MEDPAC Medicare Payment Advisory Commission

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August 31, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1352–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File code CMS–1352–P

Dear Ms. Tavenner:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed notice entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers," published in the *Federal Register*, vol. 77, no. 133, pages 40952 to 41000. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2013 and the ESRD quality incentive program (QIP) for 2015. We appreciate your staff's ongoing efforts to administer and improve payment systems for physician and other services, particularly considering the competing demands on the agency.

Our comments address the following provisions related to the 2015 ESRD QIP in the proposed rule:

- The proposed performance measures
- The proposed weighting of "clinical measures" versus "reporting measures"
- The proposed reliability adjustment for facilities with small number of patients
- Future QIP considerations

The proposed performance measures

For payment year 2015, the fourth year of the ESRD QIP, CMS is proposing 11 measures. As proposed, the 2015 QIP would continue to use six of the seven measures that the 2014 QIP uses:

- A "clinical measure" on the over-treatment of anemia that assesses the proportion of dialysis patients with a hemoglobin level greater than 12 g/dL.

- Two "clinical measures" on the vascular access type that assess the proportion of hemodialysis patients with an arterial venous fistula and a catheter.
- A "reporting measure" on the management of mineral metabolism disorders. For the 2014 QIP, the measure assesses whether facilities are measuring the serum calcium and serum phosphorus levels of dialysis beneficiaries. For the 2015 QIP, CMS is proposing to strengthen this measure's reporting requirements.
- A "reporting measure" that assesses participation in the Centers for Disease Control and Prevention's National Healthcare Safety Network Dialysis event report system, a surveillance system that tracks healthcare-associated infections. CMS is proposing to strengthen this measure's reporting requirements.
- A "reporting measure" on administering the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey instrument to obtain patient satisfaction information.

The agency is proposing that the 2015 QIP would use three "clinical measures" to assess the proportion of patients with low dialysis adequacy to replace the single low dialysis adequacy measure that the 2014 QIP used. The proposed measures would separately assess dialysis adequacy based on Kt/V for adult in-center hemodialysis patients, adult peritoneal dialysis patients, and pediatric hemodialysis patients.[1] By contrast, the 2014 measure assesses dialysis adequacy for only adult in-center hemodialysis patients based on the urea reduction ratio. Expanding the measurement of dialysis adequacy (to adult peritoneal dialysis patients and pediatric hemodialysis patients) helps to address the Commission's concern that facilities be held accountable for the quality of care furnished to all of their patients.[2]

The two new measures that CMS proposes for the 2015 QIP are:

- A "clinical measure" that assesses the proportion of patients with hypercalcemia.
- A "reporting measure" that collects information—hemoglobin/hematocrit levels and dosage of erythropoietin stimulating agents (ESA)—on anemia management.

As proposed, the 2015 QIP would include seven "*clinical measures*" and four "*reporting measures*." *Clinical measures* provide real data on the outcome of care processes (i.e., how the care affects patients), such as the proportion of a facility's dialysis patients with a hemoglobin greater than 12 g/dL. By contrast, *reporting measures* evaluate whether facilities track or report certain types of information (e.g., clinical values) to the Secretary or whether facilities attest that they are collecting certain types of information (e.g., patient satisfaction information).

In the remainder of this section, we comment on: (1) the proposed "reporting measure" on anemia management; (2) the lack of a measure to assess under-treatment of anemia; and (3) the proposed mineral metabolism measures.

[1] K=clearance, t=dialysis time, and V=volume distribution.
[2] Hackbarth, Glenn M. Medicare Payment Advisory Commission. 2011. Letter to Donald M. Berwick, Administrator, Centers for Medicare & Medicaid Services. August 30.

The proposed "reporting measure" on anemia management

For 2015, CMS is proposing a measure that would award points to facilities who report ESA dosage (if applicable) and hemoglobin and/or hematocrit levels for patients on at least one monthly claim. The agency is proposing this "reporting measure" to fully understand the effect of the change in the Food and Drug Administration (FDA) ESA label and other factors.

Since January 1, 2012, dialysis facilities have been required to report hemoglobin/hematocrit levels for all patients via claims. In addition, facilities report ESA dosage on claims in order for CMS to consider if they are eligible for outlier payments. CMS requires that facilities indicate all renal dialysis-related drugs, including dosages, on ESRD claims.[3]

The Commission believes that the measures selected for QIPs should not reward facilities for reporting information that CMS already collects from facilities on a routine basis. We raised the same concern about the Physician Quality Reporting Initiative.[4] Because facilities report the hemoglobin/hematocrit and ESA dosage in the billing process, it is redundant to include this measure in the ESRD QIP. Consequently, the Secretary should re-consider including the anemia "reporting measure" in the ESRD QIP.

Although it is redundant to include the anemia "reporting measure" in the QIP, the Secretary should continue to require that facilities report this information on at least one monthly claim. Such information would enable to Secretary to continue to evaluate whether patients' anemia is properly treated.

The 2015 ESRD QIP does not assess anemia under-treatment

The Commission remains concerned that the 2015 ESRD QIP lacks an outcome measure that holds providers accountable for the under-treatment of anemia, a comorbidity that affects many dialysis patients. The 2012 QIP includes a measure that assesses the proportion of beneficiaries receiving ESAs with an average hemoglobin level less than 10.0 g/dL. Beginning in 2013, CMS retired this measure because: (1) it could not identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs; and (2) the agency believes that it would not be appropriate for the QIP to continue to incentivize ESRD providers to achieve hemoglobin levels above 10 g/dL in all patients.

According to CMS, under-treatment of anemia can lead to adverse health outcomes for dialysis patients, such as the need for blood transfusions and hospitalizations.[5] Under the modernized payment method, facilities have a greater incentive to under-furnish services in the payment

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[3] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Medicare program; End-stage renal disease prospective payment system. *Federal Register* 75, no. 155 (August 12): 49030–49214.
[4] Hackbarth, Glenn M. Medicare Payment Advisory Commission. 2009. Letter to Charlene Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services. August 31.
[5] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Medicare program; End-stage renal disease quality incentive program. Proposed rule. *Federal Register* 75, no. 111 (August 12): 49215–49232.

bundle rather than over-furnish them. The Commission wants to ensure that beneficiaries continue to have access to effective and appropriate anemia management.

Under-treatment of anemia, in some instances, may be associated with lower ESA dosage. The Commission reported that, in 2010, providers decreased the dosage of the principal ESA (erythropoietin) furnished to dialysis patients because of the change in the FDA ESA label and in anticipation of the start of the new dialysis payment method in 2011.[6] An industry-sponsored source found that between August 2010 and December 2011 the average weekly dose of erythropoietin furnished by medium and large freestanding facilities declined by 29 percent, and the Commission's own preliminary analysis has found a similar finding.[7] Increased use of blood transfusions is one outcome of lower ESA doses and under-treatment of anemia. In the proposed rule, CMS reported that the average monthly blood transfusion rate increased from 2.7 percent in 2010 to 3.2 percent in 2011, and that a United States Renal Data System analysis presented in May 2012 found an increase in blood transfusion rates among ESRD patients concurrent with the implementation of the ESRD PPS.[8]

Consequently, the QIP should include a "clinical measure" that assesses the adverse consequences of anemia under-treatment. Options for such a measure include assessing the proportion of beneficiaries with a hemoglobin level less than a specific level or outcomes of anemia under-treatment, such as the rate of blood transfusions or the rate of inpatient hospitalizations.

In the proposed rule, CMS says that, for future payment years (not 2015), it is intending to adopt a standardized hospitalization ratio (SHR) measure. Once CMS adopts a SHR measure, it could consider retiring other measures assessing anemia under-treatment.

The proposed mineral metabolism measures

As proposed, the 2015 QIP would: (1) establish a new "clinical measure" that assesses the proportion of patients with hypercalcemia, an indicator of non-optimal mineral metabolism management (total uncorrected serum calcium) and (2) strengthen the 2014 "reporting measure" by rewarding facilities for submitting (on a monthly basis) a serum calcium and serum phosphorus level for each dialysis patient into the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb). By contrast, the 2014 QIP requires that facilities attest that they routinely monitor the serum calcium and serum phosphorus levels in their patients. CMS explains that under-treatment of mineral metabolism disease can cause severe consequences for ESRD patients.

The Commission supports the proposed 2015 "clinical measure" that assesses hypercalcemia. Such a measure rewards facilities for positive patient outcomes, not for simply tracking or relaying data to the Secretary.

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[6] Medicare Payment Advisory Commission. 2012. *Medicare Payment Policy*. Washington DC: MedPAC.
[7] Dialysis Outcomes and Practice Patterns Study. 2011. DOPPS practice monitor. http://www.dopps.org/DPM/.
[8] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare program; End-stage renal disease prospective payment system, quality incentive program, and bad debt reductions for all Medicare providers. Proposed rule. *Federal Register* 77, no. 133 (July 11): 40952–41000.

We question whether the 2015 QIP should include a "reporting measure" that rewards facilities for submitting clinical data (serum calcium and serum phosphorus level) into CROWNWeb. Medicare's conditions for coverage already require electronic submission of administrative and clinical data by Medicare-approved dialysis facilities (§494.180(h)). QIPs should evolve over time and should hold providers accountable for attaining or improving on clinical outcomes rather than simply whether providers can track them. Consequently, CMS should consider retiring the "reporting measure" on mineral metabolism management.

Under its authority specified in the conditions for coverage, the agency should continue to collect via CROWNWeb mineral metabolism clinical information. Collection of such information would enable efforts to evaluate facilities' management of mineral metabolism disease.

The proposed weighting of "clinical measures" versus "reporting measures"

For the 2015 QIP, CMS is proposing that the seven "clinical measures" would represent 80 percent of facility's total performance score and the four "reporting measures" would represent 20 percent of the score. In contrast, in the 2014 QIP, "clinical measures" represent 90 percent of the facility's score while "reporting measures" represent 10 percent of the score.

The Commission believes that QIPs should evaluate providers' performance rather than ability to track and report information, and that clinical outcomes are more important than simply tracking or relaying information to the Secretary. Consequently, the 2015 QIP should maintain the 2014 weights in which "clinical measures" represent 90 percent of the facility's score and "reporting measures" represent 10 percent of the score.

The proposed reliability adjustment for facilities with small number of patients

The 2015 QIP would maintain the requirement that facilities have at least 11 cases (patients) that meet the reporting criteria for a measure to be scored. However, CMS is proposing a new adjustment to the measure rates used to score facilities with between 11 and 25 cases for a given measure. The Commission has concerns about such an adjustment, which we discuss below.

In response to previous comments about the reliability of the QIP's measures, CMS tested the reliability of the quality measure rates and the total performance score for facilities of varying sizes using payment year 2014 measures. Specifically, the agency simulated the 2014 QIP to calculate the inter-unit reliability (IUR) statistic—the ratio of the between-facility variance to the sum of the between-facility variance and the within-facility variance—stratified by facility. CMS found that the reliability of the total performance to be acceptable for all strata (IUR > 0.6). However, the agency also found that a "favorable 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.

Based on this analysis's findings, CMS is proposing that the 2015 QIP would apply a "favorable adjustment" to the measure rates for facilities with at least 11 cases and 25 cases. Such an adjustment was not implemented in the 2012–2014 QIPs. The reliability adjustment would be

separately applied to each measure and would adjust the performance rate for a given measure based on the "average" population of patients by considering the facility's performance (standard error of the measure calculated using an analysis of variance) and the number of cases for that measure. The magnitude of the adjustment factor would increase as the number of cases decreases from 25 to 11.

We are concerned that this adjustment runs counter to the goals of quality incentive programs. Although this proposed adjustment reduces the chance that a facility would be penalized for random variation in its rate due to having a small number of cases, it weakens the incentive for a facility to improve on a given measure, and may give a facility's patients a misleading picture of its performance on quality. We raised the same concern about the adjustment in the method to determine the number of excess readmissions proposed in the fiscal year 2013 rule for the acute and long-term care hospital payment system.[9]

We also question the necessity for this adjustment given CMS's statement in the proposed rule that "the reliability of the Total Performance Score is acceptable for all strata." If CMS is concerned about the chance fluctuations in the performance data of small facilities, the agency should explore and compare other options to the proposed method, such as using multiple years of data and increasing the length of the performance period, before making any changes.[10]

Future QIP considerations

To strengthen the QIP, there are several issues that CMS should consider in updates to the program. The first issue concerns the calculation of a facility's achievement score. CMS calculates a facility's achievement score by comparing the facility's performance to the 15th percentile ("achievement threshold) and 90th percentile ("benchmark") of performance nationally.[11] The agency should consider, during the next several years, raising the achievement threshold for the "clinical measures." The threshold in the 2014 QIP and the proposed 2015 QIP is the 15th percentile of the national facility performance for a specific time period. To motivate improvement over time, the agency should consider gradually increasing the achievement threshold to levels greater than the 15th percentile of national performance.

Second, CMS should begin to convert the "reporting measures" on patient satisfaction and health care-associated infections to performance measures as soon as practical. To expedite the process to convert these measures to pay-for-performance, CMS should begin to analyze the actual data collected and reported by facilities. We are encouraged that CMS wants to adopt the NQF-endorsed measure on bloodstream infections once facilities have reported enough data to enable the agency to compute performance standards, achievement thresholds, improvement thresholds, and benchmarks for the measure. Similar progress should also be made for the patient satisfaction measure.

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[9] Hackbarth, Glenn M. Medicare Payment Advisory Commission. 2012. Letter to Marilyn Tavenner, Acting Administrator, Centers for Medicare & Medicaid Services. June 22.
[10] Medicare Payment Advisory Commission. 2012. *Medicare Payment Policy*. Washington DC: MedPAC.
[11] A facility's achievement score would be zero if the facility's performance during the performance period was lower than the 15th percentile of national performance.

Third, we support the agency's intent to include the standardized hospitalization ratio (SHR) and standardized mortality ratio (SMR) in the ESRD QIP, possibly beginning with the payment year 2018. In the Commission's letter commenting on the 2014 QIP proposed rule, we endorsed the agency's proposal to include these two measures in the 2014 QIP, and we urge the agency to include them, if practical, earlier than the payment year 2018.

Fourth, concerning the overall number of measures, we urge CMS to remain vigilant in maintaining a reasonable number of performance measures for the program. As the number of measures grows, the administrative costs to providers and CMS also increase. As we mentioned earlier, the Commission believes that QIPs should hold providers accountable for attaining or improving on clinical outcomes rather than simply whether providers can track them. The QIP should strive to include those measures that address multiple domains of CMS's value-based purchasing programs[12] and are not duplicative.

Another effective way to hold providers accountable for the care they furnish is to publicly report key quality measures (using current data) on Dialysis Facility Compare. We endorse the agency's intent to publicly report the SHR and SMR to the public via Dialysis Facility Compare. Publicly reporting facility-level data and pay-for-performance initiatives together will hold providers accountable for the care they furnish.

CMS is soliciting comments for measures to be considered for future years, particularly those that address care coordination, population/community health, and efficiency and cost of care, domains that the ESRD QIP does not currently address. The following variables could be evaluated for use in the QIP or for public reporting on Dialysis Facility Compare:

- Emergency department (ED) use. An ED measure would address multiple domains—care coordination and efficiency—of CMS's value-based purchasing programs. More than half of all dialysis beneficiaries have at least one visit to the ED annually, a portion of these visits are potentially avoidable, and care could have been more efficiently furnished in other less costly ambulatory settings.
- Thirty-day hospital readmissions. In proposed rule, the agency is seeking comment on the use of a thirty-day hospital readmission measure. Hospital readmissions are indicators of poor care or missed opportunities to better coordinate care. The Commission found, using 2007 hospital claims data, that 32 percent of hospitalized dialysis beneficiaries were readmitted to a hospital within 30 days.
- A composite variable that includes cost of care and quality metrics. For example, the Commission has constructed such efficiency measures for hospitals by considering hospital-level mortality rates, readmission rates, providers' costs (standardized inpatient costs per case), providers' payer mix, and the annual level of total fee-for-service Medicare service use per capita in the county where the hospital is located.

[12] There are currently six domains of measurement for CMS's value-based purchasing programs, based on the six priorities of the National Quality Strategy: (i) care coordination; (ii) population/community health; (iii) efficiency and cost reduction; (iv) safety; (v) patient and caregiver-centered experience and outcomes; and (vi) clinical care.

- Use of home dialysis and transplantation. As we said in last year's comment letter, CMS should start considering the development of measures that support the use of home dialysis, which offers patients more freedom, flexibility, and independence. Kidney transplantation is widely considered the best treatment option for patients with end-stage renal disease. CMS should explore whether there are mechanisms in the dialysis payment system that could be used to give facilities an incentive to increase their rates of referral of appropriate patients for kidney transplant evaluation.

Conclusion

The Commission appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. We also value the ongoing cooperation and collaboration between CMS and Commission staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

GMH/nr/w