# Issue Brief

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## KEY POINTS

- End-stage renal disease payments by will increase by 0.3 percent, bringing ESRD Medicare payments to $8.7 billion.
- New quality and performance measures will deliver better care at lower costs.

# CMS Proposes Updates to the ESRD PPS for CY 2016

The Centers for Medicare & Medicaid Services has issued a proposed rule to update payment policies and rates under the end-stage renal disease prospective payment system for renal dialysis services furnished on or after Jan. 1, 2016 (calendar year 2016).

The rule also makes numerous and significant changes to the ESRD Quality Incentive Program.

The 194-page proposal is schedule for publication in the July 1 *Federal Register*. A 60-day comment period ending Aug. 25 is provided. A copy of the display version is currently available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16074.pdf. On July 1, this link will change.

## COMMENT

Like last year's ESRD proposed rule, this year's proposal has an excellent executive summary that succinctly identifies many of the issues being addressed and corresponding proposed changes. CMS estimates that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2016 will be approximately $8.7 billion. Part of this amount will be from a 1.5 percent increase in the number of beneficiaries.

CMS says the overall impact of the CY 2016 changes is projected to be a 0.3 percent increase in payments. Hospital-based ESRD facilities would have an estimated 0.5 percent increase in payments compared with freestanding facilities with an estimated 0.2 percent increase.

CMS estimates that the proposed revisions to the ESRD PPS will result in an increase of approximately $20 million in payments to ESRD facilities. This reflects a $10 million increase from the payment rate update and a $10 million increase due to the updates to the outlier threshold amounts.

CMS' projected payment rate of increase appears too high. CMS does not identify CY 2015 spending. Nonetheless, dividing $20 million by $8.7 billion yields an increase of only 0.23 percent. As noted above, part of the $8.7 billion would be from an increase in beneficiaries. Further, CMS says $10 million of its CY 2016 increase would result from increasing the outlier payments. The increase is not because of rate changes but because CMS continues to underpay outliers.

## SUMMARY OF MAJOR CHANGES TO THE PROPOSED CY 2016 ESRD PPS

### Update to the ESRD PPS Base Rate for CY 2016

For CY 2016, CMS is proposing an ESRD PPS base rate of $230.20 down $9.23 from the current rate of $239.43 — a 3.9 percent payment reduction.

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The proposed CY 2016 ESRD bundled marketbasket increase factor is 2.0 percent. As required by the Protecting Access to Medicare Act of 2014, CMS says it must reduce the amount of the marketbasket increase factor by 1.25 percent, resulting in a proposed CY 2016 ESRDB marketbasket percentage increase factor of 0.75 percent.

A multifactor productivity adjustment for CY 2016 (the 10-year moving average of MFP for the period ending CY 2016) is projected to be 0.6 percent.

This reduces the overall increase to 0.15 percent. (ESRDB market basket of 2.0 percent, less the statutory mandate reduction of 1.25 percent, less the MFP amount of 0.6 percent — (2.0- 1.25=0.75 -0.6=0.15 percent).

CMS proposes two more adjustments — application of a wage index budget-neutrality adjustment factor (1.000332), and a refinement budget-neutrality adjustment factor (0.959703), so that total projected PPS payments in CY 2016 are equal to what the payments would have been in CY 2016 had CMS not implemented the refinement.

The proposed CY 2016 ESRD PPS base rate is $230.20 ($239.43 x 1.0015 x 1.000332 x 0.959703 = **$230.20**).

## Labor-Related Share

For the CY 2016 ESRD payment update, CMS proposes to continue using a labor-related share of 50.673 percent.

## 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 is proposing to continue to apply the current wage index floor (0.400) to areas with wage index values below the floor.

The proposed CY 2016 wage index values for urban areas are listed in Addendum A (wage indices for urban areas) and the proposed 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 CMS's website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

## Update to the Outlier Policy

Consistent with the proposal to annually update the outlier policy using the most current data, CMS is proposing to update 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.

The fixed-dollar loss amount for pediatric beneficiaries would decrease from $54.35 to $49.99 and the MAP amount would decrease from $43.57 to $37.82, as compared to CY 2015 values.

For adult beneficiaries, the fixed-dollar loss amount would decrease from $86.19 to $85.66 and the MAP amount would decrease from $51.29 to $48.15. In CY 2014, outlier payments were 0.9 percent of total ESRD PPS payment.

## Proposed Revisions of the Payment Adjustments

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

### 1) Patient Age

The CY 2016 proposed payment multipliers presented below in the following table:

*continued*

| Age | Current Payment Multipliers | Proposed 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 CY 2016, CMS is proposing to update the BSA Medicare national average from 1.87$m^2$ to 1.90 $m^2$ for CY 2016 to reflect a new Medicare ESRD national average BSA.

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

**3) Low-Body Mass Index**
The current payment adjustment for low BMI under the ESRD PPS is 1.025. CMS is proposing the CY 2016 payment adjustment would be 1.017.

**4) Onset of Dialysis**
The current onset of dialysis payment adjustment is 1.510. CMS is proposing to 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 proposing to adopt the following adjustments.

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

CMS is proposing to eliminate the case-mix payment adjustment for the comorbidity category of 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 proposing to adopt the following adjustments.

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

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

## Proposed Refinement of Facility-Level Adjustments

### 1) Low-Volume Payment Adjustment

The current amount of the LVPA is 18.9 percent. CMS is proposing 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 proposing that for the purposes of determining the number of treatments under the definition of a low-volume facility, beginning in CY 2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified would 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 proposing a payment multiplier of 1.008. This adjustment would be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area.

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

CMS is proposing adjustment factors that reflect a proposed 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. The proposed updated pediatric SB and EB multipliers are shown in the following table.

| Cell | Patient Characteristics | | PY 2011 Final Rule (based on 2006 - 2008 data) | | PY 2016 NPRM (based on 2012 and 2013 data) | | |
|---|---|---|---|---|---|---|---|
| | Age | Modality | Population % | Payment Multiplier | Population % | Separately Billable Multiplier | Expanded Bundle Payment Multiplier |
| 1 | <13 | PD | 20.58% | 1.033 | 27.62% | 0.410 | 1.063 |
| 2 | <13 | HD | 16.57% | 1.219 | 19.23% | 1.406 | 1.306 |
| 3 | 13-17 | PD | 18.20% | 1.067 | 20.19% | 0.569 | 1.102 |
| 4 | 13-17 | HD | 44.66% | 1.277 | 32.96% | 1.494 | 1.327 |

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## 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 proposes to 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. CMS proposes to 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 used to treat conditions associated with ESRD and are displayed in the table below.

| Category | Rationale for Association |
|---|---|
| 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. |
| Antiemetic | 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 | Used to treat infections. May include antibacterial and antifungal drugs. |
| Antipruritic | Drugs in this classification have multiple clinical indications and are included for their action to treat itching secondary to dialysis. |

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| Category | Rationale for Association |
|---|---|
| Anxiolytic | Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary 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 graft site pain and to treat pain medication overdose. |

### Transitional Drug Add-On Payment Adjustment

CMS proposes to 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 2 years.

### Determination of When an Oral-Only Renal Dialysis Service Drug is no Longer Oral-Only

For CY 2016, CMS proposes that an oral-only drug would no longer be considered oral-only if the FDA approves an injectable or other form of administration of the oral-only drug.

### 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 proposing to delay payment for the inclusion of oral-only ESRD drugs until that date under the ESRD PPS.

### Reporting Medical Director Fees on ESRD Facility Cost Reports

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

## ESRD QUALITY INCENTIVE PROGRAM

## COMMENT

As with all PPS programs, the issue of quality and quality reporting continues to grow in requirements. Failure to provide such information threatens payment amounts. This proposed rule addresses issues for ESRD QIP for payment years 2016, 2017, 2018 and 2019.

### 1) Proposal to 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

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(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) Proposal to Modify the Small Facility Adjuster Calculation for All Clinical Measures Beginning with the PY 2017 ESRD QIP

In the CY 2013 ESRD PPS final rule CMS adopted a scoring adjustment for facilities with relatively small numbers of patients, called the small facility adjuster, which aims to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment.

Beginning with the PY 2017 ESRD QIP, CMS proposes to use a new methodology to determine the small facility adjustment.

### 3) Proposal to Reinstate Qualifying Patient Attestations for the ICH CAHPS Clinical Measure

CMS is not proposing any new clinical or reporting measures for the PY 2017 ESRD QIP, but is proposing to 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) Proposed Requirements for the PY 2018 ESRD QIP

CMS is not proposing to adopt any new measures for PY 2018 in the CY 2016, but is proposing one modification to the previously finalized measures. CMS determined that the calculation finalized for the Pain Assessment and Follow-Up reporting measure could unduly penalize facilities that do not encounter eligible patients in one of the two six-month periods evaluated under this measure. CMS is therefore proposing that, beginning with the PY 2018 ESRD QIP, if a facility treats no eligible patients in one of the two six-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six-month period for whom the facility reports one of six conditions.

CMS is providing estimated numerical values for the performance standards, achievement thresholds, and benchmarks based on the most recent data available. CMS says it will publish updated values for the clinical measures, using data from the first part of CY 2015, in the CY 2016 ESRD PPS final rule.

| Measure | Achievement Threshold | Benchmark | Performance Standard |
|---|---|---|---|
| Vascular Access Type | | | |
| %Fistula | 53.52% | 79.67% | 66.02% |
| %Catheter | 17.44% | 2.73% | 9.24% |
| Kt/V | | | |
| Adult Hemodialysis | 89.83% | 98.22% | 95.07% |
| Adult Peritoneal Dialysis | 74.68% | 96.50% | 88.67% |
| Pediatric Hemodialysis | 50.00% | 96.90% | 89.45% |
| Pediatric Peritoneal Dialysis | 43.22% | 88.39% | 72.60% |
| Hypercalcemia | 3.86% | 0.00% | 1.13% |
| NHSN Bloodstream Infection SIR | 1.811 | 0 | 0.861 |
| Standard Readmission Ratio | 1.261 | 0.649 | 0.998 |
| Standardized Transfusion Ratio | 1.488 | 0.451 | 0.915 |
| 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 |

### 5) Proposed Payment Reductions for the PY 2018 ESRD QIP

Based on the estimated performance standards listed above, CMS estimates that a facility must meet or exceed a minimum Total Performance Score of 39 for PY 2018 to avoid any payment reductions.

| 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) Proposed Requirements for the PY 2019 ESRD QIP

*a. Proposed Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure Topic Beginning with the PY 2019 Program Year*

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<br>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<br>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<br>Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months. |
| 1454 | Hypercalcemia, a clinical measure<br>Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL. |
| N/A | Standardized Readmission Ratio, a clinical measure<br>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<br>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<br>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<br>Number of months for which facility reports serum phosphorus or serum plasma for each Medicare patient. |
| N/A | Anemia Management Reporting, a reporting measure<br>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<br>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. |
| N/A[4] | Clinical Depression Screening and Follow-Up, a reporting measure<br>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<br>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).

*b. Beginning with the PY 2019 ESRD*

QIP, CMS is proposing to replace the 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 is proposing to adopt two new reporting measures beginning in PY 2019 — the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure.

*Analysis provided for MHA by Larry Goldberg, Goldberg Consulting*