MEDPAC Medicare Payment Advisory Commission

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August 30, 2013

Marilyn Tavenner
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–1526–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 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," published in the *Federal Register*, vol. 78, no. 130, pages 40836 to 40890. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2014 and the ESRD quality incentive program (QIP) for payment year 2016. 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 provisions in the proposed rule about the proposed adjustment to the 2014 ESRD prospective payment system (PPS) base rate to reflect the change in the use of ESRD drugs. We comment also on the following provisions of the ESRD QIP for payment year (PY) 2016:

- The proposed QIP performance measures for PY 2016
- The proposed weighting of "clinical measures" versus "reporting measures" in the QIP
- The proposed minimum data requirement for scoring the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure in the QIP
- Future QIP considerations

Proposed adjustment to the 2014 ESRD PPS base rate to reflect change in use of ESRD-related drugs and biologics

Historically the implementation of PPSs in Medicare has been characterized by providers quickly reducing use of services included in the payment bundle, resulting in periods of "overpayment"—where providers benefit from the change in practice patterns and the Medicare program does not realize savings until the payment rate is adjusted. This pattern has been seen in the inpatient, home health, skilled nursing facility, and long-term care hospital PPSs for example. The Commission's long held position over many reports and comment letters is that payment rates are not intended to protect each and every provider, but instead to protect beneficiary access while conserving beneficiaries' and taxpayers' resources. In general, the Medicare program should move expeditiously to correct overpayments. At the same time, the payment adjustments should be made in a way to give providers time to respond in order to not disrupt beneficiary access.

Section 632 of the American Taxpayer Relief Act (ATRA) of 2012 mandates that the Secretary, for services furnished on or after January 1, 2014, reduce the ESRD PPS base rate to reflect the change in per patient utilization of ESRD drugs and biologicals between 2007 and 2012. The law requires that the Secretary, in making this reduction, take into account the most recently available data on average sales prices and changes in prices for drugs and biologicals reflected in the ESRD market basket.

CMS calculated the change in drug utilization between 2007 and 2012 and the proposed 2014 payment reduction of $29.52 per treatment by:

- Determining 2012 per treatment use of ESRD drugs using 2012 claims included in the National Claims History file as of December 31, 2012. For the final rule, CMS will use the calendar year (CY) 2012 claims file updated through June 30, 2013.
- Determining 2007 per treatment use of ESRD drugs as established in the CY 2011 ESRD PPS final rule.
- Applying 2014 ESRD drug prices to the 2007 and 2012 per treatment use of ESRD drugs. The agency derived 2014 prices by inflating 2011 drug prices (established in the CY 2011 ESRD PPS final rule) to 2014 levels using the ESRD market basket, the productivity adjustment, and the wage index budget-neutrality factors.
- Determining the per treatment difference (in 2014 prices) between the per treatment amounts for 2012 ($51.42) and 2007 ($83.76).
- Adjusting the net difference between the 2007 and 2012 per treatment use of ESRD drugs ($32.34) by the same standardization factors that were used to establish the 2011 ESRD PPS rate. [1] This calculation results in per treatment payment reduction of $29.52, or 11.98 percent of the 2014 proposed base rate of $246.47.

[1] These factors, which CMS established in the CY 2011 ESRD PPS final rule, are: the 94.7 percent standardization factor, the 1 percent outlier adjustment factor, and the 98 percent adjustment factor mandated by the Medicare Improvements for Patients and Providers Act of 2008.

Comment

MedPAC has conducted its own analyses of the changes in drug utilization using CMS's methods and alternative methods to test for sensitivity. We conclude that CMS's methods are consistent with ATRA's mandate and appear to be reasonable. The proposed reduction in the PPS base rate of $29.52 is comparable to our estimate, derived by using CMS's proposed method to calculate the difference, in 2014 dollars, between 2007 per treatment use of ESRD drugs and 2012 per treatment use of ESRD drugs.[2]

The next step is to consider the impact of the rebased payment. When coupled with the legislated update for PY 2014, the net impact is a rate reduction of 9.4 percent. While Medicare margins (Medicare payments relative to providers' costs averaged across providers) are not the only measure of payment adequacy, they provide a convenient reference point to consider impacts.

Historically the distribution of Medicare margins for freestanding dialysis facilities suggests that some providers will more readily be able to absorb the payment adjustment than others. Based on recently available 2011 cost report data (the first year of the new PPS) for freestanding facilities, we estimate an aggregate 2011 Medicare margin of about 4 percent (note that this is based on incomplete 2011 cost report data).[3] The distribution of margins in 2011 shows variation in performance among freestanding facilities. One-quarter of facilities had margins at or below negative 9 percent and one-quarter of facilities had Medicare margins of at least 10 percent. Our preliminary analysis suggests that nearly two-thirds of beneficiaries received treatment at dialysis facilities with positive Medicare margins.

Given the preliminary aggregate 2011 margin and the distribution of margins across providers, the Secretary should take action to freeze the payment rates for 2014 at the 2013 level, consistent with our recommendation to the Congress in our March 2013 report.[4] This would accomplish several goals. First, it would start to move the payment system toward greater accuracy and in so doing protect scarce Medicare resources paid by the beneficiary and the taxpayer. Second, it would protect beneficiary access and give the Commission the ability to report back to the Congress on any developing access issues should they occur. Third, it would give providers time to respond to payment changes by identifying efficiencies in care (one of which is discussed below). And finally it would give CMS, MedPAC, and the Congress time to consider policies that should be considered concurrent with further rebasing—targeting facilities critical to beneficiary access (rather than protecting industry-wide payment rates); improving the casemix measure; and establishing a QIP measure that assesses the adverse consequences of anemia under-management. Each of the issues is discussed below.

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[2] Inflated to 2014 prices, we found a decline between 2007 and 2012 of about $29 per treatment in the use of the 11 highest volume ESRD drugs.

[3] The aggregate 2011 Medicare margin reported in this letter is preliminary and subject to change once the Commission analyzes more complete cost report data from CMS. For this analysis cost reports for 2011 were not yet available for about 30 percent of all freestanding facilities. In addition, this analysis includes only freestanding dialysis facilities that elected to be paid under the PPS and reported 2011 cost data for at least 10 months.

[4] Medicare Payment Advisory Commission. 2013. *Medicare payment policy*. Washington, DC: MedPAC.

Regarding our estimated 2011 Medicare margin, because CMS has not yet examined the appropriateness of the costs that facilities included on their cost reports, we do not know whether the costs that dialysis facilities include on their cost reports are overstated. (If providers' costs are overstated, then the Medicare margin would be understated.) The Commission's analysis of the Medicare margin and providers' costs uses only Medicare-allowable costs. Historically dialysis facilities have included non-allowable costs on their cost reports. Several of the agency's previous audits (in 1988, 1991, 1996, and 2001) of dialysis facilities' cost reports have found that facilities' allowable costs ranged from about 90 percent to 96 percent of submitted costs.[5] CMS's recent audit of a sample (100) cost reports submitted by home health agencies demonstrates the importance of validating these data. The agency found that the majority of home health agencies in the audit sample overstated their costs by an average of about 8 percent.[6]

Medicare policy should focus on protecting facilities critical to beneficiary access

Medicare payment policy should be focused on assuring beneficiary access to needed care, not on protecting the financial viability of each and every provider. In setting payment policy, the Commission's position is to pay a rate consistent with the efficient provider and to make targeted adjustments to protect access where needed. The Medicare program should not maintain higher rates across the board as a method of protecting access.

In addition to phasing-in the payment adjustment, to ensure beneficiaries' continued access to care, CMS should expeditiously improve the design of the low-volume payment adjuster. We previously reported that some facilities receiving the low-volume adjustment in 2011 were near (within 2 miles of) another facility.[4] Medicare and dialysis beneficiaries would be better served by an adjuster that targets low-volume facilities that are not in close proximity to another facility. Only low-volume facilities that are necessary to maintain access—those located distantly from other providers—should receive enhanced payment.

Payment system may continue to stimulate more use of home dialysis

Compared with in-center dialysis, researchers have concluded that home-based dialysis offers patients greater autonomy, improved quality of life, and enhanced satisfaction.[7] Results from a survey suggest that nephrologists believe that home-based dialysis methods are underused in the United States.[8] Most industrialized countries have higher use of home dialysis than the United

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[5] Medicare Payment Advisory Commission. 2006. *Medicare payment policy*. Washington, DC: MedPAC.

[6] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. Medicare program; home health prospective payment system rate update for CY 2014, home health quality reporting requirements, and cost allocation of home health survey expenses. Proposed rule. *Federal Register* 78, no. 128 (July 3): 40271–40308.

[7] Rubin, H. R., N. E. Fink, L. C. Plantinga, et al. 2004. Patient ratings of dialysis care with peritoneal dialysis vs hemodialysis. *JAMA* 291 (6): 697–703.

[8] In addition, to maximize survival, wellness and quality of life, surveyed nephrologists supported the expanded use of home-based methods. Mendelssohn, D.C., S. R. Mullaney, B. Jung, et al. 2001. What do American Nephrologists think about dialysis modality selection? *American Journal of Kidney Diseases* 37 (1): 22–29.

States.[9] Nonetheless, in the United States, use of home dialysis methods has steadily declined, from 17 percent in the early 1990s to about 8 percent in 2010.

Compared to in-center dialysis, home dialysis is an example of an efficiency that has the potential to improve quality of life and satisfaction of care for beneficiaries as well as lower providers' costs. Historically, providers' costs for furnishing home dialysis have been lower than their costs for furnishing in-center hemodialysis; both types of dialysis offer comparable quality. Under the PPS, the use of home dialysis has modestly increased. CMS reports that the proportion of beneficiaries receiving home dialysis increased from about 8 percent in 2009 to nearly 9 percent in 2011.[10]

Reanalyze the accuracy of the PPS's case-mix adjusters

To ensure the accuracy of the ESRD PPS, the Secretary should revisit the PPS's case-mix adjusters that adjust the base rate for patients' age, gender, body surface, body mass, duration of renal replacement therapy, and six comorbidities. ATRA requires that the Secretary conduct an analysis of the case-mix payment adjustments under the PPS by January 1, 2016. It is unknown whether the changes in the use of dialysis drugs that have occurred since the PPS was implemented have affected the significance and magnitude of the PPS's case-mix adjusters.[11]

The ESRD QIP for payment year 2016

For PY 2016, the fifth year of the ESRD QIP, CMS is proposing 14 measures. The proposed PY 2016 QIP would use 9 of the measures finalized for the PY 2015 QIP and would introduce 5 new measures:

Measure topic	Measure	Type of measure
Low dialysis adequacy	Kt/V measure for adult hemodialysis patients	Clinical
	Kt/V measure for peritoneal dialysis patients	Clinical
	Kt/V measure for pediatric hemodialysis patients	Clinical
Anemia management	Hemoglobin > 12 g/dL	Clinical
	Patient informed consent for treatment*	Clinical
	Pediatric iron therapy (reporting of hemoglobin levels, dates, use of iron agents, and selected lab values*	Reporting
	Anemia management (reporting of ESA dosage and hemoglobin levels)**	Reporting
Vascular access	Use of AV fistulas	Clinical
	Use of catheters	Clinical

[9] United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2012. *USRDS 2012 annual data report*. Bethesda, MD: NIDDK.
[10] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. *ESRD prospective payment system. Overview of 2011 claims-based monitoring program*. Baltimore, MD: CMS.
[11] To develop the case-mix adjusters, CMS used regression equations for (facility-level) composite rate and (patient-level) separately billable ESRD services.

Bone mineral metabolism management	Mineral metabolism (reporting of serum phosphorus levels)** Proportion of patients with hypercalcemia*	Reporting Clinical
Patient safety	NHSN bloodstream infection in hemodialysis outpatients (the number of new positive blood culture events based on blood cultures)*	Clinical
Patient experience	ICH CAHPS survey (administering ICH CAHPS survey by a third-party approved vendor and submitting results to CMS)**	Reporting
Comorbidities	Comorbidity reporting of up to 24 comorbidities*	Reporting

Note: Kt/V (dialyzer urea clearance x dialysis time/urea volume). g/dL (grams/deciliter).
NHSN (National Healthcare Safety Network). ICH CAHPS (In-center hemodialysis Consumer Assessment of Healthcare Providers and Systems survey).
*Measure is new to the ESRD QIP. **Measure is revised, expanded, or converted to a clinical measure.

As proposed, the 2016 QIP would include nine "*clinical measures*" and five "*reporting measures*." According to CMS, "*clinical measures*" assess the quality of care provided to individual patients using facility performance on specific clinical indicators. "*Reporting measures*" assess whether a facility has reported quality of care data as outlined in rulemaking to support quality improvement efforts.[12]

In the remainder of this section, we comment on: (1) the proposed measure for reporting up to 24 comorbidities; (2) the 2016 ESRD QIP does not assess anemia under-treatment; and (3) the proposed measure that assesses high hemoglobin levels.

The proposed measure for reporting up to 24 comorbidities

For PY 2016, CMS is proposing a measure that would award points to facilities that report up to 24 comorbidities for qualifying patients on an annual basis into CROWNWeb.[13] Currently, providers report these comorbidities on CMS's Medical Evidence Reporting Form 2728 when a Medicare beneficiary begins dialysis. CMS gives two reasons for wanting to collect the comorbidity data annually:

- First, the proposed measure offers a mechanism for collecting patient comorbidity information on an annual basis. CMS might, in the future use the comorbidity data that is collected to risk adjust two potential QIP measures—a standardized hospitalization ratio

[12] CMS. 2013. http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-07-01.html.
[13] Qualifying patients are hemodialysis or peritoneal dialysis patients treated at the facility as of December 31 of the performance period. The 24 comorbidities are: congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, history of hypertension, amputation, diabetes on oral medications, diabetes without medications, diabetes currently on insulin, diabetic retinopathy, chronic obstructive pulmonary disease, tobacco use, malignant neoplasm, non-renal congenital abnormality, toxic nephropathy, alcohol dependence, drug dependence, inability to ambulate, inability to transfer, needs assistance with daily activities, institutionalization-assisted living, institutionalization-nursing home, and institutionalization-other institution.

(SHR) and a standardized mortality ratio (SMR). The National Quality Forum has endorsed the SHR and SMR measures.
- Second, the reporting data will improve CMS's understanding of the risk factors that contribute to ESRD morbidity and mortality.

If CMS considers the comorbidity data necessary for the administration of the ESRD program, then the agency should consider requiring facilities to annually update patients' comorbidities as a condition for coverage instead of including it as a QIP measure. CMS, in the Conditions for Coverage for ESRD facilities, requires facilities to provide data and other information that are necessary to support administration of the ESRD program. The Commission believes that value-based purchasing programs like the QIP should evaluate providers based on their performance rather than their ability to track and report information.

If CMS elects to finalize this measure in the 2016 QIP, the agency should:

- Convert this measure, as soon as possible, to the clinical outcome measures that hold facilities accountable for the hospitalization and mortality rates experienced by their patients.
- Limit the comorbidities that facilities are required to annually report to those comorbidities that are not reported on Medicare claims, such as patient inability to ambulate, inability to transfer, and needs assistance with daily activities. This will minimize facilities' reporting burden. CMS could use Medicare administrative data for conditions (such as diabetes, congestive heart failure, cerebrovascular disease, peripheral vascular disease) that are reported on institutional and outpatient claims.
- Evaluate the relationship of these comorbidities on providers' costs as well as on the patients' risk of hospitalization and mortality. Several of these measures, such as patient inability to ambulate, inability to transfer, and needs assistance with daily activities, may be associated with providers' costs. If a relationship is found between these comorbidities and providers' costs, CMS could consider using them as case-mix adjusters for the ESRD PPS.

The proposed 2016 ESRD QIP does not assess anemia under-treatment

The Commission continues to remain concerned that the 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 included a measure that assesses the proportion of beneficiaries receiving ESAs with an average hemoglobin level less than 10.0 g/dL. Beginning in payment year 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.[14] Under the payment method, facilities have a greater incentive to under-furnish services in the payment bundle rather than over-furnish them. The Commission wants to ensure that beneficiaries continue to have access to effective and appropriate anemia management.

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 measuring the rates of outcomes of anemia under-treatment, such as the rate of blood transfusions or the rate of inpatient hospitalizations.

The proposed measure that assesses high hemoglobin levels

CMS is proposing that the 2016 QIP continue to include an anemia measure that assesses the proportion of patients with hemoglobin levels greater than 12 g/dL. CMS should consider retiring this measure from the 2016 QIP because:

- There is little variability in facilities' performance. According to CMS, this measure's benchmark (90th percentile of facility performance) is 0 percent in 2012 and its achievement threshold (15th percentile of facility performance) is 1.2 percent. Therefore, the measure does not help distinguish performance between facilities.
- Under the PPS, facilities no longer have an incentive to overuse ESAs, which is associated with higher hemoglobin levels. Per treatment use of ESAs and iron agents that are used to manage anemia and included in the PPS payment bundle have declined in each year between 2010 and 2012.

The proposed weighting of "clinical measures" versus "reporting measures" in the QIP

For the 2016 QIP, CMS is proposing that the nine "clinical measures" would represent 75 percent of facility's total performance score and the four "reporting measures" would represent 25 percent of the score. CMS uses the same weights for clinical and reporting measures for the 2015 QIP.

As we have previously said, the Commission believes that value-based purchasing programs like the QIP should evaluate providers' performance rather than their ability to track and report information, and that clinical outcomes are more important than simply tracking or relaying information to the Secretary. Consequently, the 2016 QIP should use the 2014 QIP weights in which "clinical measures" represent 90 percent of the facility's score and "reporting measures" represent 10 percent of the score.

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[14] 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.

The proposed minimum data requirement for scoring the ICH CAHPS measure in the QIP

CMS is proposing that facilities with fewer than 30 qualifying patients (in-center hemodialysis patients 18 years and over) during the performance period would not be scored on the in-center hemodialysis CAHPS measure because survey results are more reliable if there are at least 30 surveys submitted per facility.

We are concerned that this adjustment runs counter to the goals of quality incentive programs. We think that all facilities should be held accountable for the quality of the services they furnish and that patient experience is an important aspect of quality of care. According the CMS's ESRD facility survey, in 2011, nearly 20 percent of all facilities that furnished in-center hemodialysis reported treating fewer than total (Medicare and non-Medicare) patients.[15]

If CMS is concerned about the reliability of the data for small facilities, the agency should explore and compare other options to the proposed method, such as using multiple years of data and aggregating facilities under common ownership by region.

Future QIP considerations

To strengthen the QIP, there are several issues that CMS should consider in updates to the program. 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 and are not duplicative.

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. Hospital readmissions may be indicators of poor access to follow-up primary care or missed opportunities for inpatient and ambulatory care providers 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.

[15] The facility survey measure does not differentiate adult from pediatric patients.

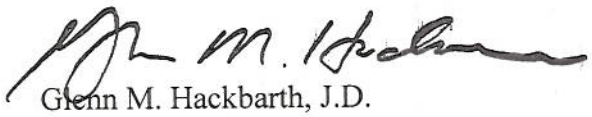
- A composite variable that includes cost of care and quality metrics. For example, the Commission has constructed such efficiency measures for hospitals by considering hospital-level mortality rates, readmission rates, providers' costs (standardized inpatient costs per case), providers' payer mix, and the annual level of total fee-for-service Medicare service use per capita in the county where the hospital is located.
- Use of home dialysis and transplantation. As we said in the last two years' comment letters, 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 ESRD. 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