MEDPAC Medicare Payment Advisory Commission

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December 16, 2009

Charlene Frizzera, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1418–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**RE: File code CMS-1418-P**

Dear Ms. Frizzera:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled Medicare Program; End-stage renal disease prospective payment system published in the *Federal Register*, vol. 74, no. 187, pages 49922 to 50102. 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 broadening the payment bundle in 2011 and implementing a quality incentive program (QIP) beginning in 2012. We appreciate your staff's ongoing efforts to administer and improve payment systems for dialysis and other services, particularly considering the agency's competing demands.

We address the following issues concerning the proposed outpatient dialysis payment method:

- defining the proposed end-stage renal disease (ESRD) payment bundle,
- defining the unit of payment,
- adjusting the base payment rate for patient-level characteristics,
- adjusting the base rate for providing self-dialysis training services,
- developing a low-volume adjustment factor,
- capturing the costs of Part D drugs when setting the base payment rate,
- implementing an outlier policy,
- monitoring the quality of care, and
- implementing the ESRD QIP.

**Defining the proposed ESRD payment bundle**

The Commission has a longstanding recommendation to modernize the outpatient dialysis payment system.[1] We have repeatedly said that Medicare can provide incentives for controlling costs and promoting quality care by broadening the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill separately and by linking payment to quality. A bundled rate would create incentives for facilities to furnish services more efficiently. For example, it would remove the financial incentives for facilities to overuse separately billable drugs under the current payment method.

Overall, CMS's proposal to broaden the payment bundle is consistent with the Commission's recommendation. CMS is proposing that the broader payment bundle include:

- injectable erythropoiesis-stimulating agents (ESAs) and their oral equivalents,
- other injectable drugs and their oral equivalents,
- laboratory tests ordered by ESRD facilities,
- laboratory tests ordered by physicians who are paid the Part B monthly capitated payment,
- dialysis-related equipment and supplies furnished by facilities,
- self-dialysis training services furnished by facilities, and
- selected ESRD-related drugs that are currently covered only under Part D.

We offer specific comments about CMS's proposal that the bundle include ESRD-related drugs currently covered under Part D and laboratory tests.

*Including ESRD-related Part D drugs in the broader payment bundle*

In our March 2009 report, the Commission said that Part D drugs used to treat ESRD-related comorbidities may be another candidate for the expanded bundle. A dialysis payment bundle that includes Part D drugs used to treat ESRD-related comorbidities would prevent providers from shifting costs by substituting Part D drugs for services covered under the payment bundle.

To implement this policy, CMS should ensure that all ESRD-related drugs—oral and injectable—are included in the outpatient dialysis payment bundle. The proposed list of national drug codes used to identify former Part D drugs should include both the injectable and oral forms of the drugs. For example, Table 6 in the proposed rule (the list of national drug codes used to identify former

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[1] Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Part D drugs) did not include all of the injectable forms of vitamin D analogues and oral levocarnitine. Finally, CMS will need to annually review and update the national drug codes of oral drugs included in the payment bundle.

*Including ESRD-related laboratory tests in the broader payment bundle*
CMS has proposed that the bundle include laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating dialysis beneficiaries. CMS should identify the specific tests that are included in the broader payment bundle. Identifying the specific tests would further enhance the transparency of the bundle for facilities, physicians, and beneficiaries.

**Defining the unit of payment**
CMS proposed to maintain the per session treatment as the unit of payment. While we agree with the agency that providers could stint on furnishing treatments without either a stringent quality monitoring system or a requirement that a minimum number of treatments be furnished to ensure that quality does not decline, the Commission has previously said that a longer unit of payment is consistent with several aspects of dialysis care.[2] For example, a weekly unit payment corresponds to the typical weekly interval for peritoneal dialysis. In addition, Medicare pays nephrologists a monthly capitated payment for caring for dialysis beneficiaries. Thus, the Secretary should reconsider the unit of payment once the agency has enhanced the dialysis quality monitoring system, as we discuss later in this letter. A strengthened monitoring system should help CMS assess the use of dialysis services, identify lapses in care, give providers an incentive to furnish all clinically necessary care, and lead to quality improvements.

**Adjusting the base payment rate for patient-level characteristics**
For patients 18 years or older, CMS is proposing to adjust the base payment rate for:

- age: 18–44, 45–59, 60–69, 70–79, and 80+;
- sex;
- measures of body mass index and body surface area;
- onset of dialysis (for the first four months of dialysis); and
- presence of the following comorbidities: alcohol and drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, infection, gastrointestinal tract bleeding, hereditary hemolytic and sickle cell anemias, cancer, myelodysplastic syndrome, and monoclonal gammopathy.

For the approximately 2,000 patients who are younger than 18 years, CMS is proposing to adjust payment for:

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[2] Medicare Payment Advisory Commission. 2003. *Report to the Congress: Modernizing the outpatient dialysis payment system*. Washington, DC: MedPAC.

- age: patients less than 13 years and between 13 and 17 years of age;
- dialysis method: hemodialysis versus peritoneal dialysis; and
- two comorbidity categories (none, and one or more comorbidities among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest, and diabetes).

In general, the Commission believes that, to ensure payment accuracy, CMS should adjust the base payment rate for factors that significantly predict facilities' resource use. In addition, CMS should use factors for which facilities are capable of reporting in an accurate manner. Ensuring payment accuracy is important for two reasons. First, inaccurate payment rates might give ESRD facilities an incentive to stint on care or to select certain patients over others. Second, when services are misvalued, Medicare is paying too much for some services and not enough for others and therefore is not spending taxpayers' and beneficiaries' money wisely.

We are concerned that paying more when beneficiaries have septicemia could give providers an incentive to not provide the necessary care to minimize the risk of infections. In addition, paying more for septicemia could reverse the effectiveness of Medicare's quality improvement effort that promotes the use of arteriovenous fistulas, which have a lower risk of septicemia than catheters. If CMS judges that paying more for septicemia improves payment accuracy, then the agency should offset the potential unintended effects by including the occurrence of septicemia in the QIP. Under such an approach, there would be a payment adjustment for beneficiaries with septicemia, but facilities that do not meet or exceed minimum performance standards for septicemia would receive payment reductions.

We are also concerned about the accuracy of the proposed payment method because of the omission of race and ethnicity. The agency stated that these variables significantly predict total composite rate costs and total separately billable payments but did not include them because: (1) current data on race and ethnicity are not of sufficient quality to use as a basis for payment adjustments, (2) racial and ethnic categories are not well defined, and (3) it is not possible to quantify an individual's race absent a genetic test to determine racial status.

If race and ethnicity significantly predict providers' resource needs, then these factors should be included as an adjuster. Alternatively, CMS could include clinical factors that are correlated with race and ethnicity that would make moot the effect of race and ethnicity on predictors' resource needs. Implementation issues should not prevent the agency from adjusting payment for race and ethnicity. CMS should consider a recent recommendation from the Institute of Medicine to use current Office of Management and Budget categories to collect race and ethnicity data.[3] There are ample opportunities to collect such data for dialysis patients, such as via the ESRD medical evidence form.

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[3] Institute of Medicine. 2009. *Race, ethnicity, and language data: Standardization for health care quality improvement.* Washington, DC: IOM. http://iom.edu/Reports/2009/RaceEthnicityData.aspx.

Including payment adjusters for beneficiaries' demographic and clinical characteristics would result in some beneficiaries having higher copayments than others. For example, according to the proposed rule, the copayments for African Americans and females would be higher than those for white beneficiaries and men, respectively. Such adjustments raise questions about the ability of certain beneficiary groups to afford higher copayments. The Commission intends to study this issue in the future.

The proposed rule did not provide sufficient information to evaluate the contribution of each adjuster to predict facilities' resource use. We urge CMS to report: (1) the contribution of each adjuster on the ability of the proposed payment method to predict cost differences at the facility level (i.e., the facility-level *R*-squared), (2) the effectiveness of the model in predicting high-cost cases, and (3) the proportionality between a facility's payments and its expected costs.

**Adjusting the base rate for providing self-dialysis training services**

Patients choosing home dialysis must take part in a training program in which they are instructed in how to self-administer dialysis. Currently, facilities receive a payment in addition to the composite rate for furnishing self-dialysis training services—$12 per training session for continuous ambulatory peritoneal dialysis and $20 per training session for continuous cycler-assisted peritoneal dialysis and for hemodialysis. CMS makes a case that self-dialysis training services are "renal dialysis services" and thus should be included in the broader payment bundle.

However, to help ensure payment accuracy and to continue to promote the use of home dialysis, CMS should adjust the base payment rate for providing training services. A prospective payment system (PPS) that includes a payment adjuster for training services should create incentives for providers to furnish such services. Later in this letter, we offer suggestions to CMS for monitoring the impact of the new payment method on the use of training services and home dialysis.

**Developing a low-volume adjustment factor**

CMS is proposing a 20.2 percent increase in the base rate to account for the costs low-volume facilities incur. A low-volume ESRD facility is defined as one that furnishes fewer than 3,000 treatments in each of the three years before the payment year and that has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. For purposes of determining eligibility for the low-volume adjuster, the number of treatments the facility furnished would be equal to the sum of the number of treatments the facility actually furnished and the number of treatments other facilities furnished that are under common ownership and 25 road miles or less from the facility in question. CMS would grandfather those commonly owned facilities that were in existence and certified for Medicare participation on or before December 31, 2010.

The Commission has previously stated that low-volume adjustments should be developed based on the proximity of a facility to all other facilities and the total volume of services a facility furnishes.[4] Consistent with this principle, the Commission urges CMS to implement a low-volume adjuster that is based on the total volume and proximity of the facility in question to other facilities. In setting the distance limit, CMS should consider the regularity and frequency of dialysis care that ESRD patients need. CMS based the distance limit on the 25-mile standard used to adjust hospital payments for low volume. Given that most dialysis patients are treated three times weekly in a facility, it is not clear whether the 25-mile standard is appropriate for the new ESRD PPS, and CMS may wish to evaluate shorter distance thresholds.

**Capturing the costs of Part D drugs when setting the base payment rate**
CMS proposes using the Retiree Drug Subsidy (RDS) payments as a proxy to capture the costs associated with ESRD-related drugs for some beneficiaries without Part D coverage. The RDS is aimed at employers that offer private prescription drug coverage to their retirees under a group health plan. Under the RDS program, Medicare provides payments to employers to continue to provide prescription drug benefits for their retirees in order to give an incentive to employers to remain the primary source for prescription drug coverage. The RDS, which equals 28 percent of each qualifying retiree's allowable prescription drug costs attributable to gross prescription drug costs between the applicable cost threshold and cost limit, was intended to be actuarially equivalent to the level of drug spending if the beneficiary had been enrolled in Part D.

CMS makes a case for estimating the costs of furnishing Part D oral drugs to dialysis patients by using Part D spending data and a portion of the RDS subsidy. Shifting the portion of RDS payments associated with ESRD-related drugs to the new ESRD PPS is consistent with the statute's budget-neutrality provision. Specifically, MIPPA required that the estimated total payments under this title for 2011 for dialysis services equals 98 percent of the estimated total payments that would have been made under title XVIII of the Social Security Act if the ESRD PPS were not implemented. CMS could estimate the ESRD-related percentage of the $3.8 billion in subsidy payments by determining the share of: (1) dialysis patients in qualifying RDS plans and (2) total Part D drug spending attributable to ESRD-related drugs.

We assessed the extent to which this proposal captures the costs facilities will incur to furnish ESRD-related Part D drugs to patients. Using the Part D enrollment file and outpatient dialysis claims data, we found that about 71 percent of dialysis patients had Part D coverage and 11 percent were in a RDS plan in 2007. The 19 percent of patients not covered under Part D or in a RDS plan fall into one of four groups:

[4] In our March 2003 report to the Congress, the Commission recommended that a 15-mile radius be used to create a low-volume adjustment to the rates in the inpatient PPS.

- receiving primary drug coverage through an employer group health plan that does not participate in the RDS but is as least as generous as Part D;
- receiving primary medical and drug coverage through other plans that Medicare does not subsidize, such as the Federal Employees Health Benefits Program and the Department of Veterans Affairs;
- receiving drug coverage from a plan of lesser value than Part D (and thus not eligible for the RDS subsidy); or
- without drug coverage.

Some observers are concerned that CMS's proposal does not sufficiently cover the costs facilities would incur in furnishing Part D ESRD drugs, because the estimated payment rate does not explicitly cover the cost of furnishing drugs to beneficiaries: (1) with Part D coverage who are not currently prescribed oral ESRD drugs, (2) without any Part D coverage, and (3) who are now receiving primary drug coverage through an employer group health plan or other plan that Medicare does not subsidize but who will eventually be covered by Medicare.

Whether Medicare's compensation for ESRD services under the new PPS adequately pays facilities remains to be seen. Including ESRD drugs now covered under Part B and Part D in the bundle may lead to better management of drug therapy, which may lead to improvements in the efficiency of care. The Commission's annual analysis of the adequacy of Medicare's payment would reveal whether Medicare's payment adequately covers facilities' costs.

**Implementing an outlier policy**

CMS is proposing to implement an outlier payment policy for the portion of the broader payment bundle composed of the drugs and services that are currently separately billable under Part B and Part D. MIPPA mandated a payment adjustment for high-cost outliers due to unusual variations in medically necessary care, including variations in the use of ESAs.

To receive outlier payments, some facilities may not efficiently furnish drugs and laboratory tests that are profitable. Consequently, CMS should continue to use its ESA monitoring policy when administering the outlier policy. In addition, the agency should develop clinical criteria for the use of other drugs and laboratory tests (that are eligible for outlier payments) to ensure their appropriate use.

**Monitoring the quality of care**

In the Commission's recommendation on modernizing the outpatient dialysis method, we have stated that it is critical that broadening the payment bundle be coupled with efforts to: (1) continue procedures that monitor, report on, and improve the quality of care; (2) develop new measures to monitor the use of services; and (3) link providers' payments to quality of care.

The proposed rule did not specifically mention the agency's plan for monitoring the quality of care. Currently, one approach researchers use to monitor quality is to analyze the drug utilization data that providers report on the Part B claims submitted for Medicare payment. CMS should continue to collect information on the volume and use of drugs and other services included in the broader bundle. In addition, the volume of drugs and other services eligible for such information would be needed under CMS's current proposal that defines outlier services as those items and services that are now separately billable under Part B or Part D.

In addition to measuring the provision of services in a broader payment bundle, we urge CMS to begin to measure and report on patients' satisfaction with their quality of care. In the proposed rule, CMS said that patient satisfaction measures do not currently exist because there is no validated data collection tool. In our March 2000 report, we recommended that the agency collect information on ESRD patients' satisfaction with the quality of and access to care. Such information would enable policymakers and providers to identify access and quality problems and vulnerable subpopulations among ESRD patients.

We also urge CMS to monitor the effect of the new payment method on use of training services and home dialysis. More specific coding would facilitate such an effort by enabling CMS and researchers to better analyze trends in the use of these services. For example, specific codes on facility claims could identify particular types of training services, home dialysis services, and in-center dialysis services.

We also urge the agency to develop a "real-time" system that reports rates of hospitalization, emergency department use, and mortality for the dialysis population. Publication of such information could help CMS and researchers monitor unintended effects of the new payment method. While hospitalization and mortality data are publicly available, there is a lag in the publication of the most recent data.

**Implementing the ESRD QIP**

For calendar year 2012, CMS is proposing a pay-for-performance initiative using two measures that assess anemia management and one measure that assesses dialysis adequacy and is proposing to obtain this information from claims submitted by ESRD facilities. MIPPA required that a QIP begin in 2012, that the program include measures of anemia management and dialysis adequacy, and that the initial performance standard for a facility be the lesser of the performance of such facility between 2007 and 2009 or a performance standard based on national rates. The payment rate of facilities that do not meet the performance standard could be reduced by a maximum of 2 percent.

We are concerned that CMS's proposed QIP for 2012 does not apply to all Medicare dialysis patients. For example, the proposed QIP does not measure anemia management for Medicare patients who do not receive an ESA. In addition, the proposed QIP does not measure dialysis adequacy for home dialysis patients and pediatric patients. CMS is seeking input about ideas about assessing adequacy for home dialysis and pediatric dialysis patients.

To ensure that facilities continue to provide clinically appropriate care, CMS should collect and the QIP should capture anemia management information for all Medicare patients. Under the new PPS, some facilities might have an incentive to underutilize services in the broader bundle, including ESAs. Anemia management information is needed for patients not on ESAs to ensure that facilities are continuing to furnish clinically appropriate care.

The QIP should hold all facilities accountable for their quality, including dialysis adequacy. We urge CMS to move forward and collect monthly information on dialysis adequacy for all Medicare patients as soon as possible. According to CMS's Renal Dialysis Facility Manual, facilities must monitor the adequacy of dialysis treatments monthly for facility patients. Home dialysis patients may be monitored less frequently, but not less than quarterly.[5] As proposed, the QIP is not holding accountable ESRD facilities that disproportionately treat home dialysis and pediatric patients.

Lastly, CMS should clarify whether facilities that do not report quality information on their claims submitted to Medicare are included in the QIP. It is not clear whether such facilities would be at risk for a reduction of up to 2 percent of their payment rate.

**Conclusion**

The Commission 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 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 Miller, MedPAC's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

GMH/nr/cw

[5] http://www.cms.hhs.gov/transmittals/downloads/R93RDF.pdf.

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