MEDPAC Medicare Payment Advisory Commission

425 I Street, NW • Suite 701
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Francis J. Crosson, M.D., Chairman
Jon B. Christianson, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

August 11, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-1674-P

Dear Ms.Verma:

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, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program" published in the *Federal Register*, vol. 82, no. 127, pages 31190 to 31233. This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2018, updates the payment rate for individuals with acute kidney injury (AKI) when furnished in dialysis facilities, and addresses the ESRD quality incentive program (QIP). 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 pricing of drugs and biologics under the ESRD PPS outlier policy,
- Medicare's payment to ESRD facilities for outpatient dialysis services furnished to AKI beneficiaries,
- The ESRD QIP and inclusion of AKI beneficiaries in the QIP, and
- Accounting for social risk factors in the ESRD QIP.

In addition, we reiterate our prior comments about the accuracy of the cost reports that dialysis facilities submit to CMS, the ongoing CMS audit, and the Dialysis Star Ratings System.

The pricing of drugs and biologics under the ESRD PPS outlier policy

CMS is proposing to allow the use of any pricing methodology available under section 1847A of the Social Security Act, including wholesale acquisition cost (WAC), to determine the cost of drugs and biologics (referred to as "*products*" in this letter) in calculating outlier payments when average sales price (ASP) data is not available.[1] CMS is also seeking comments on its proposal to exclude products from the outlier calculation that do not have ASP or WAC data or cannot otherwise be priced under section 1847A of the Act.

Comment

CMS should rely on ASP data when pricing drugs and biologics under the ESRD PPS outlier policy with one exception. New single-source drugs and biologics, and the first biosimilar to a reference biologic (that lack ASP data) should be priced using WAC data only for two to three calendar quarters to permit time for manufacturers to report sales data to CMS and for the agency to calculate an ASP. If at the end of two to three calendar quarters, ASP data are not available, CMS should not use WAC for purposes of calculating outlier payments.[2]

In our June 2017 report to the Congress, the Commission raised concerns about the accuracy of WACs. Unlike an ASP, a product's WAC does not incorporate prompt-pay or other discounts.[3] If discounts are available, then a product's WAC price would be greater than it otherwise would be under the ASP-based formula. Consequently, using WAC data to determine payments under the outlier policy could result in higher spending for beneficiaries and taxpayers.

To reduce the need to use less appropriate prices, such as WACs, and to improve the accuracy of ASP data, the Commission recently recommended that the Congress improve ASP data reporting by requiring all manufacturers of Part B drugs and biologics to report ASP and impose civil monetary penalties for failure to report.[4] Currently, not all manufacturers of Part B drugs are required to submit their ASP data. Section 1927(b)(3) of the Act requires only manufacturers with Medicaid rebate agreements in place to report their sales data to calculate ASPs for each of their Part B drugs.

With respect to the transitional drug add-on payment adjustment (TDAPA), CMS should only use ASP data for products that qualify for this payment adjustment with the same exception for new products, as we discuss above.[5] The agency will pay for select drugs (whose costs have not been

---

[1] Under 1847A of the Act, the Secretary also has the authority to disregard the ASP for a drug or biologic that exceeds the widely available market price (WAMP) or the average manufacturer price (AMP) for such drug or biologic by a threshold percentage.

[2] In some cases, even when ASP data are available for a product, Medicare pays for that product based on its AMP or WAMP because these prices are lower than ASP by the statutory threshold.

[3] WAC is the manufacturer's list price for a drug paid by wholesales or direct purchasers in the United States.

[4] Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the Health Care Delivery System.* Washington, DC: MedPAC.

[5] The following products qualify for a TDAPA because the ESRD PPS has not accounted for their costs: 1) new injectable or intravenous products that do not fall into any of the eleven ESRD PPS functional categories, and 2) the

accounted for in the ESRD PPS) under a TDAPA until sufficient claims data for rate setting analysis are available, but for not less than two years. Relying only on ASP data to pay for products under the TDAPA would likely result in savings for beneficiaries and taxpayers.

Auditing dialysis facilities' cost reports

Based on the Commission's recommendation, the Protecting Access to Medicare Act of 2014 required that the Secretary of Health and Human Services conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services.[6] To support this effort, the law authorized the Secretary to transfer $18 million (in fiscal year 2014) from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. In September 2015, CMS awarded a contract to conduct the audit.

Comment

The Commission strongly encourages the agency to accelerate the audit's completion and release its final results. The Commission has repeatedly discussed the importance of auditing the cost reports that dialysis facilities submit to CMS to ensure that the data are accurate. First, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Second, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Third, historically, facilities' cost reports have included costs that Medicare does not allow. Fourth, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors, which are derived from this data source.

Medicare's payment to ESRD facilities for outpatient dialysis furnished to AKI beneficiaries

Beginning in 2017, Medicare pays ESRD facilities (freestanding and hospital-based) the ESRD PPS base payment rate for furnishing dialysis services to AKI beneficiaries.[7] Prior to 2017, Medicare coverage of outpatient dialysis to treat AKI was permitted only when furnished by hospital outpatient departments (HOPDs) and was paid under the outpatient PPS. In 2017, Medicare's payment rate to HOPDs ($552.58) per AKI dialysis treatment is more than double the rate paid to ESRD facilities ($231.55 per dialysis treatment).

---

first new injectable or intravenous calcimimetic and phosphate binder. Drugs and biologics paid for under the TDAPA are not eligible for outlier payments.

[6] Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

[7] The Trade Preferences Extension Act (TPEA) of 2015 provided coverage of dialysis services furnished on or after January 1,2017 by freestanding and hospital-based dialysis facilities to AKI beneficiaries.

Comment

The Commission continues to be 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.[8] Payment differences between settings may cause beneficiaries and taxpayers to pay more than necessary. The Commission's position is that Medicare should base payment rates on the setting where beneficiaries have adequate access to good quality care at the lowest cost to beneficiaries and the program, adjusting for differences in patient severity.[9] 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.

CMS should explore applying a site-neutral payment policy for AKI dialysis treatment that would base payment for this service in all settings (including HOPDs) on the less costly sector (ESRD facilities). Such a policy would lower spending for beneficiaries and taxpayers, and reduce the incentive to provide services in the higher paid sector. If necessary, CMS should pursue legislative authority to implement such a policy.

The ESRD QIP and inclusion of AKI beneficiaries in the QIP

In PY 2021, CMS is proposing that the ESRD Quality Incentive Program (QIP) include 16 measures, 9 of which are "clinical" (i.e., outcome) measures that assess the outcomes of care and the remainder are "reporting" (i.e., process) measures. CMS is proposing to replace the two vascular access measures used in PY 2020 with two new vascular access measures that have been endorsed by the National Quality Forum.

In the proposed rule, CMS states that it intends to require facilities to report data on AKI patients under the ESRD QIP, and is seeking comments on whether and how to adapt any of the current measures to include this population, as well as the type of measures that might be appropriate to develop for future inclusion in the program that would address the unique needs of AKI beneficiaries.

---

[8] Medicare Payment Advisory Commission. 2016. Comment letter to CMS entitled on the proposed rule 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. August 1.

[9] Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the Health Care Delivery System.* Washington, DC: MedPAC.

The following table summarizes the measures proposed for PY 2021:

Measure	Measure type	Payment year measure used
Dialysis adequacy	Outcome	PY 2020 measure
Anemia management		
Anemia management reporting measure	Process	PY 2020 measure
Standardized transfusion ratio	Outcome	PY 2020 measure
Vascular access type		
Standardized AV fistula rate	Outcome	New measure
Standardized catheter rate	Outcome	New measure
Hypercalcemia	Outcome	PY 2020 measure
Standardized hospitalization ratio	Outcome	PY 2020 measure
ICH CAHPS survey (patient experience)	Outcome	PY 2020 measure
Standardized readmission ratio	Outcome	PY 2020 measure
NHSN measurement		
NHSN blood stream infection in hemodialysis outpatients	Outcome	PY 2020 measure
NHSN dialysis event	Process	PY 2020 measure
Clinical depression screening and follow-up	Process	PY 2020 measure
Pain assessment and follow-up	Process	PY 2020 measure
NHSN healthcare personnel influenza vaccination	Process	PY 2020 measure
Ultrafiltration rate	Process	PY 2020 measure
Serum phosphorus	Process	PY 2020 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

The Commission is chiefly concerned about the continued reliance on process measures and the future proliferation of measures. We are also concerned that Medicare's current approach to quality measurement is burdensome for providers (e.g., too many measures, measures that require chart abstraction). The Commission's standing position is that ideally Medicare's quality programs should include risk-adjusted outcomes, patient experience, and value (e.g., costs, low-value care) measures.

We commend CMS for not proposing new process measures for PY 2021. For PY 2022, CMS should consider including outcome measures that can replace one or more existing process measures. One such outcome measure is the standardized mortality measure, which captures patients' health outcomes and could be assessed using existing administrative data sources.

Previously, the agency said that it would consider this measure, which is already included in the Dialysis Facility Compare star ratings, for future inclusion in the ESRD QIP.[10]

The Commission questions the value of developing new measures for the AKI population. Because this is a small population, it may not be possible to accurately calculate their outcomes at the facility-level. In 2018, CMS estimates that about 9,000 out of 44 million dialysis treatments will be furnished to AKI beneficiaries (0.02 percent of total dialysis treatments) by 6,754 dialysis facilities. In addition, combining AKI and ESRD beneficiaries in the ESRD QIP measures may not be appropriate because treatment for AKI is short-term and distinct from ESRD. Given the small number of AKI beneficiaries, the ESRD QIP and the Dialysis Star Rating System are the best sources of information for beneficiaries to evaluate the quality of a given dialysis facility. In the future, CMS could reconsider developing outcome measures for AKI beneficiaries if the size of this population increases to permit reliable measurement at the facility-level.

Accounting for social risk factors in the ESRD QIP

CMS has been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS's value-based purchasing and quality reporting programs. CMS has also been monitoring and awaiting results from the National Quality Forum's (NQF) 2-year trial period in which quality measures seeking endorsement are assessed to determine whether risk adjustment for selected social risk factors is appropriate. At the end of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures. As CMS continues to consider the analyses from these reports and awaits the results of the NQF trial on risk adjustment for quality measures, the agency seeks public comment on whether and how to incorporate social risk factors in Medicare programs, including the ESRD QIP.

Comment

In December 2016, ASPE released the "Social Risk Factors and Performance Under Medicare's Value-based Purchasing Programs" report to the Congress mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act. The report provides empirical analysis of the effects of six social risk factors (i.e., dual eligibility, residence in low-income areas, Black race, Hispanic ethnicity, rural residence, disability) on the nine Medicare quality payment programs including the ESRD QIP. The report included two main findings:

[10]Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. 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. June 30.

1. Beneficiaries with social risk factors had worse outcomes on quality measures, regardless of the providers they saw, and dual eligibility status was the most powerful predictor of poor outcomes among the social risk factors.
2. Providers that disproportionately served beneficiaries with social risk factors tended to have worse performance on quality measures, even after accounting for their beneficiary mix.

ASPE simulated the effect of three different potential policy solutions to account for social risk factors in each of the Medicare programs.

- Adjust quality and resource use measures
- Stratify providers into groups by proportion at-risk
- Create separate payment adjustments

MedPAC supports the second solution of using peer grouping or stratification.[11] This approach is straightforward to implement, since no additional measure-level research is needed (i.e., working with measure developers to run new risk-adjustment models). The stratification report also does not minimize incentives to improve for providers with high shares of beneficiaries with social risk factors, and does not "mask" provider performance. Instead, providers would compare their unmasked performance (the rate would still have been adjusted for differences in patient age, sex, and comorbidities) with providers with similar risk factors. For example, risk-adjusted readmission performance would be compared for providers with similar shares of low-income patients, and payment adjusted based on whether providers met performance targets in their peer group.

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

The Commission continues to question why it is necessary to use two quality systems for dialysis facilities.[12] We have 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 system that is based on a reasonable number of outcomes-based

[11] Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the Health Care Delivery System.* Washington, DC: MedPAC.
[12] Medicare Payment Advisory Commission. 2014. Comment letter to CMS entitled on the proposed rule entitled: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. August 15.

performance measures would be easier to understand for beneficiaries and their families and would reduce administrative costs for providers and CMS.

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, at 202-220-3700.

Sincerely,

Francis J. Crosson, M.D.
Chairman

FJC/nr/wc