Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Releases Proposed CY 2024 ESRD PPS Update

The Centers for Medicare & Medicaid Services (CMS) have issued a proposed Calendar Year (CY) 2023 ESRD PPS Update rule.

This proposed rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) payment rates, and the payment rates for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

CMS is proposing to add three new measures to the ESRD QIP measures.

The rule is scheduled to be published in the June 30 ***Federal Register.*** A copy of the 301-page display version is currently available at: https://public-inspection.federalregister.gov/2023-13748.pdf. A 60-day comment period ending August 25 is provided.

Comment

The rule does contain a brief table of contents. The table of contents lists sections I to XI, but there is no number X.

CMS says it expects to pay $6.4 billion to approximately 7,800 ESRD facilities.

We have inserted related page numbers below in red.

Updates to the ESRD PPS for CY 2024

Proposed Annual Update

The proposed CY 2024 ESRD PPS base rate is **$269.99**, an increase from the CY 2023 ESRD PPS base rate of $265.57. This proposed amount reflects the application of the proposed combined wage index and transitional pediatric ESRD budget-neutrality adjustment factor (TPEAPA) (0.999652) and a proposed productivity-adjusted market basket percentage increase of 1.7% equaling $269.99 (($265.57 X 0.999652) X 1.017 = $269.99). (Page 8)

The overall impact of the CY 2024 changes is projected to be a 1.6% increase in Medicare payments. Hospital-based ESRD facilities have an estimated 2.6% increase in Medicare payments compared with freestanding ESRD facilities with an estimated 1.6% increase. (Page 12)

CMS estimates that the aggregate ESRD PPS expenditures would increase by approximately $130 million in CY 2024 compared to CY 2023. This reflects a $140 million increase from the proposed payment rate update, including approximately $1.7 million in estimated transitional drug add-on payment adjustment (TDAPA) amounts. CMS estimates a $10 million decrease from the proposed outlier payment update.

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 1336 or awheeler@mhanet.com.

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Proposed CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share (Page 18)

Based on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket, the proposed CY 2024 market basket percentage increase is 2.0%. (Page 19)

Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment for CY 2024 is 0.3 percentage point. Therefore, the proposed CY 2024 ESRDB market basket update is equal to 1.7% (2.0% market basket percentage increase reduced by a 0.3 percentage point productivity adjustment). (Page 21)

For the CY 2024 ESRD PPS payment update, CMS is proposing to continue using a labor-related share of 55.2%. (Page 23)

Proposed Changes to the Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) (Page 164)

As required by section 1834(r) of the Social Security Act (the Act), CMS is proposing to update the AKI dialysis payment rate for CY 2024 to equal the CY 2024 ESRD PPS base rate and to apply the CY 2024 wage index. The proposed CY 2024 payment rate is $269.99.

Proposed CY 2024 ESRD PPS Wage Indices

CMS proposes to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS for the ESRD wage index values.

The proposed CY 2024 ESRD PPS wage index is set forth in Addendum A and is 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. Addendum A provides a crosswalk between the CY 2023 wage index and the proposed CY 2024 wage index. Addendum B provides an ESRD facility level impact analysis. (Page 25)

In the CY 2023 ESRD PPS final rule, CMS finalized a permanent policy under §413.231(c) to apply a 5.0% cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. Further, CMS would apply a wage index floor of 0.6000.

Proposed CY 2024 Update to the Outlier Policy (Page 29)

For CY 2024, CMS is proposing to update the Medicare Allowable Payment (MAP) amounts for adult and pediatric patients using the latest available CY 2022 claims data. CMS is proposing to update the ESRD outlier services Fixed Dollar Loss (FDL) amount for pediatric patients using the latest available CY 2022 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021 and CY 2022, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule.

CY 2022 claims data showed outlier payments represented approximately 0.9% of total Medicare payments

The impact of this proposed update is shown in the table below.

Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2023 (based on 2021 data, price inflatedto 2022)		Column II Proposed outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$24.13	$41.36	**$23.52**	**$40.26**
Adjustments				
Standardization for outlierservices	1.0819	0.9774	1.0645	0.9777
MIPPA reduction	0.9800	0.9800	0.9800	0.9800
Adjusted average outlier services MAP amount	$25.59	$39.62	$24.53	$38.58
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$23.29	$73.19	$13.71	$78.21
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	12.90%	5.90%

*Column I was obtained from Column II of Table 1 from the CY 2023 ESRD PPS final rule.
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2020, 2021 and 2022.

The estimated FDL per treatment that determines the CY 2024 outlier threshold amount for adults (Column II; $78.21) is higher than that used for the CY 2023 outlier policy (Column I; $73.19). The higher threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $39.62 to $38.58. For pediatric patients, there is a decrease in the FDL amount from $23.29 to $13.71. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $25.59 to $24.53. (Page 30)

Update to the Average per Treatment Offset Amount for Home Dialysis Machines (Page 33)

The proposed CY 2024 TPNIES offset amount for capital-related assets that are home dialysis machines is $9.96. Applying the proposed update factor of 1.017 to the CY 2023 TPNIES offset amount results in the proposed CY 2024 TPNIES offset amount of $9.96 ($9.79 X 1.017 = $9.96).

Proposed Refinement of the Low-Volume Payment Adjustment (LVPA) (Page 34)

In order to receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in §413.232 and qualifies as a low-volume ESRD facility.

The current LVPA is 23.9%.

CMS says it recognizes the importance of revising the ESRD PPS LVPA adjustment methodology to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities, and to strive for healthcare equity for ESRD beneficiaries. The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. (Page 40)

CMS is soliciting comment on potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function. CMS provides the following table if it should decide to maintain a single threshold.

Option	Description
Status quo	4,000-treatment threshold with 23.9% payment adjuster
Maintain Treatment Threshold	4,000-treatment threshold with 17.6% payment adjuster
Maintain Payment Adjuster	Reduce treatment threshold to 3,750 treatments to maintain 23.9% payment adjuster

CMS is soliciting comments regarding establishment of multiple thresholds, including up to an eight-tiered structure for the LVPA as shown in the tables below.

LVPA Adjustment with Four Tiers
($1.20 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 5,000)	13.7%
Tier 2 (5,000 – 5,999)	8.4%
Tier 3 (6,000 – 6,999)	4.7%
Tier 4 (7,000 – 7,999)	1.9%

LVPA Adjustment with Eight Tiers
($1.80 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	**LVPA Adjusters**
Tier 1 (less than 1,000)	123.0%
Tier 2 (1,000- 1,999)	57.6%
Tier 3 (2,000-2,999)	33.9%
Tier 4 (3,000-3,999)	21.4%
Tier 5 (4,000 – 4,999)	13.7%
Tier 6 (5,000 – 5,999)	8.4%
Tier 7 (6,000 – 6,999)	4.7%
Tier 8 (7,000 – 7,999)	1.9%

LVPA Adjustment with Four Tiers
(Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	**LVPA Adjuster**	**Est. Facilities Receiving Adjustment**
Tier 1 (less than 5,000)	5.8%	767
Tier 2 (5,000 – 5,999)	3.6%	331
Tier 3 (6,000 – 6,999)	2.0%	332
Tier 4 (7,000 – 7,999)	0.8%	318

LVPA Adjustment with Eight Tiers
(Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	**LVPA Adjuster**	**Est. Facilities Receiving Adjustment**
Tier 1 (less than 1,000)	40.5%	22
Tier 2 (1,000- 1,999)	19.0%	69
Tier 3 (2,000-2,999)	11.2%	137
Tier 4 (3,000-3,999)	7.1%	250
Tier 5 (4,000 – 4,999)	4.5%	290
Tier 6 (5,000 – 5,999)	2.8%	331
Tier 7 (6,000 – 6,999)	1.5%	332
Tier 8 (7,000 – 7,999)	0.6%	318

Proposed Changes to the LVPA (Page 52)

CMS is proposing to create a new exception to the attestation process for disasters and other emergencies and is proposing to establish a process that would allow low-volume facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA.

Proposed Transitional Pediatric ESRD Add-on Payment Adjustment for Pediatric Patients with ESRD Receiving Renal Dialysis Services (Page 58)

CMS is proposing a new transitional add-on payment adjustment of 30% (adjustment factor of 1.3) for dialysis treatments furnished to Pediatric ESRD Patients for 3 calendar years, effective January 1, 2024. (Page 66)

CMS is proposing that this payment adjustment be budget neutral, which would lead to an estimated decrease of $0.12 to the ESRD PPS base rate, corresponding to a budget neutrality factor of 0.99954.

Proposed ESRD PPS Policy for Reporting of Discarded Amounts of Renal Dialysis Drugs and Biological Products (Page 77)

CMS is proposing to require that beginning no later than January 1, 2024, ESRD facilities must report information on ESRD PPS claims about 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, using the JW modifier (or any successor modifier that includes the same data).

CMS is also proposing that ESRD facilities must document any discarded amounts in the beneficiary's medical record.

Additionally, CMS is proposing to require ESRD facilities to report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2024. CMS is proposing to codify these reporting requirements in regulation at §413.198(b)(5) and (6).

Proposed New Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends (Page 81)

CMS is proposing that the post-TDAPA add-on payment adjustment would be applied for a period of 3 years following the end of the TDAPA period for those products. (Page 95)

CMS is proposing that this post-TDAPA add-on payment adjustment would not be budget neutral. (Page 97)

CMS is proposing to apply the post-TDAPA add-on payment adjustment to each ESRD PPS treatment, and to adjust it for patient characteristics. In other words, the post-TDAPA add-on payment adjustment would be multiplied by the ESRD PPS patient-level adjustments under §413.235. (Page 100)

In the CY 2020 ESRD PPS final rule that established the 65% cost-sharing proportion for TPNIES, CMS stated that the goal of TPNIES was to support ESRD facility use of new and innovative renal dialysis equipment and supplies.

CMS provides an example of the proposed calculation for CY 2024 for KorsuvaTM based on the latest available information at the time of this proposed rulemaking.

CMS estimates that total expenditure for KorsuvaTM in CY 2022 is $3,150,910 and that 19,511,284 total ESRD PPS treatments were furnished during the same time period.

Taking into account the existing ESRD PPS patient-level adjustment factors and the proposed TPEAPA the reduction to the post-TDAPA add-on payment adjustment to account for case-mix standardization for this time period is 0.900244. Accordingly, CMS would calculate a proposed case-mix adjusted post-TDAPA add-on payment adjustment for CY 2024 equal to (($3,150,910)/ (19,511,284)) x (0.900244) x (0.65) x (1.017) = $0.0961. (Page 107)

Proposal to Require "Time on Machine" Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis (Page 109)

CMS proposes to amend 42 CFR 413.198 by adding language at §413.198(b)(5) that would require each ESRD facility to submit data and information, under existing paragraph §413.198(b)(3) describing allowable costs, of the types and in the formats established by CMS, for the purpose of estimating patient-level and facility-level variation in resource use, such as data and information on the duration of

hemodialysis treatment (that is, time on machine data) involved in furnishing hemodialysis treatment. (Page 126)

CMS is proposing a January 1, 2025, effective date for this new reporting requirement. (Page 133)

Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Proposals and Application for CY 2024 Payment (Page 136)

CMS is proposing three clarifications regarding the evaluation of the TPNIES eligibility criteria that if finalized, would become effective January 1, 2024, for CY 2025 payment. First, CMS is proposing to clarify that CMS's review of the six TPNIES eligibility criteria at §413.236(b) is sequential, and as CMS proceeds through the review for a particular equipment or supply, if CMS determines that the item has failed to demonstrate having met one of the eligibility criteria, the item would be ineligible for the TPNIES. CMS would not include an analysis of the remaining criteria in the annual CY final rule. Second, CMS is proposing to clarify that the three-year newness period at §413.236(b)(2) is based on the date of the TPNIES application submission. Third, CMS is clarifying that equipment or supplies with FDA Exempt status, lacking FDA marketing authorization, would not meet the TPNIES newness criterion at §413.236(b)(2). (Page 143)

CY 2024 TPNIES Application for Buzzy® Pro (Page 149)

CMS received only one item for the CY 2024 TPINIES. That is, Buzzy® Pro which is a palm-sized external use vibration device used with unique ice packs and is intended to temporarily desensitize and physiologically block pain associated with dialysis cannulation.

CMS seeks comments on whether the product meets the eligibility criteria.

Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024 (Page 163)

There are no items previously approved for TPNIES for which payment is continuing in CY 2024.

End-Stage Renal Disease Quality Incentive Program (ESRD QIP) (Page 166)

Proposals to Update the Regulation Text for the ESRD QIP

CMS is proposing to revise the definition of "Minimum Total Performance Score (mTPS)" at §413.178(a)(8).

CMS is proposing to Codify the ESRD QIP Measure Adoption, Retention, and Removal Policies (Page 168)

Proposed Updates to Requirements Beginning with the PY 2026 ESRD QIP (Page 169)

CMS is proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026.

Previously Finalized and Proposed New Measures for the PY 2026 ESRD QIP Measure Set (Page 170)

Consensus-Based Entity (CBE)#	Measure Title and Description
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.
2496	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.
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.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
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.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
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 will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (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.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who receive a complete COVID-19 vaccination course.

Consensus-Based Entity (CBE)#	Measure Title and Description
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

Proposal to Adopt the Facility Commitment to Health Equity Reporting Measure Beginning with the PY 2026 ESRD QIP (Page 171)

CMS is proposing to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This measure, which was first adopted for use in the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2023 IPPS/LTCH PPS final rule, assesses an ESRD facility's commitment to health equity based on its responses to five equity related attestation-based questions.

Proposed Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with PY 2026 (Page 184)

CMS is proposing 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 CDC. The update reflects the status of COVID-19 transmission in the U.S., recommendations from the CDC and FDA that eligible individuals be up to date on their vaccination, and real-world data demonstrating vaccine efficacy.

Proposal to Convert the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning with the PY 2026 ESRD QIP (Page 194)

CMS is proposing to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026. CMS is also proposing to update the scoring methodology so that the measure is better aligned with current clinical guidelines for depression screening and follow-up.

Proposed Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2026 ESRD QIP (Page 202)

In the CY 2023 ESRD PPS final rule CMS finalized revisions to the ESRD QIP measure domains beginning with PY 2025. Specifically, CMS added the Reporting Domain and updated measure domains and measure weights across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting.

Beginning with PY 2026, the Clinical Depression Screening and Follow-Up reporting measure would be converted to a clinical measure and included in the Care Coordination Domain, the Standardized Fistula Rate clinical measure would be removed from the Clinical Care Domain, the Ultrafiltration Rate reporting measure would be removed from the Reporting Domain, and the Facility Commitment to Health Equity reporting measure would be added to the Reporting Domain. To accommodate the new numbers of

measures in the Care Coordination Domain, Clinical Care Domain, and Reporting Domain, CMS is proposing to update the individual measure weights in each of these domains.

Comment

As usual the discussion of quality issues is quite detailed with reporting requirements and other factors. The material is nearly 75 pages in length.

End-Stage Renal Disease Treatment Choices (ETC) Model (Page 241)

The ESRD Treatment Choices (ETC) Model is a mandatory payment model tested under the authority of section 1115A of the Act. Under the ETC Model, participating ESRD facilities and clinicians who manage dialysis patients (Managing Clinicians) will 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 June 30, 2027.

Summary of the Proposed Provisions to the ETC Model (Page 243)

CMS is proposing revisions to its regulations at §512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. In particular, CMS is proposing to add §512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

CMS is proposing that within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows: (i) decline to review the targeted review request determination made by CMS, (ii) render a final decision based on the CMS Administrator's review of the targeted review request determination, or (iii) choose to take no action on the request for administrative review.

CMS is proposing that targeted review request determinations made by the CMS Administrator are considered final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period.