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CMS Finalizes Payment Increase for ESRD Facilities in CY 2025

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) issued the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) final rule for calendar year (CY) 2025. See the fact sheet here. CMS finalizes proposals to:

- increase ESRD payment rates by 2.7 percent,
- implement a new ESRD PPS-specific wage index,
- modify the low-volume payment adjustment (LVPA) policy to create a two-tiered LVPA,
- include oral-only drugs in the ESRD PPS bundled payment,
- extend the home dialysis benefit to patients with Acute Kidney Injury (AKI),
- update the ESRD facility Conditions for Coverage (CfCs),
- make changes to the ESRD Quality Incentive Program (QIP), and
- make additional changes to the ESRD Treatment Choices (ETC) Model.

This final rule is scheduled to be published in the *Federal Register* on November 12, 2024.

CMS FINALIZES 2.7 PERCENT PAYMENT INCREASE TO ESRD FACILITIES IN CY 2025

The ESRD PPS provides a single case-mix adjusted payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a Medicare beneficiary's home. This bundled payment includes most drugs, services, supplies, and capital-related costs related to maintenance dialysis services. CMS adjusts ESRD PPS facility rates for geographic, low-volume service delivery, and other factors. CMS also provides additional ESRD PPS payment adjustments for the following:[1]

- training add-on for home and self-dialysis modalities,
- outlier payments for high-cost cases due to differences in the type or amount of medically necessary care,
- Transitional Drug Add-on Payment Adjustment (TDAPA) for certain new renal dialysis drugs and biological products,

[1] See page 17 of the unpublished rule.

- TDAPA for New and Innovative Equipment and Supplies (TPNIES) for certain new and innovative renal dialysis supplies and equipment,
- 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, and
- Post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period.

CMS finalizes a 2.7 percent (2.2 percent proposed) increase in payments to ESRD facilities in CY 2025, relative to CY 2024. For hospital-based facilities, CMS estimates a 4.5 percent (3.9 percent proposed) increase relative to CY 2024, while for freestanding facilities, CMS projects an increase in total payments of 2.6 percent (2.1 percent proposed). CMS estimates that the Medicare program will pay $6.2 billion* ($7.2 billion proposed) to ESRD facilities for furnishing renal dialysis services in CY 2025. This reflects a projected 2.1 percent decrease in Medicare fee-for-service ESRD enrollment.

For CY 2025, CMS finalizes a base rate of $273.82 ($273.20 proposed), which is a $2.80 increase to the CY 2024 finalized base rate of $271.02. This reflects CMS's finalized wage index budget neutrality adjustment of 0.988600 (0.990228 proposed), and a productivity-adjusted market basket increase of 2.2 percent (1.8 percent proposed).

CMS finalizes a new ESRD PPS-specific wage index, which combines data from the Bureau of Labor Statistics Occupation Employment Wage & Statistics and freestanding ESRD facility cost reports to adjust payments for geographic differences in wages. Previously, CMS has used the hospital wage index values for each geographic area derived from hospital cost reports. CMS also finalizes its proposal to update wage index values to reflect the latest core-based statistical area (CBSA) delineations by the Office of Management and Budget (OMB)[2]. CMS finalizes the proposal to continue to apply a wage index floor (0.6000) and a 5 percent cap on wage index decreases from the prior year.

CMS also finalizes updates to the methodology for calculating the outlier services fixed-dollar loss (FDL) and Medicare allowable payment (MAP) amounts and finalizes expansion of the list of ESRD outlier services. CMS finalizes its proposal to update the MAP amounts using CY 2023 claims data, update the outlier services FDL amount for pediatric patients using CY 2023 claims data, and update the FDL amount for adult patients using CY 2021, CY 2022, and CY 2023 claims data.

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*The final rule fact sheet contradicts the unpublished final rule, and states $6.6 billion. CMS has not released a correction as of the completion of this rule summary.

[2] OMB Bulletin No. 23-01

CMS finalizes updates to outlier payment amounts for CY 2025, as outlined in Tables 1 and 2 below.[3] CMS notes that the finalized inclusion of composite rate drugs and biological products is the reason for the significant increase in the finalized FDL and MAP amounts for pediatric patients due to high-cost composite rate drugs furnished to pediatric beneficiaries.

Table 1. Outlier Payment Changes for Pediatric Beneficiaries in CY 2025

	Final 2025 Amount	Proposed 2025 Amount	Final 2024 Amount
FDL	$234.26	$223.44	$11.32
MAP	$59.60	$58.39	$23.36

Table 2. Outlier Payment Changes for Adult Beneficiaries in CY 2025

	Final 2025 Amount	Proposed 2025 Amount	Final 2024 Amount
FDL	$45.41	$49.46	$71.76
MAP	$31.02	$33.57	$36.28

CMS Mirrors ESRD Base Rate in the Final AKI Payment Rate

Since CY 2017, Medicare provides coverage for renal dialysis services provided to individuals with AKI. CMS finalizes an updated payment rate of $273.82 ($273.20 proposed) for AKI payment in CY 2025, which mirrors the finalized base rate for the ESRD PPS. For CY 2025, CMS estimates a 2.3 percent (1.9 percent proposed) increase in payments to ESRD facilities for services provided to patients with AKI, relative to CY 2024. For hospital-based facilities, CMS estimates a 3.4 percent (2.6 percent proposed) increase relative to CY 2024. CMS estimates that aggregate payments to ESRD facilities for renal dialysis services provided to AKI patients are expected to increase by $1 million in CY 2025, relative to CY 2024.

CMS FINALIZES TWO-TIERED APPROACH FOR THE LOW-VOLUME PAYMENT ADJUSTMENT

A low-volume facility is an ESRD facility that has furnished less than 4,000 treatments in each of the three previous cost reporting years. These facilities receive an additional payment, called the LVPA. Noting that parties such as the Medicare Payment Advisory Commission (MedPAC) and Government Accountability Office (GAO) have recommended the LVPA be

[3] See page 9 of the unpublished rule.

refined to target ESRD facilities critical to beneficiary access, CMS finalizes its proposal to modify the LVPA into two tiers. ESRD facilities furnishing less than 3,000 treatments per cost reporting year would receive a 28.9 percent (28.4 percent proposed) upward adjustment to the ESRD PPS base rate, and ESRD facilities furnishing 3,000 to 3,999 treatments per year would receive an 18.3 percent (18.1 percent proposed) adjustment. Tier determination for eligible facilities would be based on the median treatment count over the three previous cost reporting years. CMS believes these changes will support LVPA goals, better aligning payment with resource use by increasing payment to the lowest volume facilities. These changes are also intended to mitigate the "cliff effect," where a facility might be incentivized to remain below 4,000 services to receive the LVPA.

In a Request for Information (RFI), CMS sought comment on potential modifications to the LVPA methodology with a focus on new ESRD facilities. Specifically, CMS sought feedback on ways a new ESRD facility could appropriately demonstrate it expects to be low volume, the role of a reconciliation process for new ESRDs, and whether the LVPA could be changed to better support ESRD facilities opening in underserved areas. CMS states it did not receive any new feedback in response to this RFI on LVPA eligibility or the attestation process, compared to what was received in the CY 2024 ESRD PPS RFI on the LVPA. CMS did not respond to comments in this rule but will take feedback into consideration for future rulemaking and policy development.

CMS TO INCLUDE ORAL-ONLY DRUGS IN THE ESRD PPS BUNDLED PAYMENT

CMS initially excluded oral-only drugs from the single, bundled payments made under the ESRD payment system because of a lack of pricing and utilization data for these drugs. Despite certain laws prohibiting payment for oral-only renal dialysis drugs to be made under the bundled payment system prior to January 1, 2025, CMS finalized a mechanism for including oral-only renal dialysis drugs in the ESRD PPS bundled payments in the CY 2016 ESRD final rule effective January 1, 2025.[4] Therefore, in this finalized rule, CMS describes how it will operationalize this policy.

In the proposed rule CMS discussed potentially increasing the TDAPA amount for phosphate binders. In response, CMS received comments noting the additional costs associated with ESRD facilities providing phosphate binders that are not currently included in the ESRD PPS base rate. CMS noted their agreement with commenters and is finalizing a policy to pay the TDAPA for phosphate binders based on 100% of the Average Sales Price (ASP) increased by $36.41. CMS expects that incorporating oral-only drugs and biological products will increase

[4] 80 FR 68968

access to these drugs based on the inclusion of Medicare Part D drugs into the ESRD PPS and resulting improved access for beneficiaries without Part D coverage.

Clarification on Medicare Payment for Phosphate Binders for AKI

CMS clarifies that ESRD facilities will not be responsible for furnishing phosphate binders to AKI patients while these drugs are covered under the TDAPA within the ESRD PPS. Instead, these medications will remain payable under Medicare Part D for AKI beneficiaries with an approved Part D indication until they are fully incorporated into the ESRD PPS bundled payment. This policy is consistent with past CMS actions, such as with calcimimetics, and ensures appropriate reimbursement without requiring budget-neutral adjustments that could reduce AKI dialysis rates.

CMS EXPANDS HOME DIALYSIS FOR AKI, ADDS TRAINING SUPPORT

The Trade Preferences Extension Act of 2015 (TPEA) extended Medicare coverage to include dialysis for individuals with AKI, enabling AKI patients to access care at ESRD facilities. With this shift, AKI dialysis payments align with ESRD payment structures, including adjustments for geographic and wage factors, ensuring consistency with broader Medicare payment standards. Initially, home dialysis was excluded for AKI patients due to perceived complexities in treatment, as AKI was viewed as short-term and requiring close monitoring. However, evolving research and public advocacy have highlighted the benefits of home dialysis for certain AKI patients, particularly through peritoneal dialysis (PD), which has shown advantages in patient recovery, quality of life, and health equity.

Based on feedback from industry stakeholders and a Technical Expert Panel (TEP), CMS re-evaluated its position on home dialysis for AKI. CMS finalizes its proposal to extend Medicare coverage for home dialysis modalities to AKI patients. Under this finalized rule, AKI patients will have access to both PD and hemodialysis (HD) at home, with Medicare providing payment parity across in-center and home-based dialysis.

Expanded Home Dialysis for AKI

AKI patients will now have the option to receive Medicare-covered home dialysis, including both PD and HD. Payment rates will align with in-center dialysis rates under the ESRD PPS base rate, with geographic and other relevant adjustments. This expansion supports greater flexibility, aligns with patient-centered care goals, and addresses disparities in dialysis treatment options.

Add-On Payment for Home Dialysis Training

To cover costs associated with training for home dialysis, CMS will provide an additional payment adjustment of $95.60 per session, up to 15 sessions for PD and 25 sessions for HD.

This payment is intended to support ESRD facilities in offering and training patients on home dialysis modalities, encouraging broader adoption of home treatment options.

Geographic and Budget Neutral Adjustments

Payment adjustments for AKI dialysis will incorporate geographic factors, while maintaining budget neutrality to avoid increasing overall Medicare costs. Although budget neutrality factors apply, the per-treatment rate reduction effectively rounds to $0.00, maintaining current levels and enabling service expansion.

CMS FINALIZES UPDATES TO ESRD QUALITY INCENTIVE PROGRAM FOR PY 2027: INTRODUCING INDIVIDUAL KT/V MEASURES AND STREAMLINING REPORTING REQUIREMENTS

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is designed to evaluate and improve the quality of care provided to patients with ESRD. In this finalized rule, CMS offers several finalized updates for payment year (PY) 2027 (performance period 2025), which aim to enhance the accuracy and relevance of performance assessments within the ESRD QIP.

CMS Finalizes Introduction of Kt/V Dialysis Adequacy Measure Topic

The current single, comprehensive Kt/V Dialysis Adequacy measure has been replaced with a "Kt/V Dialysis Adequacy Measure Topic." This topic includes four separate measures for adult and pediatric patients on HD and PD, enabling more accurate scoring based on patient age and dialysis type. Each facility's performance on these measures will now account for 11 percent of the total performance score (TPS), the same weight as the previous comprehensive measure.

CMS Removes the NHSN Dialysis Event Reporting Measure

The National Healthcare Safety Network (NHSN) Dialysis Event reporting measure will be removed from the ESRD QIP measure set in PY 2027. This decision aims to streamline the program by emphasizing high-impact measures that better promote improvements in care. Despite its removal, facilities must still adhere to the NHSN Dialysis Event protocol and report all necessary data for the NHSN Bloodstream Infection (BSI) Clinical Measure.

Finalized Revisions to Measure Domains and Weights

The Clinical Care and Reporting Measure Domains are revised to reflect these updates. The Kt/V Dialysis Adequacy Topic will maintain its 11 percent weight within the Clinical Care Domain. Meanwhile, the Reporting Measure Domain will reallocate measure weights to ensure that each measure within this domain is balanced and impactful.

UPDATES TO PERFORMANCE STANDARDS FOR THE PY 2027 ESRD QIP

The ESRD QIP requires the establishment of performance standards for selected measures each performance year, in accordance with sections 1881(h)(4)(A), (B), and (C) of the Act. These standards include levels of achievement and improvement and must be set before the performance period begins.

Performance Standards for Clinical Measures to be Based on CY 2023 Data

In the final rule, CMS sets updated benchmarks, achievement thresholds, and median performance levels for each clinical measure based on 2023 data. For example, facilities must reach specific benchmarks in measures, such as Kt/V Dialysis Adequacy, for different patient groups, vascular access type, standardized readmission, and standardized transfusion ratios. These standards are designed to encourage facilities to reach high levels of quality care across all measures. For a complete list of performance standards for PY 2027 Clinical Measures, refer to Table 15 of the unpublished final rule.[5]

Updates to Reporting Measure Requirements

Table 16 of the unpublished finalized rule[6] outlines the frequency and data elements required for successful reporting of the ESRD QIP reporting measures for PY 2027. These include:

- **MedRec:** Monthly reporting of medication reconciliation data.
- **Hypercalcemia:** Monthly reporting of total uncorrected serum or plasma calcium lab values.
- **COVID-19 Vaccination Coverage Among HCP:** Quarterly reporting of vaccination coverage data.
- **Facility Commitment to Health Equity:** Annual attestation to five domains of health equity.
- **Screening for Social Drivers of Health:** Annual reporting of the number of patients screened for five health-related social needs.
- **Screen Positive Rate for Social Drivers of Health:** Annual reporting of patients screening positive for these needs.

Additionally, each measure has specific eligibility criteria based on minimum patient volumes, types of patients, and service offerings. For example, to be scored on Kt/V measures, a facility must treat at least 11 qualifying patients per measure type (adult or pediatric, hemodialysis or

[5] Page 309 of the unpublished rule.
[6] Page 310 of the unpublished rule.

peritoneal dialysis). These criteria allow CMS to assess facilities on relevant measures while considering facility size and service limitations.

Updates to the Payment Reduction Scale

The final scale for PY 2027 payment reductions reflects a sliding scale that starts at a 0.5 percent reduction for facilities scoring 50–41 points below the minimum TPS of 51, with penalties reaching up to 2 percent for scores between 0–20.

CMS FINALIZES CHANGES TO THE ESRD TREATMENT CHOICES MODEL

The ESRD Treatment Choices (ETC) Model[7] is an alternate payment model for the care of patients with chronic kidney disease (CKD), finalized in 2020 as part of the final rule "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures" published on September 29, 2020 (85 FR 61114). The model tests the use of payment adjustments to encourage kidney transplants and home hemodialysis. The aim of this model is to encourage providers to invest in care coordination programs that will increase patient choice, reduce Medicare expenditures, and improve outcomes. The ETC Model went into effect on January 1, 2021, and is mandatory for dialysis facilities and managing clinicians in randomly selected geographic areas across all 50 states and D.C.

The ETC Model includes two payment adjustments:

- Home Dialysis Payment Adjustment (HDPA) - an upward adjustment on certain payments made to participating ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims.
- Performance Payment Adjustment (PPA) - a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis. This adjustment is based on ESRD facilities' and Managing Clinicians' home dialysis rate and transplant rate, among attributed beneficiaries during the applicable measurement year (MY).

These adjustments are made to the adjusted ESRD PPS base rate for selected facilities and to the MCP for selected managing clinicians. Greater positive and negative adjustments for model participants are phased in over the duration of the model.

CMS finalizes changes to the methodology CMS uses to identify transplant failure for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model, to decrease the likelihood that CMS is overestimating the true number of transplant

[7] https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model

failures for model purposes. Currently, beneficiaries are attributed to the ETC Model after they meet several criteria, including having a kidney transplant failure less than 12 months after the transplant date. Regulations define an ESRD Beneficiary as a beneficiary meeting either of the below criteria:

1. The beneficiary is receiving dialysis or other services for ESRD up to and including the month when the beneficiary receives a kidney transplant; or
2. The beneficiary has received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date; or less than 12 months after the beneficiary's latest transplant date and has a documented kidney transplant failure diagnosis code on a Medicare claim.

CMS finalizes the proposal to modify the second criterion to specify that the beneficiary's latest transplant date must be identified by 1) two or more MCP claims in the 180 days following the date following kidney transplant receipt, 2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date, **or** 3) indication of a transplant failure after the transplant data based on Scientific Registry of Transplant Recipients (SRTR) data. If one or more of these criteria is met, the beneficiary will be considered an ESRD Beneficiary for ETC Model purposes.

CMS also sought feedback through an RFI on topics related to increasing equitable access to home dialysis and kidney transplantation, noting barriers to home dialysis such as the need for home care support, a lack of clinical confidence in prescribing home dialysis, financial costs to patients, and storage limitations in patients' homes. Interested parties have spoken with CMS regarding challenges associated with increasing home dialysis access, especially for beneficiaries with lower socioeconomic status. The ETC Model was intended to address these barriers.

Performance accountability in the ETC Model is set to end on June 30, 2026, leading to CMS concern that the end of this performance accountability may diminish incentives for dialysis organizations to invest in home dialysis access. CMS solicited feedback on policies that could be incorporated into a successor model or more generally regarding ways to improve beneficiary access to home dialysis. In particular, CMS is interested in policies that may encourage Medicare Advantage Organizations (MAOs) to focus on these efforts. Key questions and topics CMS sought feedback on are:

1. What future Innovation Center models that include home dialysis should incorporate lessons learned from the ETC Model
2. Specific barriers to home dialysis and how they could be addressed through the ESRD PPS
3. Approaches CMS should consider to increase MA beneficiary access to home dialysis

4. How nephrologist payment for traditional FFS, Medicare and MAOs should account for clinician-level barriers to prescribing and retaining patients on home dialysis.

CMS received numerous comments in response to the RFI on a broad range of topics.[8] Several commenters encouraged ways to effectively increase transplantation, and several expressed support for testing how to address social drivers of health within future models. Comments will be used to inform future policy development, with any potential changes being proposed through separate rulemaking.

CMS RECEIVES NO APPLICATION FOR TPNIES FOR CY 2025, UPDATES TPNIES FOR CAPITAL-RELATED ASSETS

In the CY 2020 ESRD PPS final rule, CMS introduced a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS. This adjustment was established to support the use of beneficiary access to these new technologies in ESRD facilities. When applications for the TPNIES are received, CMS includes a summary of each application and its analysis of eligibility criteria for each application in the proposed and final rules. However, no applications were submitted for CY 2025.

The finalized average per treatment offset amount for TPNIES for capital-related assets that are dialysis machines is $10.22 ($10.18 proposed), though there are no capital-related assets set to receive TPNIES for CY 2025.

REQUESTS FOR INFORMATION ON TOPICS RELEVANT TO ESRD QIP

Modifying Scoring Methodology to Reward Facilities Treating Dually Eligible Patients

In its proposed rule, CMS sought feedback on potential changes to the ESRD QIP scoring methodology to reward facilities based on their performance and the proportion of patients who are dually eligible for Medicare and Medicaid. Many commenters expressed strong support for a Health Equity Adjustment (HEA) that rewards facilities treating high proportions of patients dually eligible for Medicare and Medicaid (DES). Commenters noted that ESRD is more common among underserved populations and argued that HEA could drive equitable care improvements. A few noted that HEA could counteract financial penalties that disproportionately impact facilities serving lower-income patients, while others saw HEA as an opportunity to provide necessary resources for such facilities.

Commenters largely recommended structuring HEA as a bonus to a facility's TPS, with flexibility in applying the HEA to specific performance domains. Some suggested adjustments

[8] The complete list of themes included in comments are on pages 335-341 of the unpublished final rule.

to avoid skewing scores, such as a cap on HEA points or structuring HEA as a non-budget-neutral adjustment to avoid penalizing facilities not qualifying for the bonus.

Concerns included the potential for HEA to confuse patients about TPS significance and the possibility of creating unintended financial incentives. Some urged CMS to engage further with stakeholders on HEA implementation and clarify HEA's goals and measurement approach. CMS acknowledged the value of input to refine its approach to advancing health equity in the ESRD QIP. CMS will consider these comments in future policy developments.

Updating Data Validation Policy for ESRD QIP

The second RFI requested input on improving the data validation policy to ensure accurate and comprehensive reporting for the ESRD QIP.

Commenters raised concerns about the administrative burden of data validation, especially for smaller facilities. They recommended streamlining the validation process, improving EQRS and NHSN functionality, and adopting technologies like artificial intelligence to facilitate reporting. Commenters also suggested extending compliance timeframes and reducing survey frequency, arguing that the current data validation framework is overly demanding and detracts from patient care.

Suggestions for incentivizing accurate reporting included bonuses for high-performing facilities, transparency about data validation outcomes, and targeted education initiatives. Some opposed re-selecting non-compliant facilities for validation in subsequent years, favoring random selection instead. A few also requested due process protections, similar to other CMS audit programs, to ensure fair treatment.

CMS acknowledged the suggestions and concerns, indicating that the comments would inform future enhancements to ensure accurate, efficient data validation while minimizing the burden on facilities.

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