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October 10, 2006

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Box 8011
Baltimore, Maryland 21244-1850

RE: file code CMS-1506-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates [CMS-1506-P]*, Federal Register, August 23, 2006. 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, and the OPPS determines payments as the product of the relative weights and a conversion factor. This proposed rule is similar to its predecessors in the sense that it documents changes in the composition of some APC groups and proposes changes to the relative weights based on an analysis of claims and cost report data. Also, the rule estimates the calendar year 2007 update to the conversion factor.

This proposed rule also includes a major proposed restructuring of the payment system for services provided in ambulatory surgical centers (ASCs) as well as proposals that affect the OPPS. In regard to the OPPS, the proposed rule discusses important changes to payments for separately paid drugs and a program for collecting hospital quality data that would affect OPPS payments for individual hospitals.

Our comments on the proposed rule center on five issues:

- payments for separately paid nonpass-through drugs,
- collection of hospital quality data,
- payments for multiple imaging procedures,
- expanding the number of procedures that Medicare covers in ASCs, and
- the method for setting payment rates for ASC procedures.

Payments for nonpass-through drugs, biologicals, and radiopharmaceuticals

CMS has proposed to pay for specified covered outpatient drugs and other separately paid drugs that are not pass-through drugs at a rate of 105 percent of average sales price (ASP). CMS intends for these payments to cover both the acquisition and pharmacy overhead costs of each drug.

We are concerned that this method could result in inaccurate payments for individual drugs because it does not effectively account for large differences in pharmacy overhead costs among drugs. This proportional method ties total reimbursement for each drug to the drug's ASP. For a drug that has high overhead costs in relation to its ASP, paying for the drug at 105 percent of ASP could result in reimbursements well below the drug's combined acquisition and overhead costs. Conversely, this payment method could over-reimburse for a drug that has low overhead costs in relation to its ASP.

We believe that reimbursements for pharmacy overhead costs should largely reflect methods we recommended in our June 2005 Report to the Congress and that CMS proposed in last year's rule. Both methods collect drugs into APC groups based on attributes that affect overhead costs. Both use hospital charges adjusted to cost to establish payment rates for the pharmacy overhead costs in each APC. CMS's proposed method has fewer APC groups than ours, but the methods are quite similar.

CMS decided not to make its proposed method final, in response to concerns over collecting the data necessary to set payment rates in the APCs. However, we believe it is preferable to pay pharmacy overhead costs using payment tiers because we have found that some classes of drugs—such as cytotoxic agents—have much higher overhead costs than other classes of drugs—such as those taken orally. Therefore, we encourage CMS to revisit this issue and develop a method that recognizes large differences in pharmacy overhead costs between different classes of drugs and reimburses hospitals accordingly.

Hospital quality data

CMS proposes to link updates in the OPDS to the collection of hospital quality measures. At this time, all of the measures of hospital quality that CMS intends to use are derived from surveys that hospitals initially had to submit to receive full payment updates in the inpatient

PPS. CMS has asked for suggestions on quality measures that are applicable to hospital outpatient departments. We believe that many of the questions in the hospital component of the Consumer Assessment of Health Providers and Systems (HCAHPS) are applicable to hospital outpatient care. These include:

- For nurse care
 - How often did nurses treat you with courtesy and respect?
 - How often did nurses listen carefully to you?
 - How often did nurses explain things in a way you could understand?
- For doctor care
 - How often did doctors treat you with courtesy and respect?
 - How often did doctors listen carefully to you?
 - How often did doctors explain things in a way you could understand?
- When you left the hospital
 - After you left the hospital, did you go directly to your own home, to someone else's home, or to another facility?
 - During this hospital stay, did doctors, nurses, or other hospital staff talk with you about whether you would have the help you needed when you left the hospital?
 - During this hospital stay, did you get information in writing about what symptoms or health problems to look out for after you left the hospital?
- Overall rating
 - Rate this hospital during your stay, from 1 to 10.
 - Would you recommend this hospital to you friends and family?
- About you
 - How would you rate your health?
 - What is the highest grade you have completed?
 - Are you Spanish, Hispanic, or Latino origin or descent?
 - What is your race?
 - What language do you mainly speak at home?

In addition, the surgical care improvement project (SCIP) includes several process-based measures—such as giving aspirin at arrival (e.g. in the emergency department) to a patient with acute myocardial infarction—that conceptually could be useful for evaluating outpatient quality. However, before any process-based measures for evaluating quality are used, some additional analysis may be needed to assure that these measures apply to the outpatient department setting.

MedPAC is a strong supporter of collecting measures of hospital quality, and we commend CMS for expanding the collection of quality data. However, your proposal links updates in the OPDS to the collection of quality measures. We prefer that CMS seek the authority to move

beyond pay-for-reporting toward pay-for-performance so that payment updates depend on empirical results from the quality data, not on whether the data are submitted.

Other outpatient issues

Under the OPPTS, hospitals receive full APC rates for each diagnostic imaging service on a claim, even though hospitals may save costs when they perform multiple services using the same imaging modality on contiguous body parts in the same session. In the proposed outpatient rule for 2006 (*Federal Register*, July 25, 2005), CMS cited an analysis which showed that many costs incurred for an initial imaging service are not incurred in subsequent services. The agency proposed reducing by 50 percent the OPPTS payments for multiple imaging services within the same family of codes performed in the same session. Full payment would be made for the service with the highest APC rate, and the 50 percent discount would be applied to the APC rate for each additional service in the same family performed in the same session. We supported this policy in our comment letter on the proposed rule (submitted on September 16, 2005), based on a recommendation from our March 2005 Report to the Congress.

In the final outpatient rule for 2006, CMS deferred implementing a payment reduction for multiple imaging studies subject to further study (*Federal Register*, November 10, 2005). Some commenters on the proposed policy argued that any efficiencies related to providing multiple imaging services in the same session are already reflected in hospitals' costs, which are the basis for the APC rates. Based upon initial analyses that failed to disprove this contention, CMS decided to defer the policy while it further examined ways to improve the accuracy of imaging payments, such as changing the median cost calculation for imaging services or discounting payments for multiple imaging studies. CMS did not revisit this issue in this proposed rule. We encourage CMS to continue its examination of ways to improve payment accuracy for imaging services, including a multiple procedure reduction.

ASC payable procedures

When CMS implements a revised ASC payment system in 2008, the agency proposes to expand the list of surgical services payable in an ASC by including all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. The Commission supports paying for procedures in ASCs that meet clinical safety standards and do not require an overnight stay, including services that are primarily performed in physician offices. However, we encourage CMS to seek Congressional authority to replace the current inclusionary list of ASC services with an exclusionary list, as the Commission recommended to the Congress. We agree with CMS that expanding the list of services payable in an ASC would benefit ASCs by allowing these facilities to receive payment for a much broader range of services than is now allowed.

In our March 2004 report, the Commission recommended that after the ASC payment system is revised, the Congress should direct the Secretary to replace the current list of approved ASC

procedures with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay. CMS is currently required by law to establish and update a list of services that may be safely performed in ASCs. Only procedures on the list are eligible for Medicare facility payment when provided in ASCs. CMS is required to update this list every two years, although there was no update between 1995 and 2003. Under this approach, if a new procedure is developed that can be safely performed in ASCs, Medicare will not pay for it in an ASC until the ASC list is updated and the procedure is included. This could create a time lag between the introduction of new services and their availability in ASCs. Thus, we recommended that the Congress authorize CMS to create a list of services that are specifically excluded from payment in ASCs, which is a similar concept to the list of procedures excluded from payment in hospital outpatient departments. If CMS were allowed to create an exclusionary list, Medicare could begin paying ASCs for new procedures at the same time it started paying for the procedures in other settings. CMS would have to keep an exclusionary list up to date to prevent ASCs from performing services that are not clinically safe in that setting. We support CMS's proposal to add procedures that are primarily performed in physician offices to the ASC list. Even though physicians can safely perform many surgical services on healthy beneficiaries in their offices, sicker patients may require the additional infrastructure and safeguards of an ASC or outpatient department. Physicians and patients should have the discretion to decide which setting is most clinically appropriate.

ASC ratesetting

CMS proposes to revise the ASC payment system in 2008 using the OPPS's procedure groups (APCs) and relative weights. The conversion factor, or average payment amount for each service, would be based on a budget neutrality adjustment designed to keep total payments under the new ASC payment system equal to total payments under the old system. Payments for services added to the ASC list in 2008 that are primarily provided in physician offices would be capped at the physician fee schedule nonfacility practice expense rate. The Commission supports aligning the ASC payment system with the OPPS, but we have recommended that the conversion factor should be based on the costs of ASCs. We have also recommended that ASC rates should not exceed OPPS rates for the same procedures, accounting for differences in the bundle of services covered by the base payment rate in each setting.

The current ASC payment system is outdated and should be replaced by a system based on the OPPS. The current system classifies services into only nine payment groups of clinically-unrelated procedures and sets rates based on 1986 cost data. Because these rates are based on

old cost data, they are probably no longer consistent with ASCs' costs. The broad ASC payment groups make it difficult for CMS to classify new services and increases the likelihood that many services are over- or underpaid. In addition, the ASC rates are not aligned with rates for surgical procedures provided in other ambulatory settings. If payment variations among settings are unrelated to differences in underlying costs, there could be financial incentives to shift services to the most profitable setting.

To remedy these problems, in our March 2004 report to the Congress, we recommended that the Secretary revise the ASC payment system so that its relative weights and procedure groups are aligned with those in the OPSS. This change would accomplish three objectives:

- Using a greater number of payment groups could enhance the accuracy of payments for individual ASC services.
- Linking the two payment systems would make it administratively easier for CMS to update ASC procedure groups and relative weights.
- Aligning the ASC and outpatient payment systems could minimize financial incentives to shift services between settings.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement a revised ASC payment system no later than January 2008, taking into account the recommendations of a Government Accountability Office (GAO) report. The MMA required that GAO study the relative costs of services in ASCs and hospital outpatient departments and examine whether CMS should use the OPSS's procedure groups and relative weights as the basis for the ASC payment system; this report has not yet been completed. In this regulation, CMS outlines its proposal to base the ASC system on the OPSS's groups and relative weights, along with policies for which services should be packaged into the base rate and how to set the ASC conversion factor. We comment on these issues below.

The ASC and outpatient payment systems have different packaging policies for which devices and services are included in the base rate for surgical services and which are paid separately. CMS proposes to increase the size of the ASC payment bundle but to maintain the current outpatient bundle. In both payment systems, the facility fee includes the costs of the operating and recovery rooms, nursing and other staff, most surgical supplies and equipment, and anesthesia materials. Medicare also packages other services related to the procedure, such as drugs, biologicals, and diagnostic services, in the ASC payment. However, ASCs may bill separately for prosthetic implants and implantable durable medical equipment (DME) that are inserted during a procedure. Under the OPSS, CMS packages payments for prosthetic implants and implantable DME into the base rate, but pays separately for some items and services provided in conjunction with a surgical procedure. In addition to the base payment, for example, hospital outpatient departments can receive separate pass-through payments for

certain new drugs and devices used in the delivery of services. They may also bill separately for ancillary services, such as imaging, that are provided during a procedure. In order to promote more efficient use of services, CMS proposes to expand the ASC payment bundle to include payments for prosthetic implants and implantable DME. However, the outpatient payment bundle would remain the same.

We support CMS's proposal to expand the ASC payment bundle but encourage the agency to make the payment bundles in the ASC and hospital outpatient settings even more comparable. We agree with CMS that prospective payment systems should package all items related to a service to encourage providers to use resources efficiently. However, the OPSS excludes some items and services from the payment bundle for surgical procedures. Establishing broader payment bundles in both the ASC and hospital outpatient payment systems would promote efficient resource use and better align the two payment systems, which is important if the ASC relative weights are to be based on the OPSS weights. Different bundling policies may lead to different relative payment amounts in each setting, even if the base payment rates share the same relative values in both settings.

The MMA mandates that total payments under the new ASC payment system must be equal to total payments under the old system. To ensure that the new system is budget neutral relative to the old system, CMS proposes to multiply the OPSS conversion factor by a budget neutrality adjustment of 0.62. CMS's current estimate of the 2008 ASC conversion factor is \$39.69 (the product of 0.62 and \$64.01 (the current estimate of the 2008 OPSS conversion factor)). The budget neutrality adjustment is derived by dividing projected ASC spending under the current payment system by projected ASC spending under a system that uses OPSS procedure groups and relative weights.

Ideally, the ASC conversion factor would be based on either ASCs' costs or the lowest-cost safe alternative setting for ambulatory surgical procedures. Because CMS has not collected recent ASC cost data, we are not able to estimate ASCs' costs or determine which surgical setting has the lowest costs. Thus, the Commission is unable to judge whether an ASC conversion factor that equals 62 percent of the OPSS conversion factor is appropriate. The GAO study mandated by the MMA may shed light on the relative costs of services in ASCs and hospital outpatient departments.

In the Commission's March 2004 report to the Congress, we recommended that the conversion factor under a new ASC payment system be based on the costs of ASCs. We encourage CMS to seek the statutory authority to base the conversion factor on ASCs' costs. The Commission has expressed concern that current ASC rates are based on ASC cost and charge data from 1986 and are thus probably no longer consistent with ASCs' actual costs.

In our March 2004 report, we suggested two alternatives for CMS to collect ASC cost data at the procedure level:

- CMS could periodically survey a sample of ASCs, or
- CMS could require that ASCs submit annual cost reports.

Although either approach would impose administrative burdens on CMS and ASCs, policymakers need timely data to set ASC rates that approximate the costs of efficient providers. In addition to setting the ASC conversion factor, CMS could also use cost data to monitor the overall adequacy of ASC payments.

If CMS decides to adopt its proposed method for setting the ASC conversion factor, the agency should ensure that the calculation of projected ASC spending under the current system includes payments for prosthetic implants and implantable DME, which may be billed separately under current policy.

The Commission has also recommended that ASC rates should not exceed OPPS rates for the same procedures, accounting for differences in the bundle of services covered by the base payment rate in each setting. Based on our analysis of two indirect measures of relative costliness (patient mix and regulatory burden), it does not appear that ASCs incur higher costs than outpatient departments for the same procedures (MedPAC, Report to the Congress, March 2004). We compared risk scores for patients who received similar procedures in each setting and found that outpatient department patients have higher average risk scores, which indicates that these patients are more medically complex than ASC patients (risk scores represent beneficiaries' expected costliness based on their age, sex, and diagnoses). We also found that outpatient departments are subject to additional regulatory requirements, such as the Emergency Medical Treatment and Active Labor Act, which are likely to increase their overhead costs.

CY 2007 ASC impact

The introduction to this section states that “adding the 14 procedures we are proposing in section XVII of this preamble and implementing the Pub. L. 109-171 mandate would result in a savings to the Medicare program of approximately \$150 million in CY 2007.” The conclusion to this section states that “the Office of the Actuary estimates that the Medicare program would realize a \$35 million savings as a result of implementing the changes proposed for CY 2007.” These two statements appear to be contradictory and should be clarified in the final rule.

Other ASC issues

As CMS prepares to implement a revised ASC payment system and to significantly expand the list of services payable in ASCs, we suggest that the agency update the Medicare conditions of coverage (COCs) for ASCs. To receive payment from Medicare, ASCs must meet the COCs,

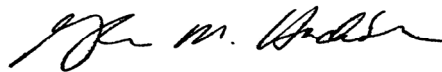
which specify minimum standards for administration of anesthesia, quality evaluation, operating and recovery rooms, medical staff, and other areas. These standards have not been revised since 1982. By contrast, Medicare's conditions of participation for hospitals were updated in 2003 with the requirement that hospitals adopt quality assessment and performance improvement programs. In April 2006, CMS announced its intention to issue proposed revisions to the ASC COCs this fall (*Federal Register*, April 24, 2006). We encourage CMS to publish this proposed rule soon.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and 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