



Policy Update

CMS Releases CY 2023 End-Stage Renal Disease Prospective Payment System Final Rule

On October 31, 2022, the Centers for Medicare & Medicaid Services (CMS) released the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Calendar Year (CY) 2023 final rule (CMS-1768-F). The rule generally builds upon policies finalized in last year's ESRD payment rule that sought to improve health equity, enhance access to treatment options and address the continuing impacts of the COVID-19 public health emergency (PHE). The rule finalizes changes to the base payment rate, updates the ESRD Quality Incentive Program (QIP) and changes the ESRD Treatment Choices (ETC) Model. These policies generally take effect on **January 1, 2023**.

Key Takeaways from the CY 2023 ESRD PPS final rule:

- CMS updated the **ESRD PPS** base payment rate, wage index and outlier policy for CY 2023. CMS also added the word “functional” to the definition of “oral-only drug” (effective on January 1, 2025) and clarified the functional category definitions accordingly.
- CMS finalized several updates to the **ESRD QIP**, including suppression of certain measures for payment year 2023 and additional updates for subsequent payment years.
- CMS finalized changes to the **ETC Model**, including a modification of the performance payment adjustment (PPA) achievement scoring methodology (beginning in performance year five) and clarifications regarding the provision of kidney disease patient education services.
- CMS considered three products for the transitional add-on payment adjustment for new and innovative equipment and supplies (**TPNIES**) but ultimately did not award TPNIES to any new products for CY 2023.

Read on for a summary of the key provisions in the final rule.

- The final rule text is available [here](#).
- The final rule CMS fact sheet is available [here](#).



ESRD Prospective Payment System

The ESRD PPS provides a bundled, per-treatment payment to ESRD facilities that includes all renal dialysis services furnished for outpatient maintenance dialysis, including drugs and biological products (except for oral-only ESRD drugs until 2025). The bundled payment rate is case-mix adjusted to account for patient characteristics. Additional adjustments to the base payment rate include facility-level adjustments for certain ESRD facilities and wage index adjustments. When applicable, adjustments may also include training add-on payment adjustments for home and self-dialysis modalities; an outlier payment adjustment for high-cost patients; and add-on payment adjustments for certain drugs, equipment and supplies.

Base Rate

CMS finalized a base payment rate of \$265.57 (a slight increase from the proposed rate of \$264.09 and an increase of \$7.67 from the final CY 2022 base payment rate of \$257.90). Medicare expects to pay \$7.9 billion to approximately 7,800 ESRD facilities. CMS projects that these updates will increase total payments to freestanding facilities by 3% and to hospital-based ESRD facilities by 3.1%.

Wage Index

CMS finalized an increase in the wage index floor from 0.5 to 0.6, as well as a permanent 5% cap on decreases in the wage index beginning in CY 2023, as proposed.

Outlier Policy

CMS finalized updates to the outlier payment policy, the outlier services fixed-dollar loss (FDL) amounts, and the Medicare allowable payment amount (MAP). The FDL amount (which determines the outlier threshold) for pediatric patients decreased from \$26.02 to \$23.29, and the MAP amount decreased from \$27.15 to \$25.59. For adult patients, the FDL amount decreased from \$75.39 to \$73.19, and the MAP amount decreased from \$42.75 to \$39.62.

Oral-Only Drugs Definition

CMS changed the definition of oral-only drugs to include the word “functional” (effective January 1, 2025), as proposed. Under the new definition, an oral-only drug is a drug or biological product with no injectable *functional* equivalent or other non-oral form of administration.

ESRD Quality Incentive Program

Under the ESRD QIP, CMS assesses the performance of ESRD facilities on quality measures specified for the payment year (PY), applies a payment reduction to each facility that does not meet a minimum total performance score, and publicly reports the results. CMS finalized several changes to the QIP, as follows.

Policies for PY 2023

As proposed, CMS will collect and publicly report data on all ESRD QIP measures but will pause the use of certain measures for scoring and payment adjustment purposes in PY 2023 (CY 2021 performance year) to ensure that facilities are not penalized for disruptions caused by the COVID-19 pandemic. As proposed, CMS will pause the following measures:



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- Standardized Hospitalization Ratio (SHR) clinical measure
- Standardized Readmission Ratio (SRR) clinical measure
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems clinical measure
- Long-Term Catheter Rate clinical measure
- Percentage of Prevalent Patients Waitlisted clinical measure
- Kt/V Dialysis Adequacy Comprehensive clinical measure.

Although CMS did not originally propose to pause the Standardized Fistula Rate clinical measure, CMS agreed with commenters and will also pause this measure for PY 2023.

While CMS will not score the paused measures for PY 2023, CMS will still provide confidential feedback reports to facilities on their measure rates on the paused measures, as well as all other PY 2023 measures. CMS will also publicly report data on the paused measures, with appropriate caveats noting the PHE-related limitations of the data. As proposed, CMS will use pre-PHE data (from CY 2019) as the baseline for the PY 2023 ESRD QIP.

Policies for PY 2024

As proposed, CMS will express the SHR and SRR clinical measure results as rates beginning with the PY 2024 ESRD QIP to make these measures more intuitive and to help providers and patients better understand their performance.

Policies for PYs 2025 and 2026

CMS finalized several ESRD QIP changes that will take effect in PYs 2025 and 2026:

- Beginning with PY 2025, CMS will add the COVID-19 Vaccination Coverage among Healthcare Personnel measure to the ESRD QIP measure set as a reporting measure. CMS finalized quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Facilities will report the measure through the Centers for Disease Control and Prevention's National Healthcare Safety Network web-based surveillance system beginning in CY 2023.
- Beginning with PY 2025, CMS will convert the Standardized Transfusion Ratio reporting measure to a clinical measure and will express the measure as a rate (to align with technical updates to the SHR and SRR clinical measures).
- Beginning with PY 2025, CMS will convert the Hypercalcemia clinical measure to a reporting measure and will continue to explore possible replacement measures that would be more clinically meaningful.
- CMS modified the technical measure specifications for the SHR and the SRR clinical measures to include a covariate adjustment for patient history of COVID-19 to capture the continuing effects of COVID-19 in the patient case-mix.
- CMS created a new domain for reporting measures and re-weighted current domains beginning with PY 2025. In addition to the four existing domains



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(Patient and Family Engagement, Care Coordination, Clinical Care and Safety), CMS created a Reporting Measure domain that includes the four current reporting measures, the proposed COVID-19 Vaccination Coverage among Healthcare Personnel reporting measure and the proposed Hypercalcemia reporting measure. CMS did not propose any changes to the Patient and Family Engagement domain, which will continue to be weighted at 15% of a facility's total performance score.

ESRD Treatment Choices Model

The ESRD Treatment Choices (ETC) Model is a mandatory model being tested in select geographic areas. Under the ETC Model, participating ESRD facilities and clinicians who manage dialysis patients (managing clinicians) receive positive or negative adjustments on certain claims for dialysis and dialysis-related services based on the home dialysis rate and transplant rate among their attributed beneficiaries. The ETC Model began January 1, 2021, and payment adjustments under the model will end in June 2027. The rule finalized modifications to the ETC Model as follows.

Performance Payment Adjustment Achievement Benchmarking Methodology

The CY 2022 ESRD PPS final rule increased achievement benchmarks by 10% over rates observed in comparison geographic areas every two model years, beginning in model year three (2022), and finalized proposals to stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually eligible for Medicare and Medicaid or receive the low income subsidy. Stratification of the achievement benchmarks recognizes that beneficiaries with lower socioeconomic status have lower home dialysis and transplant rates compared to beneficiaries with higher socioeconomic status.

However, CMS found that the stratification methodology increased the likelihood that the lowest achievement benchmark could be set at a home dialysis rate or transplant rate of zero, contrary to the policy's intention. To address this issue, CMS finalized an update to the PPA achievement methodology beginning in measurement year (MY) five (starting January 1, 2023). As proposed, CMS specified that an ETC participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score.

Kidney Disease Patient Education Services

CMS previously waived certain requirements for kidney disease patient education services because such services were billed infrequently. CMS also permitted an ETC participant to reduce or waive the 20% coinsurance requirement for kidney disease patient education services furnished on or after January 1, 2022, if several conditions are satisfied, including a requirement that the individual or entity that furnished the services be qualified staff and not be leased from (or otherwise provided by) an ESRD facility or related entity. This requirement does not apply if the ETC participant does not reduce or waive the beneficiary's coinsurance obligation for such services. In the final rule, CMS finalized a similar requirement for "clinical staff," regardless of whether the participant waives the kidney disease patient education coinsurance obligation.



Publication of Participant Performance

As proposed, CMS will publish patient de-identified results from all measurement years (MYs) of the ETC Model, including results from MYs that have already been completed. For each MY, CMS will post the aggregate results for the home dialysis rate and the transplant rate for each aggregation group, as well as the individual components of each rate for the aggregation group as a whole. This would include the number of beneficiary months in home dialysis, self-dialysis or nocturnal dialysis and the number of beneficiary months on the transplant waitlist, as well as the number of living donor transplants and (if applicable) pre-emptive living donor transplants performed. CMS will also identify all of the ESRD facilities or managing clinicians in the aggregation group for the MY. The results will be published on the ETC Model website.

Transitional Add-On Payment for New and Innovative Equipment and Supplies Applications

CMS established TPNIES to incentivize the creation and adoption of new and innovative kidney disease treatment products and services. Among other criteria, applicants must demonstrate that the product is a substantial clinical improvement compared to existing products. In the final rule, CMS declined to award TPNIES to three applicant products.

Requests for Information

The proposed rule included requests for information (RFIs) on several topics, including the following:

- Options for an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the Transitional Drug Add-on Payment Adjustment period ends
- Additional measures of care quality for home dialysis
- Use of measurement and stratification tools to identify and address healthcare disparities and to enhance health equity
- Two potential social drivers of health screening measures.

For a detailed list of the RFI topics included in the proposed rule, see our summary [here](#). In the final rule, CMS summarized comments received on these topics and noted that the agency will consider stakeholder feedback to inform policies in future rulemaking.

Conclusion

Overall, the CY 2023 ESRD PPS final rule builds upon policies finalized in last year's rule that sought to address the continuing impacts of the PHE, enhance access to treatment options and advance health equity. Unless otherwise noted, policies in the final rule will take effect on January 1, 2023.

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