MEDPAC Medicare Payment Advisory Commission

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September 23, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3206–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: File code CMS-3206-P

Dear Dr. Berwick:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled Medicare Program; End-stage renal disease quality incentive, published in the *Federal Register*, vol. 75, no. 155, pages 49215 to 49232. This proposed rule implements provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that modernize the outpatient dialysis payment method by implementing a quality incentive program (QIP) beginning in 2012. 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 that providers currently bill separately, and linking payment to quality.[1] CMS is implementing a broader payment bundle for dialysis services beginning in 2011. Importantly, the ESRD QIP will be the first Medicare program that links any provider or facility payment to performance based on outcomes.

Overall, CMS's proposal to link payment to quality is consistent with the Commission's 2004 recommendation. However, we have specific comments on the following issues concerning the QIP's implementation:

- The method for calculating the total performance score for the end-stage renal disease (ESRD) QIP measures: The values of the weights assigned to the three ESRD QIP measures.

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

- Future QIP considerations: Using ESRD QIP measures that are outcome-based and reflect the care of all dialysis patients.

Methodology for calculating the total performance score for the ESRD QIP measures

In the final rule for the Medicare ESRD prospective payment system published on August 12, 2010, CMS finalized the three performance measures for 2012—the initial year of the ESRD QIP:

- Anemia management: Percentage of beneficiaries with an average hemoglobin less than 10 g/dL. Anemia associated with chronic renal failure is often treated with erythropoietin stimulating agents (ESAs) and iron supplements. Currently, the Food and Drug Administration (FDA) recommends that patients treated with ESAs should achieve a target hemoglobin value between 10 and 12 g/dL.[2]
- Anemia management: Percentage of beneficiaries with an average hemoglobin greater than 12.0 g/dL. The labeling instructions for ESAs states that patients with chronic renal failure experience an increased risk for death and serious cardiovascular events when administered ESAs with a target hemoglobin value of greater than 13 g/dL.
- Hemodialysis adequacy: Percentage of 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. A greater percentage of patients with an average URR greater than 65 percent suggests better dialysis adequacy.

In calculating each facility's performance score, CMS proposes to weight the hemoglobin measure assessing the potential underuse of ESAs (i.e., the percentage of beneficiaries with an average hemoglobin less than 10 g/dL) as 50 percent of the total performance score. The remaining 50 percent of the score would be divided equally between the other hemoglobin measure that potentially assesses overuse of ESAs (i.e., the percentage of beneficiaries with an average hemoglobin greater than 12 g/dL) and the hemodialysis adequacy measure.

We are concerned that CMS's proposal does not assign a sufficient value to the dialysis adequacy measure. Patients who receive insufficient dialysis are at greater risk of mortality and other serious events than patients whose treatment meets adequacy guidelines. Although the proportion of patients who are currently receiving adequate dialysis is high and has increased over time, under the imminent broader payment bundle, facilities will have a greater financial incentive to undertreat patients than to overtreat them.

We suggest that CMS re-evaluate the weights assigned to each performance measures. One option for the agency to consider is to assign higher equal weights to the adequacy measure and the

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[2]FDA. 2010.Information for healthcare professionals: Erythropoiesis stimulating agents (ESA) [Aranesp (darbepoetin), Epogen (epoetin alfa), and Procrit (epoetin alfa)]. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126481.htm.

anemia measure that might suggest the under-provision of necessary care (e.g., weight each measure at 40 percent). Under this option, a lower weight could be assigned to the anemia measure that might suggest overuse of ESAs. We recognize that patients with high target hemoglobin levels are at increased risk for mortality and serious morbidity. Nonetheless, under the broader payment bundle, facilities will have less incentive to furnish larger doses of ESAs that are associated with higher hemoglobin levels compared to the current payment method in which facilities are paid according to the number of units of these drugs given to patients.

Future QIP considerations

There are several issues that CMS should consider in future QIP changes and updates. First, the Commission believes that the measures used in pay-for-performance initiatives should evolve over time.[3] In the future, CMS should consider linking payment to measures associated with improved patient outcomes, such as lower rates of dialysis-related (e.g., due to infections) hospital and emergency department utilization and higher rates of kidney transplantation. These measures are associated with improved quality as well as lower expenditures. CMS has established processes to collect data on hospitalization and transplantation and provides confidential reports to each ESRD facility about their performance compared to averages for the facilities' state, ESRD network, and all dialysis facilities. CMS should evaluate the feasibility of using—with appropriate risk adjustment—this existing data resource for the ESRD QIP.

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 our 2009 comment letter on CMS's proposed rule to implement the dialysis prospective payment method.[4] The proposed QIP does not measure anemia management for patients who do not receive ESAs, nor does it measure dialysis adequacy for home dialysis patients or hemodialysis patients receiving more than three treatments per week. In addition, the proposed QIP excludes pediatric patients (under 18 years of age).

We are encouraged that CMS is currently developing pediatric measures and that as of July 1, 2010the agency will be collecting information that can be used in the future to measure dialysis adequacy for all patients. Nonetheless, CMS lacks a plan for collecting data on anemia management for all patients, not just those receiving ESAs. As we mentioned earlier, the broader payment bundle beginning in 2011 will create incentives for facilities to under-furnish care, including therapies used to treat anemia. Our concern is that patients whose anemia is not managed appropriately may require blood transfusions, a service which will be paid for outside the new dialysis payment bundle.

CMS should consider collecting anemia management information for all patients either by requiring facilities to submit such information on ESRD facility claims or by accessing such information that will be collected by CMS's web-based system—the Consolidated Renal

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[3]Medicare Payment Advisory Commission. 2005. *Medicare payment policy*. Washington DC: MedPAC.
[4]Hackbarth, Glenn M., Medicare Payment Advisory Commission. 2009. Letter to Charlene Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services. December 16.

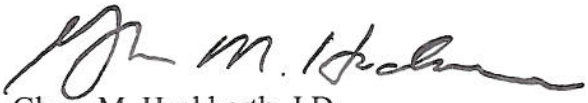
Operations in a Web-Enabled Network (CROWNWeb). Because CMS is still testing the CROWNWeb system, it may be more expedient to collect anemia management information on ESRD facility claims.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC 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, MedPAC's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

GMH/nr/w