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September 21, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: File code CMS-1695-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: "Medicare program: Proposed changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; requests for information on promoting interoperability and electronic health care information, price transparency, and leveraging authority for the competitive acquisition program for Part B drugs and biologicals for a potential CMS innovation center model" published in the *Federal Register* on July 25, 2018 (83 FR 37046–37240). 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.

As you know, the outpatient prospective payment system (OPPS) classifies services provided in outpatient departments into ambulatory payment classification (APC) groups. Each APC group has a relative weight, which is an indexed measure of the resources needed to furnish a service. The OPPS determines payment rates for APCs as the product of the relative weights and a conversion factor. The ASC payment system largely uses the APCs and relative weights from the OPPS but uses a different conversion factor to obtain payment rates. This proposed rule is similar to its predecessors in the sense that it documents changes in the composition of some APCs and proposes changes to the relative weights based on analysis of claims and cost report data. The rule also estimates the calendar year 2019 update to the conversion factors in the OPPS and the ASC payment system.

Among other policies discussed, this rule:

- Proposes to modify the definition of device-intensive procedures, including lowering from 40 percent to 30 percent the minimum device-offset percentage needed to qualify as device intensive.

- Proposes to reduce the payment rate for certain drugs from the current level of wholesale acquisition cost (WAC) + 6 percent to WAC + 3 percent when average sales price (ASP) is not available.
- Proposes to continue a policy established in 2018 to set the OPPS payment rates for non-pass-through, separately payable drugs provided in hospitals participating in the 340B Drug Pricing Program at 22.5 percent below each drug's average sales price (ASP-22.5 percent).
- Proposes to require that a Healthcare Common Procedure Coding System (HCPCS) modifier be reported with every claim line for outpatient hospital services furnished in off-campus emergency departments (OCEDs). The purpose is to collect data to assess the extent to which OPPS services are shifting to OCEDs.
- Proposes to control for unnecessary increases in the volume of hospital outpatient services by applying the same payment rate for clinic visits furnished in off-campus provider-based departments (PBDs) regardless of whether the PBD is excepted or nonexcepted from the rules of section 603 of the Bipartisan Budget Act of 2015 (BBA 15). The payment rate would be the rate currently paid in nonexcepted PBDs, which is lower than the rate currently paid in excepted PBDs.
- Proposes that if an off-campus PBD that is excepted from section 603 of BBA 15 furnishes services from any clinical family of services from which it did not furnish a service during a baseline period from November 1, 2014, through November 1, 2015, then services from these new clinical families would not be excepted from section 603 of BBA 15. These services are excepted under current policy, meaning they are paid at OPPS rates. The intent of this proposal is to limit the expansion of excepted services in off-campus PBDs.
- Solicits comments on alternatives to the proposal that would use clinical families to limit the expansion of excepted items and services in excepted off-campus PBDs.
- Proposes to pay a rate of ASP-22.5 percent for separately payable non-pass-through drugs and biologics that are obtained through the 340B program and provided in off-campus PBDs that are not excepted from section 603 of BBA 15. These drugs are currently paid at ASP+6 percent.
- Proposes to pay separately for a non-opioid drug, Exparel, in the ASC payment system (CMS does not propose to pay separately for this drug in the OPPS).
- Proposes, for a five-year period, 2019 through 2023, to change the basis for annually updating the ASC conversion factor by using the hospital market basket (MB) index instead of the consumer price index for urban consumers (CPI-U). During this period, CMS proposes to assess the feasibility of collecting ASC cost data that could be used to establish an ASC-specific market basket index.
- Proposes to remove 10 measures from the Hospital Outpatient Quality Reporting (OQR) Program and eight measures from the ASC Quality Reporting (ASCQR) Program.

- Solicits comments on design considerations for developing a potential drug purchasing model similar to the model for the competitive acquisition program that would test private market strategies and introduce competition to improve quality of care, while reducing both Medicare expenditures and beneficiaries' out-of-pocket spending.

We focus our comments on the topics listed above. We do not comment on the update to the OPPS conversion factor because the proposed update is largely consistent with the update that the Commission recommended in our March 2018 report to the Congress. In contrast, we do comment on the proposed update to the ASC conversion factor because it is inconsistent with the Commission's recommendation to provide no update and collect cost data from ASCs.¹

Modifications to the device-intensive procedure policy for 2019

In both the OPPS and the ASC payment system, CMS currently defines device-intensive procedures as those where:

- The procedure involves an implantable device that would be reported on claims if a device insertion procedure were performed.
- The device is surgically inserted or implanted and remains within the patient's body at the conclusion of the procedure (at least temporarily).
- The device-offset amount is significant, defined as exceeding 40 percent of the procedure's mean cost.

CMS proposes two substantive changes to the definition for device-intensive procedures for 2019. First, CMS proposes to allow procedures that involve surgically inserted or implanted, single-use devices that meet the device-offset percentage threshold to qualify as device intensive, regardless of whether the device remains within the patient's body after the conclusion of the procedure. Second, CMS proposes to lower the minimum required device-offset amount from 40 percent to 30 percent.

The intent of modifying the device-intensive criteria is to allow a greater number of procedures to qualify as device intensive. Also, reducing the minimum required device offset will allow for higher payment rates for these procedures in the ASC payment system, which is likely to lead to the provision of more of these procedures in ASCs.

Comment

The Commission supports this proposal. The proposed changes will likely result in a shift of device implant procedures from hospital outpatient departments to ASCs, which should lower

¹ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare spending and beneficiary cost sharing, assuming that higher use in ASCs does not increase provision of device-intensive procedures to the extent that the cost savings are offset.

Change in payment for separately payable drugs when ASP is not available

Payment rates for separately payable drugs in the OPPS are usually based on average sales price (ASP). When ASP is not available for a drug, payment is based on the drug's wholesale acquisition cost (WAC). CMS proposes to reduce the add-on percentage for separately payable drugs paid based on WAC from 6 percent to 3 percent beginning January 1, 2019.

Comment

The Commission supports CMS's proposal to reduce the add-on percentage for separately payable drugs. The Commission recommended this policy in our June 2017 report to the Congress.² The Commission noted that reducing the add-on for certain WAC-priced drugs is a modest, positive step toward lowering drug costs for beneficiaries and the Medicare program and helps equalize payment rates between the time periods when a drug is ASP-priced versus WAC-priced.

Payment rates for non-pass-through separately payable drugs purchased under the 340B Drug Pricing Program

For CY 2018, CMS established a policy of paying ASP-22.5 percent for non-pass-through separately payable drugs that are obtained through the 340B Drug Pricing Program. CMS proposes to continue this policy in CY 2019.

Before CY 2018, these drugs were paid at a rate of ASP+6 percent. The motivation for the policy change was concern about the growth in the number of providers participating in the 340B program and the high and growing prices of several separately payable drugs covered under Part B.

Comment

In our March 2016 report to the Congress, the Commission made a recommendation that would reduce the OPPS payment rates for drugs obtained through the 340B program by 10 percent of ASP and direct the savings to a Medicare-funded uncompensated care pool. As we indicated in our comments when CMS first proposed paying at ASP-22.5 percent for drugs obtained through the 340B program, the benefits of our March 2016 recommendation are threefold:

- It allows beneficiaries to share in the savings from the 340B program.
- It better targets resources to hospitals that provide the most uncompensated care. Currently, the 340B program is not well-targeted to hospitals that provide high

² Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

levels of uncompensated care. For example, we find that 40 percent of 340B hospitals provide less than the median level of uncompensated care.

- It allows the 340B hospitals to still make a profit on the covered drugs.

We prefer the Commission's recommendation over the current policy of paying a rate of ASP–22.5 percent for non–pass-through separately payable drugs obtained through the 340B program. However, implementing the Commission's recommendation would require legislative action by the Congress, and we recognize that the current policy reflects what CMS can do under its legislative authority.

Require a modifier on claim lines to facilitate collection of data on services furnished in off-campus emergency departments

CMS proposes to create a HCPCS modifier that would be reported with every claim line for outpatient hospital services provided at off-campus emergency departments (OCEDs). This proposal would allow CMS to collect data to better track the extent to which services are shifting to OCEDs.

Comment

The Commission supports this proposal. In our March 2017 report, the Commission expressed concern about the rapid growth in the number of OCEDs.³ However, it is difficult to quantify this growth and its effect on program and beneficiary spending because emergency department (ED) claims are submitted to Medicare through the affiliated hospital's provider identification number and consequently are not separately identifiable. Adding a modifier would allow CMS to distinguish ED services provided at an on-campus ED from those provided at an OCED. This would allow policymakers to identify the number of OCEDs billing Medicare, the types of services they provide, the types of beneficiaries they serve, and the quality of care they provide.

Method to control for unnecessary increases in the volume of outpatient services

CMS expressed concern about the growth in spending under the OPSS, despite efforts to constrain spending through various policies. CMS is concerned that rather than being caused by patient acuity or medical necessity, this growth is caused by payment incentives, particularly higher rates paid in HOPDs relative to the rates paid in freestanding physician offices for largely the same services.

Section 603 of the Bipartisan Budget Act of 2015 (BBA 15) aims to address the different payments for services provided in HOPDs versus freestanding offices. The Congress passed this legislation in response to hospitals acquiring freestanding physician offices, establishing these offices as off-campus provider-based departments (PBDs), and billing for their services under the OPSS. When

³ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare beneficiaries receive services in off-campus PBDs, Medicare makes separate payments to the practitioners under the PFS and to the facility under the OPSS. In contrast, when a service is provided in a freestanding office, Medicare makes only one payment (to the practitioner). Consequently, Medicare typically spends more when a service is provided in an off-campus PBD than when the same service is provided in a freestanding office. In many cases, a physician's practice that is purchased by a hospital and established as an off-campus PBD stays in the same location and treats the same patients. Therefore, the acquisition of freestanding offices has resulted in increased Medicare spending, which leads to higher costs for taxpayers and higher cost sharing for beneficiaries.

Section 603 establishes that services provided in certain off-campus PBDs are not covered under the OPSS. Section 603 further specifies that services provided in these off-campus PBDs are covered under "the applicable payment system," which CMS has established as the PFS.

To be consistent with section 603, CMS distinguished the items and services that may continue to be paid under the OPSS (the excepted items and services) from the items and services that can no longer be paid under the OPSS and must be paid under the applicable payment system (nonexcepted items and services). A category of excepted items and services that CMS has discussed extensively are those provided by excepted off-campus PBDs, defined as those billing under the OPSS before the Congress enacted BBA 15 on November 2, 2015.

However, in this proposed rule, CMS indicates that the majority of off-campus PBDs are excepted from section 603, meaning the services they provide are still covered under the OPSS. CMS also indicates that the higher payment rates under the OPSS give providers incentive to provide care in PBDs rather than in freestanding offices.

CMS proposes to use its authority under section 1833(t)(2)(F) of the Social Security Act to eliminate the difference in payment rates between excepted and nonexcepted services in off-campus PBDs for HCPCS code G0463 (hospital outpatient clinic visits). CMS proposes to apply the nonexcepted payment rate for G0463 (the rate when G0463 is furnished in a nonexcepted off-campus PBD) when G0463 is furnished in an excepted off-campus PBD. CMS believes that this proposal would be an effective method for controlling what it refers to as unnecessary increases in the volume of outpatient services. Moreover, CMS is proposing to make this payment adjustment in a non-budget neutral manner, so the change would reduce aggregate spending under the OPSS.

Finally, CMS solicits comments on how to expand the Secretary's authority under section 1833(t)(2)(F) to additional items and services covered under the OPSS.

Comment

The Commission agrees with CMS concerning the rate of growth under the OPSS. In 2012 and 2014, MedPAC recommended an approach different from the approach detailed in section 603 to address the issue of the higher Medicare payments that result from hospitals converting freestanding offices into off-campus PBDs. Our approach would identify services that meet a certain set of criteria. For services that meet these criteria, the OPSS payment rates would be

adjusted so that total Medicare payments are the same whether the service is provided in a freestanding office or an HOPD.^{4,5} Because our recommended approach does not distinguish between on-campus and off-campus PBDs, it would be less complex to administer than the policy in section 603. However, we recognize that with section 603 of BBA 15, the Congress took a different approach than ours that is based on whether an off-campus PBD began billing under the OPSS after a certain date, and CMS must implement that approach.

The Commission supports the proposal to adjust the OPSS payment rate for clinic visits when they are provided in an excepted off-campus PBD to the same payment rate when they are provided in a nonexcepted off-campus PBD. The result would be that the payment rate for clinic visits provided in off-campus PBDs would more closely match the PFS rate of payment for office visits provided in physician offices. This policy would be consistent with past Commission recommendations for site-neutral payments between HOPDs and freestanding physician offices.

We also highlight two key points from our March 2012 recommendation on site-neutral payments. While we recommended that OPSS payment rates for clinic visits be reduced so that Medicare payments for these services are the same whether they are provided in HOPDs or physician offices, we also recommended that this policy be phased in over three years to allow providers time to adjust to lower payment rates. During the phase-in, payment reductions to hospitals with a disproportionate share (DSH) patient percentage at or above the median would be limited to 2 percent of overall Medicare payments because these hospitals are often the primary source of care for low-income beneficiaries and limiting the reduction in revenue would help maintain access to care for these beneficiaries. We therefore suggest CMS include a phase-in of its proposed policy and a limit on revenue reductions to hospitals with relatively high DSH patient percentages.

Finally, in response to CMS's request for comments on expanding the Secretary's authority under section 1833(t)(2)(F), we suggest that CMS consider using the five criteria that the Commission has developed for identifying services for which it is reasonable to have site-neutral payments between freestanding physician offices and HOPDs.⁶ This approach would move beyond the proposal in this rule, where CMS proposes to pay equally between excepted and nonexcepted off-campus PBDs for clinic visits.

Use clinical families of services to limit expansion of excepted services at off-campus departments of a provider

We mentioned earlier that when CMS implemented the provisions of section 603 of BBA 15, the agency distinguished the items and services that may continue to be paid under the OPSS (the excepted items and services) from the items and services that can no longer be paid under the OPSS and must be paid under the PFS (nonexcepted items and services). CMS has been especially

⁴ Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

⁵ Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

⁶ Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

concerned about the excepted items and services provided in excepted off-campus PBDs that were being paid under the OPSS before the date that the Congress enacted BBA 15: November 2, 2015. In the CY 2017 proposed rule, CMS expressed concern that allowing these off-campus PBDs to expand the types of items and services they provide and permitting them to bill for them as excepted items and services under the OPSS would further enable hospitals to purchase new physician practices and add them to existing off-campus PBDs. In response, CMS proposed to group the APCs in the OPSS into 19 clinical families. Excepted items and services would be limited to the items and services in the same clinical families that the off-campus PBD provided before November 2, 2015. Other items and services would not be excepted and could not be paid under the OPSS. However, after consideration of public comments, CMS opted not to make this proposal final.

In this rule, CMS again proposes to implement the limits on excepted items and services to the 19 clinical families. As CMS did in CY 2017, CMS is proposing to group the APCs in the OPSS into 19 clinical families. Excepted items and services would be limited to those in the same clinical families that the off-campus PBD provided during the November 1, 2014 through November 1, 2015 period. Under this proposal, if an off-campus PBD expanded so that it provided items and services from clinical families that it did not provide before November 2, 2015, those items and services would not be excepted. However, if an off-campus PBD increased the volume of items and services in one or more of the clinical families that it was providing before November 2, 2015, the increased volume would have excepted status.

CMS is also soliciting public comments on alternate methods for limiting the expansion of excepted services in excepted off-campus PBDs for CY 2019. In particular, CMS invites comments on other methods such as the approach that the Commission recommended in our comments to the CY 2017 and CY 2018 proposed rules.

Comment

In our comment letter on the CY 2017 proposed rule, the Commission expressed concern that CMS's proposed approach to address the issue of undesirable incentives for excepted PBDs was unnecessarily complex.⁷ As we stated in our comments to the CY 2017 and CY 2018 proposed rules, we believe a better approach would be for CMS to determine how much the Medicare program had paid an off-campus PBD for items and services billed under the OPSS during a 12-month baseline period. Then, beginning January 1, 2019, annual program spending for items and services billed by the PBD under the OPSS would be capped at the amount paid to the PBD during the baseline period. Over the course of a year, the hospital would bill for items and services provided at the off-campus PBD under the OPSS. When the hospital reaches the annual cap for that location, CMS would no longer pay OPSS rates for items and services provided at that location. Instead, CMS would pay for those items and services at the nonfacility PFS rate. The annual cap could be updated based on the annual updates to the OPSS payment rates.

⁷ Medicare Payment Advisory Commission. 2016. Comment letter on 2017 proposed rule for the hospital outpatient prospective payment system and the ambulatory surgical center payment system.

CMS could implement this method using CY 2017 as the baseline because CMS began requiring hospitals to record a HCPCS modifier of “PO” with every code for items and services provided in excepted off-campus PBDs beginning in that year. Therefore, volume and spending data are readily available for excepted items and services from CY 2017. However, these claims identify the hospital that an off-campus PBD is associated with, not the specific off-campus PBD, and many hospitals have multiple off-campus PBDs. For hospitals that have more than one excepted off-campus PBD, CMS would have to determine which claims to attribute to each excepted off-campus PBD. We believe this approach would be easier to administer and would curb the ability of hospitals to benefit financially from purchasing freestanding physician practices and converting them to off-campus PBDs.

Apply the 340B drug payment policy to nonexcepted off-campus departments of a hospital

The payment policy that CMS has established for items and services that are not excepted from section 603 of BBA 15 means that non-pass-through separately payable drugs obtained through the 340B program and provided in nonexcepted PBDs are paid at ASP+6 percent. The reason is that these drugs are paid under the PFS, as are all nonexcepted items and services. At the same time, the payment policy for excepted items and services means that non-pass-through separately payable drugs obtained through the 340B program and provided in excepted PBDs are paid at the OPPS rate of ASP–22.5 percent. Therefore, Medicare pays for the same drug differently, depending on where it is provided. CMS has indicated that it has received comments that providers could respond by moving the administration of drugs obtained through 340B to nonexcepted off-campus PBDs to receive higher payment rates.

In this proposed rule, CMS states that it agrees with the commenters about the potential shift of drug administration to nonexcepted off-campus PBDs. In response, CMS proposes to pay under the PFS at a rate of ASP–22.5 percent for non-pass-through separately payable drugs that are obtained through the 340B program and furnished in nonexcepted off-campus PBDs.

This proposal to pay for drugs obtained through the 340B program at a rate of ASP–22.5 percent when they are furnished in a nonexcepted off-campus PBD raises legal questions because these drugs are covered under the PFS, where drugs are paid at a rate of ASP+6 percent in accordance with section 1847A of the Social Security Act. CMS recognizes these legal questions and explains that the agency believes that it has the flexibility to pay for non-pass-through separately payable drugs furnished in nonexcepted off-campus PBDs at a rate that is different from the PFS rate. CMS states that it is already paying for drugs differently when they are provided in a nonexcepted off-campus PBD relative to what they would pay when they are provided in a physician’s office because some drugs are packaged into the payments of the applicable services when provided in nonexcepted off-campus PBDs and paid separately when provided in a physician’s office. Moreover, CMS states that “Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted off-campus PBDs is based on a percentage of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis.”

Comment

Earlier in this letter, we stated that we prefer the Commission's recommendation on payments for drugs obtained through the 340B program over the current policy of paying for non-pass-through separately payable drugs that are obtained through the 340B program at a rate of ASP-22.5 percent. This preference extends to payments for drugs provided in off-campus PBDs. Therefore, we would prefer that payments for drugs obtained through the 340B program that are furnished in excepted and nonexcepted PBDs reflect the Commission's recommendation. However, we recognize that CMS does not have the legal authority to implement the Commission's recommendation. Moreover, the Commission supports site-neutral payments and shares CMS's concern that the lack of site-neutral payments may cause a shift of non-pass-through separately payable drugs to nonexcepted off-campus PBDs. Therefore, CMS should ensure that payment for these drugs should be equal across settings.

Payment policy for non-opioid pain management treatments

The OPPS and the ASC payment system package drugs that function as supplies in surgical procedures. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that CMS examine payment policies for non-opioid drugs that function as supplies.

CMS evaluated the effects that packaging has on the use of drugs that function as supplies in surgical procedures. In this rule, CMS discussed the effect of this packaging policy on the use of Exparel, a non-opioid drug used to manage postsurgical pain. Exparel had pass-through status from CY 2012 through CY 2014 and was therefore separately paid during that period in both the OPPS and ASC payment system. Beginning in CY 2015, Exparel has been packaged as a supply in both payment systems. Exparel is currently the only non-opioid pain management drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

In their analysis of Exparel use from 2013 to 2017, CMS found that the drug's use differed in the HOPD and ASC settings. First, even when the drug was paid separately, use of Exparel in ASCs was much lower than in HOPDs. In addition, in the HOPD setting, the use of Exparel continued to increase even after the drug began to be packaged. By contrast, in the ASC setting, the use of Exparel increased rapidly when it was paid separately as a pass-through drug from 2013 through 2014 but declined substantially when the drug was packaged from 2015 through 2017.

Because use of Exparel declined in the ASC setting after the drug began to be packaged, CMS is proposing to unpackage and pay separately for the cost of non-opioid pain management drugs that function as supplies in surgical procedures when furnished in the ASC setting in CY 2019. Exparel is currently the only drug in this category.

Comment

Though we commend CMS's interest in addressing the issue of opioid overuse and addiction, the Commission has reservations about this proposal. It goes against the policies for packaging and

comprehensive APCs that CMS has implemented in recent years to increase the size of payment bundles in the OPPI, which increases incentives for efficient delivery of care. Even though this policy currently affects one drug (Exparel), we are concerned that unpackaging of this one drug may establish a precedent. We prefer a policy that maintains the packaging of drugs that function as supplies in surgical procedures.

Use of the hospital market basket index to update the ASC conversion factor and assessing the feasibility of collecting ASC cost data

CMS proposes to increase the ASC conversion factor in 2019 by 2.0 percent, based on a 2.8 percent increase in the hospital market basket (MB) minus a 0.8 percentage point deduction for multifactor productivity growth mandated by the Patient Protection and Affordable Care Act (PPACA). Concurrently, CMS proposes to replace its use of the consumer price index for urban consumers (CPI-U) to update the ASC conversion factor with the hospital MB index for five years beginning in CY 2019. CMS seeks comment on whether the hospital MB index is an appropriate proxy for ASC costs, and the duration of the interim period in which the hospital MB will be used.

CMS also proposes to use the aforementioned five-year interim period to assess the feasibility of collecting ASC cost data in a minimally burdensome manner. CMS states that during this period the agency could propose a plan to collect cost data from ASCs. CMS is seeking comments on how CMS should go about collecting ASC cost data.

Comment

In the Commission's March 2018 report, we recommended that the Congress eliminate the update to ASC payment rates for 2019 and also that the Secretary require ASCs to report cost data.⁸ The Commission's recommendation was based on our indicators of payment adequacy for ASCs, which are positive, and the importance of maintaining financial pressure on providers to constrain costs. The Commission believes the proposed 2.0 percent increase to ASC payment rates is unnecessarily high, the use of the hospital MB is flawed, and ASCs should begin reporting cost data as soon as possible.

We have stated for several years in comment letters on proposed rules and in published reports that we concur with CMS that the CPI-U is not likely to reflect the current input costs of ASCs.⁹ However, we are opposed to using the hospital MB index as an interim method for updating the ASC conversion factor because evidence indicates that the hospital MB index does not accurately reflect the costs of ASCs. In this proposed rule, CMS acknowledges that the ASC cost structure is not identical to that of hospitals, because ASCs tend to be single specialty, for profit, and are not

⁸ Medicare Payment Advisory Commission. 2018. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC.

⁹ Medicare Payment Advisory Commission. 2013. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2014. Comment letter on 2015 proposed rule for the outpatient prospective payment system and ambulatory surgical centers. Medicare Payment Advisory Commission. 2017. Comment letter on 2018 proposed rule for the outpatient prospective payment system and ambulatory surgical centers.

required to comply with the Emergency Medical Treatment and Labor Act (EMTALA).¹⁰ We concur with these observations and add that, 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.¹¹

We strongly urge CMS to forgo the proposed five-year period to assess the feasibility of ASC cost reporting and instead use its authority and resources to act quickly in gathering ASC cost data. These data could provide information on the input costs of ASCs and the adequacy of payments to ASCs. In turn, this information could inform the creation of an ASC-specific MB index and generally inform future ASC payment updates. The Commission has recommended that ASCs be required to submit cost data since 2004.¹² In addition, CMS has previously solicited public comments on the feasibility of collecting cost information from ASCs but has yet to propose a plan to collect this information. From our perspective, it appears unnecessary for CMS to spend five additional years assessing the feasibility of cost reporting.

The Commission firmly asserts that sufficient evidence exists that ASCs are capable of submitting cost data to CMS:

- In 2006, the Government Accountability Office (GAO) conducted a survey of ASC costs, which influenced the design of Medicare's ASC payment system.¹³ Now over a decade old, GAO's survey remains the most recent data on ASC costs. This survey demonstrates that a streamlined survey of ASC costs is feasible and that ASCs are capable of providing these data.
- The Pennsylvania Health Care Cost Containment Council collects cost and charge data from freestanding ASCs in Pennsylvania on a quarterly basis and has done so since 2010. The Council uses these data to calculate ASC margins.
- Currently, several types of small health care providers submit cost data to CMS annually. Over 12,000 home health agencies, 7,000 dialysis facilities, and 3,000 freestanding hospices submit cost data to CMS.
- Ground ambulance suppliers will begin submitting cost data to CMS in 2020. The Balanced Budget Act of 2018 (enacted in February 2018) required the Secretary to collect cost, revenue, utilization, and other information determined appropriate to evaluate the extent to which reported costs relate to payment rates. Further, the Congress gave the

¹⁰ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program: Proposed changes to the hospitals outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; Requests for information on promoting interoperability and electronic health care information, price transparency, and leveraging authority for the competitive acquisition program for Part B drugs and biologicals for a potential CMS Innovation Center model. *Federal Register* 83, no. 147 (July 31), 37046–37240.

¹¹ Medicare Payment Advisory Commission. 2013. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC.

¹² Medicare Payment Advisory Commission. 2004. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC.

¹³ Government Accountability Office. 2006. *Medicare: Payment for ambulatory surgical centers should be based on the hospital outpatient payment system*. GAO report: GAO-07-06. Washington, DC: GAO.

Secretary less than two years from the date of enactment of the BBA of 2018 to specify the ambulance cost reporting system and identify a sample of ambulance suppliers required to submit cost data. The law also mandates a 10 percent reduction to ambulance payments for ambulance suppliers that fail to sufficiently submit cost data.

To minimize the burden for all involved, CMS could require ASCs to submit streamlined cost reports or, similar to the ambulance setting, select a sample of ASCs to submit cost data annually.¹⁴ In addition to more traditional Medicare cost reporting variables such as payments and costs by payer type, the ASC cost reporting device should collect cost data for items such as drugs, medical supplies (including costly implantable devices), medical equipment, employee compensation, building expenses (such as rent), and other professional services (such as legal, accounting, and billing services).

Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Reporting Program

The Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) programs require hospitals and ASCs to report data on a set of quality measures specified by CMS. If they fail to do so, their annual update factors will be reduced by 2.0 percentage points in the following year. The potential reduction is tied to reporting rather than their performance on quality measures. CMS lacks the statutory authority to establish a value-based purchasing (VBP) program for HOPDs or ASCs that would adjust payments based on performance.

Comment

In general, the Commission supports VBP (i.e., pay for performance) approaches over pay-for-reporting and has recommended such a program for ASCs.¹⁵ In VBP programs for HOPDs and ASCs, high-performing providers would be rewarded and low-performing facilities would be penalized through the payment system. The VBP programs should be based on a small number of population-based measures (i.e., outcomes, patient experience, Medicare spending per beneficiary). CMS should seek legislative authority to implement these programs.

Removal of measures

In October 2017, CMS launched the Meaningful Measures Initiative aimed at improving patient outcomes and reducing administrative burden associated with quality programs by using a reduced set of the measures. As a part of the initiative, CMS identified 19 high-priority areas for quality measurement with a focus on improving patient outcomes (e.g., admissions and readmissions to hospitals, patient's experience of care, transfer of health information, preventive care).

¹⁴ Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁵ Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

As a part of the Meaningful Measures Initiative, CMS proposes to remove 10 measures from the OQR in CY 2019. CMS determined that for five of these measures the cost to collect the measure outweighs its benefit, two of these measures are topped out (i.e., high performance and little variation in performance), two are not tied to better patient outcomes, and one is now inconsistent with current clinical guidelines. In addition, CMS is continuing the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) survey as a voluntary measure within the OQR until further notice. If finalized, this proposal will reduce the number of OQR measures to 12 by CY 2021.

At the same time, CMS proposes to remove eight measures from the ASCQR. CMS determined that for four of these measures the cost to collect and report the measure outweighs the benefit, and four other measures are “topped out” and do not show meaningful variation between facilities. As with the OQR, CMS has paused the requirement for the OAS CAHPS survey within the ASCQR until further notice. If finalized, this proposal will reduce the number of ASCQR measures to 3 by CY 2021.

Comment

The goals of CMS’s Meaningful Measures Initiative align with the Commission’s principles for quality measurement. Therefore, the Commission supports removing the 10 OQR measures and 8 ASCQR measures. As CMS continues to revise Medicare quality programs, we encourage CMS to use a uniform set of population-based outcome measures across settings and populations.

As stated in previous comment letters, there are modifications to the current set of ASCQR measures that the Commission believes CMS should make. First, the current measure on hospital transfers should be expanded to include patients who visit a hospital (inpatient admission or emergency department) in the days following their ASC procedure. Including these patients in the measure would enable CMS to more comprehensively track patients who experience serious complications or medical errors related to an ASC procedure. In 2022, CMS will add two measures assessing the number of urology and orthopedic cases, respectively, that have a hospital visit within 7 days of their release from the ASC. The Commission urges CMS to develop and implement a risk-adjusted, all-condition hospitalization measure which would capture 7-day subsequent hospitalizations that apply to every specialty area conducting procedures in ASCs. In the hospital value incentive program (HVIP) the Commission has recently designed to link hospital quality performance to payment, we used all-condition measures (e.g., readmissions) rather than condition-specific to increase the number of observations and reduce the random variation that single-condition rates may face.¹⁶ For public and provider reporting, CMS should continue to develop and implement specialty-specific hospitalization measures that apply to specialties conducting a high volume of procedures in ASCs—in particular, gastroenterology, ophthalmology, and cardiology.

The Commission believes that Medicare quality programs should also include patient experience measures, such as the OAS CAHPS survey measures. The use of surveys to query patients about

¹⁶ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

their experience in health care settings is the best and often only way to examine whether high-quality, patient-centered care actually takes place. We understand that CMS needs more information and time to implement a valid and reliable OAS CAHPS, but we encourage CMS to require patient experience measures in the OQR and ASCQR as soon as feasible.

Accounting for social risk factors in quality measurement

On the issue of accounting for social risk factors in Medicare quality measurement programs, CMS has been reviewing public comments to proposed rules and reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine. Specifically, CMS continues to consider options to address equity and disparities in value-based purchasing programs.

Comment

The Commission supports CMS's continued consideration of how to account for social risk factors in Medicare quality programs. The Commission asserts that the Medicare program should incorporate differences in providers' patient populations—which affect providers' performance on quality measures, including social risk factors—and that Medicare should account for social risk factors in quality programs by adjusting payment through peer grouping. Medicare should also target technical assistance to low-performing providers.

Competitive Acquisition Program for Part B drugs

CMS administered the Competitive Acquisition Program (CAP) for Part B drugs from 2006 to 2008. Under the CAP, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program. The program's goal was to give physicians an alternative to the system of buying and billing for drugs and eliminate any financial incentives for prescribing drugs. The program also offered the potential for economies of scale in purchasing. However, the program faced challenges. Physician enrollment was low, CMS contracted with only one vendor, and Medicare paid in aggregate more than ASP+6 percent for drugs under the program.

The proposed rule includes a request for information (RFI) from CMS's Center for Medicare and Medicaid Innovation on potential models that would test improvements to the CAP. The agency indicated that such a model could test a range of payment arrangements such as value-based pricing strategies, indication-based pricing, payment over time, shared savings or performance-based payments based on the total cost of care. The RFI asks for feedback on specific questions about how a model might be structured in several topic areas such as included providers and suppliers; included drugs and biologicals; beneficiary cost sharing, protections, and fiscal considerations; model vendors; regulatory barriers and transparency issues; and model scope.

The RFI mentions MedPAC's June 2017 recommendation for a Drug Value Program (DVP) that builds off of the CAP experience. The agency notes that, different from the CAP, under MedPAC's DVP model the vendors would not take title to the drug. The RFI indicates that CMS is considering how to structure the vendor's role and whether to test models where the vendor takes

title to the drug (similar to the CAP) or does not take title to the drug (similar to the DVP) or both types of models.

Comment

The Commission appreciates CMS's efforts to explore and seek comment on models that would improve upon the CAP, including MedPAC's DVP model. In June 2017, the Commission recommended that Medicare develop the DVP as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools to negotiate drug prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities.

Several features of the DVP model are intended to address problems inherent in the earlier CAP model. The DVP model would give vendors greater negotiating leverage with manufacturers by permitting vendors to use tools such as a formulary and, in certain circumstances, binding arbitration. The DVP model would encourage provider enrollment by modifying the way drugs are supplied under the model. Providers enrolled in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. DVP enrollment would also be encouraged by offering providers shared savings opportunities through the DVP, while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

Key features of the DVP model recommended by the Commission include:

- Physicians and outpatient hospitals could choose to enroll in the DVP
- ASP add-on would be reduced in the ASP system to encourage DVP enrollment
- Medicare contracts with a small number of private vendors to negotiate prices for Part B products
- Providers purchase all DVP products at the price negotiated by their selected DVP vendor
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings
- Beneficiaries pay lower cost sharing
- Medicare payments under the DVP cannot exceed 100 percent of ASP
- Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration

In response to the detailed questions in the RFI, below we provide more technical information on the mechanics of the DVP model as we detailed in our report to Congress. We note at the beginning of each discussion the relevant section of the RFI.

Voluntary program for physicians and outpatient hospitals *(RFI – Included providers and suppliers)*

The Commission believes that the DVP program should be a voluntary alternative to the ASP payment system for physicians and outpatient hospitals. Each year, these providers would have the choice of whether to enroll in the DVP or remain in the ASP system. Providers could not choose to enroll in the DVP on a drug-by-drug basis. Rather, providers would either choose to participate in the DVP or remain in the ASP system for all drug classes covered by the DVP.

Small number of vendors, with each provider selecting one vendor *(RFI – Model vendors)*

It would be desirable for there to be a small number of national DVP vendors. This would give providers some choice of which vendor to work with while consolidating volume among a small number of vendors to gain greater negotiating leverage. Providers could select only one DVP vendor so that vendors could effectively use management tools like a formulary.

Vendor's role to negotiate prices *(RFI – Model vendors; model scope)*

A DVP vendor's role would be to negotiate prices with manufacturers and make those prices available to providers through a network of distributors and wholesalers. Providers would order drugs from distributors or wholesalers at the vendor-negotiated price for Medicare fee-for-service (FFS) beneficiaries. Providers could use electronic accounting software to track the amount of product administered to Medicare FFS beneficiaries. A retroactive reconciliation process could then occur between the provider and distributor or wholesaler after the drugs are administered to confirm the quantity supplied to Medicare FFS beneficiaries and ensure that the price charged for those units was the DVP-negotiated price. This approach would permit providers to order drugs in the marketplace largely as they do now, without needing to acquire drugs through a special entity or to separate inventory for Medicare FFS beneficiaries from inventory for other patients.

It is important to note that, although the DVP is designed to improve pricing and payment for Part B drugs furnished to Medicare FFS beneficiaries, the potential for providers to purchase drugs for their Medicare Advantage patients through the DVP could also be explored.

Limit DVP prices to no more than 100 percent of ASP and exclude DVP prices from ASP reporting *(RFI – model vendors, manufacturer participation)*

Manufacturers whose drugs are covered under Medicare Part B would be required to offer drugs to DVP vendors at a price no higher than 100 percent of ASP. This requirement would ensure that the DVP vendor could obtain at least typical market prices for all drugs. To give DVP vendors the most negotiating leverage with manufacturers, DVP prices would be excluded from ASP.

DVP prices would not be public *(RFI – Regulatory barriers and transparency issues)*

To give DVP vendors greater negotiating leverage, DVP prices would not be public. DVP prices would be known to the government; the DVP vendor; manufacturers, wholesalers and distributors

that offered products at the DVP-negotiated price; and the DVP vendor's provider members, but these entities would not be permitted to disclose that information to others.

Payment of providers and vendors and shared savings opportunities (*RFI – Included providers and suppliers; vendors*)

Providers participating in the DVP would submit a claim to Medicare for Part B drugs administered to FFS beneficiaries, and the Medicare payment rate for the drug would be set at the DVP-negotiated price. Physicians and outpatient hospitals would also continue to be paid for drug administration services under the physician fee schedule or OPSS. It would be important to review the drug administration payment rates to ensure the inputs used to set those rates were accurate and reflected the cost of administering drugs.

Providers who participate in the DVP would have opportunities for shared savings. If the DVP led to lower aggregate costs of Part B drugs, the savings would be shared with providers. Provider eligibility for shared savings could also be contingent on quality performance (e.g., use of clinical guidelines or pathways) to avoid incentives for stinting. These shared savings opportunities for DVP providers would create greater incentives for efficient, high-quality care than exist under the ASP payment system.

Payment to DVP vendors would be structured to create incentives for vendors to negotiate discounts with manufacturers and lower the total cost of Part B drugs. Medicare would pay the vendor an administrative fee. Options for how to structure the vendor's administrative fee include a fixed dollar payment or a payment per enrolled provider (possibly varying by provider specialty) or a combination of these approaches. Vendors would also have shared savings opportunities. The vendor's shared savings could be conditioned on whether the DVP reduced the total cost of Part B drugs and whether the vendor engaged in efforts to promote quality or met other performance standards.

Several steps related to payment would help prevent conflicts of interest. With respect to vendors, it would be important that vendors not be paid based on a percentage of DVP drug spending since that would give vendors an unintended incentive for increased drug prices and spending. Similarly, DVP vendors should not be permitted to receive cash payment from manufacturers (e.g., rebates) related to the DVP (except in circumstances such as indication-specific pricing or outcomes-based contracts where the rebates are fully passed on to the government). With respect to providers, it would be important that manufacturers not be permitted to pay providers rebates based on the amount of volume purchased under the DVP.

The calculation of shared savings should also be structured to avoid conflicts of interest. A measure of savings should take into account how total Part B drug spending had changed as a result of the DVP, reflecting both changes in price and utilization. It would not be prudent to measure savings based solely on price changes because that could create incentives for choice of an expensive drug with some discount over an inexpensive drug with no discount.

Reduced cost sharing for beneficiaries and beneficiary protections (*RFI – beneficiary cost sharing, protections, and fiscal considerations*)

The DVP model would share savings with beneficiaries by reducing cost sharing. To ensure that DVP prices are not public, beneficiary cost sharing would be reduced in a formulaic way that would not reveal the actual price the DVP negotiated for a particular product. For example, if the DVP in aggregate negotiated prices equivalent to 95 percent of ASP across all drugs in the DVP, beneficiary cost sharing could be set at 20 percent of 95 percent of ASP for all DVP drugs.

Several aspects of the DVP's design would promote quality and provide beneficiary protections. As discussed previously, shared savings for both providers and vendors would be conditioned on meeting certain quality benchmarks. As discussed subsequently, CMS's formulary oversight process and the formulary exceptions and appeals process would provide beneficiary protections.

DVP vendor management tools would include a formulary (*RFI – vendor; beneficiary cost sharing, protections, and fiscal considerations*)

An important feature of the DVP would be its use of formularies designed by the program's private vendors, and, where feasible, with the input from associated physicians. Permitting vendors to exclude drugs or biologics from the formulary when other products with similar health effects exist would give them leverage to negotiate lower prices on these products. In addition to a formulary authority, several other management tools could be included in the DVP such as step therapy and prior authorization. Purchasing tools such as risk-based contracting or indication-specific pricing also could be permitted for use by DVP vendors, as long as the resulting savings are fully passed back to the Medicare program.

Criteria would need to be developed to define the terms of an acceptable formulary (e.g., how drug classes are defined, number of drugs required per class, the process and type of input DVP vendors must seek). CMS would oversee the formularies the vendors develop to ensure they meet established standards. Medicare would need to strike a balance between how much flexibility to give DVP vendors versus how prescriptive to be in the requirements. As long as beneficiaries could obtain the medicines they need, flexibility would be beneficial in terms of greater negotiating leverage and less administrative burden for DVP vendors.

The DVP model would include a formulary exceptions and appeals process to give providers and beneficiaries the opportunity to request coverage of a nonformulary product because of unique aspects of a beneficiary's condition. An exceptions process that involved prior authorization might be ideal in that it would permit providers and beneficiaries to know before administering a nonformulary drug whether an exception would be granted. If the DVP granted the provider a formulary exception, the provider would obtain the nonformulary drug at the product's DVP-negotiated price. If the DVP denied the provider's formulary exception request, the provider and beneficiary would have an opportunity to appeal the denial.

Arbitration (*RFI – Included drugs and biologicals, model vendor*)

An important tool included in the DVP model is binding arbitration. For drugs lacking competition such as the first drug in a therapeutic class or drugs that offer an advantage over existing drugs, a

formulary provides little negotiating leverage. To address this challenge, the DVP model includes binding arbitration as a tool that can be used for high-cost drugs with limited competition. In such cases, binding arbitration could be used to encourage drug manufacturers to negotiate with DVP vendors (to avoid going to arbitration) or serve as a means to arrive at an agreed-upon price if negotiations fail. Arbitration is a process by which two parties accept the verdict of a neutral third party in a dispute—in this case, a dispute over the price of a drug. The two parties entering into arbitration in this case would be the DVP vendor—not CMS—and the drug manufacturer.

Although arbitration would be available to the DVP vendor and manufacturers if price negotiations fail, the inclusion of arbitration within the DVP model is intended to motivate the parties to reach an agreement and thereby avoid arbitration. With a particular type of arbitration called final-offer arbitration (FOA), also referred to as “baseball arbitration” because of its use to resolve labor disputes in Major League Baseball, each party entering arbitration makes an offer and the arbitrator must pick one of those offers. Because each party would face the risk that the arbitrator may choose the other party’s offer, FOA is thought to encourage negotiated agreements.

Phase in DVP starting with a subset of drug classes (*RFI – Included drugs and biologicals*)

The complexity of operating the DVP and developing management tools would vary across types of drugs. Phasing in the DVP over time could address the complexity and create the opportunity to learn from experience. Medicare could choose to phase in the program first with drug classes for which the savings potential seemed largest (i.e., drug classes that include multiple products with similar health effects) and implementation seemed most straightforward.

Incentives for providers to enroll (*RFI – Included providers and suppliers*)

When considering DVP enrollment, providers would be expected to consider how their net revenues earned on drugs under the ASP system would compare with the revenues they would receive under the DVP program. Enrollment in the DVP would be encouraged by reducing the ASP add-on in the traditional ASP system, making that system less attractive to providers. Shared savings opportunities within the DVP model would also help encourage DVP enrollment. By aggregating volume across providers and using management tools such as a formulary, DVP vendors would likely have leverage to negotiate significant discounts for products with similar health effects. Phasing in the DVP by focusing on classes of drugs with the most overall savings potential could help draw attention to the shared savings opportunities for providers and encourage provider enrollment.

Potential expansions to scope of the model (*RFI – Included providers and suppliers*)

Although the Commission did not consider the DVP with respect to Part A–covered drugs such as those furnished by inpatient hospitals, there may be merit in exploring whether such a model could accommodate certain high-priced products regardless of the setting in which they are administered. Under the inpatient hospital prospective payment system, Medicare pays for drugs as a part of larger payment bundles (rather than paying for drugs separately). In general, payment bundles create incentives for providers to be price conscious and to negotiate for lower prices with manufacturers. However, when a drug has limited competition, providers may have little leverage

to negotiate with manufacturers. The recent development of CAR-T immunotherapy, which is extraordinarily expensive and can be furnished in inpatient and outpatient hospital settings, has drawn attention to the issue of very high cost drugs across settings. The DVP model, with its management tools such as a formulary and binding arbitration, may be well suited for addressing very high priced drugs across settings.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals from CMS. The Commission also 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,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive style.

Francis J. Crosson, M.D.
Chairman

FJC/dz/wc