MEDPAC Medicare Payment Advisory Commission

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July 29, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-1651-P

Dear Mr. Slavitt:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) notice of proposed rulemaking entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model" published in the Federal Register, vol. 81, no. 126, pages 42802 to 42880. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2017, introduces coverage and payment for individuals with acute kidney injury (AKI) in dialysis facilities, and addresses the ESRD quality incentive program (QIP). The proposed rule also includes provisions concerning the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). 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 home dialysis training add-on payment update, which is proposed as part of the update to the ESRD prospective payment system (PPS),
- Payment to ESRD facilities for dialysis services provided to beneficiaries with AKI, and
- The changes to the ESRD QIP for payment years 2020 and beyond.

In addition, we reiterate some of our concerns with the refinement of payment adjustments implemented in payment year 2016, which we originally described in our comment letter to you

dated August 2015, and our concerns about the Dialysis Star Ratings System, which we originally described in the MedPAC comment letter to your predecessor dated August 2014.[1] Finally, the Commission comments on the proposed changes to the method for establishing bid limits for individual items under the DMEPOS competitive bidding program.

Update of the home dialysis training add-on payment rate
CMS is proposing to increase the add-on rate for home dialysis training from $50.16 per training treatment to $95.57 per training treatment, with the maximum number of reimbursable training treatments remaining unchanged at 15 for peritoneal dialysis (PD) and 25 for home hemodialysis (HHD). The current $50.16 rate was based on an assumed 1.5 hours of training time by a registered nurse (RN) at a wage equal to the national mean. The proposed rate of $95.57 reflects an updated national mean RN wage and a modified assumption that the number of training hours provided is equal to the treatment time. CMS calculated an average home dialysis treatment time of 2.66 hours, which assumes 2 hours for PD treatment and 4 hours of HHD treatment, weighted by the number of PD and HHD training treatments provided.

CMS states that data on the cost of providing home dialysis training on dialysis facility cost reports varies substantially across facilities and that currently available cost report data cannot be used to accurately gauge the adequacy of the training add-on payment. CMS is in the process of refining the cost reporting elements to more accurately assess the appropriate amount for the training add-on payment. CMS also states that in recent public comment, HHD patients and a HHD machine vendor claimed that the current home dialysis training add-on payment was inadequate, yet large dialysis organizations found the current training add-on payment to be sufficient.

Finally, CMS is proposing to apply a budget neutrality factor to the ESRD PPS base payment rate to offset the increase in the training add-on payment.

Comment
The Commission believes that dialysis beneficiaries should have access to the alternative types of dialysis treatment – in-center dialysis, home hemodialysis, and peritoneal dialysis (which is usually performed at home). Home dialysis offers advantages such as increased patient satisfaction, better health-related quality of life, and fewer transportation challenges compared with in-center dialysis. However, if the purpose of the proposed payment change is to promote home dialysis it is important to first collect accurate data on the resources that are needed to train beneficiaries to dialyze at home. The Commission supports CMS's effort to collect more reliable data on the cost of providing home dialysis training. Once CMS collects sufficiently reliable data about the duration and composition of training treatments, the agency should assess the need to adjust the training add-on payment amount from the current rate.

Lastly, CMS is proposing to apply a budget-neutrality adjustment factor that would reduce the base PPS payment rate to offset the proposed increase of the training add-on payment. CMS is also proposing changes to the hemodialysis claims adjudication process that will allow CMS to use

[1] Available at http://medpac.gov/documents/comment-letters/medpac-comment-on-cms's-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-quality-incentive-program.pdf?sfvrsn=0 and http://medpac.gov/documents/comment-letters/08152014_esrd_medpac_comment.pdf?sfvrsn=0, respectively.

claims data to accurately track the number of HHD treatments provided. We believe that accurately accounting for all HHD treatments with claims data is important. However, it is unclear whether the proposed budget-neutrality adjustment factor accounts for any increase in the number of HHD training treatments eligible for Medicare payment that may result from the proposed claims adjudication process change. The Commission believes that CMS should make any change to the training add-on payment in a budget-neutral manner. In the final rule, the agency should clearly explain the methods used to calculate the budget-neutrality adjustment factor and identify the total number of training treatments accounted for by the factor.

Medicare's payment to ESRD facilities for outpatient dialysis furnished to acute kidney injury beneficiaries

Prior to 2012, some hospitals contracted with ESRD facilities to furnish outpatient hemodialysis for beneficiaries with acute kidney injury (AKI) in ESRD facilities.[2] In guidance issued in April 2012, CMS announced that ESRD facilities cannot furnish outpatient dialysis to beneficiaries with AKI.[3] According to CMS's guidance, Medicare coverage of outpatient dialysis for the treatment of AKI is permitted only when furnished by hospital outpatient departments (HOPDs), directly or under arrangements, in the hospital or in locations that qualify as provider-based departments of hospitals. The Trade Protection Extension Act of 2015 (TPEA) provides coverage for outpatient dialysis furnished by ESRD facilities to Medicare beneficiaries with AKI on or after January 1, 2017.

To implement the new law, CMS is proposing to pay freestanding and hospital-based ESRD facilities the ESRD PPS base payment rate for outpatient dialysis services furnished to AKI beneficiaries. ESRD facilities would also be paid separately for drugs, biologicals, and laboratory services that are not renal dialysis services but that facilities are certified to furnish and required for the treatment of AKI. According to the 2017 HOPD and ESRD proposed rules, for AKI outpatient dialysis, Medicare would pay HOPDs a rate that would be more than double the rate paid to ESRD facilities ($559.65 per dialysis treatment compared to $231.04 per treatment, respectively). In addition, Medicare pays HOPDs separately for certain drugs – erythropoiesis stimulating agents (ESAs) – that are furnished during outpatient dialysis. By contrast, ESAs are bundled in the ESRD PPS base payment rate.

Comment

The Commission is concerned about the difference in Medicare's payment rate for furnishing outpatient dialysis to AKI beneficiaries in HOPDs compared to freestanding and hospital-based ESRD facilities. Payment differences between settings may cause beneficiaries and Medicare to pay more than necessary. Neither the new law nor the proposed regulations would preclude HOPDs from furnishing outpatient dialysis to AKI beneficiaries.

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[2] http://www.renalmd.org/uploadedFiles/Content/Home_Page/Whats_New/AKI%20Fact%20Sheet%20Final%2012-3-12.pdf.

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Acute-Dialysis-Site.pdf.

Medicare should ensure that beneficiaries have access to settings that provide the appropriate level of care.[4] From this perspective, if the same service can be safely provided in different settings, a prudent purchaser should not pay more for that service in one setting than in another. Therefore, in its fee-for-service payment systems, Medicare should strive to base payment rates on the resources needed to treat beneficiaries in the most efficient (i.e., highest quality, lowest cost) setting, adjusting for differences in patient severity to the extent that severity differences affect costs. The Commission's position is that Medicare should base payment rates on the setting where beneficiaries have adequate access to care at the lowest cost to beneficiaries and the program.

The ESRD Quality Incentive Program

In PY 2020, CMS proposes to add two new measures to the ESRD Quality Incentive Program (QIP), for a total of 16 measures, 9 of which are "clinical" (i.e., outcome) measures that assess the outcomes of care and 7 are "reporting" (i.e., process) measures. CMS is proposing to add the following measures to the QIP in PY 2020:

- A reporting measure that assesses the percentage of months that patients' ultrafiltration rates exceed 13 ml/kg/hr.
- A clinical risk-adjusted measure – the standardized hospitalization ratio.

For PY 2020, CMS is also proposing to replace the mineral metabolism reporting measure that will be used in PY 2019 with a serum phosphorus reporting measure. In addition, for PYs 2019 and 2020, CMS is proposing to reintroduce the National Healthcare Safety Network (NHSN) dialysis event reporting measure, which measures whether facilities enroll in the Centers for Disease Control and Prevention's NHSN infection tracking system and submit 12 months of dialysis event data.[5]

The following table summarizes the measures proposed for PY 2020:

Measure	**Measure type**	**Payment year measure used**
Dialysis adequacy	Outcome	PY 2019 measure
Anemia management		
Anemia management reporting measure	Process	PY 2019 measure
Standardized transfusion ratio	Outcome	PY 2019 measure
Vascular access type		
Use of AV fistulas	Outcome	PY 2019 measure
Use of catheters	Outcome	PY 2019 measure
Hypercalcemia	Outcome	PY 2019 measure
Standardized readmission ratio	Outcome	PY 2019 measure

[4] http://medpac.gov/documents/reports/jun13_ch02.pdf?sfvrsn=0.

[5] The ESRD QIP included the NHSN dialysis event reporting measure in PYs 2014 and 2015, and then replaced it with the NHSN outcome measure in PY 2016.

NHSN measurement NHSN blood stream infection in hemodialysis outpatients	Outcome	PY 2019 measure
NHSN dialysis event	Process	PY 2019 measure
ICH CAHPS survey (patient experience)	Outcome	PY 2019 measure
Clinical depression screening and follow-up	Process	PY 2019 measure
Pain assessment and follow-up	Process	PY 2019 measure
NHSN healthcare personnel influenza vaccination	Process	PY 2019 measure
Ultrafiltration rate	Process	Proposed for PY 2020
Standardized hospitalization ratio	Outcome	Proposed for PY 2020
Serum phosphorus	Process	Replaces PY 2019 mineral metabolism measure

Note: PY (payment year). Kt/V (dialyzer urea clearance x dialysis time/urea volume). NHSN (National Healthcare Safety Network). ICH CAHPS (In-center hemodialysis Consumer Assessment of Healthcare Providers and Systems survey).

Comment
We are chiefly concerned about the continued reliance on process measures. Our standing position on quality measures is that CMS should use risk-adjusted outcome measures that capture the effective management of dialysis patients. We support CMS's proposal that beginning in PY 2020, the ESRD QIP will include a standardized hospitalization ratio measure. In the proposed rule, the agency states that it is considering for future inclusion in the ESRD QIP the following measures: a standardized mortality ratio (which is already included in the Dialysis Facility Compare star ratings), a measure examining hospital emergency department use, a measure examining medication reconciliation efforts (which is already used to assess quality of the ESRD Seamless Care Organizations), and a measure examining kidney transplants in ESRD patients. The Commission supports the inclusion of such measures in the ESRD QIP if they assess the outcome of care processes.

ESRD PPS refinement implemented in payment year 2016
The American Taxpayer Relief Act of 2012 required that the Secretary, no later than January 1, 2016, analyze the case-mix payment adjustments that are applied to the base payment rate under the current dialysis PPS and make appropriate revisions to the adjustments. Through the rule-making process, CMS proposed and finalized recalibrated patient- and facility-level payment adjustment factors based on regression analyses of 2012 and 2013 dialysis facilities' cost reports and claims data. Changes to the adjustment factors included the removal of two comorbidity adjusters, the addition of a rural adjuster for all facilities not located in urban areas, and the use of a revised definition of the low-volume payment adjuster. Beginning in 2016, CMS has used the recalibrated and revised payment adjusters to calculate each patient's adjusted payment rate.

Comment
In our August 6, 2015 comment letter to CMS on the dialysis PPS changes that CMS proposed (and subsequently implemented) for 2016, the Commission raised several methodological

concerns about the revisions to the payment adjustment factors.[6] The Commission believes several of these concerns remain relevant and continue to affect the accuracy of the dialysis PPS, including:

- The use of a two-equation model that separately estimates facility-level variation in former composite rate services and patient-level variation in former separately-billable services despite all services being in one bundle during analysis years 2012 and 2013.
- The lack of model robustness indicated by the shift in the empirically-determined lowest-cost reference population for age category variables from 45 to 59, to 60 to 69, and then to 70 to 79 during the last 3 reported model calibrations.
- The inclusion of adjustment factors for comorbid conditions that are poorly identified on dialysis facility claims may cause undue burden on patients undergoing additional diagnostic procedures in order to meet documentation requirements, and reflect differences only in the cost of formerly separately billable services.
- The independent estimation of BSA and BMI adjustment factors despite their correlation and likely exhibition of a joint, rather than independent, effect on treatment cost.
- The use of hospital-based facility cost reports to derive the payment adjustment factors given that the allocation of hospital costs to dialysis departments and dialysis cost categories has no guaranteed consistency across facilities.
- Neither the low-volume adjustment nor the rural adjustment are targeting facilities that are critical to beneficiary access.

As we stated in our 2015 comment letter to you, the Commission believes that once audited cost report data from freestanding ESRD facilities are available, CMS should develop payment adjustment factors based on a single-equation model. In addition, the agency should re-evaluate including the four remaining comorbidity adjustment factors, refine the low BMI and BSA adjustment to reflect the factors' joint effect on facility costs, and design a single payment adjustment that targets low-volume isolated providers.

The ESRD QIP and the Dialysis Star Ratings Systems

CMS measures quality for each dialysis facility using two measurement systems, the ESRD QIP, which was mandated by Medicare Improvements for Patients & Providers Act of 2008 and implemented in 2012, and the Dialysis Star Ratings System, which CMS established through a subregulatory process in 2015.

Comment

In our August 15, 2014 comment letter to your predecessor, the Commission questioned why CMS believed it necessary to develop a second quality system for dialysis facilities. We also raised concerns that beneficiaries and their families might be confused if a facility's star and QIP scores diverge, which could occur because the measurement systems use different methods and measures to calculate a facility's performance score. The Commission believes the ESRD quality measurement process needs greater simplicity and clarity. Moving to one quality measurement

[6] Available at http://medpac.gov/documents/comment-letters/medpac-comment-on-cms's-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-quality-incentive-program.pdf?sfvrsn=0.

system that is based on a reasonable number of outcomes-based performance measures would be easier to understand for beneficiaries and their families and would reduce administrative costs for providers and CMS.

Bid limits for individual items under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program

In the most populous areas of the country, payment rates for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items are now determined by competitive bidding. In those areas that are not competitive bidding areas (CBAs) the otherwise applicable fee schedule amounts for those items will be adjusted based on information from competitive bidding. The proposed rule considers whether those adjusted fee schedule amounts or the unadjusted fee schedule amounts should be used as the bid limits in future rounds of competitive bidding. The bid limit is the upper bound on proposed bids in the competitive bidding program (CBP). Its purpose is to ensure that the program does not cost more than payments for DMEPOS items would have been in the absence of competitive bidding; that is to ensure Medicare and its beneficiaries save money as a result of the CBP.

Comment

CMS proposes that going forward the unadjusted 2015 fee schedule amounts should be used as the bid limits rather than the adjusted amounts. The agency is concerned that if adjusted fee schedule amounts are used as the bid limits, over time the bid limits can only decrease; thus, there would be no mechanism to allow the bid limits to rise in the event of inflation in the cost of items, which would be untenable in the long run.

We agree with this concern. However, the CBP has shown substantial savings since its introduction and has proven that the fee schedule amounts were too high. Thus, some adjustment for competitive results should be factored in to the bid limit rather than using the unadjusted 2015 fee schedule amounts. In addition, the fee schedule amounts should continue to be adjusted in all parts of the country to take into account the information from the CBP. It would be inequitable, for example, if Medicare beneficiaries in rural areas were forced to continue to pay higher than necessary cost sharing because fee-schedule amounts were not adjusted despite clear indications that the associated fee schedule rates were too high.

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,

Francis J. Crosson, M.D.
Chairman

FJC/nr/wc