MEDPAC | Medicare Payment Advisory Commission

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1786-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Program; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Health Centers Conditions of Participation; Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction," *Federal Register* 88, no. 145, pp. 49552–49921 (July 31, 2023). We appreciate CMS's ongoing efforts to administer and improve Medicare's policies for hospital outpatient and ambulatory surgical center payments, particularly given the many competing demands on the agency's staff. We hope that our comments are helpful in these endeavors.

Our comments address the following provisions in the proposed rule:

- Payment for diagnostic radiopharmaceuticals in the outpatient prospective payment system (OPPS)
- OPPS payment for biologics
- Two-year extension of using the hospital market basket to update ambulatory surgical center (ASC) payment rates
- Potential payment under the inpatient prospective payment systems (IPPS) and OPPS for establishing and maintaining access to essential medicines
- Quality measure for emergency department visits in rural emergency hospitals

Payment for diagnostic radiopharmaceuticals in the OPPS

Since calendar year (CY) 2008, CMS has classified diagnostic radiopharmaceuticals as "policy packaged" in the OPPS, where "policy packaged" means that, unless a diagnostic radiopharmaceutical has pass-through status, its cost is packaged into the payment rate of the related primary service(s).[1] Over the years, CMS has repeatedly stated that packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Packaging the costs of ancillary items and services into the payment for the related primary service encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

Since CMS implemented policy packaging for diagnostic radiopharmaceuticals, the agency has received comments from stakeholders regarding alternative payment policies, such as applying the drug-packaging threshold (proposed to be $140 per day for CY 2024) to diagnostic radiopharmaceuticals and creating separate payments for diagnostic radiopharmaceuticals with a per day cost greater than $500. In this proposed rule, CMS again stated that the packaging policies are inherent principles of the OPPS and are essential to a prospective payment system. However, in an effort to balance the efficient use of resources in the OPPS while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries, CMS is seeking public comments on potential modifications to the packaging policy for diagnostic radiopharmaceuticals.

Comment

The Commission strongly encourages CMS to maintain the current policy-packaged status of diagnostic radiopharmaceuticals. We recognize the need to ensure beneficiary access to new technologies that improve outcomes while preserving incentives for efficiency. However, in our view, this goal is best achieved by relying on broad payment bundles to the greatest extent possible when determining payment amounts, particularly in the absence of evidence that a new technology provides superior clinical benefit over existing alternatives. Packaging encourages judicious consideration of the items and services provided to beneficiaries. Combining a primary service and related ancillary items into a single payment unit encourages efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss. Broader bundles also foster competition between similar items and services, which generates pressure on manufacturers and suppliers to reduce prices, in contrast to providing separately payable status on the basis of cost, which encourages manufacturers to charge higher prices.

[1] The OPPS has two categories for packaged drugs: policy packaged and threshold packaged. The costs of policy-packaged drugs are always packaged into the payment rate of the related services unless they have pass-through status under the OPPS. Threshold-packaged drugs are drugs that do not have pass-through status and have costs per day below the OPPS packaging threshold (proposed to be $140 in 2024). If these drugs have costs above the packaging threshold, they are classified as separately payable and are not packaged.

OPPS payment for biologics

Under the OPPS, drugs and biologics that are not policy packaged and do not have pass-through status receive separately payable status if their cost per day exceeds the drug packaging threshold set by CMS. Otherwise, the cost of the drug or biologic is packaged into the payment rate of the related services. For CY 2024, CMS proposes to except biosimilars from the OPPS packaging-threshold policy when their reference biologics are separately paid, meaning CMS would pay separately for these biosimilars even if their cost per day is below the packaging threshold. CMS posits that this exception will help promote biosimilar use as a lower-cost alternative to higher-cost reference biologics. In addition, CMS proposes that if a reference biologic's cost per day falls below the packaging threshold, then all the biosimilars related to the reference biologic would be packaged regardless of whether their per day costs are above the threshold.

While CMS has proposed to except the packaging of biosimilars when their reference biologics are separately paid, CMS is also soliciting comments on the packaging of a reference biologic and its biosimilar(s) into the payment for the associated service when the per day cost of the reference biologic, or any of its biosimilar(s), is less than or equal to the applicable OPPS packaging threshold.

Comment

The Commission has recommended that CMS be given the authority to include products with similar health effects in the same billing code and pay them the same rate, including biosimilars and reference biologics.[2] If CMS does not have statutory authority to implement one billing code for products with similar health effects, then we believe the best policy is to treat biosimilars and their reference biologic the same under the OPPS by either packaging all of them or paying separately for all of them. Therefore, if any one of the products (a biosimilar or reference biologic) is below the packaging threshold, it would be appropriate to treat them similarly and package all of them. In addition, the biosimilars and the reference biologic should be separately payable only if the cost of all of the products exceeds the packaging threshold.

Two-year extension of using the hospital market basket to update ASC payment rates

In the CY 2019 OPPS final rule, CMS implemented a policy of updating payment rates in the ASC payment system using the same rate update mechanism as the OPPS (the hospital market basket (MB) minus a productivity adjustment) for a five-year period (CY 2019 through CY 2023).[3] Before CY 2019, CMS had updated the ASC payment rates using the consumer price index for all urban consumers. The intent of updating ASC payment rates using the hospital MB was to encourage the migration of services from hospital outpatient departments (HOPDs) to the

[2] Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[3] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program: Changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 83: 58818–59179.

ASC setting. Also, during this five-year period, CMS intended to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner.

In this proposed rule, CMS expresses concern that the COVID-19 public health emergency (PHE) had a substantial effect on the volume of elective surgeries in 2020, confounding the agency's analysis of the effect of using the hospital MB to update ASC payment rates on the migration of surgical procedures to the ASC setting. As a result, CMS proposes to extend by two years the use of the hospital MB to update the ASC payment rates.

Comment

In the Commission's comments on the CY 2019 OPPS/ASC proposed rule, we expressed opposition to using the hospital MB as an interim method for updating the ASC payment rates.[4] We also oppose the proposal in this rule to extend by two years the use of the hospital MB to update ASC payment rates. Evidence indicates that the hospital MB index does not accurately reflect the costs of ASCs. In the CY 2019 proposed rule, CMS acknowledged that the ASC cost structure is not identical to that of hospitals, because ASCs tend to be single specialty and for profit, and they are not required to comply with the Emergency Medical Treatment and Labor Act (EMTALA). In addition, relative to hospitals, ASCs are more urban, serve a different mix of patients demographically and by payer type, have a much higher share of expenses related to medical supplies and drugs, and have a smaller share of employee compensation costs.

Moreover, analysis of ASC and HOPD service volume suggests that surgical procedures were already migrating from HOPDs to ASCs before CMS implemented the use of the hospital MB in CY 2019. For example, we compared ASC and HOPD volume for the 30 most frequently provided ASC-covered services to Medicare beneficiaries in 2013 and found that ASC volume was 1.5 percent higher; by 2018, the volume of those same services was 13 percent higher in ASCs than in HOPDs. Therefore, we conclude that boosting the ASC payment rates by updating them with the hospital MB was not necessary for encouraging surgical procedures to migrate from HOPDs to ASCs, so we do not believe there is a need for CMS to collect additional data on the effects of using the MB update on ASC volume.

Potential payment under the IPPS and OPPS for establishing and maintaining access to essential medicines

CMS maintains that it is necessary to support policies that can curtail pharmaceutical shortages of essential medicines, promote resiliency, safeguard access, and improve beneficiary care. Furthermore, CMS asserts that hospitals' procurement processes directly influence intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for essential medicines, including domestic production of essential medicines.

[4] Medicare Payment Advisory Commission. 2018. MedPAC comment on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2019.

CMS therefore proposes, effective as early as cost reporting periods beginning January 1, 2024, a new, non–budget-neutral IPPS payment to hospitals that establish and maintain a 3-month buffer stock of the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*.[5] Hospitals' buffer stock could be held at the hospital, or established through contractual arrangements with pharmaceutical manufacturers, distributors, or intermediaries. The IPPS payment would initially be based on each hospital's IPPS share of its additional reasonable costs for maintaining this buffer, as reported to its Medicare Administrative Contractor (MAC). These costs would not include the costs of the essential medicines themselves; rather, payments for drugs would remain as they are now. The new payments for maintaining a buffer stock would be lump-sum and made on a biweekly interim basis.

CMS seeks feedback on the proposed IPPS payment for maintaining a buffer stock of essential medicines as soon as 2024, as well as various technical questions related to the policy.

CMS also states that in future rulemaking it may consider expansions of this policy, including:

- Requiring a new cost-reporting form for hospitals to record the additional costs of maintaining a buffer stock of essential medicines;
- Adding a budget-neutral OPPS payment to maintain a buffer stock of essential medicines; and
- Creating a new payment to hospitals for maintaining a buffer of critical medical devices, as defined by the Food and Drug Administration.

Comment

Although we agree with CMS that ensuring a sufficient inventory of essential medicines is vitally important for the nation's public health and security, we oppose the proposed new IPPS payment. In the Commission's view, ensuring that hospitals have a sufficient inventory of essential medicines for all their patients likely involves solutions beyond the Medicare program (e.g., direct purchases and stockpiling of essential medicines by the federal government).

As we noted in a prior comment on CMS's proposal for a new payment for the purchase of domestically produced N-95 masks,[6] adding new Medicare hospital payments for specific national public health goals would create a precedent, opening opportunities to establish separate cost-based payments for other supplies and other providers. Indeed, this proposal is one such

[5] Advanced Regenerative Manufacturing Institute. 2022. *Essential medicines supply chain and manufacturing resilience assessment.* www.armiusa.org/wp-content/uploads/2022/07/ARMI_Esssential_Medicines_Supply-Chain-Report_508.pdf.
[6] https://www.medpac.gov/wp-content/uploads/2022/06/06162022_FY2023_IPPS_LTCH_MedPAC_COMMENT_v2_SEC.pdf

expansion, and CMS stated it will consider expanding to critical medical devices. The proposed policy also would increase administrative costs for hospitals.

Medicare payment policy is neither a sufficient, nor the best suited, mechanism to support adequate supplies of essential medicines for all patients (whether or not they are covered by Medicare). However, if CMS concludes that a change to Medicare payment policy is required for this purpose—a conclusion with which we strongly disagree—it should be done in a way that:

- *Maintains the integrity of Medicare's prospective payment systems*—For example, we agree with CMS that the costs of the essential medicines themselves should not be reimbursed as part of this proposed additional payment.
- *Minimizes administrative burden*—For example, instead of requiring all hospitals that maintain a buffer of essential medicines to report their associated costs to their MACs each year as part of the cost reports, CMS could episodically survey a subset of hospitals on their storage costs per unit.
- *Limits opportunity for manipulation*—For example, once CMS collects cost data, the new storage payment per unit could be based on the cost data after pooling to a national level and trimming statistical outliers.

Quality measure for emergency department visits in rural emergency hospitals

For the new rural emergency hospital quality reporting (REHQR) program, CMS proposes to adopt an existing measure of emergency department (ED) throughput efficiency. As part of the outpatient quality reporting program—which is the quality reporting program for the OPPS—hospitals use chart-abstracted data to calculate the measure "median time from ED arrival to ED departure for discharged ED patients" and report those results to CMS. CMS proposes to include this measure in the REHQR because the agency believes that ED wait times have a significant impact on patients. Improving ED throughput times is important for alleviating overcrowding, which has led to a number of avoidable problems in EDs: ambulance diversion, prolonged waiting times, and worse patient outcomes due to delays, such as in the administration of medication.

Comment

The proposed measure is appropriate for urban areas where a key quality concern is ED overcrowding resulting in prolonged patient wait times and delays in treatment. However, REHs primarily will be in small towns with limited ED volume, so overcrowding is unlikely to be a primary concern. Instead, a more pressing concern for REH patients is whether an appropriately trained clinician is present at the ED when they arrive.

REH EDs are allowed to be staffed with a nurse (e.g., a licensed practical nurse) and an on-call nurse practitioner (NP), physician assistant (PA), or physician. These on-call clinicians are required to be available within 30 minutes for most REHs (within 60 minutes for some remote or frontier REHs). A concern is that patients in the ED could deteriorate or die while waiting for an

on-call clinician to arrive at the hospital, especially during nights and weekends when staffing levels are usually reduced. The measure for median time from ED arrival to ED departure will not address this concern for two reasons. First, this measure does not address the length of time between arrival and initial clinician contact. Second, measuring response time with *medians* does not address the concern of not having staff in the ED during evening hours. For example, if it takes 5 minutes for 10 people to be seen during the day, but it takes 1 hour for the 2 people who arrive at night to be seen due to the lack of availability of a PA, NP, or physician, the median response time would be reported as 5 minutes.

Therefore, the Commission suggests replacing the proposed measure "median time from ED arrival to ED departure for discharged ED patients" with new metrics that measure the time from patient arrival to being seen by an appropriate clinician. Specifically, REHs would be required to report the share of cases in which it takes more than 10 minutes, 20 minutes, and 30 minutes after arrival for the patient to be initially seen by an NP, PA, or physician. Because REH staffing patterns may vary based on the time of day or day of the week, REHs should be required to report these metrics for night and weekend cases and separately for all other cases (e.g., weekday and daytime cases). Because low Medicare patient volume could affect the reliability of these measures, we suggest the measures be calculated based on all patients, not just Medicare fee-for-service patients. CMS should report REH-level results on the Care Compare website.

We understand that requiring REHs to report such data would involve some additional burden. However, maintaining timely access to ED care is one of the fundamental goals of the REH program for which Medicare pays REHs $3.3 million per year in fixed subsidies and a 5 percent add-on to OPPS payment rates. Requiring REHs to report such data will help beneficiaries make key decisions about how to best access timely care.

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please contact MedPAC's Executive Director, Paul Masi, at 202-220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

MC/dz/pm