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

Summary: On October 27, 2023, the Centers for Medicare & Medicaid Services (CMS) released the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Calendar Year (CY) 2024 final rule (CMS-1782-F). The rule finalizes minimal increases to the ESRD PPS base payment rate, estimated to increase overall Medicare payments to ESRD facilities by 2.1%. The rule also finalizes proposals for new add-on payment adjustments, including a Transitional Pediatric ESRD Add-on Payment (TPEAPA). Additionally, the rule finalizes proposals to add, remove and modify several ESRD Quality Incentive Program (QIP) measures and finalizes proposed changes to the ESRD Treatment Choices (ETC) Model to clarify that ETC participants can seek additional administrative review of their performance score. The rule also announces the agency's decision on one applicant for the Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES).

This chart outlines key provisions of the final rule, as compared to proposed policies. Additional information is available in a CMS fact sheet.

Issue Area	Proposed Rule	Final Rule
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.	**Base Rate Update** CMS proposed a CY 2024 base payment rate of **$269.99** (an increase of $4.42 from last year's base payment rate of $265.57). CMS estimated that the proposed base payment rate increase would result in a **1.6% overall increase** in Medicare payments to ESRD facilities. Hospital-based ESRD facilities would have an estimated 2.6% increase in Medicare payments, and freestanding ESRD facilities would have an estimated 1.6% increase in Medicare payments. CMS estimated that aggregate ESRD PPS expenditures would increase by approximately $130 million in CY 2024 compared to CY 2023. For individuals with acute kidney injury (AKI), CMS estimated that the proposed base payment rate increase would result in a 1.6% increase in Medicare payments. Hospital-based ESRD	**CMS finalized a CY 2024 ESRD PPS base payment rate of $271.02** (an increase of **$5.45** from last year's base payment rate of $265.57 and an increase of $1.03 from the proposed CY 2024 base payment rate of $269.99), **increasing total payments to ESRD facilities by approximately 2.1%.** CMS projects an increase in total payments of 3.1% for hospital-based ESRD facilities and 2% for freestanding ESRD facilities. CMS estimates that aggregate ESRD PPS expenditures will increase by approximately $190 million in CY 2024 compared to CY 2023. CMS also finalized updates to the AKI dialysis payment rate for CY 2024 to equal the ESRD PPS base payment rate update of $271.02. CMS projects an increase in total payments of 2% for individuals with AKI. CMS estimates a 2.1% increase for hospital-based ESRD facilities and a 2% increase for freestanding ESRD facilities. CMS estimates that aggregate payments made to ESRD facilities for renal dialysis services furnished to

	facilities would have an estimated 1.8% increase in Medicare payments, and freestanding ESRD facilities would have an estimated 1.6% increase. CMS estimated that aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to patients with AKI would increase by $1 million in CY 2024 compared to CY 2023.	individuals with AKI will increase by $1 million in CY 2024 compared to CY 2023. For reference, CMS increased the ESRD PPS base payment rate by $7.67 last year (increasing the base payment rate from $257.90 in CY 2022 to $265.57 in 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.	*For pediatric beneficiaries*: **The finalized FDL amount decreased from $23.29 to $11.32, and the finalized MAP amount decreased from $25.59 to $23.36**, as compared to CY 2023 amounts. This update represents a relatively significant decrease in the FDL amount (which determines the outlier threshold) for pediatric patients for CY 2024. For reference, in last year's rule, the FDL for pediatric patients decreased from $26.02 to $23.29. *For adult beneficiaries*: **The finalized FDL amount decreased from $73.19 to $71.76, and the finalized MAP amount decreased from $39.62 to $36.28**, as compared to CY 2023 amounts.

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 proposed 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 still receive the LVPA if the facility exceeded the LVPA threshold because it treated additional patients displaced by a disaster or emergency.	**CMS finalized the proposed exception to the LVPA attestation process for ESRD facilities affected by disasters and other emergencies.** The exception will allow facilities to close temporarily and reopen in response to a disaster or other emergency and still receive the LVPA. Facilities also will still be able to receive the LVPA even when they exceed the LVPA threshold if treatment counts increase because of treating additional patients displaced by a disaster or other emergency.
	"Time on Machine" Reporting CMS proposed to require ESRD facilities to report a beneficiary's "time on machine" (the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims to estimate dialysis treatment costs more precisely to inform potential future refinements to the ESRD PPS adjustment factors. CMS sought comment on the proposed January 1, 2025, effective date for this "time on machine" reporting requirement, given the operational changes necessary to comply.	**CMS finalized the new "time on machine" reporting requirement, effective January 1, 2025.** Under the new reporting requirement, ESRD facilities will report the beneficiary's "time on machine" (measured by the number of minutes that a beneficiary spends receiving in-center hemodialysis treatment) on ESRD PPS claims. CMS will use this data to more precisely estimate dialysis treatment costs.

	Proposed Transitional Pediatric ESRD Add-on Payment Adjustment CMS proposed 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 proposed new payment adjustment was 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 proposed to apply the TPEAPA in a budget-neutral manner.	**CMS finalized the TPEAPA amount 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. CMS will apply the TPEAPA in a budget-neutral manner.** CMS plans to collect additional data from cost reports to further evaluate the alignment of pediatric patient resource use with payment in the future.

	Proposed Add-On Payment Adjustment After Transitional Drug Add-on Payment Adjustment Period Ends CMS proposed a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the Transitional Drug Add-on Payment Adjustment (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.	**CMS finalized the 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 will be case-mix adjusted and set at 65% of estimated expenditure levels for the given renal dialysis drug or biological product in the prior year and will be applied to all ESRD PPS payments for a period of 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 proposed 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.	**CMS finalized the proposed reporting requirements** 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, and for any drug or biological product from a single-dose container or single-use package for which there is no discarded amount, as proposed. **In response to stakeholder comments, CMS will delay the effective date of these new reporting requirements until January 1, 2025.**

ESRD Quality Incentive Program Under the ESRD 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 proposed to **update the definition of "minimum total performance score"** (at 42 CFR § 413.178(a)(8)) so that it would more accurately capture how the agency calculates the median of national ESRD facility performance on reporting measures. CMS also proposed that if there was insufficient data available prior to the first performance period of a new reporting measure, CMS would set a proxy median of zero for the reporting measure until CMS had sufficient data to calculate the median.	**CMS finalized proposed updates to the "minimum total performance score" definition** to more accurately capture how the agency calculates the national median for facility performance on reporting measures.
	QIP Policies for PY 2026 • CMS proposed 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 proposed to **update the COVID-19 Vaccination Coverage Rate Among Healthcare Personnel 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 US Food and Drug Administration (FDA) that eligible individuals be "up to date" on their COVID-19 vaccinations. • CMS proposed to **convert the Clinical Depression Screening and Follow-Up reporting measure to a**	**CMS finalized the ESRD QIP changes for PY 2026 as proposed**, including adding the Facility Commitment to Health Equity reporting measure, updating the COVID-19 Vaccination Coverage Rate Among Healthcare Personnel reporting measure, converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure, and removing the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure. **CMS finalized the ESRD QIP changes for PY 2027 as proposed**, including adding the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health reporting measures.

	clinical measure beginning with PY 2026. CMS also proposed to update the scoring methodology to better align the measure with current clinical guidelines for depression screening and follow-up. • CMS proposed to **remove the Ultrafiltration Rate reporting measure** from the ESRD QIP measure set beginning with PY 2026. CMS proposed 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 proposed to **remove the Standardized Fistula Rate clinical measure** from the ESRD QIP measure set beginning with PY 2026. CMS proposed 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 proposed 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 proposed 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 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 proposed 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 were 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.	**CMS finalized proposed modifications to the ETC Model regulations to acknowledge the availability of administrative review for an ETC participant's targeted review request of its performance score.**

Transitional Add-on Payment for New and Innovative Equipment and Supplies CMS established the 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 proposed several clarifications regarding its 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 proposed to clarify that its review of the six TPNIES eligibility criteria is sequential. A product would be ineligible for the TPNIES if CMS determined that the product failed to meet one of the eligibility criteria, and **CMS would not include discussion of any remaining criteria in its decision published in the final rule.** In other words, the agency would review products according to the TPNIES criteria in sequence, and if a product failed to meet the requirements of one criterion, the agency would no longer publish its evaluation of the succeeding criteria in the final rule. • CMS proposed to clarify 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)). • CMS proposed to clarify 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: the Buzzy® Pro, an external vibration device used with ice packs to	**CMS finalized the proposed TPNIES criteria clarifications, effective January 1, 2024 (for CY 2025 payment).** **CMS determined that the Buzzy® Pro device did not qualify for the TPNIES for CY 2024.** CMS found that the device did not demonstrate that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries (as required under the substantial clinical improvement criteria specified in 42 CFR § 412.87(b)(1)). CMS noted that the device would be eligible to reapply for the TPNIES in future rulemaking cycles.

	temporarily block pain at needle sites. In the proposed rule, CMS provided its preliminary analysis of the product and requested public comment regarding whether the product meets the various TPNIES criteria.	
Requests for Information	The proposed rule included requests for information (RFIs) on the following topics: • CMS solicited 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 sought stakeholders' input on whether CMS should maintain a single threshold, establish LVPA tiers or use a continuous function to apply the LVPA. • CMS sought feedback on the possible creation of a **new payment adjustment that accounts for a facility's isolation, rurality and other geographic factors.**	CMS noted that it received several comments in response to the RFI on potential changes to the LVPA methodology and the possible creation of a new payment adjustment that accounts for isolation, rurality and other geographic factors. CMS plans to review these comments to inform future rulemaking in this policy area.

For more information, contact Kristen O'Brien and Lauren Knizner.

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