End-Stage Renal Disease Prospective Payment System CY 2024 Rule Update

Summary: On June 26, 2023, the Centers for Medicare & Medicaid Services (CMS) released the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Calendar Year (CY) 2024 Proposed Rule (CMS-1782-P). The proposed rule would make minimal increases to the ESRD PPS base payment rate, estimated to increase overall Medicare payments to ESRD facilities by 1.6%. The proposed rule includes proposals for new add-on payment adjustments, including a Transitional Pediatric ESRD Add-on Payment Adjustment for pediatric care and a payment adjustment for a three-year period after the Transitional Drug Add-on Payment Adjustment period ends for qualifying drugs and biological products. CMS also seeks feedback on potential changes to thresholds used to determine whether a facility qualifies as a "low-volume" facility (in order to receive the Low-Volume Payment Adjustment) and seeks feedback on the possible creation of a new payment adjustment that accounts for a facility's isolation, rurality, and other geographic factors.

Additionally, the proposed rule would add, remove, and modify several ESRD Quality Incentive Program (QIP) measures, and proposes changes to ESRD Treatment Choices (ETC) Model regulations to clarify that ETC participants can seek additional administrative review of their performance score. The proposed rule clarifies CMS's evaluation of criteria for the Transitional Add-on Payment for New and Innovative Equipment and Supplies and provides the agency's initial evaluation of one applicant product.

The following chart outlines key provisions of the proposed rule. Additional information is available in a CMS Fact Sheet. **Comments are due by August 25, 2023**, and the final rule is expected to be released in late October or early November 2023.

Major Area	CY 2024 Proposals
Payment Updates	The ESRD PPS provides a bundled, per-treatment payment to ESRD facilities for dialysis services that is case-mix adjusted to account for patient characteristics. Additional adjustments include facility-level adjustments for certain ESRD facilities, wage index adjustments, and (when applicable) 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. CMS also proposes several new add-on payment adjustments, including a Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) and a payment adjustment for a three-year period after the Transitional Drug Add-on Payment Adjustment (TDAPA) period ends. **Base Rate Update** CMS proposes a CY 2024 base payment rate of **$269.99** (an increase of $4.42 from last year's base payment rate of $265.57). For reference, CMS increased the base payment rate by $7.67 last year (increasing the rate from $257.90 in CY 2022 to $265.57 in CY 2023).

	Overall Impact: CMS estimates that the base payment rate increase will result in a **1.6% overall increase** in Medicare payments to ESRD facilities. Hospital-based ESRD facilities have an estimated 2.6% increase in Medicare payments, and freestanding ESRD facilities have an estimated 1.6 percent increase in Medicare payments. CMS estimates that **aggregate ESRD PPS expenditures will increase by approximately $130 million in CY 2024** compared to CY 2023. *Acute Kidney Injury (AKI) Impact:* For individuals with AKI, CMS estimates that the base payment rate increase will result in a 1.6% increase in Medicare payments. Hospital-based ESRD facilities have an estimated 1.8% increase in Medicare payments, and freestanding ESRD facilities have an estimated 1.6% increase. CMS estimates that **aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to patients with AKI will increase by $1 million in CY 2024** compared to CY 2023.
	Outlier Threshold and Payment Update For pediatric beneficiaries, the proposed fixed dollar loss (FDL) amount (which determines the outlier threshold) would **decrease from $23.29 to $13.71**, and the proposed Medicare allowable payment (MAP) amount would **decrease from $25.59 to $24.53**. For adult beneficiaries, the proposed FDL amount would **increase from $73.19 to $78.21**, and the proposed MAP amount would **decrease from $39.62 to $38.58.** For reference, in last year's rule, the FDL 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.
New Payment Adjustment Proposals and Other Requirements	**Low-Volume Payment Adjustment** The low-volume payment adjustment (LVPA) is available to ESRD facilities that meet the definition of "low-volume facility" as determined under 42 CFR § 413.232. CMS proposes to create an exception to the current LVPA attestation process for qualifying ESRD facilities affected by disasters and other emergencies: • The exception would allow ESRD facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. • The exception would also allow an ESRD facility to receive the LVPA, even if the facility exceeds the LVPA threshold, if the facility's treatment counts increase due to treating additional patients displaced by a disaster or emergency.

	“Time on Machine” Reporting CMS proposes to require ESRD facilities to report the beneficiary’s “time on machine” (the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims in order to estimate dialysis treatment costs more precisely to inform potential future refinements to the ESRD PPS adjustment factors. **CMS seeks comment on the proposed January 1, 2025 effective date** for this “time on machine” reporting requirement, given the operational changes necessary to comply. **Proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA)** CMS proposes to establish a new add-on payment adjustment of 30% of the per-treatment payment amount for all renal dialysis services furnished to pediatric ESRD patients, effective January 1, 2024, for CYs 2024, 2025, and 2026. This new payment adjustment is intended to better align Medicare payments for renal dialysis services furnished to pediatric patients with estimated relative costs. The three-year period would give CMS an opportunity to collect information recently added to the cost report form in CY 2023 (to further inform the alignment of pediatric dialysis payment with cost in the future) while providing increased payments in the interim to account for higher costs of pediatric care. CMS proposes to apply the TPEAPA in a budget-neutral manner. **Proposed Add-On Payment Adjustment after the Transitional Drug Add-on Payment Adjustment (TDAPA) Period Ends** CMS proposes a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. This post-TDAPA payment adjustment would be case-mix adjusted and set at 65% of expenditure levels for the given renal dialysis drug or biological product, would be applied to all ESRD PPS payments, and would be paid for three years. Overall, this proposal would provide a five-year pathway to increased payment for certain new renal dialysis drugs and biological products, which could receive the TDAPA for two years and the post-TDAPA payment adjustment for three years. **Reporting of Discarded Drug/Biological Product Units** To better monitor billing and payment for discarded amounts of renal dialysis drugs and biological products, CMS proposes that (beginning no later than January 1, 2024) ESRD facilities must report information on claims regarding the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS. Facilities would use the JW modifier (or any successor modifier that includes the same data) for discarded amounts, and would use the JZ modifier on claims when billing for any drug or biological product from a single-dose container or single-use package for which there is no discarded amount.

ESRD Quality Incentive Program	Under the ESRD Quality Incentive Program (QIP), CMS assesses facility performance 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. **Minimum Total Performance Score** CMS proposes to **update the definition of "minimum total performance score"** (at 42 CFR § 413.178(a)(8)) so that it more accurately captures how the agency calculates the median of national ESRD facility performance on reporting measures. CMS also proposes that if there is insufficient data available prior to the first performance period of a new reporting measure, CMS will set a proxy median of zero for the reporting measure until CMS has sufficient data to calculate the median. **QIP Policies for PY 2026** • CMS proposes to **add the Facility Commitment to Health Equity reporting measure** to the ESRD QIP measure set beginning with PY 2026. This measure assesses an ESRD facility's commitment to health equity based on responses to five equity-related, attestation-based questions. • CMS proposes to **update the COVID-19 Vaccination Coverage Rate Among Healthcare Personnel (HCP) reporting measure** beginning with PY 2026 to align with updated measure specifications developed by the Centers for Disease Control and Prevention (CDC). The update reflects recommendations from the CDC and the U.S. Food and Drug Administration (FDA) that eligible individuals be "up to date" on their COVID-19 vaccinations. • CMS proposes to **convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure** beginning with PY 2026. CMS also proposes to update the scoring methodology to better align the measure with current clinical guidelines for depression screening and follow-up. • CMS proposes to **remove the Ultrafiltration Rate reporting measure** from the ESRD QIP measure set beginning with PY 2026. CMS proposes to remove the measure because documentation of a patient's ultrafiltration rate may not indicate the quality of treatment and because a facility's performance on the measure may not accurately reflect the quality of care provided. • CMS proposes to **remove the Standardized Fistula Rate clinical measure** from the ESRD QIP measure set beginning with PY 2026. CMS proposes to remove this measure because updated vascular access treatment guidelines indicate a preference for increased flexibility in the choice of arteriovenous (AV) access (AV fistula or AV graft) as appropriate for the individual patient.

	QIP Policies for PY 2027 • CMS proposes to **add the Screening for Social Drivers of Health reporting measure** to the ESRD QIP measure set beginning with PY 2027. This health equity-related measure assesses the percentage of patients 18 years of age and older who are screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. • CMS proposes to **add the Screen Positive Rate for Social Drivers of Health reporting measure** to the ESRD QIP measure set beginning with PY 2027. This health equity-related measure assesses the percentage of patients 18 years of age and older who screen positive for one or more of the above-listed health-related social needs.
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 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 on January 1, 2021, and payment adjustments under the model will end in June 2027. CMS proposes to revise ETC Model regulations at 42 § CFR 512.390 to acknowledge that administrative review is available for targeted review requests. Under the ETC Model, a participant can request that CMS conduct a targeted review of its performance score and modify the score if there have been any errors in the score calculation. The proposed changes to the regulations would **inform ETC Model participants that the CMS Administrator can review the results of the targeted review,** should the participant wish to seek additional review of its targeted review request.
Transitional Add-On Payment for New and Innovative Equipment and Supplies	CMS established the Transitional Add-on Payment for New and Innovative Equipment and Supplies (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 or service is a substantial clinical improvement compared to existing products or services. **TPNIES Criteria Clarifications** CMS proposes several clarifications regarding the agency's evaluation of the TPNIES eligibility criteria under 42 CFR § 413.236(b) that would become effective on January 1, 2024 (for CY 2025 payment): • CMS clarifies that the agency's review of the six TPNIES eligibility criteria is sequential. A product would be ineligible for the TPNIES if CMS determines that the product has failed to meet one of the eligibility criteria, and **CMS will not include discussion of any remaining criteria in its decision published in the final rule.** In other words, the agency will review products according to the TPNIES

	criteria in sequence, and if a product failed to meet the requirements of one criterion, the agency will no longer publish its evaluation of the succeeding criteria in the final rule. • CMS clarifies that the **three-year newness period is based on the date of the TPNIES application submission** (the "newness" criterion is at 42 CFR § 413.236(b)(2)). • Third, CMS clarifies that **equipment or supplies with FDA Exempt status (*i.e.*, lacking FDA marketing authorization) would not meet the TPNIES newness criterion**. **TPNIES Applications** One product was submitted for TPNIES consideration in the CY 2024 rule cycle: the Buzzy® Pro, an external vibration device used with ice packs to temporarily block pain at needle sites. In the proposed rule, CMS provides its preliminary analysis of the product and **requests public comment regarding whether the product meets the various TPNIES criteria.**
Requests for Information	The proposed rule includes Requests for Information (RFIs) on the following topics: • CMS solicits comments on **potential changes to the LVPA methodology**, specifically regarding the thresholds used to determine whether a facility qualifies as a "low-volume" facility. CMS seeks stakeholders' input on whether CMS should maintain a single threshold, establish LVPA tiers, or use a continuous function to apply the LVPA. • CMS seeks feedback on the possible creation of a **new payment adjustment that accounts for a facility's isolation, rurality, and other geographic factors.**

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