/nchs/nvss/vsrr/covid19/.

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.[74] 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.[75] There were well-defined parameters for receiving the COVID–19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

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.[76] For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.[77] 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.

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[74] 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.

[75] 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.

[76] 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.

[77] 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.

On this basis, we propose removing the measure from the ESRD QIP measure set under removal factor 3, a measure does not align with current clinical guidelines or practice.

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 welcome public comment on our proposal to remove the COVID–19 Vaccination Coverage Among Healthcare Personnel measure from the ESRD QIP beginning with PY 2029.

5. Proposed 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 this proposed rule, we are proposing 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 this proposed rule, we also propose 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. If these proposals are finalized as proposed, the ESRD QIP measure set would not include any measures under the Reporting Measure Domain. Therefore, we are proposing 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 are proposing 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 proposed measure domains and weighting, see Table 20 and Table 21.

TABLE 20: 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 proposing to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this proposed rule.
**We are proposing 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 proposed rule.

TABLE 21: Proposed 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 proposing to adopt the Hyperphosphatemia clinical measure, beginning with PY 2029, as discussed in section IV.B.2. of this proposed rule.
**We are proposing to update the NHSN BSI clinical measure beginning with PY 2029, as discussed in section IV.B.3. of this proposed rule.

We welcome 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.

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 (76 FR 70277), 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 would adopt CY 2027 as the performance period and CY 2025 as the baseline period for the PY 2029 ESRD QIP. In the proposed rule, we are estimating the performance standards for the PY 2029 clinical measures in Table 22 using data from CY 2024, which were the most recent data available. We intend to update these performance standards for all measures, using CY 2025 data, in the CY 2027 ESRD PPS final rule.

TABLE 22: Updated Performance Standards for the ESRD QIP Clinical Measures for PY 2029

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th 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%	83.04%	98.91%
Hyperphosphatemia	33.01	23.08	11.72
Standardized Readmission Ratio[a]	34.27	26.50	16.18
NHSN BSI	2.251	0.817	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	89.11%	95.12%	100.00%
ICH CAHPS: Quality of Dialysis Center Care and Operations	55.82%	64.90%	76.18%
ICH CAHPS: Providing Information to Patients	71.09%	77.84%	85.11%
ICH CAHPS: Overall Rating of Dialysis Center Staff	52.57%	65.70%	80.74%
ICH CAHPS: Overall Rating of the Dialysis Facility	56.24%	69.41%	83.83%

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measure: 2024 EQRS; SRR, SHR, STrR: 2024 Medicare claims; Kt/V: 2024 EQRS and 2024 Medicare claims; Hyperphosphatemia measure: 2024 EQRS; NHSN: 2024 CDC; ICH CAHPS: CMS 2024; PPPW: 2024 EQRS and 2024 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2024 EQRS.

7. Eligibility Requirements for the PY 2029 ESRD QIP

In this proposed rule, we are proposing to update eligibility requirements as part of our

proposal to replace the Hypercalcemia reporting measure with the Hyperphosphatemia clinical measure beginning with PY 2029. Our previously finalized and proposed new minimum eligibility requirements are described in Table 23.

TABLE 23: Previously Finalized and Proposed New 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 would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
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

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. For PY 2029, we estimate using available data that a facility must meet or exceed an mTPS of 51 to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2024 instead of the PY 2029 baseline period (CY 2025) because CY 2025 data are not yet available. The estimated payment reduction scale for PY 2029 based on the most recently available data is described in Table 24. We will update the mTPS and associated payment reduction ranges for PY 2029, using CY 2025 data, in the CY 2027 ESRD PPS final rule.

TABLE 24: Estimated Payment Reduction Scale for PY 2029 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-51	0.0%
50-41	0.5%
40-31	1.0%
30-21	1.5%
20-0	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 are seeking 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.[78,79] 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.[80,81,82] Individuals with ESRD report that they often do not receive adequate information about treatment options or do not feel they are the primary decision-maker in their care.[83] 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 with clinical practice guidelines that emphasize integrating patient life goals into kidney replacement therapy decision-making and care planning as established under the

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[78] 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.

[79] 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.

[80] 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.

[81] 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.

[82] 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.

[83] 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.

ESRD Conditions for Coverage finalized in 2008 (73 FR 20370).[84] 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.[85] 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.[86,87]

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.[88] 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.[89] The D-PaLS PRO-PM survey contains a total of eight items and takes approximately 2 minutes to complete.[90] The survey includes example life goals that patients may consider when reflecting on their own life goals; however, the list of

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[84] 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.

[85] 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 (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.

[86] 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.

[87] U.S. Department of Health and Human Services. (2025). HHS Priorities. Available at https://www.hhs.gov/about/priorities/index.html.

[88] 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.

[89] For additional information on the ESRD QIP measure domains and domain weights please refer to section IV.B.5. of this proposed rule.

[90] 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.

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 items[91], 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

[91] "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.

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 are seeking public comment on the proposed 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?

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 (EO) 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 dialysis facility. EO 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 solicit 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 EO 13879 and the evolving needs of ESRD beneficiaries. Specifically, we seek 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.

We note that these RFIs are intended solely to gather information and are not proposals for specific regulatory changes. Information received in response to these RFIs will be considered as CMS develops future rulemaking and policy initiatives in furtherance of EO 13879 and CMS's broader strategic priorities of aligning payment with value and advancing patient-centered care for Medicare beneficiaries with kidney disease. We note that the proposals in other sections of this proposed rule are not final policy and responders should 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 Social Security Act (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 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 are soliciting 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 beneficiaries. We are seeking 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 are considering 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 are particularly interested in policies that would affect modality choice at or before the start of dialysis.

We are not proposing a specific numeric benchmark for the share of Medicare FFS ESRD beneficiaries who receive home dialysis. Instead, we seek comment on actionable policy changes that could measurably increase the number of incidences ESRD PPS beneficiaries select and sustain home dialysis. Commenters may wish to address how incremental increases in initiation rates would translate into additional incident beneficiaries selecting home modalities annually.

CMS emphasizes 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 provides 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 seek comment on the feasibility of achieving a significant increase in utilization of the home dialysis modality for ESRD PPS patients.

3. Request for Information

a. Patient-Level Barriers to Home Dialysis

Interested parties have identified multiple patient-level barriers affecting home dialysis initiation and retention, including limited education, fear of treatment complexity, inadequate in-home support, insufficient space for equipment and supplies, caregiver burden, and financial strain related to utilities and home modifications.

We seek comment on the following:

- What patient-level barriers directly prevent incident ESRD beneficiaries from selecting home dialysis?
- What payment or regulatory mechanisms would effectively mitigate these patient-level barriers within existing authority?
- What temporary or ongoing support would effectively enable beneficiaries to initiate and sustain home dialysis?
- How can CMS structure payment under the ESRD PPS to support beneficiaries who lack adequate care partner support?
- What policies could mitigate caregiver burnout and improve retention of home modalities?
- What approaches could reduce patients' fear of abandonment or lack of real-time support in the home setting?
- What approaches, including dialysis in a home setting, would improve ESRD beneficiaries' abilities to meet their life goals, as discussed in section IV.D. of this proposed rule?

b. Kidney Disease Education and Upstream Modality Preparation

Multiple interested parties have emphasized the importance of early and comprehensive modality education in increasing home dialysis selection.

We seek comment on the following:

- How can CMS improve access to and utilization of Kidney Disease Education (KDE) services prior to dialysis initiation?
- Whether CMS should consider revisions to payment amounts for HCPCS codes G0420 and G0421 to better support comprehensive modality education.
- Whether ESRD facilities should be permitted to furnish and bill for KDE services with appropriate safeguards.
- What policies would encourage earlier nephrology referral and shared decision-making prior to ESRD onset?
- What approaches can CMS use to ensure that beneficiaries who initiate dialysis emergently receive timely modality education and an opportunity to transition to home dialysis when clinically appropriate?
- To what extent should CMS consider if IPPS or Outpatient Prospective Payment System (OPPS) payment adjustments could incentivize urgent start PD programs?

c. Home Dialysis Training and Workforce Capacity

Current home dialysis training payments have not been substantively updated for years. Interested parties have identified payment limitations and workforce constraints as barriers to expansion. While CMS is proposing to update the home and self-dialysis training add-on amount in section II.B.10. of this proposed rule, CMS seeks further comment on opportunities to expand access to home dialysis training while maintaining patient safety and quality of care. Specifically:

- Whether CMS should revise payments outside of the ESRD PPS to promote home dialysis, such as for CPT ® codes 90989 and 90993 to reflect current training intensity and costs.
- Whether CMS should redefine a completed course of home dialysis training to reflect demonstrated independent treatment over a defined period.
- Whether any ESRD CfCs related to patient training (for example, requirements for individualized training or staff competencies) may inadvertently limit the ability of facilities to

scale home dialysis training capacity; and if so, what modifications, if any, CMS should consider.

- Whether aspects of the ESRD PPS payment structure for home dialysis training (including payment tied to individual training sessions) create incentives or operational constraints that limit the use of alternative training models (such as group-based or hybrid approaches).

- What safeguards and best practices would be necessary to ensure that alternative training approaches (e.g., group training, remote modalities, or use of multidisciplinary training staff) continue to meet the individualized needs of patients and maintain patient safety.

- What, if any, workforce development strategies would increase availability of trained home dialysis nurses, particularly in rural and underserved areas?

- To what extent can the patient education requirements regarding patient treatment modalities and setting (§ 494.70) be revised to ensure patients receive quality information through a process that is active, individualized, and iterative over time rather than a passive delivery of education materials?

- How frequently should this information (that is, regarding patient treatment modalities and setting) be offered to the patient? Should CMS specify format and delivery methods?

- How should education delivery and patient response be monitored and documented? What information should be captured and recorded? How should this be incorporated into the patient assessment and plan of care to address barriers to home dialysis to ensure it is acted upon?

- Should CMS revise minimum staff qualification requirements for those who may deliver home dialysis education? What education, qualification, and experience would be most appropriate?

d. Temporary and Staff-Assisted Home Dialysis

Interested parties have proposed other approaches for using payment policy to directly encourage home dialysis, for example temporary staff-assisted home dialysis to support beneficiaries during initiation, following hospitalization, or during periods of caregiver strain.

We seek comment on the following:

- Whether CMS should create new payment mechanisms to promote home dialysis and what timing or clinical considerations would be relevant?
- Whether patients returning home following in-patient hospitalization, outpatient surgery, or serious injury should be eligible for temporary staff assistance to prevent modality failure. Modality failure, commonly used in nephrology, refers to the transition from a chosen dialysis treatment (such as PD) to another form (such as HD) due to technical problems, complications, or inadequate clearance. It signifies the failure of a specific treatment method to sustain a patient's health.
- Whether CMS should permit limited annual respite support to mitigate caregiver burnout?
- What eligibility criteria, staffing qualifications, and supervision requirements should be present within the CfCs for staff-assisted home dialysis to ensure patient safety and high-quality care? What clinical safeguards should be in place?
- What clinical, behavioral, or medical characteristics would make staff-assisted home dialysis inappropriate or unsafe?
- What safeguards should CMS consider to mitigate risks of overutilization or inappropriate use of staff-assisted home dialysis services, while preserving appropriate access for beneficiaries?
- How should such staff-assisted dialysis payments be structured within the ESRD PPS to support initiation and retention?

e. Payment Alignment, Incentives Within the ESRD PPS and ESRD PPS Cost Report

Interested parties have identified structural payment issues that may unintentionally favor in-center dialysis, including capital investment requirements and differential procedure reimbursement.

We seek comment on whether the following policies, if implemented, would meaningfully increase home dialysis utilization:

(1) ESRD PPS Payment Structure

- Whether CMS should consider adjustments to the ESRD PPS base rate or related payment components under § 413.220 to better recognize infrastructure and support costs associated with home dialysis programs.
- Whether CMS should consider a redistribution within the ESRD PPS base rate structure under § 413.220 to facilitate home dialysis uptake.
- Whether CMS should consider a refinement of case-mix adjustments under § 413.235 to facilitate home dialysis uptake.
- Whether CMS should consider establishing a temporary add-on payment adjustment for beneficiaries initiating home dialysis, such as during the first 90 or 120 days of treatment, and how such a payment should be structured to ensure clinical appropriateness.
- Whether CMS should consider restructuring the ESRD PPS onset add-on payment adjustment under § 413.236(a)(2) to incorporate an education component tied to successful home dialysis initiation.
- Whether CMS should consider additional payment for supportive services, such as remote monitoring or enhanced clinical oversight, consistent with statutory authority.
- What costs for ESRD facilities are higher for home dialysis which are not currently accounted for by ESRD PPS payment mechanisms?
- What costs for ESRD beneficiaries are higher for home dialysis compared to in-center modalities?

(2) Home Dialysis Training Add-on Payment Adjustment

- Whether CMS should revise the home dialysis training add-on payment adjustment under § 413.235(c) to reflect actual hours required for training.
- Whether modifications to the home dialysis training add-on payment adjustment under § 413.178(b) would materially affect uptake.
- Whether payment for CPT® code 90989 should be updated to reflect current inflation and training intensity.
- Whether CMS should redefine a "completed course" of training to reflect a patient's ability to complete a full month of home dialysis treatments independently, with the date of service defined as the last treatment date of the first full month of independent home dialysis.
- Whether CMS should increase payment for CPT® code 90993 to better reflect the resources associated with partial or interrupted training.
- Whether revised training payments would influence incident home dialysis uptake within the first 60 days of treatment.

(3) ESRD PPS Onset Adjustment

- Whether CMS should consider restructuring the ESRD PPS onset add-on payment adjustment under § 413.236(a)(2) to incorporate a modality education component.
- Whether CMS should consider if the onset add-on payment should be divided into a care portion and an education portion.
- Whether CMS should consider if a potential education portion of the onset adjustment should be paid in a later month contingent upon successful home dialysis utilization for at least one month without assistance.
- Whether CMS should consider if restructuring the onset add-on adjustment could increase incident home dialysis selection and retention beyond 60 days.

(4) ESRD PPS QIP Measures and Conditions for Coverage Requirements

- Whether CMS should consider enhanced public reporting of facility-level home dialysis rates prior to any modifications to QIP scoring methodologies to emphasize home dialysis utilization or improvement.

- Whether CMS should consider a home dialysis performance-based payment adjustment under the ESRD Quality Incentive Program (QIP) established under section 1881(h) of the Act.

- Whether CMS should consider clarifications to CfC requirements related to modality education under § 494.70. What specific changes would be needed to better clarify the information related to treatment modality, treatment setting, and services not offered by the facility that would support increased use of home dialysis?

- Whether factors such as current payment policy, operational practices, or other considerations may limit the use of alternative home dialysis training approaches (for example, group-based or hybrid models), and whether CMS should consider changes to support greater flexibility while maintaining individualized, patient-centered training and ensuring patient safety.

- Whether CMS should consider technical skills and patient evaluation to expand the types of licensed dialysis staff eligible to conduct training while maintaining patient safety.

- To what extent are workforce shortages limiting incident home dialysis uptake?

- What additional ESRD PPS modifications would most directly influence incident modality selection?

- Whether CMS should CMS encourages submission of quantitative analyses, actuarial estimates, and operational assessments.

- What modifications should CMS consider making to the CfCs to align with currently permissible certification action or determination by creating within the CfCs a designation of a "home-only" ESRD facility which would not provide any in-center dialysis? Is there evidence and data that under the current certification action that such a designation requires less physical infrastructure to provide care?

- What would be the impact of updating the CfCs to create a designation of a "self-dialysis-only" ESRD facility which would not provide any in-center dialysis other than self-dialysis (patients perform dialysis on themselves in-center)? Would such a designation require less staffing to provide care? What other CfC requirements would be necessary or need to be modified for this type of facility to ensure patient health and safety?

(5) ESRD Cost Report Modifications

- Consideration as to whether modifications to the ESRD freestanding and hospital-based cost reports to capture more granular home dialysis costs will assist in aligning payment with value and encourage ESRD facilities to promote home dialysis modalities.
- Whether CMS should consider collecting separate data on travel costs for ESRD facility staff for home HD visits.
- Whether CMS should consider collecting more precise data on nursing hours per home training session.
- Whether CMS should collect data on hidden costs such as internet connectivity, equipment installation, shipping, and remote monitoring devices.
- Whether the advantages of collecting additional data on the ESRD cost reports would outweigh the administrative burdensome.

(6) Information-sharing and Cross Component Coordination with Accountable Care Organization and Medicare Shared Savings Program

- CMS recognizes that certain Medicare FFS beneficiaries with advanced chronic kidney disease (CKD) or ESRD may be aligned with Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (Shared Savings Program) or CMS Innovation Center models, like the Kidney Care Choices (KCC) Model, that incorporate accountability for Medicare Parts A and B spending and quality. We seek comments to inform potential future rulemakings on whether care coordination structures, data sharing practices, or operational alignment between ESRD facilities and ACO participants could support clinically appropriate

modality education around home dialysis and treatment planning at or prior to dialysis initiation, while preserving patient choice and avoiding duplicative or conflicting incentives across programs.

f. Home Dialysis Machine Installation. Home Modifications and Supply Chain Issues

We are interested in whether changes in home dialysis technology since implementation of the ESRD PPS in 2011 have affected equipment installation requirements, as well as issues related to the delivery and storage of supplies.

We seek comment on the following:

- Has installation of home dialysis machines since 2011 changed significantly?
- Does the cost of any of the post-2011 required additional small home modifications affect patient's willingness to initiate home dialysis?
- Whether CMS should consider engaging with the home dialysis industry to improve supply ordering and delivery processes.
- Do excess supply delivery and storage requirements deter patients from selecting home dialysis?
- Whether CMS should consider providing time-limited additional payments to ESRD facilities that establish and implement in-center self-dialysis training and support programs, including patient education, supervised self-cannulation, and progressive independence in treatment tasks, designed to prepare beneficiaries to independently perform dialysis and transition to home dialysis modalities.

g. Incentives for In-Center Self-Dialysis Programs

This includes consideration of whether temporary payment adjustments could support ESRD facilities developing in-center self-dialysis programs as transitional pathways to home dialysis.

We seek comment on the following:

- Whether CMS should consider, to the extent permitted under section 1881 of the Act and existing ESRD PPS authority, providing time-limited additional payments to ESRD facilities that establish and implement in-center self-dialysis training and support programs designed to prepare beneficiaries to independently perform dialysis and transition to home dialysis modalities.

- Whether an in-center self-dialysis program would measurably increase transition to home dialysis among incident beneficiaries.

- What staff qualifications and supervision should be required within the in-center facility during this time of transitional dialysis when the patient is progressing toward self-dialysis?

- How should CfC requirements be structured to better support patients in successfully transitioning to home dialysis? What requirements could be implemented to assist patients in reaching this goal?

h. Increasing the Number of Facilities Offering Home Dialysis

Approximately half of ESRD facilities offer home dialysis programs.

We seek comment on the following:

- What levers CMS can employ to encourage additional facilities to establish home dialysis programs?

- To what extent CMS should consider infrastructure payments or time-limited adjustments to potentially increase geographic access.

- Are there changes that could be made to the requirements for home dialysis monitoring and/or support services that would reduce burden on dialysis facilities without negatively impacting patient health and safety?

i. Payment Incentives within Physician Fee Schedule (PFS) and OPPS: Access Placement, Referral and for Physician Participation in Home Dialysis Training

This includes consideration of collaborative efforts within the PFS and OPPS to revise payment structures to recognize physician time and effort associated with referral to home dialysis and participation in home dialysis training.

We seek comment on the following:

- Whether CMS should test equalizing payments between PD catheter placement and vascular access placement to remove potential financial disincentives and whether demonstration authority should be used to test such alignment.
- Whether CMS should establish an additional payment recognizing the time physicians spend referring patients to home dialysis and coordinating training.
- Whether payment should be provided to physicians who actively participate in home dialysis training and care planning.
- Whether CMS should provide payment recognition for physicians supporting in-center self-dialysis programs that may serve as a transition pathway to home dialysis.

j. Monthly Capitation Payment (MCP) Structure for Home Dialysis Patients

Consideration of collaborative efforts within the PFS to revise the MCP payment structure for physicians treating home dialysis patients.

We seek comment on the following:

- Whether CMS should consider payment variations for home dialysis patients under the MCP framework. Should we establish additional coding and payment for home dialysis MCP services for different numbers of visits?
- Whether MCP payment amounts for home dialysis patients should be higher than in-center MCP payments to reflect increased care coordination and oversight demands.
- Acknowledging that section 1881(b)(3)(B)(ii)(I) of the Act requires that patients receiving home dialysis have face-to-face (without the use of telehealth) clinical assessments with the physician at least monthly during the initial 3 months, how would greater telehealth

flexibility for home dialysis patients improve retention and quality of care, including infection rates, within the first 60 days?

k. Skilled Nursing Facilities and Transitional Settings

Patients often discontinue home dialysis following hospitalization or skilled nursing facility (SNF) admission.

We seek comment on the following:

- What policies would encourage continued use of PD in SNFs when clinically appropriate?
- Whether CMS should consider payment adjustments or demonstrations to incentivize SNFs to support home dialysis modalities.
- What additional health and safety requirements should be considered for ESRD facilities or nursing facilities to support continuity of modalities and ensure the safe delivery of home dialysis in this setting?
- What recommendations would improve the transition of dialysis patients between different care settings (hospital, institutional, and home)?
- Are ESRD facilities receiving electronic admission, transfer, and discharge notices as patients transition through hospitals so that they can monitor and track their patients? If not, why?

l. Measuring Success

As noted previously, we are considering whether to focus on incident home dialysis initiation with a minimum duration threshold.

We seek comment on the following:

- Is a 60-day continuation threshold appropriate to ensure sustained initiation?
- To what extent CMS should consider a longer duration threshold for quality measurement purposes.

- How should CMS account for clinical contraindications or patient choice in assessing uptake?

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.[92] As a result, beneficiaries with ESRD often delay or forgo hospice services to continue receiving dialysis 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.[93] MedPAC also highlighted the potential for improved care coordination and reduced end-of-life spending when beneficiaries receive hospice services.

d. Home Dialysis and Structural Barriers

Current policy requires that home dialysis be performed independently by the 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 beneficiaries with palliative care goals who may benefit from receiving dialysis in a home-based, lower-burden setting.

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

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[92] 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.

[93] https://www.medpac.gov/wp-content/uploads/2025/09/Tab-F-Hospice-ESRD-cancer-Sept-2025-SEC.pdf

We are soliciting public comment on the following topics:

a. Definition of Palliative Dialysis

- How should CMS define "palliative dialysis" for purposes of Medicare policy?
- What clinical characteristics distinguish palliative dialysis from maintenance dialysis?
- Are there specific modalities or treatment patterns that are more consistent with palliative care?

b. Beneficiary Eligibility and Targeting

- What objective and auditable criteria should be used to identify beneficiaries appropriate for palliative dialysis?
- Should eligibility be limited based on indicators such as serious illness, frailty, functional impairment, or limited prognosis?
- What role should existing constructs (for example, homebound status or hospice eligibility) play in defining the target population?
- Should CMS consider hybrid eligibility approaches that combine functional and prognostic criteria?

c. Care Delivery and Settings

- What are the primary barriers to delivering palliative dialysis in home or community-based settings?
- Could access to staff-assisted home dialysis improve beneficiary experience for those receiving palliative dialysis?
- What services are necessary to support safe and effective home-based dialysis (for example, equipment setup, cannulation assistance, and monitoring)?
- How should CMS delineate responsibilities across ESRD facilities, home health agencies, and hospice providers? CMS also seeks comment on the potential future interaction between hospice and home health services for beneficiaries receiving dialysis.

- To what extent do current Medicare coverage and payment policies affect the ability of beneficiaries to receive home health and hospice services concurrently for different conditions, and how might these policies impact access to and coordination of dialysis services, including in the home setting?

- What operational or payment-related challenges do providers face in coordinating services across ESRD facilities, hospice providers, and home health agencies, and are there opportunities to improve alignment while maintaining program integrity and patient protections?

CMS also seeks comment on the coordination of renal dialysis services with hospice care, including in the context of palliative dialysis:

- What are the operational, clinical, and financial barriers to coordination between ESRD facilities and hospice providers in furnishing palliative dialysis?

- What factors affect the feasibility of integrating hospice and dialysis services, including care planning, payment, and provider roles?

- Are there aspects of the ESRD CfCs or Hospice Conditions of Participation (CoPs) that may create challenges for coordination or alignment of patient goals for care?

- What best practices or models exist for integrating dialysis and hospice services while supporting patient-centered, goal-concordant care?

- What considerations should CMS take regarding staff training, care planning, and interdisciplinary coordination when dialysis is furnished in conjunction with hospice services?

d. Payment Policy Considerations

- To what extent are palliative renal dialysis services currently encompassed within the ESRD PPS bundled payment?

- Are there services or supports that are not adequately reflected in current payment?

- What approaches could support palliative dialysis without creating duplicative payment across the ESRD PPS, Hospice PPS, and Home Health PPS?

- Should CMS consider time-limited or narrowly targeted payment adjustments?

e. Program Integrity and Safeguards

- What safeguards are necessary to ensure appropriate targeting and prevent overutilization?
- How should CMS ensure that any policy remains focused on comfort-oriented care?
- What documentation, certification, or care planning requirements would be appropriate?

f. Potential Models and Policy Approaches

We are interested in feedback on potential approaches, including the following: Targeted refinements within the ESRD PPS; time-limited supports for home-based dialysis; Models testing staff-assisted home dialysis for narrowly defined populations; approaches to improve coordination between ESRD care and hospice services while preserving hospice bundle integrity; and model testing under section 1115A of the Act (CMS Innovation Center), including demonstrations designed to assess quality improvement and cost impacts.

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 dialysis 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 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 days of PD 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 four decades. When thinking about 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 dialysis 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 proposing to incorporate into 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 a patient's clinical needs require more than 3 treatments per week. These requirements impose administrative burden on facilities of all sizes, and may be particularly challenging for smaller, independent providers with limited billing infrastructure. A daily rate structure would eliminate the need for the 3/7 conversion, reduce the complexity of tracking monthly treatment limits (13 or 14 per month depending on month length), and simplify billing for patients who receive care at multiple facilities or experience service interruptions. 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 dialysis—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 providers are not inadvertently incentivized to reduce the frequency or intensity of care. We seek public input on how a daily payment structure could be designed and monitored to achieve these goals.

4. Request for Information

We are soliciting public comment on the potential advantages, challenges, and operational considerations associated with changing the ESRD PPS unit of payment from a per-treatment to a monthly (daily rate) structure. We are not proposing any specific changes; rather, we are seeking information to inform potential future rulemaking. Specifically, we request comments on the following questions:

- Would it be appropriate for the ESRD PPS to adopt a daily payment rate following the methodology currently applied for home CAPD and CCPD (that is, a daily rate equal to three-sevenths (3/7) of the per-treatment base rate)? What are the advantages and disadvantages of this approach compared to the current per-treatment payment structure?

- Should a daily rate apply to all dialysis modalities, or are there specific modalities or circumstances for which we should consider a hybrid approach? If we should consider a hybrid approach, please explain why and describe how such an approach should be structured.

- What specific administrative burden associated with the current per-treatment payment structure would be reduced or eliminated under a daily rate? Conversely, what new administrative requirements might a daily rate introduce, and how could those be minimized? We are particularly interested in the perspectives of smaller, independent ESRD facilities.

- To what extent would a daily payment rate reduce barriers to alternative dialysis schedules, such as nocturnal dialysis, short daily home HD, or more frequent home HD? Are there specific treatment modalities or patient populations for which a daily rate would most meaningfully expand access to individualized care?

- How would a daily payment structure affect patients who receive care at multiple facilities or experience interruptions in service during a month? What billing and claims processing safeguards would be needed to prevent duplicate payment and ensure accurate reimbursement when a patient transfers between facilities?

- How should the daily rate be calibrated to maintain budget neutrality while accounting for differences in resource intensity between home HD and PD? Are there specific cost components or patient populations that would require special consideration in establishing a budget-neutral daily rate?

- Should CMS consider changes to the patient-level adjustment factors under the ESRD PPS to account for conditions associated with differences in the number of medically necessary treatments each month? If so, which patient conditions are the primary drivers of patient-level cost variation, and how should those conditions be reflected in a daily payment framework?

- What processes or frameworks could CMS consider to appropriately recognize changes in patient-level cost variation that may occur over time due to developments in clinical practice such as the introduction of new drugs, technologies, or other therapies that would be considered renal dialysis services?

- What, if any changes should CMS consider making to the ESRD PPS outlier policy to account for unusual variations in the type or amount of medically necessary care in the context of a monthly or daily payment rate? How should the outlier threshold and payment cap be structured under a daily payment system? We note that under the current payment system for CAPD and CCPD, we calculate outlier spending per home HD-equivalent treatment, which is compared to the standard outlier threshold values to determine the applicable outlier amount.

We note that we could apply a similar methodology for daily rate outlier calculations in the future, or we could consider changes to our methodology.

- How should CMS design quality monitoring and oversight mechanisms to ensure that a shift to a daily payment rate would not create incentives for providers to reduce the frequency, duration, or intensity of dialysis services below what is clinically appropriate for individual patients? What quality measures, data reporting requirements, or audit mechanisms would be most effective in detecting and deterring underutilization of care under a daily payment structure? We seek comment on whether the current quality monitoring infrastructure, including the ESRD QIP and the Five-Star Quality Rating System, is sufficient to support a transition to a daily payment rate, and whether any enhancements to those programs would be needed.

- What steps could CMS take toward advancing value-based purchasing in ESRD and AKI care? How does the provision of high-quality ESRD and AKI care for Medicare beneficiaries impact costs for ESRD facilities providing renal dialysis services and how does it impact beneficiaries' total cost of care across settings?

- Which patient populations would be best served by a daily payment rate? Would any patient populations—such as pediatric patients, patients with AKI, or patients receiving palliative dialysis—be better served by maintaining a per-treatment payment amount? If so, please explain why and describe how CMS should structure payment for those populations.

- What necessary changes, if any, would ESRD facilities need to make to their billing systems, internal tracking processes, and operational workflows to accommodate a change to the unit of payment? How long do ESRD facilities anticipate they would need to implement these changes? Are there specific MAC system changes or claims processing edits that would be required?

- How does the current ESRD PPS unit of payment, and conversely how would a daily unit of payment, compare to payment structures that other payors use to pay for renal dialysis services?

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 are soliciting 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 proposed 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, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. 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.[94] 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 will update the information collection burden to reflect updated facility and patient counts in the CY 2027 ESRD PPS 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 proposed 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 x $49.18), or an annual total of approximately $122.95 ($36,885 / 300 facilities) per facility in the sample. We will update the aggregate cost of EQRS data validation to reflect updated wage estimates in the CY 2027 ESRD PPS final rule. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938-1340).

2. Estimated Burden Associated with NHSN Data Validation Requirements for PY 2029

In this proposed rule, we estimate that the aggregate cost of the NHSN data validation for PY 2029 will be approximately $73,770 (1,500 hours x $49.18), or a total of approximately $245.90 ($73,770 / 300 facilities) per facility in the sample. We will update the aggregate cost of

[94] 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.

NHSN data validation to reflect updated wage estimates in the CY 2027 ESRD PPS final rule. While the burden hours estimate will not change, 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 proposing measure updates in this proposed rule that would affect the burden associated with EQRS reporting requirements beginning with PY 2029. We are proposing two measure removals and one measure adoption that would affect the burden associated with EQRS reporting requirements beginning with PY 2029. We provide the burden estimate for PY 2029 in this proposed rule to reflect the impact of these proposals if finalized and will update the information collection burden to reflect updated facility and patient counts in the CY 2027 ESRD PPS final rule. In this proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 109 data elements for 513,475 patients across 7,582 facilities, for a total of 55,968,775 elements across all patients (109 data elements x 513,475 patients). If the two measure removals and one measure adoption are finalized as proposed, the total number of data elements would decrease to 49,807,075 data

elements based on current patient and facility counts. At 2.5 minutes per element, the changes would yield approximately 274 hours per facility. Therefore, the PY 2029 burden would be 2,075,295 hours (approximately 274 hours x 7,582 facilities). Using the Medical Records Specialist wage estimates available at this time, we estimate that the PY 2029 total burden cost will be approximately $102.1 million (2,075,295 hours x $49.18). The estimated reduction in burden associated with the measure updates is described in Table 25.

TABLE 25: Updated Estimated Reduction in Burden Associated with Proposed 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**
Proposed Adoption of the Hyperphosphatemia Clinical Measure	135.45	$6,544.74	1,026,950	$49,622,224
Proposed Removal of the Hypercalcemia Reporting Measure	-67.72	-$3,272.37	-513,475	-$24,811,112
Proposed Removal of the MedRec Reporting Measure	-101.58	-$4,908.56	-770,213	-$37,216,668
	Total Change in Information Collection Burden Hours: -256,738			
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-256,738) = **-$12,405,556**			

The information collection request currently approved under the OMB control number 0938-1340 will be revised and submitted to OMB for approval.

If you comment on these information collections, that is, reporting, recordkeeping, or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this proposed rule.

Comments must be received by the date and time specified in the “DATES” section of this rule.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this

preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. 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 proposes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and proposes to rebase and revise the ESRDB market basket and labor-related share. This rule also proposes 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 proposing 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 proposed 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 proposes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed 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 proposes updates for the ESRD QIP, which would replace the Hypercalcemia reporting measure with the Facility Level Percentage of Chronic Hyperphosphatemia clinical measure. This rule also proposes updates to the NHSN BSI clinical measure. Additionally, this rule proposes to remove the MedRec reporting measure and the COVID-19 Vaccination Coverage Among HCP reporting measure from the ESRD QIP measure set beginning with PY 2029.

4. Requests for Information (RFIs) on Advancing Dialysis Care

This proposed rule includes several RFIs related to potential policies to (1) increase home dialysis utilization among incident ESRD PPS beneficiaries, (2) improve access to palliative care for ESRD beneficiaries, and (3) promoting efficiency in dialysis service delivery by reevaluating the unit of payment under the ESRD PPS and AKI dialysis payment system. This section constitutes RFIs only. CMS is not proposing specific policy changes related to the RFIs at this time.

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 Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

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 proposed revisions to the ESRD PPS would result in an increase of approximately $90 million in ESRD PPS payments to ESRD facilities in CY 2027. This includes the estimated impact of the proposed ESRD PPS market basket update of 1.6 percent ($130 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 $90 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

First, as discussed in section II.B.3.b. of this proposed rule, we estimate that outlier payments in CY 2026 will be approximately 3.0 percent of total ESRD PPS payments.

Accordingly, the proposed increases to the FDL and MAP amounts for CY 2027 are projected to reduce ESRD PPS payments by approximately 1.9 percent ($150 million). At the same time, we estimate that approximately $430 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 $430 million (5.5 percent), which is offset by the proposed 5.3 percent increase to the ESRD PPS base rate for phosphate binders and the estimated 2.0 percent increase in payments under the post-TDAPA add-on payment adjustment in CY 2027. 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 proposed incorporation of phosphate binders, is a 1.5 percent increase in payments to ESRD facilities. In addition, this amount includes, but is not impacted by, any budget neutral proposals 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 $170 million, an increase from around $34 million in CY 2026. These amounts are included in the estimated $90 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 $90 million overall increase in ESRD PPS payments to ESRD facilities in CY 2027.

2. AKI

We estimate that the proposed updates to the AKI dialysis payment rate would 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 proposing in this proposed rule, the updated ESRD QIP will result in $23.3 million in estimated payment reductions across all facilities for PY 2029.

4. RFIs on Advancing Dialysis Care

These RFIs solicit comments on increasing home dialysis uptake, improving palliative care under the ESRD PPS, and promoting efficiency in dialysis service delivery. These RFIs do not propose any policy changes and therefore do not have a direct economic impact under Executive Order 12866.

5. Summary of Impacts

We estimate that the combined impact of the policies proposed in this rule on payments for CY 2027 is approximately $90 million based on the combined estimates of the updated ESRD PPS and the AKI dialysis payment rates.[95] We estimate the impacts of the ESRD QIP for PY 2029 to be $102.1 million in information collection burden and $23.3 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 proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the proposed CY 2027 ESRD PPS and AKI dialysis payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective 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 6.3 percent based on the proposed CY 2027 ESRDB market basket percentage increase of 2.6 percent reduced by the proposed CY 2027 productivity adjustment of 1.0 percentage point, as well as the proposed increase to the ESRD PPS base rate

[95] 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.

from the inclusion of phosphate binders into the base rate, would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS would increase by 1.1 percent and payments under the AKI payment system would increase by 6.0 percent because of the proposed policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the proposals in this proposed rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2029, we intend to update the estimated costs associated with the information collection requirements under the ESRD QIP in the CY 2027 ESRD PPS 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 proposed updates to the ESRD PPS and AKI dialysis payment rates would result in a total increase of approximately $90 million in Medicare payments to ESRD facilities in CY 2027, which includes the amount associated with the proposed inclusion of phosphate binders to the base rate, the proposed updates to the outlier threshold amounts, and proposed 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 proposed updates to

the AKI dialysis payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $70 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $20 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS proposed rule, we assume that the total number of unique commenters on last year's ESRD PPS proposed rule, which was 208 for the CY 2026 ESRD PPS proposed rule, is equal to the number of individual reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2026 ESRD PPS proposed rule. For these reasons, we determined that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We used a similar methodology for calculating the regulatory review costs in the CY 2026 ESRD PPS proposed and final rules. We solicit comments on this approach.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assumed that each reviewer reads approximately 50 percent of this proposed rule. We seek comments on this assumption.

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 benefits[96] (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 320 minutes (5.33 hours) for the staff to review half of this proposed rule, which has a total of approximately 80,000 words. For each entity that reviews the rule, the estimated cost is $634.80 (5.33 hours x $119.10). Therefore, we estimate that the total cost of reviewing this regulation is $132,038.40 ($634.80 x 208 reviewers).

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 proposed 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 proposed rule, we use CY 2025 data from the Medicare Part A and Part B Common Working Files as of February 13, 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 proposed updates to the ESRD PPS base rate are described in section II.B.4. of this proposed rule. Table 26 shows the impact of the estimated CY 2027 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2026.

[96] 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.

TABLE 26: Impacts of the Proposed 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	7,551	23.6	-1.9%	1.5%	0.0%	0.0%	0.0%	0.0%	1.1%
Type									
Freestanding	7,225	22.8	-1.8%	1.4%	0.0%	0.0%	0.0%	0.0%	1.1%
Hospital-based	326	0.8	-4.8%	5.6%	0.1%	0.0%	-0.1%	-0.1%	2.0%
Ownership Type									
Large dialysis organization	5,817	18.4	-1.6%	2.0%	0.0%	0.1%	0.0%	-0.1%	1.9%
Regional chain	883	2.9	-2.9%	-4.3%	0.0%	-0.3%	0.0%	0.4%	-5.6%
Independent	484	1.5	-2.1%	6.0%	0.0%	-0.1%	0.0%	0.3%	5.6%
Hospital-based[1]	326	0.8	-4.8%	5.6%	0.1%	0.0%	-0.1%	-0.1%	2.0%
Unknown	41	0.0	-2.2%	3.8%	0.0%	0.5%	0.2%	1.2%	5.1%
Geographic Location									
Rural	1,222	3.2	-2.0%	1.5%	0.0%	1.9%	0.0%	-1.1%	1.9%
Urban	6,329	20.4	-1.9%	1.5%	0.0%	-0.3%	0.0%	0.2%	1.0%
Census Region									
East North Central	1,161	3.1	-2.1%	2.1%	0.0%	0.7%	0.0%	-0.3%	1.9%
East South Central	592	1.4	-1.9%	0.3%	0.0%	0.8%	0.0%	-1.5%	-0.8%
Middle Atlantic	844	3.0	-2.3%	2.7%	0.0%	-0.1%	0.0%	-0.1%	1.7%
Mountain	425	1.4	-1.4%	2.2%	0.0%	0.0%	0.0%	-0.8%	1.4%
New England	198	0.9	-2.1%	2.2%	0.0%	0.0%	0.0%	0.6%	2.2%
Pacific[2]	970	4.5	-1.6%	1.3%	0.0%	-0.8%	0.0%	1.8%	2.3%
Puerto Rico and Virgin Islands	54	0.1	-2.2%	5.4%	-0.1%	-0.9%	0.0%	0.5%	4.3%
South Atlantic	1,773	4.9	-2.1%	1.2%	0.0%	-0.1%	0.0%	-0.7%	-0.2%
West North Central	467	1.3	-2.0%	2.7%	0.0%	1.5%	0.0%	-0.3%	3.4%
West South Central	1,067	3.0	-1.9%	-0.1%	0.0%	-0.2%	0.0%	-0.5%	-1.1%
Facility Size									
Less than 3,000 treatments	655	0.6	-1.8%	3.4%	0.2%	1.6%	0.0%	0.0%	4.9%
3,000 to 3,999 treatments	440	0.7	-1.8%	2.4%	0.0%	4.9%	0.0%	-0.3%	6.7%
4,000 to 4,999 treatments	493	0.8	-2.0%	1.8%	0.0%	6.7%	0.0%	-0.4%	7.6%
5,000 to 5,999 treatments	586	1.1	-1.8%	2.0%	0.0%	4.4%	0.0%	-0.3%	5.8%
6,000 to 6,999 treatments	625	1.4	-2.0%	1.3%	0.0%	2.4%	0.0%	-0.3%	2.9%

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)
7,000 to 7,999 treatments	609	1.5	-2.0%	1.3%	0.0%	0.4%	0.0%	-0.4%	0.8%
8,000 or more treatments	4,143	17.5	-1.9%	1.4%	0.0%	-1.1%	0.0%	0.1%	0.0%
Percentage of Pediatric Patients									
Less than 2%	7,459	23.5	-1.9%	1.5%	0.0%	0.0%	0.0%	0.0%	1.1%
Between 2% and 49%	42	0.1	-1.4%	2.1%	-0.3%	-0.9%	0.1%	-0.5%	0.6%
More than 50%	50	0.0	-3.7%	7.4%	2.0%	-1.1%	0.0%	0.3%	6.2%

[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.

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 proposed in section II.B.3. of this proposed rule. As we previously discussed, we estimate a 1.9 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 would be approximately 4.8 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 proposed budget neutral changes to payments for pediatric ESRD patients, including the proposed revisions to the pediatric case-mix adjusters as well as the proposed expansion of the LVPA to treatments for pediatric ESRD patients. Table 26 shows that these proposed policies would increase payments by 2.0 percent to ESRD facilities with 50 percent or more pediatric patients, while the largest decrease would be 0.3 percent for ESRD facilities with between 2 and 49 percent pediatric patients.

Column F represents the impact of proposed budget neutral changes to the LVPA. The largest estimated increase would be 6.7 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 would decrease approximately 1.1 percent.

Column G represents the impact of proposed budget neutral changes to the home and self-dialysis training add-on, which we estimate would have distributional impacts of 0.1 percentage point or less for nearly all categories of ESRD facilities.

Column H represents the effect of the proposed 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 proposal to update the LRS from 55.2 percent to 63.5 percent in CY 2027. These proposed updates would be budget neutral, so the total impact of these proposed policy changes is 0.0 percent. However, we estimate there would be distributional impacts because of these proposed updates. The largest increase would be to ESRD facilities in the Pacific region, which would receive 1.8 percent higher payments because of the updated ESRD PPS wage index and LRS. The largest decrease would be for ESRD facilities in the East South Central region, which would 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 proposed rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA add-on payment adjustment amounts as well as the proposed inclusion of phosphate binders into the base rate, the proposed changes to payments for pediatric ESRD patients, the proposed LVPA changes, and the proposed changes to the home and self-dialysis training add-on. This column also reflects the proposed ESRD PPS payment rate update for CY 2027 of 1.6 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2027 of 2.6 percent reduced by the proposed productivity adjustment of 1.0 percentage point. We expect that overall ESRD facilities would experience a 1.1 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 5.6 percent decrease in CY 2027 estimated Medicare payments for regional chains to a 5.6 percent increase in estimated payments for independent facilities.

(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 would be approximately $6.2 billion. This estimate considers a projected decrease in FFS Medicare ESRD beneficiary enrollment of 1.5 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 1.1 percent overall increase in the CY 2027 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 1.1 percent in CY 2027, which translates to approximately $20 million.

(5) Alternatives Considered

(a) Proposal to Incorporate Phosphate Binders into the ESRD PPS Base Rate

In section II.B.7. of this proposed rule, we discuss our proposal to incorporate phosphate binders into the ESRD PPS base rate. We considered, but did not propose, delaying the incorporation of phosphate binders and continuing TDAPA for another year. We did not propose to continue 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 is already included in the ESRD PPS base rate. As discussed in section II.B.7. of this proposed rule, we are proposing to recalculate the operational increase based on more recent utilization and price data. We believe that this proposed 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 proposed base rate modification would 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 more than 3.0 percent in payments as a result of these changes. We believe this proposed significant increase would appropriately align payment with resource use for these small entities and therefore, we did not consider alternatives to minimize this proposed increase.

(b) Proposed Modifications to the LVPA

As discussed in section II.B.8. of this proposed rule, we are proposing to extend the LVPA beyond the current treatment volume threshold of 4,000 treatments per year in a budget neutral manner. We considered proposing this policy non-budget neutrally but did not do so because budget neutrality for this proposal is more consistent with our well-established methodologies. We also considered alternative tier structures, for example an 8-tiered structure that includes separate tiers for facilities that furnish fewer than 1,000 and 1,000 to 2,000 treatments or a 4-tier structure that stops at 6,000 treatments. As discussed in section II.B.8. of this proposed rule, we proposed the 6-tier methodology based on our analysis of cost report data and consideration of responses to comments on our CY 2024 RFI on the LVPA. We note that

this proposed policy would 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 1.6 percent. For independent and hospital-based ESRD facilities, we estimate an impact of 0.1 percentage point or less. We believe this proposed change to the LVPA would appropriately align payment with resource use for small entities and therefore, we did not consider alternatives to minimize the impact of the proposed increases for those categories of small entities that would be significantly impacted.

(c) Proposed Payment for Pediatric ESRD Patients

As discussed in section II.B.9. of this proposed rule, we are proposing to recalculate the case-mix adjustment factors for pediatric ESRD patients. We considered, but did not propose, to extend the TPEAPA rather than establish permanently increased adjustment factors. We considered this so that we could have more time to collect and evaluate pediatric specific cost report data. However, as noted in the section, we believe that we have enough information to establish permanent adjusters for CY 2027, and our evaluation of cost report data indicates that the proposed adjusters are 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 proposed policies is estimated to be 0.2 percentage point or less and therefore, we did not consider alternatives to mitigate the impact of this proposed increase on small entities.

(d) Proposed Modifications to the Home and Self-Dialysis Training Add-on

As discussed in section II.B.10. of this proposed rule, we propose increasing the home dialysis training add-on amount based on updated wage data using the methodology established in the CY 2017 ESRD PPS final rule. We considered, but did not propose, to base this add-on amount directly on cost report data. We also considered proposing separate training add-on amounts for HD and PD. As discussed in section II.B.10. of this proposed rule, we propose the single training add-on based on the established methodology because it is most consistent with

the established principles of the PPS. Basing payment directly on cost report data is not something we have historically done, and we generally maintained payment parity between HD and PD to promote efficiency.

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 proposed policies is estimated to be 0.1 percentage point or less and therefore, we did not consider alternatives to mitigate the impact of this proposed 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 proposed 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 proposed rule, we used CY 2025 data from the Medicare Part A and Part B Common Working Files as of February 13, 2026, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2025 claims to 2026 and 2027 using various updates. The proposed updates to the AKI dialysis payment amount are described in section III.C. of this proposed 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.

TABLE 27: Impacts of the Proposed 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	5,176	315.6	5.7%	-1.1%	-0.1%	0.0%	6.0%
Type							
Freestanding	5,072	310.1	5.7%	-1.1%	-0.1%	0.0%	6.0%
Hospital-based	104	5.6	5.7%	-1.1%	-0.1%	-0.1%	5.9%
Ownership Type							
Large dialysis organization	4,240	241.6	5.7%	-1.1%	-0.1%	-0.1%	6.0%
Regional chain	604	34.1	5.7%	-1.1%	-0.1%	0.3%	6.4%
Independent	211	33.7	5.7%	-1.1%	-0.1%	-0.1%	5.9%
Hospital-based[1]	104	5.6	5.7%	-1.1%	-0.1%	-0.1%	5.9%
Unknown	17	0.6	5.7%	-1.1%	-0.1%	1.0%	7.2%
Geographic Location							
Rural	853	44.6	5.7%	-1.1%	-0.1%	-1.1%	4.9%
Urban	4,323	271.0	5.7%	-1.1%	-0.1%	0.1%	6.2%
Census Region							
East North Central	821	55.5	5.7%	-1.1%	-0.1%	-0.5%	5.6%
East South Central	382	18.1	5.7%	-1.1%	-0.1%	-1.4%	4.6%
Middle Atlantic	567	40.2	5.7%	-1.1%	-0.1%	0.1%	6.2%
Mountain	315	22.6	5.7%	-1.1%	-0.1%	-1.0%	5.1%
New England	151	7.5	5.7%	-1.1%	-0.1%	0.5%	6.6%
Pacific[2]	686	49.5	5.7%	-1.1%	-0.1%	2.3%	8.5%
Puerto Rico and Virgin Islands	6	0.1	5.7%	-1.1%	-0.1%	-4.0%	1.8%
South Atlantic	1,237	71.9	5.7%	-1.1%	0.0%	-0.8%	5.3%
West North Central	325	16.2	5.7%	-1.1%	-0.1%	-0.4%	5.7%
West South Central	686	34.0	5.7%	-1.1%	-0.1%	-0.7%	5.3%
Facility Size							
Less than 3,000 treatments	255	10.4	5.7%	-1.1%	0.0%	-0.1%	6.0%
3,000 to 3,999 treatments	251	11.8	5.7%	-1.1%	-0.1%	-0.5%	5.5%
4,000 to 4,999 treatments	302	13.4	5.7%	-1.1%	-0.1%	-0.6%	5.4%
5,000 to 5,999 treatments	379	18.3	5.7%	-1.1%	-0.1%	-0.5%	5.5%
6,000 to 6,999 treatments	436	21.0	5.7%	-1.1%	-0.1%	-0.4%	5.7%

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)
7,000 to 7,999 treatments	434	20.5	5.7%	-1.1%	-0.1%	-0.4%	5.7%
8,000 or more treatments	3,119	220.1	5.7%	-1.1%	-0.1%	0.1%	6.2%
Percentage of Pediatric Patients							
Less than 2%	5,158	314.9	5.7%	-1.1%	-0.1%	0.0%	6.0%
Between 2% and 49%	17	0.7	5.7%	-1.1%	0.0%	-0.7%	5.4%
More than 50%	1	0.0	5.7%	-1.1%	-0.1%	-1.5%	4.5%

[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.

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 proposal to increase the ESRD PPS base rate to incorporate payment for phosphate binders, which directly increases the AKI dialysis payment rate by approximately 5.7 percent. Column D shows the combined budget neutral impact associated with the proposed 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 proposed budget neutrality factor of 0.98898 associated with the proposed changes to the LVPA. As we noted earlier in this rule, the proposed changes to pediatric payments result in a budget neutrality factor of 0.99999.

Column E shows the impact from the proposed changes to the home dialysis training add-on, which have a 0.1 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. Column F shows the effect of the proposed CY 2027 wage index described in section II.B.2. of this proposed rule as well as the proposed increase to the LRS for CY 2027.

Column G shows the overall impact of all policies discussed in this proposed rule, including the 1.6 percent increase to the ESRD PPS base rate, which reflects the proposed ESRDB market basket percentage increase for CY 2027 of 2.6 percent reduced by the proposed productivity adjustment of 1.0 percentage point as well as the proposed incorporation of phosphate binders into the ESRD PPS base rate. We expect that overall ESRD facilities would experience a 6.0 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 1.8 percent for the Puerto Rico and the US Virgin Islands to an increase of 8.5 percent for the Pacific 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 proposing updates to the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this proposed change will have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate that approximately $90 million in total payments would 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 proposing applying other facility-level or case-mix adjustment factors, for example the LVPA with the changes proposed 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 7,582 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 45.6 percent or 3,458 of the facilities that

have sufficient data to calculate a TPS would receive a payment reduction for PY 2029. Among an estimated 3,458 facilities that will receive a payment reduction, approximately 53.1 percent or 1,835 facilities will receive the smallest payment reduction of 0.5 percent. Based on our proposals, the total estimated payment reductions for all the 3,458 facilities expected to receive a payment reduction in PY 2029 will be approximately $23,324,157. Facilities that do not receive a TPS do not receive a payment reduction.

Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2029 ESRD QIP.

TABLE 28: Estimated Distribution of PY 2029 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	3935	53.2%
0.5%	1835	24.8%
1.0%	1091	14.8%
1.5%	423	5.7%
2.0%	109	1.5%

*189 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 were calculated using the most recent data available (specified in Table 28) in accordance with the proposals in this proposed rule. Measures used for the simulation are shown in Table 29.

TABLE 29: Data Used to Update the Estimate 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 2023-Dec 2023	Jan 2024-Dec 2024
SRR	Jan 2023-Dec 2023	Jan 2024-Dec 2024
SHR	Jan 2023-Dec 2023	Jan 2024-Dec 2024
PPPW	Jan 2023-Dec 2023	Jan 2024-Dec 2024
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2023-Dec 2023	Jan 2024-Dec 2024
Pediatric HD Kt/V	Jan 2023-Dec 2023	Jan 2024-Dec 2024

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
Adult PD Kt/V	Jan 2023-Dec 2023	Jan 2024-Dec 2024
Pediatric PD Kt/V	Jan 2023-Dec 2023	Jan 2024-Dec 2024
VAT Long-term Catheter Rate	Jan 2023-Dec 2023	Jan 2024-Dec 2024
STrR	Jan 2023-Dec 2023	Jan 2024-Dec 2024
NHSN BSI	Jan 2023-Dec 2023	Jan 2024-Dec 2024
Clinical Depression	Jan 2023-Dec 2023	Jan 2024-Dec 2024
Hyperphosphatemia	Jan 2023-Dec 2023	Jan 2024-Dec 2024

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 proposed policies outlined in section IV.C. of this proposed 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 proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2024 and December 2024 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 30 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.

TABLE 30: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029

	Number of Facilities	Number of Treatments 2024 (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	7582	24.8	7393	3458	-0.39%
Facility Type:	7237	23.9			-0.39%
Freestanding			7106	3352	
Hospital-based	345	0.9	287	106	-0.35%
Ownership Type:	5839	19.3			-0.37%
Large Dialysis			5776	2715	
Regional Chain	894	3.1	868	329	-0.30%
Independent	477	1.5	451	304	-0.75%
Hospital-based (non-chain)	345	0.9	287	106	-0.35%
Unknown	27	0.0	11	4	-0.36%
Facility Size:	6733	22.4			-0.36%
Large Entities			6644	3044	
Small Entities[1]	822	2.4	738	410	-0.59%
Unknown	27	0.0	11	4	-0.36%
Rural Status:	1227	3.4			-0.34%
Yes			1187	499	
No	6355	21.4	6206	2959	-0.40%
Census Region:	1060	4.0			-0.32%
Northeast			1009	404	
Midwest	1642	4.7	1587	762	-0.41%
South	3419	10.0	3370	1722	-0.43%
West	1397	6.0	1364	540	-0.31%
US Territories[2]	64	0.2	63	30	-0.34%
Census Division:	1172				-0.43%
East North Central		3.3	1135	575	
East South Central	591	1.5	585	283	-0.40%
Middle Atlantic	860	3.1	819	342	-0.34%
Mountain	429	1.4	419	168	-0.32%
New England	200	0.9	190	62	-0.23%
Pacific	968	4.5	945	372	-0.31%
South Atlantic	1765	5.3	1733	881	-0.42%
West North Central	470	1.4	452	187	-0.36%
West South Central	1063	3.2	1052	558	-0.45%
US Territories[2]	54	0.1	53	23	-0.27%
Unknown	10	0.1	10	7	-0.70%
Facility Size (# of total treatments):	1190	1.5			-0.32%
Less than 4,000 treatments			1047	380	
4,000-9,999 treatments	3389	8.4	3355	1527	-0.37%
Over 10,000 treatments	3003	14.8	2991	1551	-0.42%

[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.

(2) Effects on the Medicare Program

For PY 2029, we estimate that the ESRD QIP will contribute approximately $23,324,157 in Medicare savings. For comparison, Table 31 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2029.

TABLE 31: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2029

Payment Year	Estimated Payment Reductions
PY 2029	$23,324,157
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 proposed rule, we are proposing to replace the Hypercalcemia reporting measure with the Facility Level Percentage of Chronic 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 proposed 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 32 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 32: Accounting Statement: Classification of Estimated Transfers, and Costs

ESRD PPS and AKI (CY 2027)	
Category	**Primary Estimate**
Annualized Monetized Transfers	$70 million
From Whom To Whom	Federal Government To ESRD Providers
Category	**Primary Estimate**
Increased Beneficiary Co-insurance Payments	$20 million
From Whom To Whom	Beneficiaries To ESRD Providers
ESRD QIP for PY 2029	
Category	**Primary Estimate**
Annualized Monetized Transfers	-$23.3 million
From Whom To Whom	Federal Government To ESRD Providers

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to evaluate alternatives that may reduce regulatory burden on small entities when a proposed 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 proposed rule on small entities. Overall, this proposed rule includes proposed updates to the ESRD QIP, as well as proposed revisions to payment rates and policies applicable to the ESRD PPS and AKI dialysis payment. These proposed 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 proposed rule would 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, which would include NAICS category 622110, hospitals, and NAICS category 622310, specialty hospitals (which can include children's hospitals). We focus 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 proposed in this rule would not have significant impact on hospitals overall. Furthermore, as shown in Table 26, we estimate that payments to hospital-based ESRD facilities would increase by approximately 2.0 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, would increase by approximately 6.2 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.[97] The U.S. Census Statistics of U.S. Businesses (SUSB) data shows there are 459 firms below this threshold.

As shown in Table 33, 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 G8 only reflects data at the firm level and not at the establishment level, where multiple establishments could be owned by a firm.

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 above. As shown in Table G8, the impact of the proposed QIP measure changes in this rule would 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 proposed changes have an impact that falls below the 3 to 5 percent threshold.

TABLE 33: (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%

[97] http://www.sba.gov/content/small-business-size-standards.

Firm Size (by Receipts)	Avg. Annual Revenue	Firm Count	Annualized Cost Savings per Firm	% of Small Firms	Revenue Test
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 SUSB.

We also considered the impacts of changes in transfers due to proposed payment policy changes in this proposed 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 484 ESRD facilities that are independent and 326 ESRD facilities that are hospital-based, as shown in the ownership category in Table 26, 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 753 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 342 nonprofit ESRD facilities that are also considered

small businesses, there are 1,216 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 proposed 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 26, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 1.1 percent. For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.0 percent increase in Medicare FFS payments for CY 2027. An independent facility (as defined by ownership type) is likewise estimated to receive a 5.6 percent increase in Medicare FFS payments for CY 2027. Although not displayed in Table 26, we have found that among the 810 ESRD facilities that are small businesses, approximately 29.4 percent (238 out of 810) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive a 6.7 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 4.1 percent increase in Medicare FFS payments. Additionally, among the 753 nonprofit ESRD facilities, approximately 19.1 percent (144 out of 753) furnish fewer than 3,000 treatments per year. These ESRD facilities are estimated to receive a 7.7 percent increase in Medicare FFS payments. By contrast, those furnishing 3,000 or more treatments per year are estimated to receive a 1.4 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 $90 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 proposed rule. This analysis is based on the assumptions described earlier in section VIII.C of this proposed rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 3,458 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2029 ESRD QIP, 410 are ESRD small entity facilities. The overall payment reduction for small entities would be approximately 0.59 percent of total ESRD payments, which is below the 3 to 5 percent threshold HHS uses to assess significant economic impact. We present these findings in Table 28 ("Estimated Distribution of PY 2029 ESRD QIP Payment Reductions") and Table 30 ("Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2029"). Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2029 ESRD QIP. Table 30 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 proposed 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 proposed ESRD PPS base rate increase. In addition, the proposed updates to the ESRD QIP are expected to generate cost savings for small entities. As discussed in section VIII.C.5.a.(5) of this CY 2027 ESRD PPS proposed rule, CMS considered alternative policy approaches to minimize the impact of this proposed rule on small entities. However, CMS did not propose these alternatives, because the proposed 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.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not anticipate that this proposed 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 3.7 percent under this proposed rule. Accordingly, the Secretary has determined that the proposed 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 proposed rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under the threshold criteria of

Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of 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, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 regulatory action, generating annualized costs of approximately $0.1 billion.

IX. 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-P, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices. In addition to the Addenda, limited data set files (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 June 5, 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 proposes to amend 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 1395ww.

2. Section 413.232 is amended by--

a. Revising paragraphs (b)(1), (c) introductory text, (f), (g)(5), and (g)(6)(i), (ii), and (iv); and

b. Adding paragraph (g)(7).

The revisions and addition 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:

* * * * *

(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.

* * * * *

(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, based on the additional amount added to the transitional drug add-on payment adjustment amount for phosphate binders under paragraph (c)(4) of this section.

(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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