Issue Brief

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CMS Releases Final CY 2023 ESRD PPS Update

The Centers for Medicare and Medicaid Services (CMS) have issued its final Calendar Year (CY) 2023 ESRD PPS Update rule.

This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury AKI). In addition, the rule updates requirements for the ESRD Quality Incentive Program and finalizes changes to the ESRD Treatment Choices Model.

These regulations are effective on January 1, 2023, except for the amendments to 42 CFR 413.234, which are effective January 1, 2025.

The rule is scheduled to be published in the November 7 ***Federal Register.*** A copy of the 472-page display version is currently available at: https://public-inspection.federalregister.gov/2022-23778.pdf.

COMMENT

While the rule does contain a table of contents, it is limited by the number of subheads identified. Therefore, we are providing page numbers corresponding to the display copy of the final rule. The rule does contain very good "Final Decision" sections.

As evidenced by the length of this rule, once again, CMS is providing too much unnecessary history.

CMS says that the overall impact of the CY 2023 changes is projected to be a 3.1 percent increase in payments. (Page 10)

Hospital-based ESRD facilities have an estimated 3.1 percent increase in payments compared with freestanding facilities with an estimated 3.0 percent increase. CMS estimates that the aggregate ESRD PPS expenditures will increase by approximately $300 million in CY 2023 compared to CY 2022. This reflects a $300 million increase from the payment rate update, approximately $2.5 million in estimated Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) payment amounts and approximately $2.3 million in estimated Transitional Drug Add-on Payment Adjustment (TDAPA) payment amounts.

For CY 2023, Medicare expects to pay $7.9 billion to approximately 7,800 ESRD facilities for furnishing renal dialysis services.

CMS notes that because of the projected 3.1 percent overall payment increase, it estimates there will be an increase in beneficiary coinsurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

The ESRD payment rate will be **$265.57**. The current amount is $257.90.

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Updates to the ESRD PPS for CY 2023

Payment Rate
The final CY 2023 ESRD PPS base rate is $265.57. This amount reflects the application of a wage index budget-neutrality adjustment factor (0.999730) and a productivity-adjusted market basket increase of 3.0 percent equaling $265.57 (($257.90 X 0.999730) X 1.030 = $265.57). (Pages 61 and 122)

The productivity adjustment is -0.1 percent. It was proposed at -0.4 percent.

CMS estimates that the updates to the AKI payment rate will result in an increase of approximately $2 million in payments to ESRD facilities. The payment rate will be the same as the regular ESRD amount of $265.57

Rebasing and Revising of the ESRDB Market Basket (Page 19)
CMS is rebasing and revising the ESRDB market basket to a base year of CY 2020. This section consumes some 32 pages.

A comparison of the yearly differences of increase factors from CY 2019 to CY 2023 for the 2016-based ESRDB market basket and the 2020-based ESRDB market basket showed that the CY 2023 ESRDB market basket increase factor would be 0.2 percentage point lower if CMS continued to use the 2016-based ESRDB market basket. (Page 49)

Another outcome of the rebasing is a change in the labor component. Effective for CY 2023, CMS is adopting a labor-related share of **55.2 percent**, compared to the current 52.3 percent that was based on the 2016-based ESRDB market basket. (Page 51)

Wage Index
The ESRD PPS uses the latest core-based statistical area (CBSA) delineations and the latest available "pre-reclassified" hospital wage data collected under the Hospital Inpatient Prospective Payment System.

The CY 2023 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 2022 wage index and the CY 2023 wage index.

Addendum B provides an ESRD facility level impact analysis. Addendum B 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.

Permanent Cap on Wage Index Decreases (Page 66)
An ESRD facility's wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, regardless of whether the ESRD facility is part of an updated CBSA, and that for subsequent years, an ESRD facility's wage index would not be less than 95 percent of its wage index calculated in the prior CY. This also would mean that if an ESRD facility's prior CY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the ESRD facility's capped wage index in the prior CY.

Update to ESRD PPS Wage Index Floor (Page 75)
A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values.

After considering the public comments received regarding the wage index floor, CMS is finalizing an increase to the wage index floor from 0.5000 to 0.6000 for CY 2023 and subsequent years as proposed.

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Update to the Outlier Policy (Page 89)
For CY 2023 and subsequent years, CMS is will continue to calculate the adult and pediatric Medicare Allowable Payment (MAP) amounts for the rule year (CY 2023) following its established methodology, but CMS will prospectively calculate the adult Fixed Dollar Loss (FDL) amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.

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

	Column I Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)*		**Column II Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)****	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$25.91	$44.49	$24.13	$41.36
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0809	0.9774
MIPPA reduction	0.9800	0.9800	0.9800	0.9800
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.59	$39.62
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$23.29	$73.19
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 2022 ESRD PPS final rule (86 FR 61883).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2019, 2020, and 2021.

The CY 2023 outlier threshold amount for adults (Column II; $73.19) is lower than that used for the CY 2022 outlier policy (Column I; $75.39). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.75 to $39.62. For pediatric patients, there is a decrease in the FDL amount from $26.02 to $23.29. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $27.15 to $25.59. (Page 118)

Update to the Average per Treatment Offset Amount for Home Dialysis Machines (Page 123)
CMS is finalizing its proposal to calculate the CY 2023 TPNIES offset amount using the most recent data available. The CY 2022 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.50. The final CY 2023 ESRDB market basket increase factor minus the productivity adjustment is 3.0 percent (3.1 percent minus 0.1 percent). Applying the update factor of 1.030 to the CY 2022 TPNIES offset amount results in a final CY 2023 TPNIES offset amount of $9.79 ($9.50 x 1.030).

Revision to the Oral-only Drug Definition and Clarification Regarding the ESRD Functional Category Descriptions (Page 126)
CMS is finalizing its proposal to include the word "functional" in the definition of oral-only drug at § 413.234(a). To apply this change effective January 1, 2025 as

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proposed, CMS is finalizing a technical modification to the amendatory language to update the regulation text at § 413.234(a).

Accordingly, CMS is updating the definition of oral-only drug at § 413.234(a) (effective January 1, 2025) to read as follows: "Oral-only drug. A drug or biological product with no injectable functional equivalent or other form of administration other than an oral form." (Page 150)

Revisions to Clarify the ESRD PPS Functional Category Descriptions (Page 150)

CMS is finalizing the changes to the descriptions of the ESRD PPS functional categories as proposed, as noted in the following table. These changes will be effective January 1, 2023.

Final ESRD PPS Functional Category Descriptions

Functional Category	Description and Examples
Access Management	Drugs/biological products used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/biological products used to stimulate red blood cell production and/or treat or prevent anemia. Examples of drugs/biological products in this category include ESAs and iron.
Bone and Mineral Metabolism	Drugs/biological products used to prevent/treat bone disease secondary to dialysis. Examples of drugs/biological products in this category include phosphate binders and calcimimetics.
Cellular Management	Drugs/biological products used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Drugs/biological products used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Drugs/biological products used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/biological products in this category are included for their action to treat itching secondary to dialysis but may have multiple clinical indications.
Anxiolytic	Drugs/biological products in this category are included for the treatment of restless leg syndrome secondary to dialysis but may have multiple clinical indications.
Excess Fluid Management	Drugs/biological products/fluids used to treat fluid excess or fluid overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/biological products/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/biological products used to treat graft site pain and to treat pain medication overdose.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2023 (Page 162)

CMS received three applications for the TPNIES for CY 2023.

CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System).

CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the CloudCath System meets all eligibility

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criteria to qualify for the TPNIES for CY 2023. As a result, the CloudCath System will not be paid for using the TPNIES per § 413.236(d). (Page 194)

SunWrap™ System.

CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the SunWrap™ System meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, the SunWrap™ System will not be paid for using the TPNIES per § 413.236(d). (Page 208)

THERANOVA 400 Dialyzer / THERANOVA 500 Dialyzer (THERANOVA).

CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that THERANOVA meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, THERANOVA will not be paid for using the TPNIES per § 413.236(d). (Page 241)

COMMENT

CMS spends nearly 80 pages describing these 3 items and the agency's final actions on each. While the material is extremely detailed, it is simple to understand the basics. Who submitted what and CMS' decisions. No prior history and updates clouds the outcomes.

Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2023 (Page 241)
The table below identifies the one item that was approved for CY 2022 and which is still in the TPNIES payment period, as specified in § 413.236(d)(1), for CY 2023. CMS will continue paying for this item using the TPNIES for CY 2023.

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
E1629	Tablo hemodialysis system for the billable dialysis service	1/1/2022	12/31/2023

Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products for CY 2023 (Page 242)
The table below identifies the one drug item that was approved for CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2023.

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment EndDate
J0879	Injection, difelikefalin, 0.1microgram, (for esrd on dialysis)	4/1/2022	3/31/2024

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

Suppression of Seven ESRD QIP Measures for PY 2023 (Page 268)
CMS will continue to collect and publicly report all ESRD QIP measures while pausing the use of certain measures data for scoring and payment adjustment purposes in the PY 2023 ESRD QIP.

continued

CMS will suppress the following ESRD QIP measures for PY 2023.

Standardized Hospitalization Ratio (SHR) clinical measure;
Standardized Readmission Ratio (SRR) clinical measure;
In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure;
Long-term Catheter Rate clinical measure;
Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure; and the
Kt/V Dialysis Adequacy Comprehensive clinical measure; and
Although CMS did not propose to pause the Standardized Fistula Rate clinical measure, CMS agreed with commenters and is finalizing that this measure will also be paused for PY 2023.

Updates to the Performance Standards Applicable to the PY 2023 Clinical Measures (Page 309)
CMS will calculate the performance standards for PY 2023 using CY 2019 data, which are the most recently available full calendar year of data to calculate those standards.

Technical Updates to the SRR and SHR Clinical Measures Beginning with the PY 2024 ESRD QIP
CMS will begin expressing the Standardized Hospitalization Ratio (SHR) clinical measure and Standardized Readmission Ratio (SRR) clinical measure results as rates beginning with the PY 2024 ESRD QIP. CMS believes that expressing these measure results as rates will help providers and patients better understand a facility's performance on the measures and will be more intuitive for a facility to track its performance from year to year.

Current Performance Standards for the PY 2024 ESRD QIP SHR and SRR Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance
Standardized Readmission Ratio	1.268	0.998	0.629
Standardized Hospitalization Ratio	1.230	0.971	0.691

Numerical Values for the Performance Standards for the Updated PY 2024 ESRD QIP SHR and SRR Clinical Measures, Expressed as Rates, Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance
Standardized Readmission Ratio	34.27	26.97	17.02
Standardized Hospitalization Ratio	187.80	148.33	105.54

continued

Technical Measure Specification Updates to Include a Covariate Adjustment for COVID-19 for the SHR and SRR Measures Beginning with PY 2025

CMS is modifying the technical measure specifications for the SHR and the SRR clinical measures to include a "covariate" adjustment for patient history of COVID-19 in the 12 months prior to measure eligibility.

Updates to Requirements Beginning with the PY 2025 ESRD QIP (Page 319)

The PY 2025 ESRD QIP measure set would include the same 14 measures as the PY 2024 ESRD QIP measure set with an additional measure regarding COVID Vaccination.

CMS is adopting the COVID-19 Healthcare Personnel (HCP) Vaccination reporting as a reporting measure. This measure will assess the percentage of healthcare personnel employed at the facility who receive a complete COVID-19 vaccination course. CMS is finalizing quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Under this policy, facilities will report the measure through the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) web-based surveillance system beginning in CY 2023.

CMS is modifying the technical measure specifications for the SHR and the SRR clinical measures to include a covariate adjustment for patient history of COVID-19 in the 12 months prior to measure eligibility.

CMS is finalizing its proposal to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning in PY 2025. CMS believes that previous validity concerns have been adequately examined and addressed, and the finalized STrR clinical measure will more closely align with National Quality Forum (NQF) measure specifications. In addition to converting the STrR reporting measure to a clinical measure, CMS is also finalizing updates to the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements will receive a score on the STrR clinical measure based on the actual clinical values reported by the facility, rather than the successful reporting of the data. Consistent with the technical updates to the SHR clinical measure and the SRR clinical measure, the STrR clinical measure results will be expressed as a rate beginning in PY 2025.

CMS is converting the Hypercalcemia clinical measure to a reporting measure while it explores possible replacement measures that would be more clinically meaningful for purposes of quality improvement. CMS is also updating the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements will receive a score on the Hypercalcemia reporting measure based on the successful reporting of the data rather than the actual clinical values reported by the facility.

Currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety. Based on changes to the measure set since PY 2021, CMS has reassessed the impact of the ESRD QIP measure domains and domain weights on Total Performance Scores (TPSs) and believes it is necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, such as measures that assess patient clinical outcomes.

Therefore, CMS is finalizing the creation of a new Reporting Measure Domain, which will include the four current reporting

continued

measures in the ESRD QIP measure set, as well as the finalized COVID-19 Vaccination Coverage among HCP reporting measure and the finalized Hypercalcemia reporting measure. CMS is also finalizing its proposal to update the domain weights and individual measure weights in the Care Coordination Domain, Clinical Care Domain, and Safety Domain accordingly to accommodate the new Reporting Measure Domain and individual reporting measures therein. CMS did not propose any changes to the Patient & Family Engagement Domain, which will continue to be weighted at 15 percent of a facility's TPS. As the ESRD QIP measure set has evolved over the years, CMS believes this will help to address concerns regarding the impact of individual measure performance on a facility's TPS, while also further incentivizing improvement on clinical measures.

PY 2025 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
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 NQF #2979	Standardized Transfusion Ratio (STrR), a reporting 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.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
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 clinical 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 NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #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).

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National Quality Forum (NQF) #	Measure Title and Description
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.
N/A	COVID-19 Vaccination coverage among HealthCare personnel, a reporting measure**** Percentage of HCP who receive a complete COVID-19 vaccination course.

* CMS is updating the SHR clinical measure and the SRR clinical measure to be expressed as risk-standardized rates beginning in PY 2024.

** CMS is finalizing its proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025.

*** CMS is finalizing its proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025.

**** CMS is adopting the COVID-19 HCP Vaccination measure beginning in PY 2025.

COMMENT

As usual the discussion of quality issues is quite detailed with reporting requirements and other factors. The material is nearly 100 pages in length.

End-Stage Renal Disease Treatment Choices (ETC) Model (Page 409)

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.

The purpose of the ETC Model is to test the use of certain payment adjustments to increase rates of home dialysis and transplantation, thereby improving or maintaining quality and reducing Medicare expenditures.

ETC Participants are subject to two payment adjustments.

The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation

Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment is the Performance Payment Adjustment (PPA). For the PPA, CMS assesses ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period – a 6-month period that begins 6 months after the conclusion of the MY. CMS adjusts certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

continued

Updates to the ETC Model

CMS is finalizing its proposal to add a requirement, by revising § 512.370(b) and adding § 512.370(b)(3), to specify that, for MY5 through MY10, an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate.

CMS is finalizing its proposal to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1), beginning for MY5, only "clinical staff" that are not leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity may provide kidney disease patient education services.

FINAL THOUGHT

Something is awry with the constant increase in the size of these rules. At least this rule contains clear and concise final decision sections. Nonetheless, the rule contains much, too much unneeded history. There is no reason to provide years old information that has already been replaced.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting