MEDPAC Medicare Payment Advisory Commission

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August 30, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1524–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: File code CMS-1577-P

Dear Dr. Berwick:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed notice entitled Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, end-stage renal disease quality incentive program for PY 2013 and PY 2014; ambulance fee schedule; and durable medical equipment, published in the *Federal Register*, vol. 76, no. 131, pages 40498 to 40550. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2012 and the ESRD quality incentive program (QIP) for 2013 and 2014. We appreciate your staff's ongoing efforts to administer and improve payment systems for physician and other services, particularly considering the agency's competing demands.

The Commission has a longstanding recommendation to modernize the outpatient dialysis payment system, including broadening the payment bundle to include services for which providers bill separately, and linking payment to quality.[1] CMS has successfully implemented the broader payment bundle for dialysis services in 2011, with most dialysis facilities choosing to be paid under the new payment system. Importantly, beginning in 2012, the ESRD QIP will be the first Medicare program that links any provider or facility payment to performance based on outcomes.

[1] Medicare Payment Advisory Commission. 2004. *Medicare payment policy.* Washington DC: MedPAC.

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

- Proposed performance measures for the 2013 ESRD QIP
- Proposed performance measures for the 2014 ESRD QIP
- Participation in the 2013 and 2014 QIPs
- Differential impact of the QIP in 2013 and 2014 on ESRD providers
- Ensuring the accuracy of information reported by providers in the QIP
- Future QIP considerations

Proposed performance measures for the 2013 ESRD QIP

The 2012 ESRD QIP's provisions, which CMS finalized, will use three measures—one on under-treatment of dialysis adequacy, one on under-treatment of anemia, and one on over-treatment of anemia.[2]

In 2013, the second year of the QIP, CMS proposes to use two of the three performance measures that it will use in 2012:

- The dialysis adequacy measure assesses the percentage of in-center hemodialysis beneficiaries with an average urea reduction ratio (URR) greater than 65 percent. Individuals with a URR value of less than 65 percent may not have sufficient wastes removed from their bloodstream during dialysis.
- The anemia management measure assesses the percentage of beneficiaries receiving erythropoietin stimulating agents (ESAs) with an average hemoglobin greater than 12.0 g/dL. The Food and Drug Administration (FDA) label states that in controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs targeting a hemoglobin level of greater than 11 g/dL.

CMS proposes to retire the 2012 measure assessing the under-treatment of anemia—the percentage of beneficiaries receiving ESAs with an average hemoglobin less than 10.0 g/dL 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.

The Commission recognizes that over-treatment of anemia increases patients' risk for mortality and serious morbidity. However, under-treatment of anemia can also lead to adverse health outcomes for dialysis patients, such as the need for blood transfusions and hospitalization, which

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[2] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Medicare program; end-stage renal disease prospective payment system. Final rule and proposed rule. *Federal Register* 75, no. 155 (August 12): 49029–49214.

CMS pointed out in the 2011 ESRD QIP final rule.[3] In its updated black box warning for ESAs, the FDA instructed providers to use the lowest dose sufficient to reduce the need for red blood cell transfusions.

Neither the new ESRD payment system nor the proposed 2013 QIP would hold ESRD providers accountable for the adverse clinical outcomes of under-treatment of anemia, including blood transfusions and hospital admissions. Under the new payment system (with ESAs in the broader payment bundle), ESRD providers will have less incentive to furnish larger doses of ESAs that are associated with higher hemoglobin levels compared to the composite rate (old) payment method in which providers were paid according to the number of units of these drugs given to patients. In addition, under the new payment system, ESRD providers are paid separately for furnishing blood and blood products, which could create an incentive for some providers to treat anemia with blood transfusions.

We believe that it is important that the QIP recognize the adverse clinical consequences associated with both over-treatment and under-treatment of anemia. The Commission wants to ensure that beneficiaries continue to have access to receive effective and appropriate anemia management. Consequently, CMS should include performance measures that assess the adverse consequences of anemia under treatment.

One option is to include a performance measure in the 2013 QIP that assesses the percentage of beneficiaries with a hemoglobin level less than a specific level. Another option is to include a measure that assesses an outcome of under-treatment of anemia, such as total hospital admissions. In the 2014 QIP, CMS proposes to include a risk-adjusted standardized hospitalization ratio, calculated by comparing the actual number of admissions versus expected admissions, adjusted for case mix. Since 1995, the agency has reported this measure to ESRD facilities in its Dialysis Facility Reports. Although not all admissions are due to inappropriate anemia treatment, CMS points out in the proposed rule that a majority (greater than 90 percent) of admitting diagnoses are related to ESRD. Inclusion of this measure in the 2013 QIP would increase the accountability of ESRD providers for the adverse consequences of ineffective anemia management as well as other aspects of renal care.

As mentioned earlier, use of blood transfusions is one adverse consequence associated with anemia under treatment. If, over the next few years, there is an increase in the use of blood transfusion services related to ESRD, CMS should again consider including these services in the payment bundle and not paying for their administration in other outpatient settings. In the final rule for the new ESRD payment system, CMS stated that it did not include blood transfusions in the broader bundle because: (1) blood transfusions are not standard clinical practice; and (2) such services are infrequently furnished by ESRD providers; administration is usually performed in a hospital outpatient setting generally for non-ESRD reasons. However, the agency stated that if practice patterns changed then it will re-examine the service's exclusion from the bundle.[2]

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[3] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011. Medicare program; end-stage renal disease quality incentive program. Final rule. *Federal Register* 76, no. 3 (January 5): 627–646.

In addition to performance measures assessing under-treatment of anemia, CMS should consider re-weighting the performance measures, as we suggested in our comment letter on the 2012 proposed ESRD QIP.[4] In general, the agency should give higher weights to measures that suggest the under-provision of necessary care and lower weights to measures that suggest the overuse of services. Under the broader payment bundle, facilities have a greater financial incentive to undertreat patients than to overtreat them.

Proposed performance measures for the 2014 ESRD QIP

In 2014, the third year of the QIP, CMS is proposing to use eight measures. Five of the measures assess providers' clinical performance and would be weighted equally to comprise 90 percent of a facility's score: (1) over-treatment of anemia; (2) low dialysis adequacy; (3) type of vascular access; (4) presence of vascular access infection; and (5) standardized hospitalization ratio. The other three are structural measures that would be weighted equally and comprise 10 percent of a facility's score: (1) participating in the Centers for Disease Control's National Healthcare Safety Network Dialysis event reporting system; (2) administering the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS) instrument to obtain patient satisfaction information; and (3) monitoring mineral metabolism (phosphorous and calcium) levels on a monthly basis.

The Commission believes that the measures used in pay-for-performance initiatives should evolve over time.[5] We endorse CMS's proposal to link payment to measures associated with improved patient outcomes, including higher rates of AV fistulas and lower rates of vascular access infections and hospitalizations.

The Commission also supports CMS's proposal for collecting information on patient satisfaction. In our March 2000 report, we recommended that the agency collect information on ESRD patients' satisfaction with the quality of and access to care.[6] Such information would enable policymakers and providers to identify access and quality problems and vulnerable subpopulations among ESRD patients. Our October 2003 report also discussed the importance of collecting and monitoring patient satisfaction information.[7]

Concerning the three proposed structural measures, the Commission urges CMS to convert them into outcome 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 reported for health care-associated infections, patient satisfaction, and mineral metabolism levels. Such analyses would expedite the process for converting the measures to evaluating attainment and improvement in those levels, not simply whether a facility can track them.

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[4] Hackbarth, Glenn M., Medicare Payment Advisory Commission. 2010. Letter to Donald Berwick, Administrator, Centers for Medicare & Medicaid Services. September 23.
[5] Medicare Payment Advisory Commission. 2005. *Medicare payment policy*. Washington DC: MedPAC.
[6] Medicare Payment Advisory Commission. 2000. *Medicare payment policy*. Washington DC: MedPAC.
[7] Medicare Payment Advisory Commission. 2003. *Modernizing the outpatient dialysis payment system*. Washington DC: MedPAC.

Participation in the 2013 and 2014 QIPs

According to the proposed rule, the number of facilities with QIP scores is projected to drop from 89 percent in 2013 to 80 percent in 2014 (see table below). Within each year, hospital-based and small facilities are expected to be less likely to have a QIP score while freestanding and the large dialysis organizations are more likely to have a QIP score. In each year, there is little or no difference between the proportion of urban and rural facilities with a QIP score, but, for both groups, the proportion of facilities with a QIP score is expected to decrease between 2013 and 2014.

CMS should explain why certain facility types (e.g., small and hospital-based facilities) are less likely to have QIP scores than other facility types (e.g., large and freestanding facilities). The agency should also explain the reasons behind this estimated drop in facilities with a QIP score. If it stems from the statistical methods that require a minimum number of cases for a facility to be included in a measure's calculation, then CMS needs to develop and adopt statistical methods for lower volume facilities, such as pooling of data over multiple years. For the QIP to ensure the quality of dialysis care for all beneficiaries with ESRD, all facilities must be included in the program.

	Percent of facilities with a QIP score	
Type of facility	2013	2014
All	89%	80%
Freestanding	91	86
Hospital-based	69	30
Large dialysis organizations	93	88
Regional chain	89	79
Independent	83	76
Urban	88	80
Rural	91	80
< 4,000 treatments	55	41
4,000-9,999 treatments	95	87
>10,000 treatments	98	91

Source: Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2001. Medicare program; Changes to the end-stage renal disease prospective payment system for cy 2012, end-stage renal disease quality incentive program for py 2013 and py 2014; ambulance fee schedule; and durable medical equipment. Proposed rule. *Federal Register* 75, no. 155 (July 8): 40497–40550.

Differential impact of the QIP in 2013 and 2014 on ESRD providers

Using CMS's projections in the proposed rule for the 2013 and 2014 QIP and final rule for the 2012 QIP, 26 percent of providers would experience a payment reduction in 2012, rising to nearly 39 percent of providers in 2013, and then falling to 14 percent of providers in 2014. The

percentage of providers experiencing a 2 percent reduction in payments (the maximum permitted by law) increases from about 1 percent in 2012 to nearly 11 percent in 2013 and then drops to about 2 percent in 2014. The impact on providers' payments parallels the proportion of providers experiencing a payment reduction: in 2012, the QIP is expected to reduce overall payments by 0.19 percent in 2012, 0.57 percent in 2013, and 0.17 percent in 2014.

We are concerned about the volatility of the QIP between 2012 and 2014. The effect of the QIP from year-to-year should be relatively stable and predictable. In the final rule, CMS should explain the reasons for the differential impact in 2013 and 2014 or consider options that would even out the QIP's effect on providers.

Ensuring the accuracy of information reported by providers in the QIP

Nearly all of the performance measures used in the 2013 and 2014 QIPs depend on the validity of the data and information reported by providers. Dialysis facilities will report information about dialysis adequacy, anemia management, type of vascular access, and presence of vascular infections on the claims they submit to Medicare for payment. Facilities will attest through CROWNWeb that they are administering CAHPS and monitoring, on a monthly basis, patients' mineral and bone disease. However, CMS has not explained how it will ensure the accuracy of the data and information reported by facilities either via claims or CROWNWeb, such as through periodic audit of a sample of facilities. The QIP has financial implications for facilities as well as for beneficiaries and taxpayers. Thus, CMS should develop a system for ensuring that the data and information reported by ESRD providers for the QIP is accurate.

Future QIP considerations

There are several issues that CMS should consider in updates to the QIP. First, CMS should start considering the development of measures that support the use of home dialysis and more frequent hemodialysis. Home dialysis offers patients more freedom, flexibility, and independence and can promote an individual's effort to continue to work or gain employment. A recent randomized clinical trial sponsored by the National Institutes of Health reported that, compared to thrice-weekly conventional hemodialysis, more frequent hemodialysis was associated with more favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score.[8] Measures that CMS could explore using include ones assessing health-related quality of life (physical health and mental health status); control of blood pressure; and control of phosphate levels. Researchers have used these measures in comparing more frequent hemodialysis and home dialysis to conventional in-center hemodialysis.

Second, the Commission remains concerned that the proposed QIP does not hold all facilities accountable for the quality of care furnished to all of their patients. We raised this issue in previous

[8] The FHN Trial Group. 2010. Incenter hemodialysis six times per week versus three times per week. *New England Journal of Medicine* 363, no. 24: 2287–2300.

comment letters on CMS's proposed rule to implement the dialysis prospective payment method and 2012 QIP.[9] We are encouraged that beginning in 2014, peritoneal dialysis patients will be included in the measure assessing dialysis adequacy. However, this measure does not assess dialysis adequacy for hemodialysis patients receiving more than three treatments per week. In addition, pediatric patients are not included in the clinical performance measures proposed for the QIP in 2013 and 2014.

Finally, the Commission will begin modeling the effects of increasing the percentage of payments set aside for quality. Beginning with a small set-aside had several advantages, including minimizing the adverse effect on providers who initially are not able to meet the quality criteria. But as ESRD providers become more accustomed to their payment being linked to quality, Medicare should consider expanding the proportion of payments that are set aside.[1]

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

[9] Hackbarth, Glenn M., Medicare Payment Advisory Commission. 2009. Letter to Charlene Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services. December 16.