KIDNEY CARE PARTNERS

SUMMARY OF THE MEDICARE END-STAGE RENAL DISESASE PY 2014 AND PY 2015 QUALITY INCENTIVE PROGRAM PROPOSED RULE

On July 2, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a Proposed Rule (CMS-1352-P) to make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2013 and Quality Incentive Program (QIP) for payment year (PY) 2015 and beyond. This memorandum summarizes the Agency's proposals related to modifications for PY 2014 and the quality measures and scoring methodologies that will be used in the QIP in PY 2015. We also summarize CMS' proposal to implement the changes to the reductions in Medicare bad debt payments enacted by The Middle Class Tax Extension and Job Creation Act of 2012 (P.L. 112-96).[1]

I. PY 2014 ESRD QIP (pages 67-69)

CMS proposes to modify the Mineral Metabolism reporting measure included in the PY 2014 QIP to address concerns raised by commenters. In order for a facility to receive 10 points on the PY 2014 Mineral Metabolism measure, CMS proposes to require that facilities attest that it monitored on a monthly basis the serum calcium and serum phosphorus levels for every Medicare ESRD patient under the following conditions: (1) the patient is alive for the entirety of the month; and (2) the patient was treated at the same facility at least twice during the claim month (if the patient is treated in-center). In addition, a facility must report the levels regardless of number of treatments if the patient receives dialysis at home. The Agency proposes that for a patient who is hospitalized or transient during a claim month, the facility may monitor levels for the patient month if the patient had labs drawn by another provider or facility, the labs were evaluated by an accredited laboratory, and the dialysis facility reviews the levels. The Agency requests comments on the proposal to lower the attestation to monthly monitoring of 98 percent of Medicare ESRD patients.

II. PY 2015 ESRD QIP

CMS notes that its measure development and selection take into account national quality priorities as outlined by the National Priorities Partnership, the Department of Health and Human Services (HHS) Strategic Plan, the National Strategy for Quality Improvement in Healthcare, and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs). CMS proposes to add new measures to the clinical quality of care domain and to expand the scope of the NHSN Dialysis Event reporting measure and the Mineral Metabolism reporting measure. In total, CMS proposes to include 11 measures in the QIP for PY 2015 and subsequent years. The Agency explains that once a it has finalized inclusion of a quality measure for a PY, the measure will be included in subsequent PYs unless the measure is removed or replaced through rulemaking or guidance.

[1] The page numbers reference the display copy of the Final Rule.

CMS outlines the following criteria for considering quality measures for removal or replacement:

> (1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made;
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> (2) performance or improvement on a measure does not result in better or the intended patient outcomes;
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> (3) a measure no longer aligns with current clinical guidelines or practice;
>
> (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available;
>
> (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available;
>
> (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or
>
> (7) collection or public reporting of a measure leads to negative unintended consequences.

If CMS believes that a measure raises potential safety concerns, it would take immediate action to remove the measure from the ESRD QIP and not wait for the annual rulemaking cycle.

In addition, CMS clarifies that it will use subregulatory processes to incorporate non-substantive updates to measures, such as "changes to definition or extension of the measure endorsement to apply to other settings." It also notes that it plans to "provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary."

A. PY 2015 Performance Measures (pages 69-90)

CMS proposes to continue using five of the six measures that were finalized for the PY 2014; although, the Agency proposes changes to the NHSN Dialysis Event reporting and Mineral Metabolism reporting measures. CMS proposes to remove the URR Dialysis Adequacy measure from the PY 2015 QIP. In addition, the Agency proposes two new clinical measures for dialysis adequacy (a composite measure of three different measures) and hypercalcemia and a new reporting measure for anemia management. Specifically, the Agency proposes to continue using the following measures:

> Percent of Patients with Hemoglobin Greater Than 12 g/dL;
>
> Vascular Access Type Composite Measure, (a) Hemodialysis Vascular Access – Maximizing Placement of Arterial Venous Fistula (AVF); and (b) Hemodialysis Vascular Access – Minimizing Use of Catheters as Chronic Dialysis Access; and
>
> In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Reporting.

CMS proposes to modify the NHSN Dialysis Event reporting measure as well as the Mineral Metabolism reporting measure. The Agency proposes to require dialysis facilities to retain the NHSN Dialysis Event measure and expand the reporting period so that facilities submit 12 full months of dialysis event data, rather than three or more consecutive months as required under the PY 2014 QIP. CMS would require facilities to report dialysis event data on a monthly basis to NHSN, but would provide facilities with one month to report the monthly data. The Proposed Rule notes that the Agency intends to propose a bloodstreatm infection measure (NQF #1460) once facilities have reported enough dialysis event data to enable CMS to develop performance standards, achievement and improvement thresholds, and benchmarks for the National Quality Forum (NQF)-endorsed measure.

The Agency proposes to expand the Mineral Metabolism measure to require facilities to report a serum calcium and serum phosphorus level for each patient each month. The Proposed Rule states that the facilities would be required to enter patients' levels into CROWNWeb on a monthly basis, but would be allowed one month to report. In order for a facility to receive 10 points, CMS proposes for PY 2015 to require that facilities attest that they have monitored on a monthly basis the serum calcium and serum phosphorus levels for every Medicare ESRD patient under the following conditions (the same as those proposed for PY 2014): (1) the patient is alive for the entirety of the month and (2) the patient was treated at the same facility at least twice during the claim month (if the patient is treated in-center). In addition, a facility must report the levels regardless of number of treatments if the patient receives dialysis at home. The Agency proposes that for a patient who is hospitalized or transient during a claim month, the facility may monitor levels for the patient month if the patient had labs drawn by another provider or facility, the labs were evaluated by an accredited laboratory, and the dialysis facility reviews the levels. The Agency requests comments on the idea of lowering the attestation to monthly monitoring of 98 percent of Medicare ESRD patients.

The Agency proposes new measures of dialysis adequacy applicable to different patient populations:

> Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy – HD Adequacy – Minimum Delivered Dose (NQF #0249);
>
> Peritoneal Dialysis Adequacy Clinical Performance Measure III – Delivered Dose of Peritoneal Dialysis Above Minimum (NQF #0318); and
>
> Minimum spKt/V for Pediatric Hemodialysis Patients (NQF #1423).

It clarifies that the methodology for calculating Kt/V should be consistent with the methodology specified in Change Request 7640.

CMS notes that if the Agency decides not to adopt the adult hemodialysis Kt/V measure, the Agency proposes to continue using the URR as a measure of dialysis adequacy. In addition, if CMS does not adopt the adult hemodialysis Kt/V measure, it proposes not to adopt the Kt/V measure for pediatric hemodialysis patients. CMS proposes to adopt a Kt/V peritoneal dialysis adequacy measure, even if it does not adopt the adult hemodialysis Kt/V measure.

In the Proposed Rule, the Agency explains that the Medicare Improvements for Patients and Providers Act (MIPPA) requires the Secretary of HHS, to the extent possible, to include measures of bone mineral metabolism in the ESRD QIP. CMS proposes to adopt an NQF-endorsed measure of hypercalcemia (NQF #1454). The measure assesses the number of patients with serum calcium

(not corrected for serum albumin concentration) greater than 10.2 mg/dL for a three-month rolling average. The Agency would calculate the first measure rate using the first three months of data and then would calculate a rate every month by dropping the oldest month and adding the newest month. The Agency in the Proposed Rule explains that the hypercalcemia measure will enable CMS to develop a comprehensive bone mineral metabolism measure for use in future years QIP.

The Agency acknowledges that MIPPA requires "measures on anemia management that reflect the labeling approved by the Food and Drug Administration (FDA) for such management." CMS states that it has been monitoring trends and indicators of anemia management and found that average monthly blood transfusion rates have increased from 2.7 percent in 2010 to 3.2 percent in 2011. The Agency highlights that a United States Renal Data System (USRDS) analysis found that the increase in blood transfusion rates was concurrent with the implementation of the ESRD PPS, even though the Agency admits it is not clear whether the label changes, PPS implementation, or other factors have resulted in these observations. As a result, CMS proposes to include an anemia management reporting measure and notes that as it continues to monitor the rate of transfusions, it may consider adoption of related quality measures. In order to mitigate the possibility of facilities under-reporting hemoglobin or hematocrit levels, CMS proposes to require facilities to report a hemoglobin or hematocrit value, and if applicable, an erythropoiesis-stimulating agent (ESA) dosage for all Medicare patients at least once a month on the claims form. CMS will not count claims with the default value as meeting the requirements of the measure.

CMS proposes to require that facilities obtain the hemoglobin or hematocrit readings and ESA dosage, if applicable, for every Medicare ESRD patient monthly under the following conditions: (1) the patient is alive for the entirety of the month; and (2) the patient was treated at the same facility at least twice during the claim month (if the patient is treated in-center). In addition, a facility must report the levels regardless of number of treatments if the patient receives dialysis at home. The Agency proposes that for a patient who is hospitalized or transient during a claim month, the facility may monitor levels for the patient month if the patient had labs drawn by another provider or facility, the labs were evaluated by an accredited laboratory, and the dialysis facility reviews the levels. The Agency requests comments on the idea of lowering the reporting requirement to 98 percent of Medicare ESRD patients.

B. Future Year Measures (pages 90-94)

CMS requests comments on the following measures under consideration for adoption in future years of the ESRD QIP: (1) Standardized Hospitalization Ratio for Admissions (SHR) (NQF #1463); (2) Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (SMR) (NQF #0369); (3) a 30-Day Hospital Readmission measure to address care coordination; (4) an access to care measure to address population/community health; and (5) an efficiency measure.

The Agency in the Proposed Rule notes its intention to include the SHR and SMR measures in the ESRD QIP as early as PY 2018. CMS states that it will publicly report the SHR data and the SMR rates/ratio on Dialysis Facility Compare (DFC) effective January 2013. The Agency explains that it will use data from the Minimum Data Set (MDS) to identify individuals in nursing homes to risk-adjust the NQF-endorsed measures for ESRD patients that reside in nursing homes. CMS highlights that it elected not to finalize the SHR measure for the PY 2014 program due to concerns regarding the accuracy of co-morbidity data used to calculate the measure. The Agency notes that it has identified claim form UB 92 that allows a facility to record up to 17 co-morbid conditions per claim submission.

The Agency notes that a 30-day hospital readmissions measure is being developed for the ESRD patient population. CMS seeks comments on adopting a 30-day hospital readmission measure as well as an efficiency measure and measures that would mitigate any unintended consequences of the ESRD QIP that affect access to care.

C. Performance Period (pages 94-95)

CMS proposes to establish CY 2013 as the performance period for all measures included in the PY 2015 ESRD QIP.

D. Performance Standards (pages 95-102)

a. Clinical Measure Performance Standards

The Agency proposes to establish the performance standard for each of the seven clinical measures at the national performance rate (50th percentile) of all facilities' performance on the measure during CY 2011. CMS acknowledges that the proposed performance standard would use six months of data used to calculate the PY 2014 performance standard and only six months of more recent data. It notes that the proposal may not address stakeholder concerns regarding data lag between the dates used to calculate the performance standard and the performance year. The Agency requests comments on whether it should set the performance standards using July 1, 2011 – June 30, 2012 data. CMS states that it does not have data for all of CY 2011 for Kt/V Dialysis Adequacy and Hypercalcemia; however, it has data on which it can base performance standards.

b. Estimated Performance Standards

The Agency explains that it does not have data to calculate the proposed performance standards for the clinical measures because some data from CY 2011 is not yet available. CMS estimates the performance standard for the clinical measures as follows:

Measure	Performance Standard
Hemoglobin > 12 g/dL	2%
Vascular Access Type	
Percent Fistula	59%
Percent Catheter	13%
Kt/V	
Adult Hemodialysis	93%
Adult, Peritoneal Dialysis	83%
Pediatric Hemodialysis	90%
Hypercalcemia	3%

The Agency indicates that performance standards should never be lower than the previous years. As a result, CMS will substitute the PY 2014 performance standards for a measure if the final numerical values for the PY 2015 performance standards are worse than the PY 2014 standards for a measure.

c. Reporting Measure Performance Standards

For the ICH CAHPS reporting measure, CMS proposes to establish the performance standard as requiring facilities to attest that they successfully administered the survey through a third

party. CMS proposes that facilities must complete the attestation in CROWNWeb by January 31, 2014.

CMS proposes to establish the performance period for the NHSN Dialysis Event reporting measure as successfully reporting 12 months of data from CY 2013. If a facility has not yet enrolled and trained in the NHSN dialysis event system, CMS proposes to include those requirements as part of the performance standards.

The performance standard for the Mineral Metabolism reporting measure would be established as successfully reporting serum phosphorus and calcium values for all 12 months of the reporting period for in-center hemodialysis patients the facility treats at least twice during the month and all peritoneal and home dialysis patients that the facility treats.

CMS proposes to set the performance standard for the anemia management reporting measure as successfully reporting hemoglobin or hematocrit and ESA dosage, if applicable, for all 12 months of the reporting period for in-center hemodialysis patients the facility treats at least twice during the month and all peritoneal and home dialysis patients that the facility treats.

E. Performance Scores (pages 102-109)

The Agency proposes to adopt a scoring methodology similar to the scoring for PY 2014 ESRD QIP that assesses facilities on both their achievement and improvement on clinical measures. CMS proposes to award points to facilities along an achievement range that spans from the achievement threshold to the benchmark. The Agency defines the achievement threshold for each of the clinical measures as the 15th percentile of the national facility performance for CY 2011. The benchmark would be established as the 90th percentile of the national facility performance during CY 2011.

For calculating a facility's improvement score for clinical measures, CMS would award points on a scale ranging from the improvement threshold and the benchmark. The Agency proposes to define the improvement threshold as the facility's rate on the measure during CY 2012. CMS would calculate an improvement score by comparing the facility's performance on the measures during CY 2013 and CY 2012. Because CMS did not require data collection for the Hypercalcemia measure until June 2012, CMS proposes to use the data from May 2012-December 2012 to establish the improvement threshold for this measure.

CMS notes that it does not have the data to calculate numerical values for the proposed achievement thresholds and benchmarks for the clinical measures; however, it has estimated the achievement thresholds and benchmarks as outlined in the table below.

Measure	Achievement Threshold	Benchmark
Hemoglobin > 12 g/dL	7%	0%
Vascular Access Type		
Percent Fistula	46%	74%
Percent Catheter	23%	5%
Kt/V		
Adult Hemodialysis	86%	97%
Adult, Peritoneal Dialysis	58%	94%
Pediatric Hemodialysis	78%	96%
Hypercalcemia	6%	0%

CMS proposes to use the PY 2014 achievement thresholds and benchmark for measures that the final PY 2015 numerical values are worse than the PY 2014 values.

The Agency proposes to award 1 to 10 points for the achievement score and 0 to 9 points for the improvement score for each of the clinical measures. CMS proposes to score the reporting measures as follows:

Anemia Management, Mineral Metabolism, and NHSN Dialysis Event Reporting Measures:

- 5 points for meeting the reporting requirements for at least 6-consecutive months during the performance period;
- 10 points for meeting the reporting requirements for all 12 months of performance period; and
- 0 points for meeting the reporting requirements for less than 6-consecutive months during the performance period.

ICH CAHPS Reporting Measure:

- 0 points for not conducting a patient care survey during the performance period; or
- 10 points for conducting a patient care survey during the performance period.

CMS seeks comments regarding whether facilities should receive points for partially reporting data and whether partial reporting of data need be for consecutive months.

F. Weighting the Measures (pages 109-113)

In determining how to weight the measures, CMS considered the number of proposed PY 2015 measures and the National Quality Strategy priories. CMS proposes to calculate a measure topic score for the Kt/V dialysis adequacy measures and the composite Vascular Access Type Measure. CMS proposes to score each of the component measures for each of the topics separately using the achievement and improvement methodologies. CMS then proposes to calculate a score for each measure topic using the following methodology: (1) divide the number of patients in the denominator of each component measure by the sum of the denominators for all of the component measures in the measure topic; (2) multiply the figure by the facility's score on the measure; (3) add the results achieved for each measure; and (4) round the sum. The Agency proposes that the measure topic score would be equal to one clinical measure in the calculation of the Total Performance Score (TPS).

CMS proposes to weight all of the clinical measures/measure topics for which a facility receives a score as equal to 80 percent of the TPS. The reporting measures would be equally weighted as 20 percent of the TPS.

CMS proposes to modify its policy of including any facility that receives a score on the measure in the ESRD QIP. CMS proposes to require a facility to have at least one clinical and one reporting measure in order to receive a TPS.

The Agency also proposes that all Total Performance Scores be rounded to the nearest number (half would be rounded up).

G. Minimum Cases (pages 119-125)

The Agency proposes to maintain the minimum number of cases at 11 cases for a facility to be scored. CMS undertook an analysis to test the reliability of the quality measure rates and TPS for facilities of varying sizes. As a result of its analysis, CMS proposes a favorable reliability adjustment to the measure rates for facilities with at least 11 cases and fewer than 26 cases. The adjustment would decrease as case size increase and no adjustment is made for facilities with 26 or more cases.

H. New Facilities and Reporting Measures (pages 125-127)

In order to incentivize improvements in all facilities, CMS proposes to score any facility that receives a CCN before July 1, 2013, on reporting measures. Given that the new facilities would not be able to report 12 full months of data if a CCN were obtained after January 1, 2013, CMS proposes to score the facilities proportionately for the time which they have a CCN during the performance period.

A new facility that receives a CCN between January 1, 2013, and June 30, 2013, could earn 10 points on the ICH CAHPS measure by attesting that it successfully administered the survey through a third-party during the time for which it had a CCN during the performance period.

CMS proposes that for the anemia management, NHSN Dialysis Event, and mineral metabolism reporting measures that if a facility receives a CCN on or after January 1, 2013, but before July 1, 2013, it could receive 10 points for reporting all months for which it has a CCN and five points for consecutively reporting half of the months for which it has a CCN during the performance period.

The Agency proposes to consider the first month a facility is open as the first day of the month after the facility receives a CCN. Facilities that receive a CCN on or after July 1, 2013 are excluded from the requirement of the reporting measures. The Agency requests comments regarding whether there is a more appropriate way to score new facilities on reporting measures so that facilities can be eligible for inclusion in the ESRD QIP.

I. Payment Reductions (pages 127-129)

CMS proposes modifications to its payment reduction scale for PY 2015 as illustrated in the below table, which was included in the Proposed Rule.

Score	Reduction
100 to 52	0%
51 to 42	0.5%
41 to 32	1.0%
31 to 22	1.5%
21 or below	2.0%

J. Data Validation (pages 129-130)

The Agency proposes to launch a pilot data validation program for the ESRD QIP beginning in CY 2013. The first year of data validation will not result in payment reductions to facilities. CMS intends to randomly sample the records of 750 facilities. Facilities would be required to comply with the request for records within 60 days of receiving the notice. CMS is considering a

data validation measure for future years that would score facilities on the accuracy of their records. CMS is considering increasing a facility's payment reduction by one tier if data is found to be incorrect beyond a specified threshold.

K. Change in Ownership and Scoring (pages 130-131)

Unless a facility receives a new CCN as a result of change in ownership, CMS intends to consider any facility that changes ownership as the same facility for purposes of the ESRD QIP.

L. Public Reporting (pages 131-134)

The Agency proposes to generally apply public reporting requirements finalized in the ESRD QIP Final Rule for PY 2012. However, it proposes several modifications. First, the Agency proposes to publish a list of facility performance. CMS would also require eliminate the requirement that facilities post their Performance Score Certificates within five days of their availability; instead, facilities would be required to post their certificates on or before the first day after January 1 of each PY beginning with PY 2014. CMS proposes to require facilities to post two copies of the Performance Score Certificate – one in English and one in Spanish.

III. Reduction in Medicare Bad Debt Payments (pages 134-142)

The regulation proposes to codify the reduction in Medicare bad debt payments that was enacted in The Middle Class Tax Extension and Job Creation Act of 2012 (P.L. 112-96). CMS explains that the allowable Medicare bad debt for ESRD facilities would be reduced from 100 percent in Fiscal Year (FY) 2012 to 88 percent in FY 2013, 76 percent in FY 2014, and 65 percent in FY 2015 and subsequent years. In addition, the Agency states that the ESRD facility bad debt payments will continue to be subject to the cap up to the facility's reasonable costs. CMS explained that it considered applying the FY reduction percentage after the cap is applied, but believes its proposal is more consistent with the current calculation of the allowable bad debt that is capped at the facility's cost.