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MEMORANDUM

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To: Kidney Care Partners
From: Kathy Lester and Julie Black
Date: July 2, 2013
Subject: Summary of the Payment Year 2016 End Stage Renal Disease Quality Incentive Program Proposed Rule

On Monday, July 1, 2013, the Centers for Medicare and Medicaid Services (CMS) issued the End Stage Renal Disease (ESRD) Calendar Year (CY) 2014 Prospective Payment System (PPS) and Payment Year (PY) 2016 Quality Incentive Program (QIP) Proposed Rule. This memorandum summarizes the quality measures and scoring methodologies that CMS proposes to adopt for PY 2016 ESRD QIP.

I. Proposed Measures for the PY 2016 ESRD QIP and Future Years (pg. 69, 73)

The Agency explains that its measure development and selection processes consider national quality priorities outlined in 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 Prevention Healthcare Associated Infections. CMS indicates that it sought to adopt measures that were endorsed by a national consensus organization, recommended by stakeholder organizations, and developed with feedback from stakeholders.

CMS proposes to adopt 14 measures for PY 2016 and future years – 9 clinical measures and 5 reporting measures. Although the Agency does not propose measures related to care coordination, population and community health, or cost of care, CMS seeks comments on potential measures for inclusion in the QIP in future years. As required by the Affordable Care Act (ACA), the Secretary of HHS issued a list of quality measures under consideration for use in quality reporting or payment programs to the National Quality Forum's Measures Application Partnership (MAP). CMS considered MAP feedback when proposing quality measures for the PY 2016 ESRD QIP.

A. Continuing Measures for PY 2016 (pg. 74)

The Agency proposes to continue using six performance measures that were adopted previously for the PY 2016 ESRD QIP, including:

- Anemia Management: Hgb > 12
- Hemodialysis Adequacy: Minimum delivered hemodialysis dose (NQF #0249)

- Peritoneal Dialysis Adequacy: Delivered dose above minimum (NQF #0318)
- Pediatric Hemodialysis Adequacy: Minimum spKt/V (NQF #1423)
- Vascular Access Type: Arterial Venous (AV) Fistula (NQF #0257)
- Vascular Access Type: Catheter ≥ 90 days (NQF #0256)

B. Modified Measures for PY 2016 (pg. 75)

CMS proposes to modify three quality measures for PY 2016.

ICH CAHPS: The Agency proposes to expand the ICH CAHPS reporting measure with the goal of implementing NQF measure #0258 (CAHPS In-Center Hemodialysis Survey) as a clinical measure in PY 2018. In PY 2016, CMS proposes requiring each dialysis facility to arrange by July 2014 for a CMS-approved vendor to conduct the survey according to CMS specifications.[1] Facilities will be required to administer through the vendor the survey once during the performance period and by January 28, 2015, report the survey data to CMS. The Agency proposes that for PY 2017 and subsequent payment years facilities must have the survey administered twice during each performance period and report the data to CMS. The Agency notes that the frequency of the survey is less than the monthly requirement for other providers, but will still enable CMS to gather sufficient data without burdening facilities.

Mineral Metabolism: The Agency proposes three changes to the mineral metabolism reporting measure for PY 2016 and future years. First, CMS proposes to include home peritoneal patients in the measure specifications. The Agency notes that these patients were inadvertently excluded from previous rulemaking. CMS explains that a qualifying case for the measure would be defined as: (1) an in-center Medicare patient who had been treated at least seven times by the facility; and (2) a home dialysis Medicare patient for whom the facility submitted a claim at least once per month.

Second, the Agency proposes to change the specifications for the reporting measure so that facilities are no longer required to report on serum calcium levels. CMS explains that because it proposes to adopt the hypercalcemia measure, reporting information on serum calcium levels as part of the mineral metabolism measure would be redundant. The Agency requests comments on whether it should retain reporting of serum calcium levels as part of the mineral metabolism measure if CMS does not finalize the proposed hypercalcemia measure.

Finally, CMS proposes that in order to receive full points on the measure, facilities that treat 11 or more qualifying cases during the entire performance period would have to report at the lesser of the 50th percentile of facilities in CY 2013 or 97 percent per month, on a monthly basis, for each month of the performance period. Facilities that treat fewer than 11 qualifying cases during the performance period would be required to report on a monthly basis the levels for all but one qualifying case. Facilities that have only one case during the performance period would be required to attest to the fact in CROWNWeb by January 31 of the year following the performance period and would not be scored on the measure.

[1] CMS ICH CAHPS Survey Specifications available at https://ichcahps.org.

Anemia Reporting: The Agency proposes two modifications to the anemia reporting measure. First, it inadvertently excluded home peritoneal patients from the anemia management reporting measure and proposes to include these patients in the measure for PY 2016. CMS proposes to define a qualifying case as: (1) an in-center Medicare patient who had been treated at least seven times by the facility; and (2) a home dialysis Medicare patient for whom the facility submitted a claim at least once per month.

Second, CMS proposes that in order to receive full points on the measure, facilities that treat 11 or more qualifying cases during the entire performance period would have to report at the lesser of the 50th percentile of facilities in CY 2013 or 99 percent per month, on a monthly basis, for each month of the performance period. Facilities that treat less than 11 cases would be required to report on a monthly basis the levels for all cases except for one. Facilities that have only one case during the performance period would be required to attest to the fact in CROWNWeb by January 31 of the year following the performance period and would not be scored on the measure.

C. New Measures for PY 2016 (pg. 81)

CMS proposes to include in the FY 2016 ESRD QIP the following new measures:

- Anemia of chronic kidney disease: patient informed consent for anemia treatment clinical measure;
- Hypercalcemia clinical measure;
- Use of iron therapy for pediatric patients reporting measure;
- NHSN bloodstream infection measure in hemodialysis outpatients clinical measure; and
- Comorbidity reporting measure.

Patient Informed Consent for Anemia Treatment: CMS proposes to include the patient informed consent for anemia treatment in the QIP as a measure of the proportion of dialysis patients that a facility attests that it evaluated the risk, benefits, and alternative treatment options for anemia and that the patient participated in making a decision about an anemia treatment strategy. Facilities would be required to attest in CROWNWeb for each patient on an annual basis that informed consent was obtained from the patient (or the patient's legally authorized representative) during the performance period. CMS defines qualifying cases as individuals who receive dialysis in the facility for 30 days or more.

If this measure were adopted, it would be combined with the Hgb>12 measure to form a new Anemia Management Clinical Measure Topic. If it is not adopted, Hgb>12 would remain an independent measure.

Hypercalcemia: The Agency reports that it has obtained sufficient baseline data that can be used to calculate performance standards, achievement thresholds, and benchmarks for a hypercalcemia measure. CMS proposes to adopt NQF measure #1454: Proportion of Patients with Hypercalcemia. The metric measures the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a three-month rolling average. Facilities would be required to report on a monthly basis the uncorrected calcium level for each in-center and home dialysis patients ages eighteen or older. The

Agency proposes to begin calculating the three-month rolling average of the proportion of patient-months for which the three-month rolling average exceeds 10.2 mg/dL in March 2014 and each month thereafter. For PY 2017, CMS would measure hypercalcemia beginning in January of the performance period for that payment year.

Iron Therapy for Pediatric Patients: Although CMS identifies a number of issues with a clinical measure on the use of iron therapy for pediatric patients, the Agency proposes a reporting measure for PY 2016. The Agency's goal is to collect baseline data to develop a clinical measure for use in the QIP in future years.

CMS proposes to require facilities to report via CROWNWeb on a quarterly basis the following information for each qualifying case: (1) patient admit/discharge date; (2) hemoglobin levels; (3) serum ferritin levels; (4) TSAT percentages; (5) the dates that the lab measurements were taken for hemoglobin, serum ferritin, and TSAT; (6) intravenous IV iron received or oral iron prescribed; and (7) the date that the IV iron was received or oral iron was prescribed.

The Agency defines qualifying cases as in-center and home dialysis patients under the age of eighteen. CMS proposes to award full points on this measure to facilities that treat at least 11 qualifying cases during the performance period that report at the lesser of the 50th percentile of facilities in CY 2013 or 97 percent per quarter. Facilities that treat less than 11 cases would be required to report on a quarterly basis the levels for all cases except for one. Facilities that have only one case during the performance period would be required to attest to the fact in CROWNWeb by January 31 of the year following the performance period and would not be scored on the measure.

NHSN Bloodstream Infection: The Agency proposes to replace the NHSN dialysis event reporting measure that it finalized in the CY 2013 ESRD PPS rule with a measure that is based on NQF measure #1460 (Bloodstream Infection in Hemodialysis Outpatients). The proposed measure evaluates the number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis months.

CMS proposes to require facilities to submit 12 months of accurately reported dialysis event data (data reported by facilities that follow the NHSN enrollment and training guidelines specified by the Centers for Disease Control and Prevention[2]). Facilities would be required to report each quarter's data three months after the end of that quarter. CMS will not award partial credit to facilities that submit less than 12 months of data. The Agency proposes to exclude facilities with a CCN open date after January 1, 2014.

Comorbidity: CMS acknowledges concerns raised by stakeholders that the NQF-endorsed Standardized Mortality Ration (SMR) and Standardized Hospitalization Ration (SHR) measures are not adequately risk adjusted and that facilities have difficulty capturing information about comorbidities that develop after the initiation of dialysis. However, CMS continues to consider adopting these metrics in future rulemaking. In order to develop a risk-adjustment methodology for SHR and SMR measures, CMS proposes a measure to collect data about patient comorbidities. Because there is no

[2] Centers for Disease Control and Prevention NHSN enrollment and training guidelines are available online at http://www.cdc.gov/nhsn/dialysis/enroll.html and http://www.cdc.gov/nhsn/training/dialysis/index.html.

measure specified that has been endorsed by the NQF, CMS proposes adopting this measure using its statutory authority that allows it to specify a measure that is not endorsed.

The Agency proposes to require facilities to update information regarding up to 24 comorbidities annually in CROWNWeb for each qualifying case (hemodialysis or peritoneal dialysis patient being treated at the facility as of December 31 of the performance period). The 24 comorbidities are:

• Congestive heart failure	• Diabetes, on oral medications	• Drug dependence
• Atherosclerotic heart disease (ASHD)	• Diabetes, without medications	• Inability to ambulate
• Other cardiac disease	• Diabetic retinopathy	• Inability to transfer
• Cerebrovascular disease (CVA, TIA)	• Chronic obstructive pulmonary disease	• Needs assistance with daily activities
• Peripheral vascular disease	• Tobacco use (current smoker)	• Institutionalization – Assisted Living
• History of hypertension	• Malignant neoplasm, Cancer	• Institutionalization – Nursing Home
• Amputation	• Toxic nephropathy	• Institutionalization – Other Institution
• Diabetes, currently on insulin	• Alcohol dependence	• Non-renal congenital abnormality
• None of the above		

D. Other Measures under Development (pg. 94)

CMS is considering developing measures in other areas including blood transfusions, kidney transplantation, quality of life, health information technology, residual renal function, complications associated with ESRD, and frequently comorbid conditions such as diabetes and heart disease. CMS seeks comments on these potential areas of future measure.

II. Scoring for the PY 2016 ESRD QIP and Future Payment Years (pg. 95)

With few exceptions, CMS proposes to adopt the scoring methodology outlined in the CY 2013 ESRD PPS Final Rule.

III. Performance Period for the PY 2016 ESRD QIP (pg. 95)

CMS proposes to establish CY 2014 as the performance period for all measures.

IV. Performance Standards for the PY 2016 ESRD QIP (pg. 96)

A. Clinical Measure Performance Standards (pg. 96)

CMS proposes to adopt the performance standards – achievement and improvement – based on the national performance rate (50th percentile) of performance in CY 2012, with a few exceptions.

This performance standard will not apply to the following measures: (1) NHSN bloodstream infection in hemodialysis outpatients; (2) patient informed consent for anemia treatment clinical measure; and (3) the hypercalcemia measure.

NHSN Bloodstream Infection: CMS proposes to use the 50th percentile of the national performance rate on the measure during CY 2014 for the NHSN bloodstream infection in hemodialysis outpatients clinical measure for PY 2016. Facilities would only be scored on achievement because CMS does not have the baseline data necessary to calculate an improvement score.

Patient Informed Consent for Anemia Treatment: The Agency proposes to define the achievement threshold as obtaining patient informed consent for anemia treatment for 92 percent of qualifying cases during the performance period. A small facility adjuster would be applied to facilities with between 11 and 25 qualifying patients. CMS would calculate the performance standard using the average of the benchmark and achievement threshold, which is 94 percent. Facilities would only be scored on achievement.

Hypercalcemia: The Agency proposes to establish the performance standard as the 50th percentile of national performance from May 2012 through November 2012.

B. Estimated Performance Standards for Proposed Clinical Measures (pg. 99)

CMS estimated the performance standards based upon the most recently available data. The Agency will publish the updated values for all measures except the NHSN bloodstream infection in hemodialysis outpatients clinical measure in the CY 2014 ESRD PPS Final Rule. The estimated performance standards for the PY 2016 are illustrated in Table 8 in the Proposed Rule, which is replicated below. CMS proposes that if the performance standards for PY 2016 are worse than PY 2015 standards, CMS would substitute the PY 2015 performance standard for the measure.

Measure	Performance Standard
Vascular Access Type	
Percent Fistula	62.4%
Percent Catheter	10.5%
Kt/V	
Adult Hemodialysis	93.6%
Adult, Peritoneal Dialysis	85.4%
Pediatric Hemodialysis	92.5%
Anemia Management	
Hemoglobin > 12 g/dL	0%
Patient Informed Consent for Anemia Treatment	94%
Hypercalcemia	2.3%
NHSN Bloodstream Infection in Hemodialysis Outpatients	50th percentile of eligible facilities' performance during the performance period

C. Performance Standards for Reporting Measures (pg. 101)

ICH CAHPS: The Agency proposes to establish the performance standard for the ICH CAHPS reporting measure as the facility's successful submission by January 28, 2015, of the survey data collected during the performance period according to the measure specifications. CMS will maintain this performance standard for PY 2017 with the exception that data from two surveys must be submitted by dates specified.

Mineral Metabolism: CMS proposes to set the performance standard for the mineral metabolism reporting measure as successfully reporting the measure for the number of qualifying cases specified for each month of the performance period.

Anemia Management Reporting: The performance standard for the anemia management reporting measure would be set as successfully reporting the measure for the number of qualifying cases specified for each month of the performance period.

Pediatric Iron Therapy Report: CMS proposes to establish the performance standard for the anemia management: pediatric iron therapy reporting measure as successfully reporting the required information for each qualified case on a quarterly basis.

Comorbidity: The Agency proposes to set the performance standard for the comorbidity reporting measure as successfully updating in CROWNWeb the patient's comorbidities at least once during the performance period.

V. Scoring for the PY 2016 ESRD QIP Proposed Measures (pg. 102)

CMS proposes to define the achievement threshold for the clinical measures as the 15th percentile of the national performance rate during CY 2012 and the benchmark as the 90th percentile of the national performance rate during CY 2012, except for the NHSN bloodstream infection in hemodialysis outpatients measure, the patient informed consent for anemia treatment measure, and the hypercalcemia measure.

NHSN Bloodstream Infection: CMS proposes to establish the achievement threshold and benchmark for the proposed bloodstream infection measure as the 15th and 90th percentiles, respectively, of national performance during CY 2014.

Patient Informed Consent for Anemia Treatment: CMS proposes to define the achievement threshold as 92 percent of qualifying cases and the benchmark as 96 percent of qualifying cases.

Hypercalcemia: The Agency proposes to establish the achievement threshold at the 15th percentile and the benchmark at the 90th percentile of national performance from May 2012 through November 2012.

Using the most recently available data, CMS estimated the proposed achievement thresholds and benchmarks for the proposed clinical measures. The estimates are included in Table 9 in the Proposed Rule and replicated below. CMS proposes that if the performance standards for PY 2016 are

worse than PY 2015 standards, CMS would substitute the PY 2015 performance standard for the measure.

Measure	Achievement Threshold	Benchmark
Vascular Access Type		
Percent Fistula	49.8%	77.1%
Percent Catheter	19.6%	3%
Kt/V		
Adult Hemodialysis	85.9%	97.5%
Adult, Peritoneal Dialysis	66.7%	94.8%
Pediatric Hemodialysis	83.3%	98.8%
Anemia Management		
Hemoglobin > 12 g/dL	1.2%	0%
Patient Informed Consent for Anemia Treatment	92%	96%
Hypercalcemia	6.1%	0.2%
NHSN Bloodstream Infection in Hemodialysis Outpatients	15th percentile of eligible facilities' performance during the performance period	90th percentile of eligible facilities' performance during the performance period

CMS proposes to retain the methodology finalized in the CY 2013 ESRD PPS Final Rule to award between 0 and 10 points for each of the clinical measures and the score would be the higher of either the achievement or improvement score on the measure. A facility would receive 10 points for achievement if its measure rate during the performance period is equal to or greater than the benchmark, 0 points for achievement if its measure rate is less than the achievement threshold, or between 1 to 9 points if a facility's measure rate is equal to or greater than the achievement threshold. CMS would award 0 points for improvement if a facility's measure rate is less than the improvement threshold or between 1 to 9 points based upon a formula if a facility's measure rate is equal to or greater than the improvement threshold, but below the benchmark.

CMS proposes to use the formula that was finalized in the CY 2013 ESRD PPS Final Rule for awarding points for the mineral metabolism and anemia management measures: ((number of months facility successfully reports/number of months in the performance period facility has CNN) x 12) – 2.

The Agency proposes the following formula for the pediatric iron therapy measure: (number of quarters facility successfully reports/number of quarters in the performance period facility has CCN) x 10.

In the Proposed Rule, CMS proposes to award 10 points to a facility if it satisfies the performance standard for the ICH CAHPS and comorbidity reporting measures and 0 points if a facility does not.

VI. Weighting the PY 2016 ESRD QIP Measures and Calculating the PY 2016 ESRD QIP Total Performance Score (pg. 109)

CMS proposes to maintain the methodology to calculate a score for each measure topic by: (1) dividing 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) multiplying the figure by the facility's score on the measure; (3) adding the results achieved for each measure; and (4) rounding the sum.

The Agency also proposes to continue weighting clinical measures as 75 percent and reporting measures as 25 percent of the total performance score (TPS). Facilities would be required to have at least one clinical and one reporting measure score to receive a TPS. TPS would be rounded to the nearest number (half a number would be rounded up).

VII. Minimum Data for Scoring Measures for the PY 2016 ESRD QIP and Future Payment Years (pg. 117)

CMS proposes to maintain 11 as the minimum number of cases for the clinical measures. The Agency proposes to establish one as the minimum number of cases for the reporting measures, except for the ICH CAHPS measure. CMS proposes that facilities with less than 30 qualifying cases during the performance period not be scored on the measure. A facility will be considered as having met the 30-patient threshold unless it attests in CROWNWeb by January 31, 2015, for PY 2016 that it cared for 29 or fewer adult in-center hemodialysis patients during the performance period.

The Agency proposes to continue applying an adjustment to the measure rates for facilities with at least 11 cases and fewer than 26 cases. The adjustment would decrease as case size increases and no adjustment would be made for facilities with 26 or more cases.

CMS proposes that only facilities with a CCN open date before July 1, 2014, be scored on the proposed reporting measures with the exception of the ICH CAHPS survey. Only facilities with a CCN open date before January 1 of the performance period will be scored on the measure. The Agency proposes that facilities with CCN open dates after January 1, 2014, will not be scored on the NHSN.

VIII. Payment Reductions for the PY 2016 ESRD QIP and Future Payment Years (pg. 119)

Although CMS cannot yet calculate the performance standards for each clinical measure, based on the estimated performance standards the Agency estimates that a facility must meet or exceed a TPS of 46 in PY 2016 to avoid a payment reduction. The proposed payment reduction scale for PY 2016 is below.

Total Performance Score	Reduction
100-46	0%
45-36	0.5%
35-26	1.0%
25-26	1.5%
15-0	2.0%

IX. Data Validation (pg. 121)

As described in previous rules, CMS established a data validation pilot program. The Agency reports that it is in the process of securing the services of a data-validation contractor whose first priority will be to develop a methodology for validating data submitted through CROWNWeb. The Proposed Rule notes that the Agency will publicize the methodology through a CROWN Memo and provide an opportunity for public comments. CMS proposes to extend the data validation pilot program to include data submitted to CROWNWeb during CY 2014. The Agency will reimburse facilities that are sampled for the costs associated with copying and mailing the requested records. CMS proposes to reduce the sample size for CY 2014 from 750 to 300. CMS intends to continue its policy that no facility will receive a payment reduction resulting from the validation process for CY 2014 during PY 2016. The Agency reports that it is also considering a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module.

X. Scoring Facilities Whose Ownership has Changed (pg. 123)

CMS proposes to maintain its policy to consider any facility that changes ownership as the same facility unless it receives a new CCN as a result of change in ownership for purposes of the ESRD QIP.

XI. Public Reporting Requirements (pg. 123)

The Agency proposes to maintain the requirement that facilities post two copies of the Performance Score Certificate – one in English and one in Spanish. CMS proposes to modify the timing of when facilities must post their certificates. Facilities would be required to post their Performance Score Certificates within fifteen business days of the certificates being available for download from dialysisreports.org.