MEDPAC Medicare Payment Advisory Commission

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August 28, 2009

Charlene Frizzera, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1414-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: File code CMS-1414-P

Dear Ms. Frizzera:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates* [CMS-1414-P]. We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient departments and ambulatory surgical centers, 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 APC groups as the product of the relative weights and a conversion factor. This proposed rule describes CMS's proposed changes to the composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. The rule also estimates the calendar year 2010 update to the conversion factor.

This rule also proposes to:

- Improve the accuracy of the method used to set payment rates for drugs that are paid separately from the associated procedure. This would be accomplished by redistributing estimated pharmacy overhead costs from drugs that are packaged with the associated procedure to drugs that are paid separately.
- Set prospective payments for brachytherapy sources and therapeutic radiopharmaceuticals, which are currently paid on the basis of hospital-specific charges adjusted to cost.
- Invite comments on the policy of allowing hospitals to satisfy outpatient quality data reporting using clinical registries.
- Defer ASC quality data reporting for at least one additional year.

- Not collect cost data from ASCs.
- Continue considering the impact of extending to the OPPS a provision of the inpatient prospective payment system (IPPS) regarding non-payment for treatment of healthcare-associated conditions (HACs) under certain circumstances.

We focus our comments on these six topics.

Pharmacy overhead costs and setting payments for separately paid drugs

Under the OPPS, CMS pays separately for drugs whose costs exceed a set threshold, proposed to be $65 in 2010. For drugs whose costs do not exceed this threshold, CMS packages their costs into the payment rate of the applicable outpatient service.

From 2006 through 2009, CMS estimated the cost to hospitals of both separately paid and packaged drugs using hospital drug charges from claims. CMS adjusted these charges to costs by multiplying them by the cost-to-charge ratio (CCR) from the cost center for drugs from the hospitals' cost reports. For separately paid drugs, CMS compared the average of these estimated costs across all separately paid drugs to the average of the average sales price (ASP) for these drugs. CMS has set the payment rates for separately paid drugs on the basis of how much the average estimated cost of separately paid drugs exceeds the average of their ASPs. We will refer to this method of ratesetting as the "standard method." The payment rates that result from the standard method are intended to cover the acquisition cost and the pharmacy overhead cost of the separately paid drugs.

A group of industry stakeholders has argued the standard method produces payment rates that are below hospitals' costs for separately paid drugs. The cause of the underpayment is CMS's use of the same CCR to estimate the cost of both packaged and separately paid drugs furnished by a hospital. Hospitals have stated that they mark-up charges for low-cost drugs (which tend to packaged) by a greater proportion than they mark-up high-cost drugs (which tend to be separately payable). This implies that hospitals redistribute some pharmacy overhead costs from high-cost, separately paid drugs to low-cost, packaged drugs. To obtain accurate estimates of costs, CMS should adjust charges to costs using a larger CCR for separately paid drugs than for packaged drugs. However, CMS uses the same CCR for both classes of drugs. Consequently, the standard method underestimates the costs of separately paid drugs, including their overhead costs.

The stakeholders and the APC advisory panel recommended a method that was intended to more accurately reimburse hospitals for pharmacy overhead costs by redistributing pharmacy overhead costs from the packaged drugs to the separately paid drugs. Under this method, CMS would

- Identify separately paid drugs the same way as it does in its standard method, those having costs that exceed $65 per day. Drugs that cost less than $65 per day would be packaged.
- Calculate the acquisition cost of all separately paid drugs at ASP+6 percent.
- Use ASP+6 percent as the total cost (pharmacy overhead and acquisition cost) of all packaged drugs. Setting the cost of packaged drugs at ASP+6 percent would result in costs

for packaged drugs that are below the costs that CMS estimates for them using the standard method.
- CMS would use this difference to reimburse hospitals for the pharmacy overhead costs of separately paid drugs.

Under this method, combined acquisition and overhead costs for all drugs is the same as what CMS obtains using the standard method, but it redistributes overhead costs from packaged drugs to separately paid drugs.

CMS rejected the method recommended by industry stakeholders and the APC panel and has proposed its own method for redistributing pharmacy overhead costs from packaged drugs to separately paid drugs. Under its standard method for setting rates, CMS estimates that one-third to one-half of the pharmacy overhead costs that are allocated to packaged drugs actually should be allocated to separately paid drugs. In response, CMS has proposed for 2010 to redistribute to the cost of the separately paid drugs about 38 percent ($150 million) of the overhead costs that are allocated to the packaged drugs under the standard method. After this redistribution, CMS estimates that the average cost of separately paid drugs is 4 percent above ASP. Based on that result, CMS proposes for 2010 to pay separately paid drugs at ASP+4 percent.

In the past, MedPAC has recommended separate payments for drug acquisition and overhead costs. But, given CMS's decision to combine acquisition and overhead costs into a single payment, we view CMS's proposal for redistributing pharmacy overhead costs as a reasonable alternative. CMS presented strong arguments for rejecting the method recommended by the industry stakeholders and the APC panel. In addition, we support redistributing a portion of the overhead costs from packaged drugs to separately paid drugs. However, in its analysis of how much overhead costs to redistribute, CMS excluded drugs that did not have HCPCS codes or ASP data. We are concerned that excluding these drugs results in an underestimate of total overhead costs for packaged drugs, which could result in an underestimate of how much overhead costs should be redistributed to the separately paid drugs. We encourage CMS to investigate this issue.

Payment rates for brachytherapy sources and therapeutic radiopharmaceuticals

Brachytherapy sources and therapeutic radiopharmaceuticals are radioisotopes of certain elements and are used by physicians to treat some types of cancers. Both are inserted into the patient at or near the cancerous area. Radiation from the isotopes kills the cancer cells.

Although they are inputs to services, all brachytherapy sources and therapeutic radiopharmaceuticals that exceed the threshold that identify separately paid drugs (proposed to be $65 per day in 2010) have their own APCs and are paid separately from the services that use them. The separately paid items are covered under the OPPS but are not paid on a prospective basis. Under current law, payment for these items must equal hospital reported costs, defined as the product of hospital charges and a hospital-specific cost-to-charge ratio (CCR). For example, if a hospital charges $200 for a brachytherapy source and has a CCR of 0.5, the hospital would receive a payment of 0.5*$200 = $100 for this source.

CMS has attempted to establish prospective rates for these items. In the 2007, 2008, and 2009 rulemaking process, CMS established a prospective rate for each brachytherapy source that was based on the median cost of each source, as derived from hospital charge data. In the 2008 and 2009 rulemaking, CMS established prospective rates for therapeutic radiopharmaceuticals based on mean hospital costs for each drug. In each of these instances legislation extended payment on the basis of hospital-specific charges adjusted to costs. Under current law, payment on the basis of hospital-specific cost expires at the end of calendar year 2009.

In the 2010 proposed rule, CMS has again proposed prospective payments for brachytherapy sources and therapeutic radiopharmaceuticals. To set prospective payments for each brachytherapy source, CMS would identify all instances that hospitals bill a brachytherapy source on a Medicare claim. CMS will adjust the claim charges for each brachytherapy source to cost. CMS would then identify the median cost for each brachytherapy source, and this median cost serves as the basis for setting the prospective payment. For therapeutic radiopharmaceuticals, CMS would base payment rates on the drugs' ASPs. If ASP data are not available, CMS would base payment rates on the drugs' mean unit cost derived from 2008 claims data.

We support CMS's attempts to establish prospective payments for brachytherapy sources and therapeutic radiopharmaceuticals. The hospital-specific payments violate the intent of a prospective payment system, which is to provide incentive for hospitals to improve efficiency and hold down costs. In contrast, the hospital-specific payments can be manipulated because the hospital knows in advance the CCR that CMS will use to determine the costs and payments for these items.

Collection of quality data through clinical registries and electronic health records (EHRs)

CMS has implemented a quality reporting system for hospital outpatient services known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). As required by Section 1833(t)(17) of the Social Security Act, hospitals that fail to report data for quality measures specified by the Secretary for a given year will have their annual payment update factor in the following year reduced by 2.0 percentage points.

For the 2009 annual payment update, CMS required hospitals to report data in 2008 (beginning April 1, 2008) on seven measures for hospital outpatient services—five measures of emergency department care for acute myocardial infarction (AMI) and two perioperative care measures. For all seven of these measures, hospitals must submit data extracted from patient medical records. For the 2010 payment update, CMS mandated that hospitals in 2009 continue to submit data derived from medical records for these seven measures, and added four imaging efficiency measures that are calculated by CMS using Medicare Part B claims data (i.e., they do not require any data submission by hospitals). In the current proposed rule for the 2010 reporting period—that is, for the 2011 payment update determination—CMS proposes to use the same 11 measures.

CMS seeks comments on the idea of expanding the HOP QDRP measures in the future using data from clinical registries and electronic health records (EHRs). Noting that many hospitals currently submit data to and participate in existing registries, CMS suggests that it could collect quality

measure data directly from registries (with the permission of the hospital), thereby enabling CMS to expand the measure set without increasing the data collection burden on hospitals.

In our March 2005 Report to the Congress, we recommended that the Congress grant CMS the authority to base payments on pay-for-performance, and we encourage CMS to request this authority from the Congress so that a portion of payments will depend on providers' performance on the selected quality measures, not simply on whether they report the specified data to CMS. In the meantime, we support CMS's efforts to collect measures of hospital quality as a valuable step toward pay-for-performance (referred to by CMS as "value-based purchasing"), and we also commend CMS for preparing to publicly report on the hospital outpatient quality measures.

The Commission has discussed the value of patient registries and other tools that aggregate clinical data from a provider's entire patient population and enable these data to be analyzed and tracked over time for adherence to evidence-based medicine and health outcomes. The Commission has recommended that providers should be able to generate lists of patients with specific clinical conditions, for example, a registry of patients with diabetes or congestive heart failure that can be used to actively manage their care, or a list of patients who have been prescribed a particular drug that could be used for post-market surveillance of clinical outcomes. The latter function will be increasingly important if and when a pathway is created for the approval and use of follow-on biologics, many of which are delivered in the hospital outpatient setting. For all these reasons, we support CMS's proposal to integrate measures that rely on data from clinical registries into the HOP QDRP as soon as practicable.

Concerning the use of data from EHRs to support quality measurement, the Commission strongly supports the use of EHRs and other health information technology (IT), such as computerized provider order entry (CPOE) and clinical decision support (CDS), as tools to improve the quality and reduce the cost of care for Medicare beneficiaries. One of the uses of EHRs can be to capture, store, and readily report the types of clinical data not available from medical claims data, such as diagnostic laboratory test results and prescription drug dispensing data. In its March 2005 Report to the Congress, the Commission specifically recommended that Medicare use quality measures that rely on clinical laboratory test results and prescription drug data, and would support CMS proposals to retrieve these data from EHRs for use in quality measures.

Collection of quality data from ambulatory surgical centers

Section 109(b) of Tax Relief and Health Care Act of 2006 authorizes, but does not mandate, the Secretary to require ASCs to submit data on quality measures and to reduce the annual payment update in a year by 2.0 percentage points for ASCs that fail to do so.

In the 2008 OPPS/ASC final rule with comment period, CMS decided not to require ASCs to begin reporting quality data in CY 2008. In that rule, CMS stated that the transition to a revised ASC payment system in CY 2008 posed such a significant challenge to ASCs that it would be most appropriate to allow ASCs to gain some experience with the revised payment system before introducing other new requirements such as quality measure reporting. CMS deferred quality

reporting for ASC services again in 2009 and proposes to defer this requirement again in the 2010 proposed rule.

We are concerned about further delay in implementing quality measurement for the rapidly-growing ASC setting. By now it should be technically feasible for ASCs to report in 2010 on at least the set of five quality measures that were developed by the industry-sponsored ASC Quality Collaboration and endorsed by the National Quality Forum (NQF) in April 2008. These five facility-level ASC quality measures endorsed are:

- Patient being burned
- Patient fall in the ASC
- Wrong site, wrong side, wrong patient, wrong procedure, wrong implant
- Prophylactic intravenous antibiotic timing
- Hospital transfer/admission upon discharge from the ASC

The first three of these measures are patient safety measures identified by the NQF as "serious reportable events" (also referred to as "never events"), defined as errors in medical care that are clearly identifiable and measurable, usually preventable, serious in their consequences for patients, and that indicate a problem in a health care facility's safety systems. The fourth measure (prophylactic antibiotic timing) is similar to a measure already required to be reported for surgical patients in the hospital inpatient and outpatient settings, and it may be voluntarily reported by physicians under the Physician Quality Reporting Initiative (PQRI). Requiring the reporting of this measure by ASCs would harmonize use of this measure across four settings of care, a small but important step toward the goal of consistent use of quality measures across care settings in the future. The fifth measure, tracking ASC patients who are transferred or admitted to a hospital upon discharge from the ASC, may be a useful measure of the occurrence of adverse patient safety events during an ASC procedure.

Given that all five of these measures were developed by an ASC industry coalition—and therefore their reporting presumably is considered by the industry to be technically feasible without imposing an undue administrative burden—and also have received NQF endorsement, we believe CMS should require ASCs to report on these measures without further delay. However, we regard pay for reporting as a first step towards improving quality, and pay for performance should be the ultimate goal.

Collection of cost data from ambulatory surgical centers

CMS does not propose requiring ASCs to submit cost data, noting that it does not use ASC cost data to set payment rates. CMS also expresses concern that such a requirement could be administratively burdensome for ASCs. Nevertheless, CMS asks for comments on the feasibility of collecting cost data from ASCs.

In the Commission's March 2004 and March 2009 Reports to the Congress, we recommended that ASCs be required to submit cost data to CMS to help policymakers assess the adequacy of Medicare payments to ASCs and examine whether the consumer price index for all urban

consumers is an appropriate market basket index for ASCs. Although ASCs are generally small facilities that may have limited resources for collecting cost data, other small providers submit cost reports to CMS, including home health agencies and hospices. Therefore, we do not believe that the resources involved in submitting cost data would be an insurmountable obstacle. Although the scale of ASCs' cost reporting should be more limited than that of hospitals and other large facilities, the cost data should include enough information to allow analysts to assess the adequacy of Medicare payments and evaluate the ASC market basket. If CMS determines that a streamlined annual cost report would be too burdensome for ASCs, it would also be acceptable to survey a random sample of facilities. If a survey method is used, CMS should mandate that ASCs respond to the survey to ensure an adequate response rate.

Payment policy for healthcare-associated conditions

In the 2009 OPPS proposed rule, CMS did not propose new Medicare policy with regard to hospital outpatient healthcare-associated conditions (HOP-HACs) as they relate to the OPPS. Instead, the agency sought public comments on options and considerations related to extending the current IPPS hospital-acquired conditions payment policy to the OPPS.

In the 2010 proposed rule, CMS again does not propose a new Medicare policy with regard to HOP-HACs, but states that it may be appropriate in future rule-making on the OPPS to expand the principles of the hospital-acquired conditions (HAC) program currently applied in the IPPS. Under the IPPS HAC program, if a beneficiary is admitted to a hospital for a condition with no comorbidities then develops an additional condition during the inpatient stay, the hospital does not receive a higher payment because of the acquired condition. For 2010, CMS is evaluating the impact of the IPPS HAC program on Medicare IPPS payments, and the agency plans to consider any relevant findings from that evaluation as it decides whether to expand HAC payment policy to other care settings.

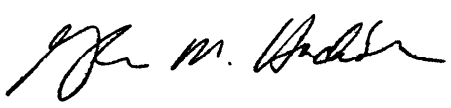
The Commission commends CMS for considering an extension of the current IPPS policy to other care settings and payment systems, including the OPPS. We believe that quality measures should apply to a broad range of care and providers; the greater the proportion of providers whose care is measured, the broader the impact will be on beneficiaries. Thus, we believe the current inpatient payment policy should be expanded to other care settings as supported by the clinical evidence base. For the hospital outpatient setting, it may be reasonable to start with patient safety-related conditions such as object left in during surgery, air embolism, blood incompatibility, falls and trauma fractures, dislocations, intracranial injuries, crushing injuries, and burns.

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 Miller, MedPAC's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

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