Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers

[CMS-1352-P]

Summary of Proposed Rule
July 11, 2012

I. Introduction

On July 2, 2012, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule updating and making revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013, and proposing requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2015 and beyond.

The proposed rule also addresses reductions in bad debt payments for all Medicare providers, suppliers, and other entities eligible to receive bad debt payments. These changes were mandated by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Public Law 112-96) and are generally considered to be self-implementing. The summary of the bad debt portion of the proposed rule begins on page 15.

The proposed rule is published in the July 11, 2012 issue of the *Federal Register*. The 60-day comment period will end on August 31, 2012 (that is, 60 days after the date of public display).

Addenda to the proposed rule are only available at http://www.cms.gov/ESRDPayment/PAY/list.asp. Readers experiencing any problems in accessing these addenda are asked to contact Michelle Cruse at 410-786-7540.

II. CY 2013 ESRD PPS

CMS began implementing a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011. This proposed rule would implement the third year of the required 4-year transition period for those ESRD facilities going through the transition rather than electing to receive payment based on 100 percent of the payment amount under the ESRD PPS. For these transitioning facilities, a blended rate equal to the sum of 75 percent of the full ESRD PPS amount and 25 percent of the basic case-mix adjusted composite payment amount would apply during CY 2013. [A CMS fact sheet accompanying the release of the proposed rule notes that more than 87 percent of facilities have elected to be paid entirely under the ESRD PPS.]

Update

For CY 2013, CMS proposes an ESRD PPS base rate of $240.88, which reflects the forecasted increase in the ESRD bundled (ESRDB) market basket (3.2 percent) reduced by the forecasted productivity adjustment (0.7 percent) and a wage index budget-neutrality adjustment factor of 1.000826 to the CY 2012 ESRD PPS base rate of $234.81. CMS further proposes a composite rate portion of the ESRD PPS blended payment of $145.49, which reflects the CY 2012 composite rate of $141.94, increased by the ESRDB market basket reduced by the productivity adjustment. The productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP), published by the Bureau of Labor Statistics and accessible at http://www.bls.gov/mfp.

CMS proposes to use the same methodology described in the CY 2011 ESRD PPS final rule to compute the CY 2013 ESRDB market basket increase factor and labor-related share based on the best available data. CMS notes that IHS Global Insight (IGI), a nationally recognized economic and financial forecasting firm, is responsible for forecasting the ESRDB market basket update. CMS adds that it will continue to use a labor-related share of 41.737 percent for the ESRD PPS payment and the ESRD PPS portion of the blended payment, and also continue to use a labor-related share of 53.711 percent for the ESRD composite rate portion of the blended payment for all years of the transition. CMS warns that the availability of more recent data could alter the market basket update and productivity estimates contained in the proposed rule.

Drug Add-On

With respect to the drug add-on to the composite rate for CY 2013 (to account for the difference between the prior payments for separately billed drugs and the revised pricing specified under current law), CMS is proposing no changes to the current methodology for calculating the add-on. Although CMS projects a 7.3 percent decrease in per patient growth of drug expenditures for CY 2013 (reflecting an estimated 3.0 percent decrease in aggregate drug expenditures and a 4.6 percent increase in enrollment), and projects that the combined growth in per patient utilization and pricing for CY 2013 would result in a decrease to the drug add-on equal to 1.0 percentage point, CMS proposes to apply a zero update to the drug add-on adjustment and maintain the $20.33 per treatment amount for CY 2013 (which when applied to the new composite rate for CY 2013 amounts to a 14.0 percent add-on rather than the current 14.3 percent). CMS says this decision reflects its understanding of the governing statutory language, which authorizes the Secretary to annually “increase” the drug add-on. The $20.33 per treatment amount was initially adopted for CY 2008 and has remained unchanged since then. CMS notes that it intends to use additional updated CY 2011 claims (all those received, processed, paid and passed to the National

Claims History File as of June 30, 2012) for purposes of re-estimating the drug expenditure growth as it develops the final rule.

Transition Budget-Neutrality Adjustment

CMS again proposes a zero percent transition budget-neutrality adjustment (as it did for CY 2012) and proposes no change to the methodology used to calculate either part of this adjustment factor.

Wage Index Values and Related Budget-Neutrality Adjustments

For CY 2013, CMS is not proposing any changes to the methodology used to calculate ESRD facility wage index values and will update these values using the FY 2013 hospital inpatient prospective payment system (IPPS) pre-floor, pre-reclassified hospital wage data. CMS does note that the wage index floor will again be reduced (from 0.55 to 0.50). This wage index floor, which is applied to both the composite rate portion of the blend and to the ESRD PPS, would apply only to areas located in Puerto Rico. CMS adds that it will no longer apply a wage index floor beginning January 1, 2014 because the presumptive wage index floor for CY 2014 (0.45) would be lower than the wage index values for areas with low values.

For urban areas with no hospital data, CMS computes the average wage index value of all urban areas within the State and uses that value as the wage index. For rural areas with no hospital data, CMS computes the wage index using the average wage index values from all contiguous core-based statistical areas (CBSAs) to represent a reasonable proxy for that rural area. CMS notes that subsequent to the issuance of the CY 2012 ESRD PPS final rule, it determined that for CY 2012 there was a rural hospital with wage data to base an area wage index on for rural Massachusetts and emphasizes that the wage index value for rural Massachusetts for CY 2012 was correctly based on that rural hospital's data. The wage index value for rural Massachusetts will continue to be based on wage data for this rural hospital. CMS also notes that Yuba City, California now has hospital data to calculate a wage index, leaving Hinesville-Fort Stewart, Georgia as the only urban area without hospital wage index data.

In CY 2013, CMS is also not proposing any changes to the application of the wage index budget-neutrality adjustment factor. For the CY 2013 wage index budget-neutrality adjustment factors, CMS is using the FY 2013 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2011 outpatient claims (paid and processed as of December 31, 2011), and geographic location information for each facility, which may be found through Dialysis Facility Compare (http://www.cms.gov/DialysisFacilityCompare). The FY 2013 hospital wage index data for each urban and rural locale by CBSA may be accessed at http://www.cms.gov/AcuteInpatientPPS/WIFN/list.asp (see the file labeled "FY 2013 Proposed Rule Occupational Mix Adjusted and

Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA" under the FY 2013 Proposed Rule data files). The methodology yields an adjustment of 1.001538 for application to the wage index values for the composite rate portion of the blended payment, and an adjustment of 1.000826 for application to the ESRD PPS base rate. CMS also applies the wage index budget-neutrality adjustment factor to the wage index floor for the composite rate portion of the blended payment (producing a floor of 0.501); under the ESRD PPS, the wage index floor for CY 2013 is 0.50 because the wage index budget-neutrality adjustment factor is applied to the base rate.

Addendum A and Addendum B to the proposed rule provide wage index values for facilities located in urban and rural areas, respectively. In each table, one column represents the wage index values for the composite rate portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied, and the other column lists the wage index values for the ESRD PPS, which do not reflect the application of the wage index budget-neutrality adjustment factor (which, as noted earlier, is applied to the ESRD PPS base rate).

Drug Policies

CMS proposes to permit separate payment for daptomycin when used to treat non-ESRD related conditions for CY 2013 and subsequent years; facilities would place the AY modifier on the claim for the drug in such cases.

For CY 2013, CMS proposes that thrombolytic drugs (alteplase and others) would not be considered eligible for separate payment under the composite rate portion of the blended payment for those ESRD facilities that are receiving a blended payment under the transition. In the CY 2012 ESRD PPS final rule, CMS excluded thrombolytic drugs from the ESRD PPS outlier policy (because they were not separately billed prior to January 1, 2011) and recomputed the outlier Medicare Allowable Payment (MAP) amounts to reflect this change, but did not exclude separate payment of thrombolytic drugs under the composite rate portion of the blended payment. CMS believes doing so now is consistent with its prior changes.

CMS proposes for CY 2013 and subsequent years to continue to use the average sales price (ASP) methodology, including any modifications finalized in the Physician Fee Schedule final rules, to compute the outlier MAP amounts, the drug add-on, and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS and for the composite rate portion of the blended payment during the transition.

Outlier Policy

For CY 2013, CMS is not proposing any changes to the methodology used to compute the MAP or fixed dollar loss amounts under its ESRD PPS outlier

payment policy but proposes to update these amounts to reflect the utilization of outlier services reported on the 2011 claims using the December 2011 claims file. The estimated fixed dollar loss amounts that determine the 2013 outlier threshold amounts ($50.15 for patients less than 18 years of age and $113.35 for older patients) are lower than those used for the 2012 outlier policy ($71.64 and $141.21, respectively) mainly because of lower-than-expected utilization of epoetin and other outlier services in the first year of the ESRD PPS. Similarly, the estimated average outlier services MAP amount per treatment for CY 2013 ($41.49 and $62.95 for pediatric and non-pediatric populations, respectively) are also lower than the comparable amounts for CY 2012 ($46.26 and $81.73, respectively). CMS reminds readers that the pediatric outlier MAP and fixed dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services.

CMS notes that the 1 percent target for ESRD outlier payments was not achieved in CY 2011; based on the 2011 claims, these payments represented only about 0.52 percent of total payments. CMS believes that the proposed outlier MAP and fixed dollar loss amounts for CY 2013 will satisfy the 1 percent outlier policy.

Clarifications

The proposed rule includes a number of clarifications. First, CMS reiterates that composite rate items and services are not to be reported on the ESRD facility claim, and notes that the agency is continuing to monitor the reporting of such items and services and plans to take actions to recoup inappropriate and duplicative payments. Second, CMS notes that ESRD facilities are responsible for furnishing renal dialysis items and services that are required to meet patient needs and may not require, induce or coerce beneficiaries to purchase any renal dialysis item or service. Third, CMS reminds facilities and laboratories that the AY modifier is intended to allow separate payment for non-ESRD-related drugs and laboratory tests and that it should not be appended for items that are ESRD-related. CMS warns that continued inappropriate use of the AY modifier could cause CMS to discontinue the modifier and cease to make separate payment for non-ESRD-related drugs and laboratory tests.

III. ESRD QIP for PY 2015

CMS established the ESRD QIP for PY 2012, the initial year of the program in which payment reductions are being made. For PY 2015, CMS is proposing to add five new measures in the clinical quality of care domain and to expand the scope of the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure (safety domain) and the Mineral Metabolism reporting measure (clinical quality of care domain). CMS also proposes to remove the PY 2014 urea reduction ratio (URR) Dialysis Adequacy measure. The end result is a total of 11 proposed measures in the PY 2015 ESRD QIP. ***CMS notes that it is not proposing to adopt measures that address care coordination (for***

example, hospital readmissions), population/community health, or efficiency and cost of care, but solicits comments on potential measures that would fall into each of these areas.

PY 2014 Measure Change

CMS proposes to alter the PY 2014 Mineral Metabolism Measure to accommodate situations where the monthly blood draw does not happen within the dialysis facility. Under this change, CMS would require that, in order for a facility to receive the maximum 10 points on the Mineral Metabolism measure, it must attest that it monitored on a monthly basis the serum calcium and serum phosphorus levels for every Medicare ESRD patient provided that: (i) the patient is alive for the entirety of the applicable month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a facility must report this information regardless of the number of treatments, provided that a claim is submitted for that patient. CMS also proposes that if a patient is hospitalized or transient during a claim month, the facility may monitor the serum calcium and serum phosphorus readings for that patient for the month if a patient has labs drawn by another provider/facility, those labs are evaluated by an accredited laboratory, and the dialysis facility reviews the readings. CMS believes the above policies will provide more flexibility for facilities and will prevent them from drawing blood, even when not necessary, each time a patient visits for fear that he or she will fail to come to the facility again during that month. ***However, CMS also requests comments on the alternative of lowering the attestation to monthly monitoring of 98 percent of Medicare ESRD patients.***

Measure Adoption and Modification Processes

CMS proposes that once a quality measure is finalized for the ESRD QIP through rulemaking, the measure would continue to remain part of the program for all future years, unless the agency removes or replaces it through rulemaking or notification. If there is reason to believe that a measure raises potential safety concerns, CMS proposes to take immediate action to remove it from the ESRD QIP and not wait for the annual rulemaking cycle. CMS also proposes that if an adopted measure is updated in a manner the agency considers to not substantially change the nature of the measure, the agency would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. CMS would continue to use the rulemaking process to adopt substantive changes to a measure.

Proposed PY 2015 Measures

For PY 2015, CMS proposes to retain the following four PY 2014 measures:

- The Hemoglobin Greater than 12 g/dL measure;

- The Vascular Access Type measure topic comprised of two measures: (a) the Hemodialysis Vascular Access—Maximizing Place of Arterial Venous Fistula (AVF) measure, NQF #0257, and (b) the Hemodialysis Vascular Acess—Minimizing use of Catheters as Chronic Dialysis Access measure, NQF #0256; and
- The In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting measure.

CMS also proposes to expand two PY 2014 reporting measures. First, it proposes to expand the reporting for the NHSN Dialysis Event reporting measure to a full 12 months (instead of the current 3 or more consecutive months). Thus, during CY 2013, the proposed performance period for the PY 2015 ESRD QIP, facilities would need to report dialysis event data monthly to the NHSN (a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention). Facilities would have a "grace period" of one month to report the data; for example, data for January 2013 would need to be reported on or before February 28, 2013. Further information regarding the NHSN's dialysis event reporting protocols can be accessed at http://www.cdc.gov/nhsn/psc_da_de.html. CMS notes that the proposed NHSN measure only applies to facilities treating in-center patients and that the measure only assesses whether facilities report data, not their performance. Nonetheless, CMS says it intends to propose adoption of an NQF-endorsed bloodstream infection measure, NQF #1460, once facilities have reported enough data to enable the agency to compute performance standards, achievement thresholds, improvement thresholds, and benchmarks for the measure. The technical specifications for the NHSN measure are located at http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-NPRM.pdf.

CMS also proposes to expand the current Mineral Metabolism reporting measure by requiring facilities to report a serum calcium and serum phosphorus level for each qualifying patient each month according to the requirements in CROWNWeb. A patient would be considered qualified for the measure (i) if the patient is alive at the end of the month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a claim is submitted for that patient. Further, CMS is not proposing that the facility itself must draw the patient's blood for the serum calcium/phosphorus levels (for example, in the case of a patient who is hospitalized or transient during a given claim month). CMS also notes that the expanded measure would assess only whether facilities report serum calcium and phosphorus levels, not their actual performance with respect to these measures. ***Once again, CMS acknowledges that it considered lowering the threshold to reporting 98 percent of patients and requests comments on this alternative.*** The technical specifications for the Mineral Metabolism Reporting measure can be found at

http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2015-NPRM.pdf.

Of the 5 new measures proposed for PY 2015, three focus on dialysis adequacy based on Kt/V (K = clearance, t = dialysis time, and V = volume of distribution). The measures focus on different populations: adult hemodialysis (HD) patients (in-center and home hemodialysis (HHD)) receiving three treatments weekly; adult peritoneal dialysis (PD) patients; and pediatric HD patients receiving three or four treatments weekly. These three measures are as follows:

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

The technical specifications for these three measures can be found at http://dialysisreports.org/pdf/esrd/public-measures/HemodialysisAdequacy-ktv-2015-NPRM.pdf, http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015-NPRM.pdf, and http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysisAdequacy-ktv-2015-NPRM.pdf.

The fourth new measure proposed for PY 2015 is NQF #1454, Proportion of patients with hypercalcemia. This measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average (uncorrected means not corrected for serum albumin concentration). Technical specifications for this measure can be found at http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2015-NPRM.pdf.

The fifth new measure proposed for PY 2015 is an Anemia Management reporting measure, which would require facilities to report a hemoglobin or hematocrit value and, as applicable, an erythropoiesis stimulating agent (ESA) dosage for all qualified Medicare patients at least once per month via claims (default hemoglobin/hematocrit values of 99.99 would not meet the requirements of the measure). Patients would be considered qualified for this measure if they met the same ground rules stated above for the Mineral Metabolism reporting measure and, once again, facilities would not need to be the ones drawing blood for hospitalized and transient patients. ***In addition, CMS again asks for comment regarding the alternative of a 98 percent patient reporting threshold.*** In proposing the Anemia Management reporting measure, CMS notes that the average monthly blood transfusion rate increased from 2.7 percent in 2010 to 3.2 percent in 2011. The agency adds that it plans to monitor the rate of transfusions and may consider the adoption of relevant quality measures

through future rulemaking if necessary. The technical specifications for the Anemia Management reporting measure can be found at http://www.dialysisreports.org/pdf/esrd/public-measures/AnermiaManagement-Reporting-2015-NPRM.pdf.

Future ESRD QIP Measures

CMS announces that it intends to adopt two measures, NQF #1463: Standardized Hospitalization Ratio for Admissions (SHR), and NQF #0369: Dialysis Facility Risk-adjusted Standardized Mortality Ratio (SMR), for future payment years of the ESRD QIP, possibly beginning with the PY 2018 program. The SHR measure describes, as a ratio, the number of ESRD Medicare patient actual admissions versus expected hospitalizations adjusted for the facility's Medicare patient case mix. Similarly, the SMR describes, as a ratio, the number of ESRD Medicare patient actual deaths versus expected deaths adjusted for the facility's Medicare patient case mix. Additional information about both measures can be found at the NQF Website (www.qualityforum.org). CMS notes that it began reporting the SMR measure on Dialysis Facility Compare (DFC) in January 2001 (using three categories, "as expected," "worse than expected," and "better than expected" to rate facility performance), and plans to add the SHR data effective January 2013. At that time, the agency also plans to begin reporting the actual SMR rates/ratios.

CMS acknowledges that it had originally proposed to adopt the SHR measure for the PY 2014 program but did not finalize the proposal, in part, because commenters voiced concerns regarding the accuracy of the co-morbidity data used in the calculation of the measure. CMS now notes that the claim form UB 92 with the type of bill field 72x allows a facility to input up to 17 co-morbid conditions per claim submission and the agency believes that the best means for facilities to update patient co-morbidities is through the ESRD 72x claim form (details on the form can be found in the Medicare Claims Processing Manual, Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims, https://www.cms.gov/manuals/downloads/clm104c08.pdf). CMS adds that because the NQF-endorsed SHR and SMR measures are risk-adjusted for ESRD patients that reside in nursing homes, it will utilize data from the Minimum Data Set to identify those individuals in nursing homes.

CMS also notes that the agency is considering the feasibility of developing quality measures in areas such as kidney transplantation, quality of life, health information technology for quality improvement at the point of care and the electronic exchange of information for care coordination, and transfusions. ***CMS requests comment on these potential areas of future measurement and welcomes suggestions on other topics for measure development.***

Measure Scoring and Weighting

CMS proposes to adopt a scoring methodology for the PY 2015 ESRD QIP that is nearly identical to that used for the PY 2014 ESRD QIP. CMS proposes to establish CY 2013 as the performance period for all the PY 2015 measures, believing that a 12-month performance period best meets its policy objectives. In order to ensure enough time to calculate and assign numerical values to the proposed performance standards for the PY 2015 program, CMS proposes to set the performance standards based on the national performance rate (that is, the 50th percentile) of facility performance in CY 2011. The agency notes, however, that this would only capture 6 months of more recent data when compared to PY 2014 and would also overlap with 6 months of data used to calculate the PY 2014 performance standards. CMS adds that the alternative of using data for the July 1, 2011 through June 30, 2012 period would not allow it to publish numerical values for the performance standards until late 2012 or early 2013. ***Nonetheless, CMS invites comment on the data that should be used to determine performance standards for the PY 2015 program.***

CMS also acknowledges that for the three proposed Dialysis Adequacy measures and the Hypercalcemia measure, it does not possess data for the entirety of CY 2011. In fact, CMS notes that it did not begin collecting uniform data on hemodialysis adequacy until January 1, 2012 and facilities were not required to report serum calcium values until their submission of May 2012 data with the June 2012 national implementation of CROWNWeb. However, about 63 percent of facilities, which treat about 80 percent of the Medicare ESRD population, have been voluntarily reporting serum calcium levels via CROWNWeb piloting since July 2008, and CMS proposes to calculate performance standards for the Hypercalcemia measure using the data that it collected via CROWNWeb Pilots during CY 2011. CMS also reports finding that 88 percent of facilities that reported to CROWNWeb had reported Kt/V values using a NQF specified calculation method. **CMS proposes to calculate the performance standards for the three proposed Kt/V measures using CY 2011 claims data, but acknowledges that stakeholders may be concerned about "the nuances of the data" and invites comment regarding its proposed plan.** CMS also notes that it considered calculating performance standards for the Kt/V Dialysis Adequacy measures based on data from January 1, 2012 through June 30, 2012 but believes that a shortened data period may affect the measure rates' reliability.

If, after consideration of public comments on the proposed rule, CMS decides not to adopt the adult hemodialysis Kt/V measure for PY 2015, the agency proposes to continue to use the URR as a measure of hemodialysis adequacy for this population. CMS adds that if it does not adopt the Kt/V measure for adult hemodialysis patients, it would also not adopt the Kt/V measure for pediatric hemodialysis patients but it would still adopt the Kt/V peritoneal dialysis measure. And since the NQF endorsed measure for Kt/V for peritoneal dialysis adequacy

does not specify the body surface area formulas or the total body water formulas to utilize, CMS says it would accept the submission of peritoneal adequacy Kt/V values that utilize the methods currently in use as industry standards.

Under the ESRD QIP, CMS scores facilities based on an achievement and improvement scoring methodology, with a facility's performance on each of the clinical measures determined based on the higher of an achievement score or an improvement score. The achievement score of 0 to 10 points depends upon where a facility's performance falls along a scale that runs from the achievement threshold to the benchmark, with CMS proposing to define the achievement threshold for each of the proposed clinical measures as the 15th percentile of national facility performance during CY 2011 and the benchmark as the 90th percentile. The improvement score of 0 to 9 points is based on a facility's performance along a scale running between the improvement threshold (its score based on past performance) and the benchmark, with CMS proposing to base the improvement threshold on data from CY 2012 (because, as noted earlier, CMS does not have complete facility level CY 2011 data for the Dialysis Adequacy and Hypercalcemia measures). In fact, for the Hypercalcemia measure, the data CMS is proposing to use to set the improvement threshold for each facility would only include May 2012 through December 2012 data. To mitigate data lags in setting improvement thresholds, CMS acknowledges that it considered deriving the improvement threshold from either the first quarter of CY 2013 or the first 6 months of CY 2013 and then comparing it to the facility's performance in the last quarter of CY 2013 or the last 6 months of CY 2013 but concluded that it preferred using 12 months of data whenever possible.

The proposed rule includes estimates of the performance standard, achievement threshold, and benchmark for each of the 7 clinical measures, as noted below.

Measure	Performance Standard	Achievement Threshold	Benchmark
Hemoglobin > 12 g/dL	2%	7%	0%
Vascular Access Type			
%Fistula	59%	46%	74%
%Catheter	13%	23%	5%
Kt/V			
Adult Hemodialysis	93%	86%	97%
Adult Peritoneal Dialysis	83%	58%	94%
Pediatric Hemodialysis	90%	78%	96%
Hypercalcemia	3%	6%	0%

CMS notes that if the final numerical values for the PY 2015 performance standards, achievement thresholds, and benchmarks are worse than PY 2014 for a measure, it proposes to substitute the PY 2014 values because it believes that the ESRD QIP should not have lower values than previous years.

In terms of the other PY 2015 measures, CMS proposes to establish the same performance standard for the ICH CAHPS reporting measure for PY 2015 that it

established for PY 2014 (an attestation that a facility successfully administered the ICH CAHPS survey via a third party in accordance with the measure specifications, with this attestation completed in CROWNWeb by January 31, 2014. For the NHSN Dialysis Event reporting measure, CMS proposes to set the performance standard as successfully reporting 12 months of data from CY 2013; if a facility has not yet enrolled and trained in the NHSN system, that facility must also complete these requirements. For the Mineral Metabolism reporting measure, CMS proposes to set the performance standard as successfully reporting serum phosphorus and calcium values for all 12 months of the performance period for (i) in-center hemodialysis patients the facility treats at least twice during the applicable month and (ii) all peritoneal and home dialysis patients that the facility treats. Finally, for the Anemia Management reporting measure, CMS proposes to set the performance standard as successfully reporting hemoglobin or hematocrit and ESA dosage (if applicable) for all 12 months of the performance period for the same patient populations noted for the Mineral Metabolism reporting measure.

With respect to the proposed Anemia Management, Mineral Metabolism and NHSN Dialysis Event reporting measures, CMS proposes to award 5 points for meeting reporting requirements for at least 6 consecutive months, 10 points for meeting reporting requirements for all 12 months, and 0 points for less than 6 consecutive months of reporting. ***CMS notes that it is concerned that awarding points for 6 non-consecutive months of reporting may cause facilities to be less diligent in their reporting efforts overall but requests comments regarding whether facilities should receive points for partially reporting data and whether such reporting need be for consecutive months.*** For the proposed ICH CAHPS reporting measure, CMS proposes awarding 10 points if a facility attests that it successfully administered the ICH CAHPS survey via a third party and 0 points if it does not so attest.

For the Dialysis Adequacy measure topic (3 measures) and the Vascular Access measure topic (2 measures), CMS proposes to calculate a measure topic score using the following steps:

1. Dividing the number of patients in the denominator of each measure by the sum of the denominators for all of the applicable measures in the measure topic;
2. Multiplying that figure by the facility's score on the measure;
3. Summing the results achieved for each measure; and
4. Rounding this sum (with half rounded up).

The proposed rule provides two detailed examples of how this scoring methodology would work. CMS further proposes that if a facility does not have enough patients to receive a score on one of the measures in the measure topic, that measure would not be included in the measure topic score for that facility. And only one measure within the measure topic need have enough cases to be

scored in order for the measure topic to be scored and included in the calculation of the Total Performance Score.

In developing a facility's Total Performance Score, CMS proposes to weight the finalized clinical measures/measure topics equally, out of the belief that this will incentivize facilities to improve and achieve high levels of performance across all of the measures. CMS further proposes to weight the clinical measures slightly less for the PY 2015 ESRD QIP than it did for the PY 2014 QIP (80 percent of the Total Performance Score instead of 90 percent for PY 2014), with the remaining 20 percent allotted to the reporting measures (in lieu of the 10 percent for PY 2014), all equally weighted. One important proposed change from PY 2014 is that CMS would require a facility to have at least one clinical and one reporting measure to receive a Total Performance Score (rather than including any facility that receives a score on one measure). Note that if a facility has sufficient data to calculate an achievement score but not sufficient data to calculate the improvement threshold, CMS proposes to only calculate its achievement score. CMS also proposes that all Total Performance Scores be rounded to the nearest integer, with half being rounded up. The proposed rule provides detailed examples of the how the proposed PY 2015 scoring methodology would work.

For purposes of scoring clinical measures, CMS again proposes a minimum case threshold of 11 cases (in part to address privacy concerns). However, CMS also proposes a new methodology to adjust clinical measure rates for facilities having between 11 and 25 cases for a given measure. Based on an analysis of Inter-Unit Reliability (IUR) of PY 2014 QIP scores stratified by facility size, CMS has determined that an adjustment (which CMS labels a "favorable reliability adjustment") to the two strata with the lowest number of cases would reduce the risk of penalizing facilities in those strata for random within-facility variation. IUR is a statistic commonly adopted for assessing the reliability of measures or scores. The magnitude of CMS' proposed adjustment factor increases as the number of cases decreases from 25 to 11. And because the adjustment factor takes into account a facility's performance (standard error of the measure) and the number of cases for the measure, it must be computed separately for each measure. The proposed rule includes the statistical formula that would be used in calculating the adjustment.

In the case of new facilities receiving a CMS Certification Number (CCN) after January 1, 2013 but before July 1, 2013, CMS proposes to score their performance on the reporting measures proportionately for the time for which they have a CCN. Thus, these facilities could receive 10 points for reporting data for all of the months during which the facility is open (with CMS proposing to begin counting the number of months on the first day of the month after the facility receives a CCN) and 5 points for reporting data for half of the months for which it is open, consecutively. CMS gives the following example: a facility that receives a CCN on March 15, 2013, would receive 10 points for reporting data

from April 1, 2013 through December 31, 2013 (9 months) and 5 points for reporting 4 consecutive months of data (CMS proposes to round 4.5 months, half of 9 months, down to 4). CMS also proposes to exclude facilities receiving a CCN on or after July 1, 2013 from the requirements of the reporting measures. ***CMS invites comment on whether there would be a more appropriate way to score new facilities on reporting measures so that they may be eligible for inclusion in the ESRD QIP.***

Payment Reductions

For PY 2014, CMS adopted an approach under which a facility did not have to meet or exceed the performance standards with respect to each of the finalized clinical measures to avoid receiving a payment reduction under the ESRD QIP. And in calculating the minimum Total Performance Score for PY 2014, CMS excluded the reporting measures. For PY 2015, CMS proposes to retain the same approach. CMS also proposes to follow the same payment reduction scale that was used for the PY 2014 program--for each 10 points a facility falls below the minimum Total Performance Score, it receives an additional 0.5 percent payment reduction, with a maximum reduction of 2 percent. CMS is unable to calculate the minimum Total Performance Score for PY 2015 at this time but estimates that a facility must meet or exceed a minimum score of 52 to avoid a payment reduction. The estimated payment reduction scale for PY 2015 is shown below.

Total Performance Score	Reduction
100-52	0%
51-42	0.5%
41-32	1.0%
31-22	1.5%
21-0	2.0%

CMS reports that it has procured the services of a data validation contractor. Beginning in CY 2013, CMS proposes to begin a pilot validation program for the ESRD QIP that would involve a random sample of records of about 750 dialysis facilities (about 10 records from each facility). CMS believes that the first year of this validation should result in no payment reductions to facilities. Targeted facilities would have 60 days to submit records requested by the validation contractor. In future years, CMS expects to have in place a full data validation effort, to score facilities based on the accuracy of their records, and to increase a facility's payment reduction by one tier (for example from 0.5 to 1 percent) if its data is incorrect beyond a certain threshold.

Where facility ownership changes, if the facility's CCN remains the same, CMS would consider the facility to be the same facility for purposes of the ESRD QIP and would apply any ESRD QIP payment reduction for the transferor to the transferee. However, if a facility receives a new CCN, CMS would treat the

facility as new for purposes of the ESRD QIP as of the date it received the new CCN.

Public Reporting

In terms of public reporting of ESRD QIP scores, beginning in January 2013, CMS proposes to publish a list with the name and address, measure rates (which may include numerators and denominators) and scores, and Total Performance Scores of each dialysis facility for each payment year, after facilities have the ability to review their scores. The list will also indicate those facilities that do not have enough data to calculate one or more measure rates and/or a Total Performance Score.

Beginning with the PY 2014 program, CMS proposes to require facilities to post the certificate with their Total Performance Score on or before the first business day after January 1 of each payment year (rather than requiring such posting within 5 days of their availability, as is currently the case). Certificates are typically available for download on or around December 15 of each year. Beginning PY 2014, CMS also proposes to require facilities to post two copies of the certificate, one in English and one in Spanish (rather than only one in English as is currently the case).

IV. Limitation on Payments to All Providers, Suppliers and Other Entities Entitled to Bad Debt

Table 9 of the proposed rule (reproduced below with some modifications) compares current Medicare bad debt payment policies with those mandated under The Middle Class Tax Extension and Job Creation Act for various categories of providers, including hospitals, skilled nursing facilities (SNFs), swing bed hospitals, critical access hospitals (CAHs), ESRD facilities, community mental health centers (CMHCs), Federally qualified health centers (FQHCs), rural health clinics (RHCs), cost-based health maintenance organizations (HMOs), health care pre-payment plans, and competitive medical health plans. For both SNFs and hospital swing beds, the policy differs depending on whether the patients are—or are not—full dual eligibles (that is eligible for both Medicare and Medicaid). CMS estimates that the "self implementing" bad debt provisions will result in Medicare savings of $10.92 billion over the period from 2012 through 2022.

Table 9—Summary of Medicare Bad Debt Reimbursement by Provider Types For Cost Reporting Periods That Begin During FY 2013, 2014, 2015 and Subsequent Years

Provider Type	Allowable Bad Debt Amount During FY 2012	Allowable Bad Debt Amount During FY 2013	Allowable Bad Debt Amount During FY 2014	Allowable Bad Debt Amount During FY 2015 & Subsequent FYs
Hospitals	70%	65%	65%	65%
SNFs: Non-Full Dual Eligibles	70%	65%	65%	65%
Swing Bed Hospitals: Non-Full Dual Eligibles	100%	65%	65%	65%
SNFs: Full Dual Eligibles	100%	88%	76%	65%
Hospital Swing Beds: Full Dual Eligibles	100%	88%	76%	65%
CAHs, ESRD facilities, CMHCs, FQHCs, RHCs, cost based HMOs, health care pre-payment plans, and competitive medical health plans	100%	88%	76%	65%

CMS also proposes to remove and reserve 42 CFR 413.178 of the Medicare regulations (which addresses current Medicare bad debt payment policies), move specific requirements to reimburse ESRD bad debt amounts from §413.178 to §413.89, and make a technical correction to 42 CFR 417.536(f)(1) to refer to §413.89. CMS also proposes to clarify that the limits on bad debt payments are reductions to the amount of allowable bad debt.

The single area in which CMS acknowledges having some discretion relates to the treatment of ESRD facility bad debt. CMS currently reimburses an ESRD facility 100 percent of its allowable bad debt up to the facility's reasonable cost. CMS says that it considered applying the FY reduction percentage after the cap is applied but is proposing instead to apply the reduction to allowable bad debt prior to applying the cap. The proposed rule gives several examples of what this would mean. In one of these, a facility with unrecovered costs of $90 and allowable bad debt of $110 in FY 2014, would see its allowable bad debt reduced by 24 percent (to $83.60). Since this amount does not exceed the unrecovered costs, the facility would receive $83.60.

V. Collection of Information Requirements

There is the usual opportunity to submit comments regarding information collection requirements associated with the proposed rule. These comments may be submitted as part of the overall comments on the proposed rule or submitted directly to the Office of Management and Budget at the following address: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-1352-P], FAX 202-395-6974 or email OIRA_submission@omb.eop.gov.

The proposed rule emphasizes that CMS is not proposing any changes to regulatory text for the ESRD PPS in CY 2013. However, the proposed rule discusses four additional information collection requirements.

First, the new requirement to post a Spanish language certificate of each dialysis care provider/facility's Total Performance Scores under the ESRD QIP (not just an English language certificate) is not expected to add more time or burden to the Collection of Information requirements outlined in the CY 2011 ESRD PPS final rule. Nonetheless, for purposes of information collection burden for PY 2015 and beyond, CMS estimates that it will take each facility 10 minutes per year to print, prominently display, and secure the ESRD QIP certificates, that about one-third of ESRD patients will ask a question about the certificates, and that it will take each facility about 5 minutes to answer each question. This yields a total per-facility estimate of 1.52 hours per year at a mean hourly wage of $33.23 for a registered nurse or about $51.

Second, the proposed NHSN Dialysis Event Reporting Requirements for the PY 2015 ESRD QIP are estimated to require 12 hours of time per facility to collect and submit data on an estimated 0.08 events per patient per month for an average of 75 patients per facility, for a total per-facility cost of $399 (at the same $33.23 per hour labor cost noted above). In addition, new facilities would need to devote an estimated 8 hours to enroll in, and complete the required training for, the NHSN, at an estimated cost of about $266 per new facility.

Third, CMS estimates that it will take each facility's third-party administrator 16 hours per year to be trained on ICH CAHPS survey features, that it will take each patient 30 minutes to complete the survey, and another 5 minutes for each facility to submit the annual attestation to CMS that they have successfully administered the survey. This is estimated to impose a total per-facility cost of about $1,794 per year.

Fourth, CMS estimates that each of the 750 facilities subject to the annual data validation requirements would take 2.5 hours to submit validation data, at an estimated annual per-facility cost of $83.08 (assuming the same $33.23 per hour labor cost adopted for the other data collection requirements).

Copies of the supporting statement and any related forms for the proposed paperwork collections described above can be obtained at the following CMS Web address: http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage.

VI. Economic and Related Analyses

The proposed rule has been designated economically significant. CMS estimates that the proposed revisions to the ESRD PPS will increase Medicare payments to ESRD facilities by about $320 million in CY 2013, which will translate into increases in beneficiary co-insurance amounts of about $70 million. CMS further estimates that the proposed requirements related to the ESRD QIP for PY 2015 will cost about $12.4 million (for data collection and submission) and produce payment reductions of about $8.5 million. As noted earlier, CMS also estimates that the "self implementing" bad debt provisions will result in Medicare savings of $10.92 billion over the period from 2012 through 2022.

Table 11 of the proposed rule estimates the impact on various facility types (e.g., by ownership type, geographic location, and facility size). This table separately assesses the effect of changes in outlier policy, changes in wage indexes, and all 2013 changes. Selected excerpts from Table 11 are shown below.

Impact of Proposed Changes in Payments to ESRD Facilities for CY 2013

Facility Type	Effect of 2013 Changes in Outlier Policy	Effect of 2013 Changes in Wage Indexes	Effect of Total 2013 Changes
All facilities	0.4%	0.0%	3.1%
Freestanding	0.4%	0.0%	3.0%
Hospital-based	0.2%	0.2%	3.7%
Large dialysis organization	0.5%	0.0%	3.0%
Regional chain	0.3%	0.1%	3.1%
Independent	0.2%	0.0%	3.2%
Hospital-based*	0.2%	0.3%	3.7%
Rural	0.5%	-0.2%	3.0%
Urban	0.4%	0.0%	3.1%
Puerto Rico/Virgin Islands Census Region	-0.2%	-2.4%	0.4%

*Includes hospital-based facilities not reported to have large dialysis organization or regional chain ownership.

CMS notes that most ESRD facilities are anticipated to experience a positive payment effect in CY 2013 as a result of the proposed outlier policy changes.

In terms of the QIP, CMS estimates that 14 percent or 801 facilities would likely receive an aggregate payment reduction of about $8.5 million for PY 2015, and

further estimates the distribution of these reductions (in percentage terms) as follows:

Payment Reduction	Number of Facilities	Percent of Facilities
0.5%	470	8.8%
1.0%	190	3.5%
1.5%	77	1.4%
2.0%	64	1.2%

Table 14 of the proposed rule assesses the impact of the QIP payment reductions across different facility types, but CMS warns that the actual impact may vary significantly from the values it provides (since the time periods used for the estimates differ from those it proposes to use for the PY 2015 QIP). Selected excerpts from Table 14 are shown below.

Impact of Proposed QIP Payment Reductions for PY 2015

Facility Type	Number of Facilities	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All facilities	5,633	801	-0.12%
Freestanding	5,089	679	-0.10%
Hospital-based	544	122	-0.31%
Large dialysis organization	3,663	459	-0.09%
Regional chain	915	119	-0.12%
Independent	617	125	-0.20%
Hospital-based (non-chain only)	429	96	-0.33%
Large entities	4,578	578	-0.09%
Small entities	1,046	221	-0.24%
Rural	1,249	173	-0.11%
Urban	4,384	628	-0.12%

Note that the percentage reductions in payment shown above are for all facilities of a specified type, not just the facilities of that type receiving the payment reduction. For example, CMS anticipates that the payment reductions would average about $10,462 per facility among the 801 facilities experiencing a payment reduction, and they would average $12,509 per small entity facility receiving a payment reduction, which would amount to a decrease of 0.24 percent in aggregate ESRD payments across all 897 ESRD small entity facilities.

As a result, the Secretary concludes that the proposed rule will not have a significant economic impact on a substantial number of small entities.

CMS also asserts that the proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals (because most dialysis facilities are freestanding), surpass the unfunded mandates threshold, or have substantial direct effects on the rights, roles, and responsibilities of State, local or Tribal governments.