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September 13, 2019

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

**Re: File code CMS-1717-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; price transparency of hospital standard charges; proposed revisions of organ procurement organizations conditions of coverage; proposed prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; proposed changes to grandfathered children's hospitals-within-hospitals" published in the *Federal Register* on July 30, 2019 (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 HOPDs 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 2020 update to the conversion factors in the OPPS and the ASC payment system.

Among other policies discussed, this rule:

- Proposes an alternative to the substantial clinical improvement requirement for medical devices to qualify for pass-through status in the OPPS. CMS proposes that devices that have been approved through the Breakthrough Devices Program and have received Food

and Drug Administration (FDA) marketing authorization would meet the requirement for substantial clinical improvement.

- Proposes to change the minimum required level of supervision of therapeutic services provided in HOPDs from direct supervision to general supervision.
- Proposes to complete the transition established in the 2019 OPSS/ASC final rule to pay clinic visits furnished in off-campus provider-based departments (PBDs) that are excepted from section 603 of the Bipartisan Budget Act of 2015 (BBA 15) at the same rate as clinic visits furnished in off-campus PBDs that are not excepted from the rules of section 603 of BBA 15.
- Proposes to continue to pay separately at a rate of average sales price (ASP) + 6 percent for nonopioid pain management drugs that function as supplies in the ASC payment system. CMS also proposes to continue to package the cost of these drugs, as well as other pain management alternatives, into the payment rates of the applicable surgical procedures in the OPSS.
- Proposes to remove one measure from the Hospital Outpatient Quality Reporting (OQR) Program, add four measures to the Hospital OQR, and add one measure to the ASC Quality Reporting (ASCQR) Program.
- Proposes to require prior authorization for some services provided in HOPDs that CMS asserts are largely performed for cosmetic purposes.

We focus our comments on the topics listed above. We do not comment on the update to the OPSS conversion factor because the proposed update is largely consistent with the update that the Commission recommended in our March 2019 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 to collect cost data from ASCs.<sup>1</sup>

### **Revise the requirement for substantial clinical improvement for pass-through devices in the OPSS**

The OPSS packages the cost of most medical devices into the payment rates of the procedures that use them. However, for new medical devices that are innovatively different from existing devices, cost data are not initially available to allow CMS to incorporate their costs into the payment rates of the applicable services. Therefore, the OPSS allows separate pass-through payments for some new devices. The number of medical devices that have pass-through status in a given year is usually very small. CMS's stated purpose of pass-through payments for select medical devices is to "facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to

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<sup>1</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

incorporate the costs for these devices into the procedure APC rate.”<sup>2</sup> The amount of a pass-through payment for a device is the difference between the hospital charges for the device adjusted to cost and the estimated cost for devices in the payment rate for the applicable procedure.

Medical devices must meet a number of requirements for CMS to grant pass-through status. One requirement is that the device must show substantial clinical improvement, meaning that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to at least one other currently available and appropriate treatment or diagnostic test. CMS has a list of possible clinical improvements whereby a device can meet this requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than is currently possible and this earlier diagnosis results in better outcomes.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments.

CMS proposes a new pathway for new devices to meet the substantial clinical improvement requirement for pass-through devices in the OPSS: A new medical device that is part of the Breakthrough Devices Program and has received marketing authorization from the FDA would not be required to show substantial clinical improvement to be granted pass-through status. CMS’s rationale for this proposal is that it would improve administrative efficiency, reduce barriers to health care innovation, and ensure Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes.

#### *Comment*

CMS recently finalized a similar proposal in regard to new technology add-on payments under the inpatient prospective payment system (IPPS). The Commission did not support this proposal in its comment letter on the fiscal year (FY) 2020 IPPS proposed rule, and the Commission similarly does not support this proposal in the current OPSS proposed rule.

The Commission recognizes the need to promote beneficiary access to new technologies that improve outcomes while preserving the incentives for efficiency within the OPSS. The Commission also appreciates CMS’s desire to improve efficiency when bringing new medical devices to the Medicare population. However, the Commission does not support the use of the

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<sup>2</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. *Process and information required to apply for additional device categories for transitional pass-through payment status under the hospital outpatient prospective payment system.* [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough\\_payment.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html).

FDA’s Breakthrough Device Program for qualification for pass-through payment unless the device in question also meets the current substantial clinical improvement requirement—that is, unless there is some evidence that the new device results in improved care for beneficiaries. The Commission maintains that the Medicare program, not the FDA, should make spending determinations based on the specific needs of the Medicare population. Moreover, CMS’s stated purpose of pass-through payments for new devices is to “facilitate access for beneficiaries to the advantages of new and *truly innovative* (emphasis added) devices.” If CMS does not explicitly require substantial clinical improvement, we question in which way a device would be truly innovative.

The Commission recognizes the importance of the unique roles across Health and Human Services agencies with different standards for approval. The FDA’s role in the device development process as a regulator is distinct and separate from the role of CMS as a payor. The FDA regulates whether a device is “safe and effective” for its intended use by consumers. The FDA approval process may or may not include the new device’s safety or effectiveness with regard to the Medicare population. Through the Breakthrough Device Program, the FDA considers whether a device is reasonably expected to provide more effective treatment or diagnosis relative to the current standard of care. The device manufacturer or sponsor could demonstrate this expectation through literature or preliminary bench, animal, or clinical data.<sup>3</sup> In its FY 2020 IPPS proposed rule, CMS acknowledged that “...*the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.*” Therefore, participation in the Breakthrough Device Program on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. As specified in regulation, CMS’s evidence base for pass-through determination should rely on the device’s ability to offer clinical improvement over other devices or treatments. CMS should not pay more for a new technology without evidence that it improves outcomes for Medicare beneficiaries. Therefore, the evaluation of the evidence of these outcomes should rest with CMS.

There have been many examples where devices approved through expedited FDA approval have not resulted in improvements in care relative to existing technologies. The Breakthrough Device Program is available for devices subject to review under a premarket approval application (PMA), premarket notification (510(k)) clearance, or De Novo marketing authorization. In a July 2011 report, the Institute of Medicine of the National Academies concluded that the 510(k) process “is not a determination that the cleared device is safe or effective.” Further, a review of several studies that presented clinical trial evidence of certain approved devices under the FDA’s Priority Review Program (which was superseded by the Breakthrough Device Program) found that 4 out of 9 expert advisory panel reviews did not find the devices to be effective and, as of May 23, 2018, recalls had been issued for 6 of 14 devices.<sup>4</sup> The Commission is concerned about inappropriate

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<sup>3</sup> Food and Drug Administration. 2018. Breakthrough Device Program: Guidance for industry and Food and Drug Administration staff. December 18.

<sup>4</sup> Jones, C. L., S. S. Dhruva, and R. Redberg. 2018. Assessment of clinical trial evidence for high-risk cardiovascular devices approved under the Food and Drug Administration Priority Review Program. *JAMA Internal Medicine* 178, no. 10 (October): 1418–1419.

incentives (through increased payment) for providers to use new technology without proven safety or efficacy.

Lastly, the Commission has long held that Medicare should pay similar rates for similar care. To protect the well-being of beneficiaries and ensure good value for the Medicare program and thus the taxpayers, Medicare should not pay more for technologies that have not yet been proven to provide better outcomes for beneficiaries. Therefore, new devices should not qualify for the pass-through program if there is no evidence that the device is an improvement relative to existing care.

### **Require general supervision for all hospital outpatient therapeutic services**

Under the OPSS, CMS has required direct physician supervision of the provision of hospital outpatient therapeutic services. Direct supervision requires that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician is not required to be present in the room where the procedure is performed or within any other physical boundary, as long as the physician is immediately available. An alternative is general supervision, which is less strict, as it requires the service to be under a physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.

Many hospitals have raised concerns about the burden of direct supervision, in particular critical access hospitals (CAHs) and small rural hospitals, asserting that they would have difficulty in meeting the direct supervision requirement. In response, CMS instructed the Medicare Administrative Contractors (MACs) not to evaluate or enforce the direct supervision requirement for services provided in CAHs in 2010. CAHs and small rural hospitals continued to express concern about the direct supervision requirement, so CMS extended this notice of nonenforcement for 2011, and expanded it to include rural hospitals having 100 or fewer beds. CMS then extended this nonenforcement for 2012 and 2013. From 2014 through 2017, the Congress legislatively extended the nonenforcement of direct supervision for CAHs and rural hospitals having 100 or fewer beds. Finally, in the OPSS/ASC final rule for 2018, CMS reinstated the nonenforcement of direct supervision for CAHs and rural hospitals having 100 or fewer beds for 2018 and 2019.

CMS proposes to end what has been a two-tiered system of physician supervision of outpatient therapeutic services by changing the minimum level of supervision required of all hospitals from direct supervision to general supervision. CMS does not anticipate problems with quality of care because CMS has not learned of any data or information from CAHs or small rural hospitals indicating that the quality of outpatient therapeutic services has been affected during the period of nonenforcement of direct supervision. Also, CAHs, and hospitals in general, continue to be the subject of conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services to ensure that medical services Medicare patients receive are properly supervised.

#### *Comment*

The 21st Century Cures Act of 2016 mandated that MedPAC report to the Congress about the effects of extending the direct supervision nonenforcement instruction on Medicare beneficiaries'

access to and quality of care as well as its economic impact on the affected hospitals.<sup>5</sup> As detailed in our December 2017 report to the Congress, in interviews with the leadership of CAHs, we heard that CAHs have put in place processes with current staff to offer what they believe to be the appropriate supervision (e.g., using family physicians in the same building as a chemotherapy suite), but they were not certain whether these processes satisfy the supervision requirements. If a hospital can contract with the appropriate specialists and has the necessary volume of patients, it offers its patients access to these services using processes hospital staff believe meet the supervision requirements, or it may limit the hours or days the services are offered based on the specialist's availability.

The Commission believes that CMS should use clinical judgment regarding the patient's safety when deciding the most appropriate supervision level for outpatient therapeutic services and that its clinical determination should apply to both urban and rural hospitals. While, in general, we support CMS's proposal to create a uniform standard of general supervision for all hospital outpatient therapeutic services, we believe that CMS should perform due diligence in monitoring the quality of outpatient therapeutic services under general supervision, particularly for those services most likely to involve the risk of life-threatening complications.

#### **Method to control unnecessary increases in the volume of clinic visits furnished in excepted off-campus provider-based departments**

Under direction from section 603 of the Bipartisan Budget Act of 2015 (BBA 15), CMS has established distinctly different OPPS payment rates for off-campus provider-based departments (PBDs) of hospitals that are excepted from the rules of section 603 of BBA 15 (excepted off-campus PBDs) and for off-campus PBDs that are not excepted from the rules of section 603 of BBA 15 (nonexcepted off-campus PBDs). Hospitals receive full OPPS payments for services they provide in excepted PBDs but receive OPPS payments reduced by 60 percent for services they provide in nonexcepted PBDs.

In the calendar year (CY) 2019 OPPS/ASC final rule, CMS expressed concern about unnecessary growth in volume and spending in the OPPS. To address this issue, CMS used its authority under section 1833(t)(2)(F) of the Social Security Act to eliminate the difference in payment rates between excepted and nonexcepted off-campus PBDs for Healthcare Common Procedure Coding System (HCPCS) code G0463 (hospital outpatient clinic visits).<sup>6</sup> This policy applies the (lower) nonexcepted payment rate for outpatient clinic visits when hospitals furnish that service in excepted off-campus PBDs. CMS believes that this proposal is an effective method for controlling what it refers to as unnecessary increases in the volume of outpatient services. However, CMS chose to phase in this policy over a two-year period, so the 2019 payment for outpatient clinic visits when hospitals furnish them in an excepted off-campus PBD is a blend of the standard OPPS payment rate and the nonexcepted payment rate for outpatient clinic visits. For 2020, CMS

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<sup>5</sup> Medicare Payment Advisory Commission. 2017. *Report to the Congress: Physician supervision requirements in critical access hospitals and small rural hospitals*. Washington, DC: MedPAC.

<sup>6</sup> 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, no. 225 (November 21), 58818–59179.

proposes to complete the phase-in of this policy and pay for outpatient clinic visits when hospitals provide them in excepted off-campus PBDs at the nonexcepted payment rate. CMS proposes to implement this policy in a budget-neutral manner.

*Comment*

The Commission shares CMS's concerns about the rate of growth in volume and spending under the OPSS. In 2012 and 2014, MedPAC recommended an approach different from the approach mandated by section 603 of BBA 15 to address the issue of the higher Medicare payments that result from hospitals converting freestanding physician offices into off-campus PBDs. Our approach would identify services that meet a certain set of criteria.<sup>7</sup> 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.<sup>8,9</sup> Because our recommended approach does not distinguish between on-campus HOPDs and off-campus PBDs, it would be less complex to administer than the current policy. However, we recognize that CMS must implement the approach legislated by section 603 of BBA 15.

The Commission supports the proposal to adjust the OPSS payment rate for clinic visits that are provided in excepted off-campus PBDs so that it is the same as the payment rate for clinic visits provided in nonexcepted off-campus PBDs. The result would be that the payment rate for clinic visits provided in off-campus PBDs would more closely match the rate paid under the Medicare physician fee schedule 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.

**Require prior authorization for some HOPD services**

CMS proposes to require hospitals to obtain prior authorization for some services covered under the OPSS. CMS based its decision for this proposal on its finding of a significant increase in the volume of services that CMS asserts are likely cosmetic procedures or that are directly related to cosmetic surgical procedures that are not covered by Medicare. CMS found that many of these services fall into these categories:

- Blepharoplasty (eyelid surgery; brow lift)
- Botulinum toxin injections (Botox injections)
- Panniculectomy (excision of excess skin and subcutaneous tissue)
- Rhinoplasty (changing the shape of the nose)
- Vein ablation.

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<sup>7</sup> The criteria include: (1) Frequently performed in physician offices; (2) Minimal packaging differences between the Medicare physician fee schedule (PFS) and the OPSS; (3) Infrequently provided with an emergency department visit when furnished in an HOPD; (4) Patient severity is no greater in HOPDs than in freestanding offices; and (5) Are not designated as 90-day global surgical codes in the PFS.

<sup>8</sup> Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

<sup>9</sup> Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

CMS's motivation for this proposal is to control growth in volume and spending in the OPPTS. CMS asserts that it has authority to take this action under section 1833(t)(2)(F) of the Social Security Act. CMS believes that the growth in the volume of these services far exceeds what would be expected relative to growth in the number of Medicare beneficiaries and is not aware of other factors that might contribute to clinically valid increases in the volume for these procedures.

Under this proposal, providers would have to submit prior authorization requests to CMS before furnishing the services in question and before submitting claims. Prior authorization requests would have to include all documentation necessary to show that the services meet all applicable Medicare coverage, coding, and payment rules.<sup>10</sup> CMS or a contractor would review prior authorization requests for compliance with applicable coverage, coding, and payment rules. If CMS or the contractor approves the prior authorization request, CMS or the contractor would issue a provisional affirmation to the provider.<sup>11</sup> If CMS or the contractor do not approve the request, a non-affirmation decision will be issued to the provider.

Claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors would be denied under this proposal. Also, even with a provision of affirmation, CMS may deny a claim based on either technical requirements that can only be evaluated after the claim has been submitted or information that was not available at the time the request was received.

Providers would have the opportunity to submit prior authorization requests for expedited review when a delay could seriously jeopardize a patient's life, health, or ability to regain maximum function. Finally, CMS may exempt from the prior authorization process those providers that achieve a prior authorization rate of provisional affirmation of at least 90 percent during a semiannual assessment.

#### *Comment*

The Commission shares CMS's concern about the growth of unnecessary services in the OPPTS. Also, the Commission has recommended the use of prior authorization to ensure appropriate use of imaging services.<sup>12</sup> Therefore, the Commission supports this proposed policy. However, the Commission has a number of concerns about this proposed policy: a lack of experience in using prior authorization in fee-for-service Medicare, a lack of administrative structure for implementing this proposed policy, and a lack of guidelines through which providers would obtain prior authorization. In addition, the Commission is concerned that access to necessary care could be adversely affected. Therefore, CMS should proceed carefully in using prior authorization and consider the potential burden on providers, the agency's resources, beneficiaries, and taxpayers.

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<sup>10</sup> CMS proposes to define *prior authorization* as a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted.

<sup>11</sup> CMS proposes to define *provisional affirmation* as "a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules."

<sup>12</sup> Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.



### **Payment policy for nonopioid pain management treatments**

CMS has established a policy that the OPPS and the ASC payment system package the cost of a drug into the payment rate of a surgical procedure when the drug functions as a supply in that procedure. Under this policy, a hospital receives the same payment irrespective of whether an analgesic drug prescribed in conjunction with a surgical procedure is an opioid or a nonopioid alternative. However, the President's Commission on Combating Drug Addiction and the Opioid Crisis expressed concern that this policy creates unintended incentives for providers to prescribe opioid medications for postsurgical pain. The President's Commission recommended that CMS examine payment policies to encourage providers to use nonopioid pain management alternatives.

In this proposed rule, CMS evaluated the use of drugs that function as supplies in surgical procedures as well as peripheral nerve blocks and neuromodulation alternatives to determine if packaging policies in the OPPS adversely affect the use of those nonopioid alternatives. All of these alternatives showed consistent or increasing use in recent years, even when paid on a packaged basis. For example, CMS found substantial growth in the use of Exparel, a nonopioid drug used to manage postsurgical pain. From 2013 through 2018, the volume of Exparel in HOPDs increased rapidly (491 percent).

CMS concluded that the trend in the use of nonopioid alternatives for postsurgical pain indicates that use of those items has not been adversely affected by OPPS packaging policies. Therefore, CMS does not believe that changes are necessary to the OPPS packaging policies for drugs that function as supplies in surgical procedures, nerve blocks, surgical injections, and neuromodulation products.

The ASC payment system has largely the same packaging policies as the OPPS with an exception for nonopioid pain management drugs that function as surgical supplies. In CY 2019, CMS implemented a policy of paying separately for these drugs at a rate of ASP + 6 percent. CMS implemented this policy in response to a finding that use of these drugs in the ASC setting had declined while they were paid as packaged drugs from 2014 through 2017. In this proposed rule, CMS indicated that more recent data showed that use of these drugs continued to decline in the ASC setting. Therefore, CMS is proposing to continue the policy of paying separately at ASP + 6 percent in the ASC setting for nonopioid pain management drugs that function as supplies in the performance of surgical procedures.

#### *Comment*

We commend CMS's interest in addressing the issue of opioid overuse and addiction. We support CMS's proposal to maintain the packaging policies for pain management treatments in the OPPS based on the agency's conclusion that Medicare's packaging policies in the OPPS have not constrained hospitals' ability to use alternatives to opioid medications where clinically appropriate. This policy is consistent with the Commission's March 2019 finding that there is no clear

indication that the OPPS provides systematic payment incentives that promote the use of opioid analgesics over nonopioid analgesics.<sup>13</sup>

However, we do not support the proposal to pay separately at ASP + 6 percent for nonopioid drugs that function as surgical supplies in the ASC system. This policy is contrary to policies that CMS has implemented in recent years to increase the size of payment bundles in the OPPS, which increases incentives for efficient delivery of care. The Commission prefers 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 2020 by 2.7 percent, based on a 3.2 percent increase in the hospital market basket (MB) minus a 0.5 percentage point deduction for multifactor productivity growth mandated by the Patient Protection and Affordable Care Act of 2010. Concurrently, CMS proposes to continue its use of the hospital MB in place of the consumer price index for urban consumers (CPI-U) to update the ASC conversion factor from CY 2019 through CY 2023.

CMS also intends to use the aforementioned five-year period (CY 2019 through CY 2023) to assess the feasibility of collecting ASC cost data in a minimally burdensome manner. During this period, the agency could propose a plan to collect cost data from ASCs.

*Comment*

In the Commission's March 2019 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.<sup>14</sup> 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 2.7 percent increase to ASC payment rates is unnecessarily high, that the use of the hospital MB is flawed, and that ASCs should begin reporting cost data as soon as possible.

For several years, we have stated 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. However, we do not support using the hospital MB index as an interim method for updating the ASC conversion factor because evidence indicates that neither does the hospital MB index accurately reflect the costs of ASCs. CMS has acknowledged that the ASC cost structure is not identical to hospitals because ASCs tend to be single specialty, for profit, and are not required to comply with the Emergency Medical Treatment and Labor Act.<sup>15</sup> We concur with these

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<sup>13</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

<sup>14</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress. Medicare Payment Policy*. Washington, DC: MedPAC.

<sup>15</sup> 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

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.<sup>16</sup>

We strongly recommend that CMS forgo the final four years of its planned 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 for 15 years, since 2004.<sup>17</sup> 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 is unnecessary for CMS to spend any additional time 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.<sup>18</sup> 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 (PHC4) 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. The data released by PHC4 are not specific enough to be used to create an MB index for ASCs, but the fact that PHC4 is able to collect these data indicates that ASCs are able to submit the necessary cost data.
- 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 (BBA) of 2018 required the Secretary to collect cost, revenue, use, and other information determined appropriate to evaluate the extent to which reported costs

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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.

<sup>16</sup> Medicare Payment Advisory Commission. 2013. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC.

<sup>17</sup> Medicare Payment Advisory Commission. 2004. *Report to the Congress. Medicare payment policy*. Washington, DC: MedPAC.

<sup>18</sup> 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.

relate to payment rates. Further, the Congress gave the 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 select a sample of ASCs to submit cost data annually. 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 are reduced by 2.0 percentage points in the following year. The potential reduction is tied to reporting rather than their actual 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.<sup>19</sup> In VBP programs for HOPDs and ASCs, high-performing providers would be rewarded and low-performing facilities would be penalized through the payment system. 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 measure**

CMS proposes to remove the web-based measure of *External Beam Radiotherapy for Bone Metastases* from the OQR for the CY 2022 program year on the basis that because of the administrative complexity of the measure, specifically in using current radiation delivery codes, the costs associated with the measure outweigh the benefit of its use. CMS is not proposing to remove any measures from the ASCQR.

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<sup>19</sup> Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

*Comment*

The Commission supports removing the OQR measure because it is a clinical process measure that is burdensome for providers to report. 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.

**Proposed measures**

CMS is proposing to adopt one claims-based measure in the ASCQR, *7-Day Hospital Visits after General Surgery Procedures Performed at ASCs*. CMS is requesting comment on potentially adding to the OQR, in future rulemaking, four patient safety measures currently part of the the ASCQR: *Patient Fall; Patient Burn; Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and All-Cause Hospital Transfers/Admissions*.

*Comment*

For several years, MedPAC has requested that CMS develop and implement a risk-adjusted, all-condition hospitalization measure that 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 recommended to link hospital quality performance to payment. We used all-condition measures (e.g., readmissions) rather than condition-specific measures to increase the number of observations and reduce the random variation that single-condition rates may face.<sup>20</sup> We support CMS's proposal to add the hospitalization measure to the ASCQR, and we encourage CMS to implement it sooner than CY 2024 because it is a claims-based measure that CMS can calculate and implement without provider reporting.

The Commission asserts that ASCQR measures should be synchronized with measures included in the OQR to facilitate comparisons between ASCs and HOPDs.<sup>21</sup> We support CMS's proposal to include the four patient safety measures in both quality reporting programs, in particular because they are outcome measures important to beneficiaries and the Medicare program.

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<sup>20</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

<sup>21</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC

**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.

Sincerely,

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

Francis J. Crosson, M.D.  
Chairman

FJC/dz/wc