MEDPAC Medicare Payment Advisory Commission

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

Re: File code CMS-1753-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals" published in the *Federal Register* on August 4, 2021 (86 FR 42018–42360). We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), particularly considering the agency's competing demands.

This proposed rule documents changes in the composition of some of the ambulatory payment classifications (APCs) used to classify services provided in HOPDs and ASCs and proposes changes to the relative weights based on analyses of claims and available cost report data. The rule also proposes a calendar year (CY) 2022 update to the conversion factors used to make payments in the outpatient prospective payment system (OPPS) and the ASC payment system.

Among other policies discussed, this rule proposes to:

- Update OPPS payment rates using claims and cost report data from 2019 rather than 2020.
- Continue to package non-opioid pain management drugs that function as supplies in the OPPS but pay separately for them in the ASC payment system.
- Solicit comments on methods that would mitigate the burden on ASCs of reporting cost data.
- Amend regulations for hospital price transparency by specifying that "the hospital must ensure that the standard charge information is easily accessible, without barriers,

including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website."

- Request information on rural emergency hospitals.

We focus our comments on the topics listed above.

Use 2019 data for 2022 OPPS ratesetting

To set OPPS payment rates for CY 2022, CMS typically would use the CY 2020 hospital outpatient claims and the FY 2019 Healthcare Cost Report Information System (HCRIS) dataset, which consists of all cost reports beginning in FY 2019, including those that end in FY 2020. However, both sources reflect cost and use of outpatient services affected by the COVID-19 public health emergency (PHE).

CMS has observed several changes, likely caused by the PHE, in the CY 2020 outpatient claims data. The most significant is a substantial decrease in overall hospital outpatient volume relative to CY 2019, resulting in approximately 20 percent fewer claims in CY 2020 usable for ratesetting purposes compared to the prior year. CMS also observed an even larger decline in the volume of emergency department and clinic visits, which decreased by approximately 30 percent from 2019 to 2020. As a result, CMS proposes to use CY 2019 claims data rather than CY 2020 claims data for setting 2022 OPPS payment rates. Consistent with the proposal to use CY 2019 claims, CMS also proposes to use cost report data from the same set of cost reports CMS used in the 2021 OPPS ratesetting.

Comment

The Commission appreciates the challenge that CMS faces in setting rates for CY 2022. While the Commission supports CMS's long-standing practice of using the most recent full calendar year of data to update the OPPS payment rates, given the effects of the PHE on cost and use in HOPDs in CY 2020, we concur that CY 2019 data better approximate typical patterns of hospital outpatient department use compared to CY 2020, and we support CMS's proposal to use CY 2019 hospital outpatient claims and the same cost reports that CMS used in 2021 OPPS ratesetting.

Non-opioid pain management drugs: Package in OPPS but pay separately in ASC payment system

Under both the OPPS and the ASC payment system, the cost of drugs that function as supplies to the related service are packaged in the payment rate of the related service, except when these drugs have pass-through status. Since 2019, however, CMS has implemented an exception to this policy, packaging the costs of non-opioid pain management drugs into the payment rate of the related service under the OPPS but providing separately payable status for non-opioid pain management drugs under the ASC payment system.

CMS's decision to pay separately for non-opioid pain management drugs in ASCs originated with a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis to examine payment policies for non-opioid drugs that function as supplies. CMS evaluated the effects that packaging has on the use of non-opioid pain management drugs that function as supplies in surgical procedures. CMS found that the use of these drugs decreased in ASCs after the drugs moved from pass-through status—under which they are paid separately from the related service—to packaged status. By contrast, CMS also found that use of these drugs increased in HOPDs after the drugs moved from pass-through status to packaged status in the OPPS.

For 2022, CMS proposes to continue to package the costs of non-opioid pain management drugs that function as supplies under the OPPS but pay separately for these drugs under the ASC payment system. CMS is soliciting comment as to whether the current policy to pay separately for non-opioid drugs that function as supplies under the ASC system should be applied in the OPPS.

CMS is also soliciting comment on several policy options, including whether the agency should adopt a payment revision to drugs and biologicals that function as surgical supplies in the ASC setting only when evidence in peer reviewed literature indicates that use of the product in question decreases opioid use. CMS made this solicitation in the interest of consistency with section 1833(t)(22)(A)(iii) of the Social Security Act, which requires the Secretary to consider the extent to which revisions to drug payments for opioids and non-opioid alternatives would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

Comment

We commend CMS's interest in addressing the issue of opioid overuse and addiction, but the Commission has reservations about the policy to pay ASCs separately for non-opioid pain management drugs that function as supplies, especially in the absence of evidence of whether this policy has led to reduced use of opioids in the ASC setting.[1] This policy is contrary to CMS's efforts to increase the size of payment bundles in the OPPS to increase incentives for efficient delivery of care. In addition, this policy further distorts payment differences between two settings that are the sites of many of the same services, creating financial incentives for providers to direct patients to one setting over another.

The Commission supports a policy that maintains the packaging of drugs that function as supplies in surgical procedures. Further, the Commission has recommended that drugs that function as supplies should receive separately payable status only if the drugs show clinical superiority over other drugs that have similar clinical uses.[2] If a drug that functions as a supply does not show clinical superiority over competing drugs, it should be packaged. Therefore, if CMS chooses to continue a policy of separate payment for non-opioid pain management drugs that function as supplies, the Commission asserts that separately payable status should be granted only when

[1] Medicare Payment Advisory Commission. 2018. MedPAC comment on the OPPS/ASC proposed rule for 2019.
[2] Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

evidence in peer-reviewed publications indicates that the drug in question reduces the use of opioid alternatives.

Methods that would mitigate burden on ASCs of collecting cost data

CMS has shown interest in collecting cost data from ASCs that would be used to evaluate the adequacy of ASC payment rates and to create an ASC-specific market basket that could be used to update ASC payment rates. In the 2018 OPPS/ASC proposed rule, CMS sought comment on whether the Secretary should collect cost data from ASCs to use in determining ASC payment rates.[3] In the 2019 OPPS/ASC final rule, CMS implemented a five-year policy in which annual updates to the ASC payment rates would be based on the hospital market basket.[4] During this period, CMS planned to assess the feasibility of collecting ASC cost data in a minimally burdensome manner.

In this proposed rule, CMS solicits comments on methods that would mitigate the burden on ASCs of reporting costs while collecting enough data to reliably determine ASC costs.

Comment

Since 2010, the Commission has repeatedly recommended that CMS require ASCs to submit cost data, most recently in our March 2021 report to the Congress. Currently, ASC payment rates are largely tied to OPPS payments, which are based on data from hospital outpatient claims and hospital cost reports. Although ASCs and HOPDs have similarities in their cost structures, important differences likely exist because HOPDs provide a much broader range of services and face costs that ASCs do not, such as requirements for standby capacity and emergency care. These differences in cost structure coupled with ASC payment rates based on OPPS payment rates likely create misalignments between ASC costs and ASC payment rates. These payment and cost misalignments likely make some services more financially beneficial to ASCs than other services, and ASCs have an incentive to furnish only the most financially beneficial services.

As we have recommended for many years, CMS should collect cost data from ASCs so that CMS can set ASC payment rates that accurately reflect the costs of efficient providers and eliminate the payment misalignments that currently exist. In addition, cost data would enable analysts to examine the growth of ASCs' costs over time, which would help inform decisions about annual updates to ASC payment rates.

The Commission contends it is feasible for ASCs to provide cost information. All other facility providers submit cost data to CMS, including small providers such as home health agencies and

[3] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare program: Changes to the hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 82, no. 138 (July 20): 33558–33724.
[4] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program: Changes to the hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 83, no. 225 (November 21): 58818–59179.

hospice providers. Moreover, ASCs in Pennsylvania submit cost and revenue data annually to a state agency that uses the data to estimate margins for those ASCs.[5]

If the reporting burden on ASCs is of legitimate concern, CMS could create a streamlined process for ASCs to track and submit a limited amount of cost data. The streamlined cost reporting would include a set of cost variables from all ASCs that is more limited than what is collected through formal cost reports, which would require less time for ASCs to complete. Alternatively, CMS could require ASCs to submit cost data from their existing cost accounting systems, provided the definitions of their reported cost variables are consistent with CMS's definitions.

Amend regulations for hospital price transparency

In previous rulemaking, CMS implemented two requirements for hospitals to make public their standard charges, which include the negotiated charges for each payer: (1) as a comprehensive machine-readable file; and (2) in a consumer-friendly format.[6] However, concerns have arisen that many hospitals have not complied with the requirements for making their charges publicly available. Therefore, CMS proposes to amend the policies for price transparency. CMS included in this proposal a prohibition of certain conduct that the agency has concluded is a barrier to public access of the standard charge information.

In regulations 45 CFR 180.50(d)(2) through (5), CMS set the accessibility requirements that hospitals must meet for their charge information. These requirements include:

- The standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated.
- The charge information must be easily accessible, without barriers, including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information.
- The charge information must be contained in a digital file, within which the standard charge information is digitally searchable.

In some cases, it appears that hospitals have made standard charge data available online but have embedded it in websites without any ability for users to download a single machine-readable file easily or directly. In other cases, hospitals have posted a link to a single machine-readable file but have—perhaps unintentionally—placed barriers that make it more challenging for the public to find and access the file and its contents.

[5] Pennsylvania Health Care Cost Containment Council. 2020. *Financial analysis 2019: Volume 2, ambulatory surgery centers*. Harrisburg, PA: PHC4.

[6] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. Medicare and Medicaid programs: CY 2020 hospital outpatient PPS policy changes and payment rates and ambulatory surgical center payment system policy changes and payment rates. Price transparency requirements for hospitals to make standard charges public. *Federal Register* 84, no. 229 (November 27): 65524–65606.

In response, CMS proposes to amend the regulations by adding paragraph (d)(3)(iv) to 45 CFR 180.50 to specify that hospitals must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website.

Comment

The Commission supports this proposal to ensure that patients can access hospital charge data without excessive difficulty. The standard charge data include prices negotiated by payers. Having access to these prices can help patients make informed decisions about their health care costs and can increase price competition among hospitals.

Request for information on rural emergency hospitals

In the Consolidated Appropriations Act (CAA), 2021, Congress established a new Medicare provider type: rural emergency hospitals (REHs). The law defines an REH as a facility that:

- does not provide any acute care inpatient services (other than services furnished in a distinct part unit licensed as a skilled nursing facility);
- furnishes services that do not exceed an annual per patient average of 24 hours, including emergency department (ED) services, observation care services, and other outpatient services;
- has an ED that is staffed 24 hours a day, 7 days a week and a physician, nurse practitioner, clinical nurse specialist, or physician assistant that is available to furnish rural emergency hospital services in the facility 24 hours a day; and
- meets other requirements, such as having a transfer agreement with a level I or level II trauma center and meets certain conditions of participation applicable to critical access hospitals (CAHs).

REHs can bill Medicare beginning in 2023 and are limited to those facilities that were a CAH or a rural hospital with 50 or fewer beds at the time the CAA was passed. For each service, Medicare will pay REHs standard provider-based rates plus a 5 percent add-on for services billable under the OPPS. In addition, Medicare will pay REHs a monthly fixed payment equal to 1/12 of the average excess amount CAHs received in 2019 over what Medicare would have paid these hospitals under the inpatient, outpatient, and skilled nursing facility prospective payment systems. In 2024 and after, the monthly fixed payment amount will be updated based on the hospital market basket.

Beyond the requirements stipulated in law, the Secretary has discretion to determine additional requirements that should apply to REHs. CMS solicits comments on these requirements, the calculation of the monthly fixed payments, and, more broadly, on a variety of topics related to the establishment of REHs.

Comment

The Commission appreciates CMS's efforts to carefully design the rules that will apply to REHs. The Commission has a long history of monitoring and making recommendations to improve rural beneficiaries' access to care. Over the last decade, the Commission has conducted numerous site visits to rural communities, analyzed rural beneficiaries' claims data to assess use of services, surveyed rural beneficiaries regarding their access to care, and conducted focus groups with rural beneficiaries. In 2018, the Commission recommended that Medicare allow isolated stand-alone EDs to bill the Medicare program, a proposal that is broadly consistent with the newly established REH designation.[7]

Monthly fixed payment rates to REHs

The Commission contends that CMS could reasonably interpret the statute in ways that would result in substantially higher or lower monthly fixed payments for REHs. A key factor driving this potential difference is whether to include beneficiary cost sharing or only program payments in the calculation of the monthly fixed rates. Rural beneficiaries pay high cost-sharing amounts at CAHs relative to what they would pay if the same services were billed under prospective payment systems.[8] Thus, including beneficiary cost sharing will materially increase the monthly fixed payments that REHs receive. For example, the Office of Inspector General has found that beneficiaries paid nearly half the cost for outpatient services at CAHs.[9] In contrast, beneficiaries are generally responsible for 20 percent of the Medicare payment rate when the same service is billed under the OPPS.

Beyond the consideration of whether to include cost sharing, CMS should make technical adjustments to the calculation of the monthly fixed rate to ensure it is not excessive (such as making an adjustment to account for diagnostic coding differences between CAHs and PPS hospitals) and monitor the number of hospitals that become REHs and adjust the monthly fixed payment rate as necessary.[10]

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[7]Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

[8]Beneficiaries' cost sharing for outpatient services at CAHs is substantially higher because they are responsible for 20 percent of charges, not payments or costs, at CAHs. CAHs often charge double (or more) the cost of the outpatient service provided.

[9]Office of Inspector General, Department of Health and Human Services. 2014. *Medicare beneficiaries paid nearly half of the costs for outpatient services at critical access hospitals*. OEI-05-12-00085. Washington, DC: OIG.

[10]Hospitals paid under the inpatient prospective payment system have an incentive to fully document the health conditions of their patients because their Medicare payment rates are higher if their patients have comorbidities. CAHs do not have that incentive because they are paid on costs. Therefore, when CMS calculates what CAHs would have been paid under the various prospective payment systems, the agency should approximate the effect of this coding differential and incorporate its effect into the calculation of the monthly fixed payment rate, which will have the effect of lowering the payment rate.

ED staffing requirements

As CMS notes in the proposed rule, the statute requires REHs to staff their EDs 24/7 and to meet the CAH conditions of participation with regard to emergency services (42 CFR 485.618). Under these rules, CAHs are allowed to meet ED personnel standards by having a clinician immediately available by telephone and available on the hospital's campus within 30 minutes (or 60 minutes in certain frontier areas). In addition, CAHs are allowed to close and be unstaffed if there are no inpatients in the hospital. Given the level of investment Medicare's new monthly fixed payments represent, we do not believe that REHs should be allowed to meet the 24/7 ED staffing requirements using the standards in the CAH conditions of participation. Instead, the Commission believes the Secretary should use his authority to require REHs to have at least one physician, nurse practitioner, clinical nurse specialist, or physician assistant with training or experience in emergency care staffing their ED 24 hours a day, 7 days a week. These clinicians should be required to be physically located on the hospital campus to meet the REH staffing requirements.

The creation of REHs represents a substantial investment by Medicare in maintaining or improving access to ED care among rural beneficiaries. In essence, Medicare will be providing extra funding to make sure rural beneficiaries do not face excessive travel times when seeking emergency care. Long travel times can prevent some rural beneficiaries from accessing needed care and can even increase mortality for certain conditions.[11,12] However, without requiring a clinician to be physically present at REHs 24/7, the Commission is not convinced the new REH program will achieve its goals, as some REHs might staff their EDs the way they previously have staffed CAHs. For example, during a MedPAC site visit to a CAH, we found that the most advanced staff available 24/7 in the ED was often a licensed practical nurse (LPN); when a patient presented to the ED, the LPN would call an off-site physician located in a neighboring town (which also had a CAH) who then needed to travel to the hospital to treat the patient. The CAH's medical director and administrator both acknowledged that while this arrangement met CAH conditions of participation, it was insufficient to deal with emergencies, and in some cases, the hospital administrator directed ambulances to bypass their hospital and travel to a CAH that was staffed 24/7 by a physician, nurse practitioner, or physician assistant. For the REH program to achieve its primary goal of providing emergency access, the CAH conditions of participation are insufficient and should not be used for REHs. Staffing REHs 24/7 creates standby costs, but that is precisely the purpose of having the additional fixed monthly payment that supplements fee-for-service payments.

Finally, as CMS considers the conditions of participation and quality reporting rules for REHs, the Commission encourages CMS to firmly require clinicians trained in emergency medicine to be in the facility 24/7, but to provide flexibility for rural communities regarding other services provided. For example, the Commission contends that REHs should be given broad latitude to perform outpatient services for which the hospital is equipped but does support requiring REHs to furnish any services beyond those that are critical for ensuring timely access to ED care. Rural

[11]Jena, A. B., N. C. Mann, L. N. Wedlund, A. Olenski. 2017. Delays in emergency care and mortality during major U.S. marathons. *New England Journal of Medicine* 376 (15): 1441–1450.
[12]Buchmueller, T. C., M. Jacobson, C. Wold. 2006. How far to the hospital? The effect of hospital closures on access to care. *Journal of Health Economics* 25 (4): 740–761.

communities are diverse, and the needs of local communities vary. The local hospitals should be given as much flexibility as is practicable to respond to those local needs. In addition, many small, rural hospitals have limited resources to manage administrative rules, so simplifying and streamlining any additional administrative requirements would be beneficial.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals from CMS. The Commission values the ongoing cooperation and collaboration between CMS and MedPAC 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 James E. Mathews, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair