Issue Brief

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KEY POINTS

- The payment updates to ESRD facilities are expected to increase by 0.2 percent in calendar year 2016.
- The final rule continues to build on moving health care systems to one that values quality over quantity and includes changes to the ESRD Quality Incentive Program for payment years 2017-2019.

CMS Issues Updates to the ESRD PPS for CY 2016

The Centers for Medicare & Medicaid Services has issued a final rule to update payment policies and rates for the End-Stage Renal Disease Prospective Payment System for services furnished on or after Jan. 1, 2016.

In addition, the rule makes numerous and significant changes to the ESRD Quality Incentive Program.

The 407-page proposal is schedule for publication in the November 6 *Federal Register*. A copy of the display version is currently available at: https://www.federalregister.gov/articles/2015/11/06/2015-27928/medicare-program-end-stage-renal-disease-prospective-payment-system-and-quality-incentive-program.

After publication, the above link will no longer operate.

COMMENT

While this rule has a helpful executive summary, the rest is both difficult to navigate and to find decision actions. Most subject discussions do not have a clear and concise final action section. Further, the rule has too much history, which clouds and to a certain degree confuses the reader. The material pertains to CY 2016, yet, the material recites too much of CY 2011 decisions.

CMS estimates "that the final revisions to the ESRD PPS will result in an increase of approximately $10 million in payments to ESRD facilities in CY 2016, which includes the amount associated with updates to outlier threshold amounts, updates to the wage-index, changes in the CBSA delineations, changes in the labor-related share, update to the payment rate and changes involved with the refinement."

The overall impact of the CY 2016 changes is projected to be a 0.2 percent increase in payments to both hospital-based and freestanding ESRD facilities.

CMS estimates that Medicare spending for ESRD facilities in CY 2016 will be approximately $9.6 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 percent in CY 2016.

Numbers due fluctuate. In the CY 2016 proposed rule, CMS estimated that CY 2016 spending (total Medicare program payments) for ESRD facilities would be approximately $8.7 billion. Part of this amount would be from a 1.5 percent increase in the number of beneficiaries.

In responding to numerous comments, CMS identifies some as LDO (large dialysis organization), medium (MDO) or small (SDO)(this acronym is not defined in the rule). The question is why there a need to do so.

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SUMMARY OF MAJOR CHANGES TO THE CY 2016 END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM

1. Update to the ESRD PPS base rate for CY 2016

The final CY 2016 ESRD PPS base rate is $230.39 up slightly from a proposed amount of $230.20, but down $9.04 from the current rate of $239.43 – a 3.77 percent payment reduction.

This amount reflects a reduced market-basket increase as required by section 1881(b)(14)(F)(i)(I) — (0.15 percent), application of a wage-index budget-neutrality adjustment factor (1.000495), and a refinement budget-neutrality adjustment factor (0.960319).

For CY 2016, CMS says it will complete its two-year transition to both the updated core-based statistical area delineations and the labor-related share to which the wage-index is applied (50.673 percent).

The multifactor productivity adjustment for CY 2016 (the 10-year moving average of MFP for the period ending CY 2016) is 0.4 percent down from a proposed value of 0.6 percent.

2. Final CY 2016 Marketbasket Update

CMS is finalizing a CY 2016 ESRD marketbasket update of 1.8 percent, based on the IHS Global Insight third quarter 2015 forecast (with historical data through the second quarter 2015) (the proposed increase was 2.0 percent). CMS is also reducing the 1.8 percent ESRD marketbasket update by 1.25 percent as required by section 217(b)(2)(A) of the Protecting Access to Medicare Act of 2014. Therefore, the CY 2016 marketbasket percentage increase factor is 0.55 percent.

Adding the multifactor productivity reduction of 0.4 percent, the overall increase amounts to 0.15 percent (ESRDB marketbasket of 1.8 percent, less the statutory mandate reduction of 1.25 percent, less the MFP amount of 0.4 percent – (1.80-1.25 = 0.55 -0.4 = 0.15 percent).

3. Update to the wage-index and wage-index floor

For CY 2016, CMS is not proposing any changes to the application of the wage-index floor and will continue to apply the current wage-index floor (0.4000) to areas with wage-index values below the floor.

The CY 2016 wage-index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the CY 2016 wage-index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS' website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

4. Update to the Outlier Policy

CMS is updating the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments for adult patients for CY 2016 using 2014 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries increases from $54.35 to $62.19 and the MAP amount decreases from $43.57 to $39.20.

For adult beneficiaries, the fixed-dollar loss amount increases from $86.19 to $86.97 and the MAP amount decreases from $51.29 to $50.81. The 1.0 percent target for outlier payments was not achieved in CY 2014 (0.8 percent rather than 1.0 percent).

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CMS provides the following table reflecting CY 2016 outlier changes.

Outlier Policy				
	Column 1 Final outlier policy for CY 2015		Column 2 Final Outlier policy for CY 2016	
	Age< 18	Age>= 18	Age< 18	Age>= 18
Average outlier services MAP amount per treatment	$39.89	$52.98	$40.20	$53.29
Adjustments Standardization for outlier services	1.1145	0.9878	0.9951	0.9729
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$43.57	$51.29	$39.20	$50.81
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$54.35	$86.19	$62.19	$86.97
Patient months qualifying for outlier payment	6.3%	6.3%	5.8%	6.5%

COMMENT

Once again, CMS has failed to pay the full ESRD outlier amount in FY 2014. It seems that CMS under estimates outlier payments in most of the various PPS programs much more so than it overpays.

In fact, CMS says "that the l.0 percent target has not been achieved since 2011 primarily because our annual update of the fixed-dollar loss amounts and MAP amounts could not keep up with the continued decline in the use of outlier services (primarily ESAs). That is, facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target."

A commenter suggested that CMS make adjustments for this shortfall. CMS argues that it would not reduce outlier payment if it overpaid the 1.0 percent factor. I suggest this is an irrational response. All under and over projections should be reconciled.

5. Revisions to the Case-Mix Payment Adjustments

CMS is making revisions to the following case mix payment adjustments.

1) Patient Age

The CY 2016 payment multipliers, unchanged from their proposed values, are presented in the following table.

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Age	Current Payment Multipliers	CY 2016 Payment Multipliers
18-44	1.171	1.257
45-59	1.013	1.068
60-69	1.000	1.070
70-79	1.011	1.000
80 +	1.016	1.109

2) Body Surface Area

For computing a patient's BSA and the updated Medicare national average BSA of l.90m^2, CMS is adopting that the BSA payment adjustment would be 1.032 and the BSA payment adjustment would be based on the following formula: 1.032((Patient's BSA- 1.90)/0.1).

3) Low-Body Mass Index

The current payment adjustment for low BMI under the ESRD PPS is 1.025. CMS is adopting a CY 2016 payment adjustment of 1.017.

4) Onset of Dialysis

The current onset of dialysis payment adjustment is 1.510. CMS will change the factor to 1.327.

5) Acute Comorbidity Categories

There are three acute comorbidity categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage).

CMS is adopting the following adjustments for CY 2016.

Acute Comorbidity Category	Current Payment Multiplier	CY 2016 Payment Multiplier
Pericarditis	1.114	1.040
Bacterial Pneumonia	1.135	--
Gastrointestinal Tract Bleeding w/Hemorrhage	1.183	1.082

CMS is eliminating the case-mix payment adjustment for bacterial pneumonia beginning in CY 2016.

6) Chronic Comorbidity Categories

There are three chronic comorbidity categories (hereditary hemolytic and sickle cell anemias, myelodysplastic syndrome, and monoclonal gammopathy).

CMS is adopting the following adjustments for CY 2016.

Chronic Comorbidity Category	Current Payment Multiplier	CY 2016 Payment Multiplier
Hereditary Hemolytic or Sickle Cell Anemias	1.072	1.192
Myelodysplastic Syndrome	1.099	1.095
Monoclonal Gammopathy	1.024	--

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CMS is eliminating the case mix payment adjustment for the comorbid condition of monoclonal gammopathy beginning in CY 2016.

6. Refinement of Facility-Level Adjustments

1) Low-Volume Payment Adjustment
The current amount of the LVPA is 18.9 percent. CMS is adopting a new LVPA adjustment factor of 23.9 (1.239) percent for CY 2016 and future years.

2) Elimination of the Grandfathering Provision
CMS is eliminating its grandfather provision. Beginning with CY 2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified will be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) under common ownership with; and (ii) 5 road miles or less from the ESRD facility in question.

3) Geographic Payment Adjustment for ESRD Facilities Located in Rural Areas
CMS is adopting a payment multiplier of 1.008. This adjustment will be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area.

4) Refinement of the Case-Mix Adjustments for Pediatric Patients

CMS says it did not make changes to the pediatric model and is therefore finalizing the updated pediatric SB and EB multipliers as shown below.

	Patient Characteristics		CY 2016 Final Rule (Based on 2012 and 2013 data)		
Cell	Age	Modality	Population %	Separately Billable Multiplier	Expanded Bundled Payment Multiplier
1	<13	PD	27.62%	0.410	1.063
2	<13	HD	19.23%	1.406	1.306
3	13-17	PD	20.19%	0.569	1.102
4	13-17	HD	32.96%	1.494	1.327

7. Section 217(c) of PAMA and the ESRD PPS Drug Designation Process

As part of the CY 2016 ESRD PPS rulemaking, section 217(c) of PAMA requires the Secretary to implement a drug designation process for:

1) Determining when a product is no longer an oral-only drug; and
2) Including new injectable and intravenous products into the bundled payment under such system.

CMS will include new injectable and intravenous products in the ESRD PPS bundled payment by first determining whether the new injectable or intravenous products are reflected currently in the ESRD PPS.

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CMS will make this determination by assessing whether the product can be used to treat or manage a condition for which there is an ESRD PPS functional category. If the new injectable or intravenous product can be used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product would be considered reflected in the ESRD PPS bundled payment and no separate payment would be available. Specifically, any new drug, biosimilar, or biologic that fits into one of the ESRD functional categories would be considered to be included in the ESRD PPS.

If, however, the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product would not be considered included in the ESRD PPS bundled payment.

CMS has established the following functional categories that are to be used to treat conditions associated with ESRD and are displayed in the table below.

ESRD PPS Functional Categories

Category	Rationale for Association
DRUGS ALWAYS CONSIDERED USED FOR THE TREATMENT OF ESRD	
Access Management	Drugs 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 used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
DRUGS THAT MAY BE USED FOR THE TREATMENT OF ESRD	
Antiemetic	Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis.
Anxiolytic	Drugs in this classification have multiple actions. Use within an ESRD functional category include treatment of restless leg syndrome related to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain.

8. Transitional Drug Add-On Payment Adjustment

CMS will pay for new injectable or intravenous product using a transitional drug add-on payment adjustment. The transitional drug add-on payment adjustment would be based on the ASP pricing methodology and would be paid until the agency has collected sufficient claims data for rate setting for the new injectable or intravenous product, but not for less than two years.

COMMENT

This section is a good example of the rule's failure to communicate clearly and succinctly. While CMS discusses this issue, it really doesn't tell us in simple language what final action it is taking. Rather, it says, "After consideration of the public comments, we are finalizing the drug designation process and the corresponding regulation text at 42 CFR 413.234." Is CMS finalizing with or without changes to the material that was proposed?

9. Determination of When an Oral-Only Renal Dialysis Service Drug is No Longer Oral-Only

CMS is finalizing the definition of oral-only drug at 413.234(a), which provides that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. CMS is also finalizing its process at 42 CFR 413.234(d) for determining that an oral only drug is no longer considered oral-only when a non-oral version of the oral-only drug is approved by the FDA.

CMS will include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. For at least two years CMS will pay for the existing oral-only drugs — phosphate binders and calcimimetics — using the transitional drug add-on payment adjustment, which will be calculated, based on the payment methodologies under section 1847A of the Act. CMS will add the oral and non-oral forms of the phosphate binders and calcimimetics to the ESRD PPS bundled payment through notice-and-comment rulemaking. For future oral-only drugs for which a non-oral form of administration comes on the market, CMS will apply its drug designation process as for all other new drugs.

10. Delay of Payment for Oral-Only Renal Dialysis Services

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 provides that payment for oral-only ESRD drugs cannot be made under the ESRD PPS prior to Jan. 1, 2025. Accordingly, CMS is will delay payment for the inclusion of oral-only ESRD drugs until that date under the ESRD PPS.

11. Reporting Medical Director Fees on ESRD Facility Cost Reports

Beginning in CY 2016 CMS will eliminate the Reasonable Compensation Equivalent limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports.

12. Laboratory Renal Dialysis Services

CMS is finalizing the removal of the lipid panel from the ESRD PPS consolidated billing list and will issue sub-regulatory guidance to that effect. However, CMS notes that even though lipid panels are being removed from the ESRD PPS consolidated billing list, if an ESRD patient's ordering practitioner orders a lipid panel for the treatment of

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ESRD then it should not be billed separately.

END-STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM

1) Use the Hypercalcemia Measure as a Measure Specific to the Conditions Treated with Oral-Only Drugs

The Hypercalcemia clinical measure was adopted beginning with the PY 2016 program. CMS says it believes that the current Hypercalcemia clinical measure (NQF #1454) meets the requirement that the ESRD QIP measure set include for 2016 and subsequent years measures that are specific to the conditions treated with oral-only drugs.

2) Modifying the Small Facility Adjuster Calculation for All Clinical Measures Beginning with the PY 2017 ESRD QIP

CMS is adopting the 90th percentile of facility performance as the measure score threshold for facility eligibility for the small facility adjuster instead of the proposed 50th percentile of facility performance. Under this methodology, facilities treating between 11 and 25 patients and scoring below the benchmark (that is, the 90th percentile of national facility performance) for a measure will receive an adjustment to their measure scores.

3) Reinstating Qualifying Patient Attestations for the ICH CAHPS Clinical Measure

CMS will reinstate the qualifying patient attestations for the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems measure for PY 2017 and subsequent years, using the eligibility criteria finalized in the CY 2015 ESRD PPS final rule.

4) Requirements for the PY 2018 ESRD QIP

The table below lists the finalized numerical values for all of the finalized PY 2018 ESRD QIP clinical measures except the ICH CAHPS clinical measure.

Measure	Achievement Threshold	Benchmark	Performance Standard
Vascular Access Type			
%Fistula	53.51%	79.60%	65.94%
%Catheter	16.79%	2.59%	8.80%
Kt/V			
Adult Hemodialysis	91.08%	99.35%	96.89%
Adult Peritoneal Dialysis	75.42%	97.06%	89.47%
Pediatric Hemodialysis	84.16%	99.06%	94.44%
Pediatric Peritoneal Dialysis	43.22%	88.39%	72.60%
Hypercalcemia	3.92%	0.00%	1.19%
NHSN Bloodstream Infection SIR	1.812	0	0.861
Standard Readmission Ratio	0.996	0.555	0.996
Standardized Transfusion Ratio	1.470	0.431	0.923
ICH CAHPS	50th percentile of eligible facilities' performance during CY 2015	15th percentile of eligible facilities' performance during CY 2015	90th percentile of eligible facilities' performance during CY 2015

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5) Payment Reductions for the PY 2018 ESRD QIP

CMS estimates that a facility must meet or exceed a minimum total performance score of 39 for PY 2018 to avoid any payment reductions. These amounts are unchanged from the proposed factors.

Total Performance Score	Reduction
100 – 39	0.0%
38 – 29	0.5%
28 – 19	1.0%
18 – 9	1.5%
8 – 0	2.0%

6) Requirements for the PY 2019 ESRD QIP

The following table identifies the 12 ESRD QIP measures that will be continued in PY 2019.

NQF #	Measure Type and Description
257	Vascular Access Type: AV Fistula, a clinical measure Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter > 90 days, a clinical measure Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A[1]	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients, a clinical measure Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
2496	Standardized Readmission Ratio, a clinical measure Standardized hospital readmissions ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions.
N/A	Standardized Transfusion Ratio, a clinical measure Risk-adjusted standardized transfusion ratio for all adult Medicare patients.
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey in accordance with survey specifications and submits survey results to CMS.
N/A[2]	Mineral Metabolism Reporting, a reporting measure Number of months for which facility reports serum phosphorus or serum plasma for each Medicare patient.
N/A	Anemia Management Reporting, a reporting measure Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.
N/A[3]	Pain Assessment and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.

NQF #	Measure Type and Description
N/A[4]	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient once before February 1 of the year following the performance period.
N/A[5]	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15 of the performance period.

[1] CMS notes that this measure is based upon a current NQF-endorsed bloodstream infection measure (NQF#1460).
[2] CMS notes that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).
[3] CMS notes that this measure is based upon a current NQF-endorsed pain assessment and follow-up measure (NQF #0420).
[4] CMS notes that this measure is based upon a current NQF-endorsed clinical depression screening and follow-up measure (NQF #0418).
[5] CMS notes that this measure is based upon an NQF-endorsed HCP influenza vaccination measure (NQF #0431).

Beginning with the PY 2019 ESRD QIP, CMS will replace four measures in the Kt/V Dialysis Adequacy measure topic — (1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy — with a single more broadly applicable measure for the topic. The new measure, Delivered Dose of Dialysis above Minimum – Composite Score clinical measure ("Dialysis Adequacy clinical measure") (Measure Applications Partnership #X3717), is a single comprehensive measure of dialysis adequacy assessing the percentage of all patient-months, for both pediatric and adult patients, whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified Kt/V threshold during the performance period.

Also, CMS proposed to adopt two new reporting measures beginning in PY 2019 — the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure. Neither is being adopted.

COMMENT

The issue of quality grows and grows. This rule contains 125 pages on the subject or more than 30 percent of the rule's length. Organizational folks with quality knowledge need to be reviewing this material in great detail.

FINAL COMMENT

As noted at the beginning of this analysis, this rule is difficult to navigate. Two suggestions. First, CMS should eliminate all the "appreciates and thank you" responses to comments. This could save much unneeded verbiage and reduce greatly the overall length of the document. Second, the table of contents seem to grow longer and longer every year. Perhaps CMS needs to index the table of contents to the material.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting