

Issue Brief

FEDERAL ISSUE BRIEF



Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Releases Final CY 2024 ESRD PPS Update

The Centers for Medicare & Medicaid Services (CMS) have issued its final Calendar Year (CY) 2024 ESRD PPS Update rule.

This rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) payment rates, 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.

The rule is scheduled to be published in the November 6 **Federal Register**. A copy of the 445-page display version is currently available at: <https://public-inspection.federalregister.gov/2023-23915.pdf>.

Comments

The rule's introductory information provides an excellent overview of the changes for CY 2024.

The rule contains "final action" sections. This is extremely helpful and expedient for the reader.

As usual, we are adding numbers, in red, to items mentioned below.

UPDATES TO THE ESRD PPS FOR CY 2024

Annual Update

The CY 2024 ESRD PPS base rate will be \$ **\$271.02**, an increase from the CY 2023 ESRD PPS base rate of \$265.57. This amount reflects the application of the combined wage index and transitional pediatric ESRD budget-neutrality adjustment factor (TPEAPA) (0.999531) and a productivity-adjusted market basket percentage increase of 2.1 percent equaling \$271.02 ($(\$265.57 \times 0.999531) \times 1.021 = \271.02). (Page 7)

The overall impact of the CY 2024 changes is projected to be a 2.1 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 3.1 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.0 percent increase. CMS says it estimates that the aggregate ESRD PPS expenditures will increase by approximately \$190 million in CY 2024 compared to CY 2023. CMS says it expects to pay \$6.7 billion to approximately 7,900 ESRD facilities.

Because of the projected 2.1 percent overall payment increase, CMS estimates there will be an increase in beneficiary coinsurance payments of 2.1 percent in CY 2024, which translates to approximately \$40 million. This amount is included in the \$190 million cited above. (Page 11)

The following table identifies the impacts associated with the provisions of this final rule. (Page 427)

Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2024)	
Category	Transfers
Annualized Monetized Transfers	\$150 million
From Whom to Whom	Federal Government to ESRD facilities
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$40 million
From Whom to Whom	Beneficiaries to ESRD facilities
ESRD PPS (CY 2025)	
Category	Costs
Increased Reporting Burden for Time on Machine	\$13 million
For Whom	ESRD Facilities
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-\$16.0 million
From Whom to Whom	Federal Government to ESRD facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-\$13.8 million
From Whom to Whom	Federal Government to ESRD facilities
ETC Model for July 1, 2022, through June 30, 2027	
Category	Transfers
Annualized Monetized Transfers	\$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share (Page 20)

The final productivity-adjusted CY 2024 ESRDB market basket update is 2.1 percent, representing a ESRDB market basket increase of 2.4 percent reduced by a productivity adjustment of 0.3 percent.

For the CY 2024 ESRD PPS payment update, CMS will continue using a labor-related share of 55.2 percent. (Page 54)

Requests for a Forecast Error Payment Adjustment (Page 44)

CMS says that it is not adopting/ not making any adjustments to account for errors in estimating market basket increases.

CMS states that “while there is ***no precedent*** (emphasis added) to adjust for market basket forecast errors in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.”

Comment

To say the least, this is a poor excuse for not adopting an ESRD market basket correction error. CMS does note that such exists for the Skilled Nursing Facility PPS program.

It’s time for CMS to make such adjustments for all PPS programs.

Changes to the Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) (Page 258)

As required by section 1834(r) of the Social Security Act (the Act), CMS is updating 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 CY 2024 payment rate is \$271.02.

CY 2024 ESRD PPS Wage Indices (Page 56)

CMS is finalizing its proposal to update the ESRD PPS wage index for CY 2024 to use the most recent hospital wage data. The final CY 2024 ESRD PPS wage index is set forth in Addendum A and is available on CMS’s website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

CMS will apply the wage index floor of 60 percent and a 5.0 percent cap on wage index decreases from the prior year.

Addendum A provides a crosswalk between the CY 2023 wage index and the CY 2024 wage index.

Addendum B provides an ESRD facility level impact analysis. Addendum B is available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

CY 2024 Update to the Outlier Policy (Page 60)

CY 2022 claims data showed outlier payments represented approximately 0.8 percent of total Medicare payments. In other words, CMS did not pay its expected 1.0 percent of ESRD payments as outliers. (Page 63)

The impact of outlier changes is shown in the table below, which compares the outlier services Medicare Allowable Payment (MAP) amounts and Fixed Dollar Loss (FDL) amounts used for the outlier policy in CY 2023 with the updated estimates for this final rule.

The estimates for the CY 2024 MAP amounts, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2024 prices for ESRD outlier services.

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

	Column I		Column II	
	Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)		Final 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	\$22.30	\$37.92
Adjustments				
Standardization for outlier services	1.0819	0.9774	1.0691	0.9763
MIPPA reduction	0.9800	0.9800	0.9800	0.9800
Adjusted average outlier services MAP amount	\$25.59	\$39.62	\$23.36	\$36.28
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$23.29	\$73.19	\$11.32	\$71.76
Patient-month-facilities qualifying for outlier payment	12.90%	5.90%	20.86%	4.87%

Update to the Average per Treatment Offset Amount for Home Dialysis Machines (Page 70)

The CY 2024 Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) offset amount for capital-related assets that are home dialysis machines is **\$10.00**. Applying the update factor of 1.021 to the CY 2023 TPNIES offset amount results in the CY 2024 TPNIES offset amount of \$10.00. ($\$9.79 \times 1.021 = \10.00).

Refinement of the Low-Volume Payment Adjustment (LVPA) (Page 72)

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 percent.

Changes to the LVPA (Page 87)

CMS is finalizing its proposals to establish an exception process to allow a facility to close and reopen in response to a disaster or emergency and still receive the LVPA, and to allow a facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a closure or operational disruption caused by a disaster or other emergency, as proposed, with two modifications.

CMS is finalizing one modification to § 413.232(g)(5)(ii) to change the deadline by which the ESRD facility must request the exception to § 413.232(b)(1) to the later of the attestation deadline or 30 days after the end of the cost reporting year for which the ESRD facility is attesting. Specifically, CMS is finalizing § 413.232(g)(5) which states that if an ESRD facility exceeds the 4,000-treatment volume threshold due to temporary patient shifting from an ESRD facility that experiences a closure or operational disruption due to a disaster or other emergency, the accepting ESRD facility would be able to apply for an exception to the requirement at 413.232(b)(1) and, if the exception is approved, the ESRD facility would not be disqualified from receiving the LVPA on the basis of 413.232(b)(1) due to exceeding the 4,000-treatment volume threshold in that cost reporting year.

Transitional Pediatric ESRD Add-on Payment Adjustment for Pediatric Patients with ESRD Receiving Renal Dialysis Services (Page 98)

CMS will adjust the per treatment base rate for Pediatric ESRD Patients to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during CYs 2024, 2025, and 2026.

CMS is codifying this payment adjustment in the regulations at § 413.235(b)(2). The budget-neutrality factor for the CY 2024 TPEAPA is 0.999503. This change will be effective January 1, 2024, as proposed.

Comment

Note, CMS previously said the TPEAPA is 0.999534 and here it says its 0.999503. Yes, there are reasons associated with these differences. But, it makes the issue confusing.

Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS (Page 115)

CMS is finalizing its proposed reporting requirement for discarded amounts of renal dialysis drugs and biological products from single-dose containers and single-use packaging, with a modified effective date of January 1, 2025. (Page 130)

ESRD facilities must report information on ESRD PPS claims using the JW modifier (or any successor modifier that includes the same data). CMS is also finalizing that ESRD facilities must document any discarded amounts in the beneficiary's medical record.

New Add-on Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends (Page 131)

CMS is finalizing, as proposed, to establish, beginning for CY 2024, a post-TDAPA add-on payment adjustment for any new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate that is paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment will be applied for a period of 3 years following the end of the TDAPA period for those products. (Page 150)

CMS will begin making payment under this new post-TDAPA add-on payment adjustment 8 calendar quarters after the beginning of the TDAPA payment period for the new renal dialysis drug or biological product. Payment of the post-TDAPA add-on payment adjustment will end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product. (Page 167)

CMS is finalizing the application of the post-TDAPA add-on payment adjustment as a non-budget neutral payment adjustment, beginning for CY 2024. (Page 169)

This payment adjustment will be case-mix adjusted and set at 65 percent of estimated expenditure levels for the given renal dialysis drug or biological product in the prior year.

Require "Time on Machine" Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis (Page 169)

CMS is finalizing its proposal to require the reporting of in-center hemodialysis duration on ESRD PPS claims, beginning January 1, 2025. CMS is requiring that ESRD facilities report the number of minutes between the start and end of hemodialysis treatment, without accounting for interruptions, a beneficiary receives during the billing period in center in an ESRD facility. (Page 208)

ESRD facilities are to report this information using the D6 value code on ESRD PPS claims.

Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Clarifications and Application for CY 2024 Payment (Page 212)

CMS is finalizing its clarification regarding the sequential order of CMS review of the TPNIES eligibility criteria as proposed.

In the annual ESRD PPS proposed rule, CMS will continue to summarize the information from an application for new TPNIES regarding each of the six eligibility criteria and include any questions or concerns that it identifies during its analysis of the application.

CY 2024 TPNIES Application for Buzzy® Pro (Page 227)

CMS received only one item for the CY 2024 TPNIES. 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 has determined that the evidence and public comments submitted are not sufficient to demonstrate that Buzzy® Pro meets all eligibility criteria to qualify for the TPNIES for CY 2024. As a result, Buzzy® Pro will not be paid for using the TPNIES per § 413.236(d).

Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024 (Page 258)

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

Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2024 (Page 258)

Two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2024: Korsuva® (difelikefalin) that was approved for the TDAPA effective in CY 2022, and Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023.

END-STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM (ESRD QIP) (Page 263)

Updates to the Regulation Text for the ESRD QIP

CMS is revising the definition of “Minimum Total Performance Score (mTPS)” at § 413.178(a)(8).

CMS is Codifying the ESRD QIP Measure Adoption, Retention, and Removal Policies. (Page 265)

Updates to Requirements Beginning with the PY 2026 ESRD QIP (Page 267)

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

The table below describes the previously finalized measures and the measures being finalized in this final rule.

Previously Finalized and Newly Finalized Measures for the PY 2026 ESRD QIP Measure Set

Consensus -Based Entity (CBE)#	Measure Title and Description
0258	<p>In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure</p> <p>Measure assesses patients’ self-reported experience of care through percentage of patient responses to multiple survey questions.</p>

Consensus -Based Entity (CBE)#	Measure Title and Description
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 CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure

Consensus -Based Entity (CBE)#	Measure Title and Description
	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.
N/A	Facility Commitment to Health Equity, a reporting measure*** Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of 10 points.

*CMS is finalizing its proposal to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026.

**CMS is finalizing its proposal to update the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2026.

*** CMS is finalizing its proposal to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026.

Adoption of the Facility Commitment to Health Equity Reporting Measure Beginning with the PY 2026 ESRD QIP (Page 268)

CMS is finalizing its proposal to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with payment year (PY) 2026. This measure, which we first adopted for use in the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule, assesses an ESRD facility's commitment to health equity based on its responses to five equity related attestation-based questions.

Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with PY 2026 (Page 291)

CMS is finalizing its proposal 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.

Conversion of the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning with the PY 2026 ESRD QIP (Page 306)

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

Removal of Two Measures from the ESRD QIP Measure Set, Beginning with PY 2026
(Page 314)

CMS is finalizing its proposal to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026.

CMS is finalizing its proposal to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026. (Page 318)

Revisions to Measure Domains and to Measure Weights Used to Calculate the Total Performance Score (TPS) Beginning with the PY 2026 ESRD QIP (Page 323)

CMS is finalizing its proposal to update the measure domains and measure weights for the PY 2026 ESRD QIP. The newly finalized ESRD QIP measure domains and measure weights are reflected in the table below.

Newly Finalized ESRD QIP Measure Domains and Weights for PY 2026

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	9.00
SRR clinical measure	9.00
PPPW measure	6.00
Clinical Depression Screening and Follow-Up measure*	6.00
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Facility Commitment to Health Equity measure**	2.00
Hypercalcemia reporting measure	2.00
MedRec reporting measure	2.00

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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Measures by Domain	Measure Weight as Percent of TPS
NHSN Dialysis Event reporting measure	2.00
COVID-19 HCP Vaccination reporting measure	2.00

Payment Reduction Scale for the PY 2026 ESRD QIP (Page 333)

Under current policy, which is codified at § 413.177, CMS implements payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility’s TPS falls below the mTPS.

The mTPS for PY 2026 will be 53, and the finalized payment reduction scale is shown in the following table.

Updated Payment Reduction Scale for PY 2026 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-53	0%
52-43	0.5%
42-33	1.0%
32-23	1.5%
22-0	2.0%

Updates to Requirements Beginning with the PY 2027 ESRD QIP (Page 334)

CMS is finalizing its proposal to add the Screening for Social Drivers of Health reporting measure beginning with PY 2027.

CMS is finalizing its proposal to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027. (Page 362)

Comment

As usual the discussions of quality issues are quite detailed with reporting requirements and other factors. This material extends almost 125 pages.

END-STAGE RENAL DISEASE TREATMENT CHOICES (ETC) MODEL (Page 381)

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.

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

CMS is finalizing its proposed modifications to the ETC Model regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. CMS is adding § 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.

Summary of Impacts (Page 397)

CMS estimates that the combined impact of the policies finalized in this rule on payments for CY 2024 is \$190 million based on the estimates of the updates to the ESRD PPS and the AKI payment rates, as well as \$10 million in projected new TDAPA spending in CY 2024.

CMS estimates an additional \$12 million in costs associated with the final policy to require ESRD facilities to report time on machine data. CMS estimates the **impacts of the ESRD QIP for PY 2026 to be \$120.9 million in information collection burden** and \$16 million in estimated payment reductions across all facilities.

Additionally, CMS estimates the impacts of the ESRD QIP for PY 2027 to be **\$130.5 million in information collection burden** and \$13.8 million in estimated payment reductions across all facilities.

Finally, CMS estimates that the changes to the ETC model in this final rule will not impact the Model's projected direct savings from payment adjustments alone.

Comment

CMS seems to gloss over the collection of information burdens in PYs 2026 and 2027. In part, CMS acknowledges that the collection burdens identified above have been ongoing. CMS says that "the net increase in burden from PY 2026 (approximately \$120.9 million) to PY 2027 (approximately \$130.5 million) is estimated to be less than \$10 million. By contrast, the estimated burden for PY 2026 is approximately \$100 million less than the estimated burden for PY 2025, which is approximately \$220 million. (Page 393)

Yes, the cost from PY 2026 will increase \$10 million to \$130 million in PY 2027. However, no matter how CMS tries to explain these items, bottom line is ESRD providers are incurring these costs each year.