MEDPAC Medicare Payment Advisory Commission

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August 13, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: File code CMS-1633-P

Dear Mr. Slavitt:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: "Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; short inpatient hospital stays; transition for certain Medicare-dependent, small rural hospitals under the hospital inpatient prospective payment system" [published in the *Federal Register*, volume 80, no. 130, pages 39200–39375]. 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 2016 update to the conversion factors in the OPPS and the ASC payment system.

This rule also proposes to:

- Expand payment bundles in the OPPS in three ways:
  - Create nine new comprehensive APCs (C-APCs), including one for observation care, C-APC 8011 (comprehensive observation services).

    - Take initial steps for an ultimate goal of including in the payment rates of C-APCs the planning and preparation services related to a C-APC that are provided on dates before provision of the primary procedure, even when they appear on different claims.
    - Continue to expand the list of ancillary items that are packaged with a primary service rather than be paid separately. The specific additions include conditional packaging of the services in APC 5734 (level 4 minor procedures), APC 5673 (level 3 pathology), and APC 5674 (level 4 pathology).
- Reduce the OPPS conversion factor for 2016 because of an overestimate of the adjustment to OPPS payment rates that was necessary to account for new packaging of laboratory tests in 2014 and an underestimate of spending that would continue for laboratory tests paid under the clinical laboratory fee schedule outside the OPPS. The proposed reduction to the OPPS conversion factor is 2.0 percent.
- Require that any application for a device to receive pass-through payment in the OPPS must have received FDA approval or clearance within three years of the date of application for pass-through status.
- Remove one current quality measure for payment determination in 2017, add one new quality measure for payment determination in 2018, and one new quality measure for payment determination in 2019 in the Hospital Outpatient Quality Reporting (OQR) Program.
- Solicit comments on two potential quality measures for the ASC Quality Reporting Program (ASCQR): normothermia outcomes and unplanned anterior vitrectomy.
- Implement several modifications to policies related to the two-midnight rule and short hospital stay policy in the inpatient prospective payment system.

We focus our comments on the updates to the OPPS and ASC conversion factors and the six topics listed above.

Proposed 2016 update to OPPS conversion factor

CMS has proposed to update the OPPS conversion factor by -0.1 percent in 2016. CMS obtained this result starting with the estimated increase in the hospital market basket of 2.7 percent and subtracting

- an estimate of productivity of 0.6 percentage points;
- 0.2 percentage points as required by the Patient Protection and Affordable Care Act of 2010 (PPACA); and
- 2.0 percentage points to redress the excessive Medicare payments that resulted from the overestimate of the adjustment to OPPS payment rates needed to account for new packaging of laboratory tests in 2014 and an underestimate of the spending that would continue for laboratory tests paid under the clinical laboratory fee schedule (CLFS).

The adjustment for excess payments related to the packaging of laboratory tests originated with CMS's decision to package the costs of all clinical laboratory tests that are provided on the same

date as a primary service covered under the OPPS and are ordered by the same practitioner who ordered the primary service. Before 2014, these laboratory tests had been paid separately under the CLFS. Providers continue to receive separate payment for laboratory services when they are the only service(s) provided to a beneficiary on a date of service or when they are provided on the same date as a primary service but are ordered for a different purpose than the primary service by a practitioner that is different from the practitioner who ordered the primary service. CMS has discovered that fewer of these laboratory tests than they anticipated have been provided with a primary service and more have been provided in ways that have resulted in them being paid separately under the CLFS. The result has been an overadjustment to the OPPS payment rates for primary services and an underestimate of how much would be paid for these laboratory tests at CLFS rates. CMS is proposing the 2.0 percentage point adjustment to the OPPS conversion factor to recover the excess payments.

Comments
We understand that CMS is required by law to implement the 2016 update to the OPPS conversion factor as stated in PPACA. We commend CMS for recognizing the excess Medicare payments in the OPPS because of the overadjustment of OPPS payment rates for the packaging of laboratory tests. The proposal to recover these excess payments is consistent with adjustments that CMS made in the inpatient prospective payment system, Medicare Advantage, and home health prospective payment system. We have not independently verified the extent of the excess payments in the OPPS, but we believe that excess payments should be recovered, so we support this proposal on principle.

Proposals to expand payment bundles

This rule has three proposals that would further expand the size of payment bundles in the OPPS:

- Create nine new C-APCs, including one for observation care (C-APC 8011, comprehensive observation services), which will replace APC 8009;
- Conditionally package services in APC 5734 (level 4 minor procedures), APC 5673 (level 3 pathology), and APC 5674 (level 4 pathology)[1]; and
- Take initial steps toward packaging all planning and preparation services that occur on dates before the primary services of C-APCs.

Comments
The proposal to replace APC 8009 with C-APC 8011 and the proposal to conditionally package the services in APCs 5734, 5673, and 5674 would immediately expand the size of payment bundles in the OPPS. MedPAC has long supported larger payment bundles in the OPPS because they provide hospitals with opportunities to find flexibilities in the provision of care and incentives to use the most cost-efficient methods. Therefore, we support the principle of replacing APC 8009 with C-APC 8011 and conditionally packaging the services in APCs 5734, 5673, and 5674.

[1] In these cases, conditionally packaged means that services in APC 5734 are packaged when provided with primary services that have OPPS status indicator S, T, or V, and services in APCs 5673 and 5674 are packaged when provided with primary services that have OPPS status indicator T. In all other situations, services in APCs 5734, 5673, and 5674 are paid separately.

The proposal to take initial steps to package planning and preparation services for C-APCs that occur on dates before the provision of the primary service of the C-APC is different from the other two proposals. This proposal would take a step back by creating smaller payment bundles before moving forward by creating larger bundles.

The rationale that CMS cites for creating smaller bundles then later creating larger bundles is fairly complex. It starts with the intended purpose of C-APCs, which is to provide a single payment for an entire encounter. Specifically, payments for C-APCs are based on charges for a primary service and all related and adjunctive services on applicable claims, except for charges for the following: self-administered drugs that are not considered supplies; services excluded from the OPPS; preventive services; brachytherapy seeds; pass-through drugs and devices; and services assigned OPPS status indicator "F" (certain certified nurse anesthetist services, Hepatitis B vaccines, and corneal tissue acquisition). However, CMS has identified instances in which planning and preparation services take place before the primary services of C-APC 5631 (single-session stereotactic radiosurgery (SRS)) are provided and are billed on different claims. The separate billing of the planning and preparation services from the primary services of C-APC 5631 is inconsistent with the intent of C-APCs.

As a first step in creating payment rates for C-APCs that include all planning and preparation services, CMS proposes to identify planning and preparation services for C-APC 5631 that appear on the same claim or claims up to one month before the claim that contains the primary services for C-APC 5631. CMS proposes to remove these planning and preparation services from the payment bundle for C-APC 5631 in 2016 and 2017 and to pay for them separately during that timeframe, even when they appear on the same claim. CMS also proposes to require hospitals to record a modifier with the planning and preparation services with the intent to use this information to assess the accuracy of the claims data used to set payment rates for C-APC 5631. The goal is to eventually use this information to include all planning and preparation services—including those that are provided on dates before the primary service—in single payments for entire encounters and to discontinue separate payment for these planning and preparation services.

Working toward payment rates for C-APCs that include all planning and preparation services fits nicely with the steps that CMS has taken in recent years to expand payment bundles in the OPPS. Expanding payment bundles that cover entire encounters would provide more opportunities for hospitals to find flexibilities in the provision of care and incentives to use cost-efficient methods. Therefore, although there are technical issues to be addressed—such as how to handle situations where planning and preparation services are provided in settings outside HOPDs—we encourage CMS to implement this proposal to begin an effort to include all planning and preparation services in the payment bundles for C-APCs.

Require that for a device to receive pass-through payment in the OPPS, it must have received FDA approval or clearance within three years of the date of application

The OPPS packages the cost of most medical devices into the payment rates of the procedures that use the devices. However, some devices are eligible for pass-through payments that are separate

from the payments for the related procedures for two to three years. After pass-through eligibility expires for a device, the cost of the device is packaged into the payment rates of relevant procedures.

A device must meet several criteria to be eligible for pass-through payment. In the interest of brevity, we will not list them here. In this proposed rule, CMS cites an issue that the criteria for pass-through eligibility do not include evaluations for the "newness" of devices. CMS believes that a device category should be new for it to be eligible for pass-through payments. CMS believes that the pass-through payments are intended as an interim measure to allow for adequate payment for new devices while the agency collects the data that are needed to incorporate the costs of these devices into the appropriate APC payment rates.

The lack of a requirement that device categories be new has resulted in CMS receiving applications for pass-through payments for devices that have been on the market for several years. In response, CMS is proposing to augment one of the criteria for a device to receive pass-through payments. Currently, a device must have received FDA premarket approval or clearance or received from the FDA an exemption from premarket approval or clearance. CMS proposes to augment this criterion by requiring that if the FDA requires the device to have premarket approval or clearance the device must have received that approval or clearance within three years of the date of the application for pass-through payment.

Comments
We agree with CMS that the pass-through payments are intended to provide adequate payment for new devices while CMS collects the data needed to incorporate the costs of a new device into the appropriate APC payment rates. Therefore, we do not believe it is appropriate for devices that have been available for several years to be eligible for pass-through payments. Consequently, we support this proposal.

Hospital Outpatient Quality Reporting Program

The Hospital Outpatient Quality Reporting (OQR) Program requires hospitals to report data on a set of quality measures specified by CMS. If they fail to do so, their OPPS payment update factor will be reduced by 2.0 percentage points in the following year. The payment update determination is not based on a hospital's performance on the set of measures required for that year, only on whether the hospital successfully reported the measures that CMS required. In the first year of the OQR program in 2008, CMS required hospitals to report on seven quality measures in order to receive the full OPPS payment update in 2009. For payment determination in 2015, the program consists of 23 measures, 12 of which require hospitals to extract and report data from samples of patient medical records. The other measures are reported by hospitals through a web-based reporting tool or calculated by CMS from Medicare claims data.

In this rule, CMS proposes to remove one claims-based process measure from the OQR measure set beginning with the 2017 payment determination: use of brain computed tomography in the emergency department for atraumatic headache. The basis for removing this measure from the OQR measure set is it "does not align with the current clinical guidelines or practice."

CMS also proposes to add two web-based measures to the OQR measure set, one for payment determination beginning in 2018 and one for payment determination beginning in 2019. The measure proposed for 2018 payment determination is external beam radiotherapy (EBRT) for bone metastases. Providers use EBRT to provide pain relief for many patients who have painful bone metastases. The purpose of adding this measure is to address concerns over unnecessary exposure to radiation, and a desire for shorter and less painful treatments.

The measure proposed for 2019 payment determination is emergency department transfer communication (EDTC). The purpose of this measure is to prevent gaps in care for patients transferred from emergency departments to other settings caused by inadequate or insufficient information. This measure is based on 27 elements that hospitals would have to answer "yes" or "no" as to whether it recorded and transferred patient data pertaining to the element.

Comments
In general, the commission supports value-based purchasing approaches over pay-for-reporting, and in fact has recommended such a program for ASCs.[2] In a value-based purchasing (VBP) program for HOPDs, high-performing providers would be rewarded and low-performing facilities would be penalized through the payment system. The VBP program should be based on a small number of outcomes-based measures. CMS should seek legislative authority to implement this program. In regard to the proposals in this rule, the Commission supports any steps that will simplify and reduce the administrative burden of the OQR program. Therefore, we support the proposed elimination of one claims-based measure. However, because it is a claims-based measure, the reduced burden on hospitals would not be substantial.

The two proposed web-based measures would provide useful information about hospitals' performance and encourage hospitals to provide better care. However, both measures appear to be fairly burdensome because they would require hospitals to gather data on patients. Also, we question whether the measure for EDTC is needed. Most, if not all, of the 27 elements that are the basis for this measure should already be communicated by EDs to another facility in the event of a transfer. At the same time, we do not know how frequently EDs fail to provide this information when they transfer patients to other facilities. Therefore, CMS should only adopt this measure if it has evidence that EDs are not routinely providing this information to a receiving facility when transferring a patient.

Calculation of the proposed ASC conversion factor and the proposed ASC payment rates

CMS proposes to increase the conversion factor in the ASC payment system in 2016 by 1.1 percent. This proposed update is based on CMS's estimate of a 1.7 percent increase in the consumer price index for all urban consumers (CPI–U) minus a 0.6 percent deduction for multifactor productivity growth mandated by PPACA.

[2] Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare Payment Policy.* Washington, DC: MedPAC.

Comments
In the Commission's March 2015 report, we recommended that the Congress eliminate the update to ASC payment rates for 2016. This 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.

CMS bases its ASC update on the CPI-U. However, in the proposed rule for 2013, CMS noted that the CPI–U may not be an ideal index for the cost of providing ASC services because the CPI–U is highly weighted for housing and transportation. In an effort to identify alternatives to the CPI-U for setting ASC payment rates, CMS solicited public comments on the feasibility of collecting cost information from ASCs but has not proposed a plan to collect this information.

We agree that the CPI–U may not reflect ASCs' cost structure.[3] Using data from a Government Accountability Office (GAO) survey of ASC costs, we found that ASCs have a different cost structure than hospitals and physicians' offices.[4] Therefore, CMS should collect new cost data and use that information to examine whether an existing Medicare price index is an appropriate proxy for the cost of these facilities or an ASC-specific market basket should be developed. We believe it is feasible for ASCs to provide a limited amount of cost information. To minimize the burden on ASCs and CMS, CMS could require all ASCs to submit streamlined cost reports or require a random sample of ASCs to respond to annual surveys.[5]

Proposed requirements for the Ambulatory Surgical Center Quality Reporting Program

In the final rule for 2012, CMS established a Quality Reporting Program for ASCs that required them to submit quality data beginning in 2012; ASCs that do not submit data on a specified set of measures have their annual payment update reduced by 2.0 percentage points. Medicare payments to ASCs are adjusted based upon whether the facilities successfully report these measures and not on their actual performance on these measures. CMS lacks the statutory authority to establish a VBP program for ASCs that would reward high-performing facilities.

Under the ASC Quality Reporting (ASCQR) Program, in 2016 ASCs will report 10 patient safety, outcome, and process measures. In addition, CMS has included the voluntary reporting of a measure of improvement of patients' visual function 90 days following cataract surgery for 2017, and a mandatory claims-based measure of an ASC's seven-day risk-standardized hospital visit rate following outpatient colonoscopy for 2018. In this proposed rule, CMS solicits comment on two potential measures for future years, normothermia outcomes and unplanned anterior vitrectomy. In addition, CMS proposes that as a part of the planned process to publicly report ASC quality data, it

[3] Medicare Payment Advisory Commission. 2014. Comment letter on 2015 proposed rule for the outpatient prospective payment system and ambulatory surgical centers.
[4] Medicare Payment Advisory Commission. 2010. *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.

will report these data at the level of the individual facility, if possible. Therefore, when an ASC reports its quality data using its National Provider Identifier (NPI) number, CMS will publicly report information at the NPI level. However, if an ASC reports its quality data using its CMS Certification Number (CCN), CMS will publicly report information for that CCN. The NPI is generally a subset of the CCN, representing an individual facility rather than a group of facilities.

Comments
The Commission supports the establishment of a VBP program for ASCs in which high-performing ASCs would be rewarded and low-performing facilities would be penalized through the payment system. In our March 2012 report, we recommended that the Congress direct the Secretary to implement a VBP program for ASC services no later than 2016.[6] The VBP program should be based on a small number of outcomes-based measures. CMS should seek legislative authority to implement this program. The current ASCQR program could lay the foundation for a VBP program.

As the Commission has stated in previous ASC comment letters, there are several quality measures used in the ASCQR program that could be used for an ASC VBP program; in addition, modifications to the current set of measures should be made. The modifications noted in our 2015 ASC comment letter include the following:

- The current measure on hospital transfer or admission after a procedure should be expanded to include patients who return home after the ASC procedure but are admitted to a hospital shortly thereafter because of a problem related to the 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.

- CMS should develop a surgical site infection (SSI) measure that applies to common ASC procedures. Researchers have found that lapses in infection control practices were common among a sample of ASCs in three states.[7] Problems with infection control could increase the rate of SSIs.

- CMS should eliminate its ASC facility volume measure. Research finding a correlation between higher volume of surgical procedures and better outcomes is based on analyses of high-risk procedures, which are typically not performed in ASCs. This measure could encourage ASCs to increase their volume to improve their performance on this measure.

- Quality measures are considered "topped out" when performance among providers is so high and unvarying that meaningful distinctions among providers and improvement in performance can no longer be made. Topped-out measures should be removed from the ASCQR because their reporting burden outweighs their value. Specifically, we encourage

[6] Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare Payment Policy.* Washington, DC: MedPAC.
[7] Schaefer, M. K., M. Jhung, M. Dahl, et al. 2010. Infection control assessment of ambulatory surgical centers. *Journal of the American Medical Association* 303, no. 22 (June 9): 2273-2279.

CMS to examine whether the measure of prophylactic IV antibiotic timing is topped-out in the ASC setting, as was determined in the HOPD setting.

In response to new proposals in this rule, the Commission requests more information about the two new quality measures being considered for future rulemaking: normothermia outcomes and unplanned anterior vitrectomy. We request more information about the volume of these events and how CMS would collect data on and calculate these two measures. To minimize provider burden, we prefer for quality measures to be based on claims data, rather than require providers to report data from medical records to CMS.

Finally, with regard to making data reported by ASCs publicly available, we encourage CMS to make these data available to the public as soon as possible to help patients, policymakers, and researchers compare quality among facilities. We also support CMS's decision to report these data on a disaggregated level. Therefore, when ASCs report quality data on the NPI-level, we prefer that CMS make NPI-level data available to the public rather than aggregated to the CCN-level.

Proposed modifications to policies related to short hospital stays

In the FY 2014 IPPS final rule, CMS implemented the two-midnight rule to clarify criteria for the appropriateness of inpatient hospital admissions, alleviate concerns about increased use of outpatient observation care and its impact on beneficiary liability, and mitigate hospitals' concerns about audits by the Recovery Audit Contractors (RACs). Under the two-midnight rule, auditors are instructed to presume hospital stays spanning two midnights are appropriate for the inpatient setting. Therefore, these stays will not be subject to review based on patient status. Auditors are also to presume that stays spanning less than two midnights are appropriate for the outpatient setting, except under certain circumstances. This policy has had broad implications for the Medicare program, potentially altering hospitals' and physicians' admission patterns and refining Medicare's oversight initiatives.

For 2016, CMS proposes several modifications and technical changes to policies related to the two-midnight rule and short hospital stays including:

- Modifying the two-midnight rule to allow cases that do not meet the two-midnight benchmark to be payable as inpatient on a case-by-case basis if the medical record supports the need for inpatient care (despite an expected length of stay of less than two midnights).
- Implementing a post-payment medical review process involving an auditor reviewing a sample of paid claims for inpatient appropriateness. Auditors will refer any overturned claims to the Medicare Audit Contractors (MACs) for payment reversal and refer the names of providers with aberrant patterns of admission to the RACs for further evaluation.
- Reassigning the post-payment medical reviews from the MACs to CMS's Quality Improvement Organization (QIO) contractors.
- Prioritizing reviews on stays that last less than one midnight in length.
- Reiterating the December 30, 2014 changes to the Recovery Audit Program to begin with the next contract awards, which includes establishing a six-month look-back period for certain claims and limits on audit requests based on hospital compliance.

- Creating a new C-APC for observation services, C-APC 8011. This new observation C-APC consolidates a broader bundle of services related to observation cases and increases the payment amount for observation cases from approximately $1,200 to more than $2,000.

Our comments below include discussion of these and other related policies in this proposed rule.

Comments
Subsequent to the implementation of the two-midnight rule, the Commission undertook an analysis of the various issues related to short hospital stays, which culminated in the Commission making recommendations to either the Secretary of Health and Human Services or the Congress.[8] To specifically address concerns with the Medicare RAC program, in its June 2015 report, the Commission recommended that the Secretary should:

- direct RACs to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay,
- modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate,
- ensure that the RAC look-back period is shorter than the Medicare rebilling period for short inpatient stays, and
- withdraw the "two-midnight" rule.

In addition, the Commission recommended three beneficiary-focused policies and that the Secretary evaluate the concept of a payment penalty for hospitals with excess rates of short inpatient stays.

The Commission is generally supportive of CMS's proposal for more targeted auditing of short hospital stays by the RACs and the modifications CMS is making to the RAC contracts, as they are largely reflective of the Commission's recommendations. However, the Commission has concerns about the continuation of the two-midnight rule.

The Commission recommended that CMS withdraw the two-midnight rule because it becomes redundant in light of our other RAC-related recommendations. In our view, the audit relief provided through the two-midnight rule is unnecessary if steps to hold RACs more accountable and target their audits are implemented, as the Commission has recommended. The Commission is concerned that the two-midnight rule provides hospitals with an incentive to lengthen hospital stays in order to avoid audit scrutiny. Longer stays generally increase costs and expose beneficiaries to greater physical risk. Longer stays also conflict with the general incentives of the prospective payment system to reduce length of stay. Thus, we reiterate the Commission's recommendation to withdraw the two-midnight rule.

The Commission supports CMS's proposal to prioritize cases that do not span one midnight for medical review and CMS's proposal for medical reviewers to refer the names of providers to

[8] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

RACs that exhibit patterns of high denial rates or aberrant admission practices. These components of the proposed rule are consistent with the Commission's recommendation for RACs to target hospitals for auditing.

Lastly, the Commission supports the creation of C-APC 8011 for observation stays. The payment of over $2,000 for the observation C-APC will result in an increase in the average payment for observation stays and should moderately reduce the financial incentive to admit a patient for a short inpatient stay when a patient could be effectively treated through outpatient observation.

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 Mark E. Miller, MedPAC's Executive Director.

Sincerely,

Francis J. Crosson, M.D.
Chairman

FJC/dz/wc