MEDPAC Medicare Payment Advisory Commission

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October 11, 2006

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1321–P
Box 8015
Baltimore, Maryland 21244-8015

RE: file code CMS-1321-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Medicare program; Revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B* [CMS-1321-P] Federal Register, August 22, 2006. We appreciate your staff's ongoing efforts to administer and improve the payment system for physicians' services, particularly considering the agency's competing demands.

Deficit Reduction Act of 2005 (DRA) proposals

Section 5102 – Proposed adjustments for payments to imaging services

In the physician fee schedule final rule for 2006, CMS adopted a policy to reduce the technical component payment for multiple diagnostic imaging services when they are performed on contiguous body parts during the same session. We recommended this policy in our March 2005 Report to the Congress because there are cost efficiencies when multiple studies of the same modality are performed on contiguous areas. CMS initially proposed a 50 percent reduction for subsequent imaging services when providers furnish more than one service from the same family of codes (e.g., computed tomography of the spine). CMS justified a 50 percent reduction based on an analysis of the clinical activities that are not duplicated for subsequent procedures, such as positioning and escorting the patient, providing education and obtaining consent, and preparing and cleaning the room. In addition, CMS assumed that supplies, with the exception of film, are not duplicated. Removing the costs of the activities and supplies that are not duplicated supported a payment reduction ranging from 40 to 59 percent for the additional services; the midpoint of this range was 50 percent. To allow for a transition, CMS decided in the final rule to phase in this reduction over two years by implementing a 25 percent reduction in 2006 and

planning to adopt a 50 percent reduction in 2007, subject to additional review. CMS also solicited data from providers on the efficiencies associated with different combinations of imaging studies.

In this proposed rule, CMS proposes to maintain the current 25 percent reduction for 2007 for two reasons:

- The interaction between this policy and a provision from the Deficit Reduction Act of 2005 (DRA) that caps the physician fee schedule technical component (TC) rate for an imaging service at the outpatient prospective payment system (OPPS) rate, and
- Data submitted by the American College of Radiology (ACR) for 25 common combinations of services that supports a reduction between 21 and 44 percent.

It is unclear why the DRA provision that caps the physician fee schedule TC rate at the OPPS rate justifies maintaining the 25 percent reduction for 2007 for all imaging services, rather than implementing a 50 percent reduction. The DRA policy does not apply to all imaging services, only to those for which the TC rate exceeds the OPPS rate.

In the final rule, we ask that CMS provide more information on the ACR cost data on multiple imaging services cited in the proposed rule. Are the data based on a physician survey or an analysis of practice expense inputs? If the data are from a survey, how representative was the survey and what questions were asked? Which combinations of codes did the ACR examine? What were the cost savings for each combination? How did the ACR's estimated cost savings compare to CMS's estimated savings (published in last year's final rule) for the same combinations of services? Given the lack of detailed information in the proposed rule, we are not convinced that the ACR data justify maintaining a 25 percent reduction for 2007.

Section 5107 – Revisions to payments for therapy services

The proposed rule notes that CMS is considering coding edits for therapy services in addition to the edits it implemented in 2006. The DRA required that clinically appropriate edits, including edits of clinically illogical combinations, for therapy services be implemented by July 2006. To comply with this requirement, CMS implemented the correct coding initiative (CCI) edits in all facility-based providers in January 2006. CMS also notified providers that it would implement additional edits in January 2007 to limit the number of untimed services that can be billed on the same day for one beneficiary.

The edits that CMS has implemented represent a good start in controlling inappropriate billings. We encourage further work and consultation with experts in areas such as utilization management and appropriateness of therapy services to develop clinically appropriate edits for timed services. Edits for timed services are especially important because they represent the majority of therapy services. Edits could limit the number of

timed units based on the amount of therapy that is typically tolerated by an elderly person. Other edits might target certain combinations of services that do not make clinical sense.

ASP Issues

In 2005, Medicare began paying for Part B drugs using the average sales price (ASP) methodology. In the first quarters of 2005, the new payment system produced dramatic price decreases for many products as Medicare payment rates began to approach the prices providers paid. By 2006, payment rates were more stable. In cases where generic products became available or branded drugs competed for market share, the payment rate has continued to decline. In other cases, payment rates are slowly increasing but, to date, less than other outpatient drug prices.

The Congress directed the Commission to conduct two studies on the effect of the changes in the payment rate. For these studies, we have conducted interviews with physicians, hospital administrators, wholesalers, manufacturers, and other stakeholders. Most physicians have told us that they can buy most drugs at the Medicare payment level but all report they cannot purchase some drugs at that payment rate. Interviewees talked about two issues: the gap between the average payments received by manufacturers and the average prices physicians pay when the calculation of ASP includes discounts that are not passed on to physicians, and how discounts are allocated in the calculation of ASP when drugs produced by one manufacturer are sold in a bundle.

The Commission encourages the Secretary to look into these issues and we intend to examine them further in the coming months as part of our mandated study. Although not perfect, the Commission views ASP as a vast improvement over the former payment method based on AWP. The objective of the ASP system should be to achieve accurate prices without creating inflationary incentives. Regarding the case of bundled discounts, the Commission is concerned about this issue and will be exploring whether to change the ASP calculation rules on how discounts are allocated between two drugs if a higher discount is provided when they are purchased together.

Finally, to ensure the accuracy of Medicare payments, the Secretary should monitor the acquisition costs of all providers who the Secretary pays under the ASP payment system, including physicians and dialysis providers. In this regulation, the Secretary is extending the 2006 payment policy of ASP plus 6 percent for separately billable drugs furnished by dialysis providers through 2007 and subsequent years. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that the payment rates for dialysis drugs approximate the costs that dialysis providers incur.

The Secretary initially set the payment rate for physicians and dialysis providers at ASP plus 6 percent to account for the variation in their acquisition costs. However, there is no recent evidence that this payment rate reflects the variation in the acquisition costs of physicians and dialysis providers so the Secretary should not set the payment rate indefinitely. In our June 2005 Report to the Congress, the Commission recommended that

the Secretary periodically collect acquisition cost data from dialysis providers and compare it to ASP data. Analysis could lead to a resetting of the rate at a different percentage.

ESRD provisions

CMS proposes a new method to annually calculate the growth update to the add-on payment to the composite rate (as mandated by the MMA). Using this new method, the agency proposes to update the add-on payment by 0.6 percent, thus increasing the total add-on payment from 14.5 percent in 2006 to 15.2 percent in 2007.

In our June 2005 report, the Commission recommended combining these two payments. The add-on payment is complex and administratively burdensome for the agency to maintain. Increasing the add-on payment to post-MMA spending for dialysis drugs risks overpayment for use of the drugs. For these reasons, the Secretary should seek Congressional authority to combine the composite rate and the add-on payment.

Reassignment and physician self-referral

CMS proposes changes to the reassignment and physician self-referral rules designed to eliminate "pod labs" for pathology services. In a pod lab arrangement, an entity leases an office building, subdivides it into separate cubicles, equips each space with laboratory equipment, and hires staff to perform the technical and professional components of pathology tests. The entity then subleases each cubicle to a physician group practice, which may be located far away. The group practice sends its specimens to this lab and pays the entity a fee to perform the pathology tests. The practice then bills Medicare for the services, typically at a markup from the fee it has paid the management entity. Some commenters alleged that these arrangements lead to the generation of unnecessary biopsies, kickbacks, and referrals that would otherwise be prohibited by the physician self-referral statute.

CMS proposes to prohibit pod lab arrangements by amending the reassignment provision, under which a physician may bill for a service performed by another provider. CMS also proposes to limit the in-office ancillary exception under the physician self-referral law. We support policies to restrict arrangements between physicians and other entities that create financial incentives for inappropriate use of services.

IDTF issues

In response to concerns about fraud and abuse involving independent diagnostic testing facilities (IDTFs), CMS proposes to establish 14 new standards for IDTFs to ensure that they follow good business practices and provide quality care. IDTFs are entities—independent of a hospital or physician office—in which nonphysician personnel furnish diagnostic procedures under physician supervision. Medicare requires that IDTFs meet minimum standards for staff qualifications, equipment, and the supervising physicians.

Carriers must verify through a site visit and document review that IDTFs meet these standards when they enroll in Medicare but are usually not required to perform follow-up monitoring. A recent report by the Office of Inspector General (OIG) found that many Medicare payments to IDTFs were improper due to poor documentation or lack of medical necessity (Office of Inspector General, Review of claims billed by independent diagnostic testing facilities for services provided to Medicare beneficiaries during calendar year 2001, June 2006). OIG also learned that IDTFs did not always comply with their initial enrollment applications and update requirements (IDTFs are required to inform carriers when they begin to furnish new types of services or change their supervising physicians). OIG recommended that CMS consider performing site visits to monitor compliance with IDTFs' enrollment applications and subsequent updates should funding become available. In response, CMS stated that it lacked the funds to require Medicare carriers to conduct site visits to monitor IDTF compliance and that it instead planned to propose business standards for these providers.

The IDTF business standards proposed by CMS are modeled on Medicare's standards for durable medical equipment suppliers. Examples of the requirements include:

- Maintaining a comprehensive liability insurance policy
- Agreeing to not directly solicit patients
- Maintaining a primary phone number and address
- Using testing equipment that is calibrated per equipment instructions and in compliance with national standards
- Ensuring that technical staff with appropriate credentials are on duty.

In our March 2005 Report to the Congress, we described rapid growth in imaging services paid under the physician fee schedule, quality problems with at least some imaging providers, and the lack of quality oversight for imaging tests provided in non-hospital settings. Consequently, the Commission recommended that the Congress direct the Secretary to set quality standards for providers who bill Medicare for performing and/or interpreting diagnostic imaging studies. We also recommended that, to reduce the burden on CMS, the Secretary should select private sector organizations to administer the standards. We encouraged CMS to set standards in at least the following areas: the imaging equipment, qualification of technicians, qualifications and responsibilities of the supervising and interpreting physicians, quality of the images produced, and patient safety procedures.

Our recommendations apply to imaging providers in all settings, but we encourage CMS to move forward with strengthening quality standards for IDTFs. About 85 percent of Medicare payments for IDTFs in 2002 were for imaging services (MedPAC, A data book: Healthcare spending and the Medicare program, June 2004). We support CMS's proposal to improve IDTF standards related to testing equipment and technical staff, and we urge the agency to go further by adopting standards for image quality, patient safety procedures, and the qualifications of physicians who interpret studies performed in IDTFs

(the professional component). CMS should also explore opportunities to set quality standards for imaging services performed in physician offices. To the extent necessary, CMS should pursue statutory authority to adopt such standards. We recognize that CMS has limited resources to enforce IDTF standards. Thus, the agency should consider authorizing private accreditation organizations to verify that IDTFs meet CMS's quality requirements for imaging. Private plans often rely on accreditation programs to certify that their imaging providers meet quality standards.

Clinical diagnostic lab tests

In the proposed rule, CMS seeks input on requiring laboratories to submit the clinical results of tests that they perform on the claims they make for payment. Steps toward this new requirement should begin now.

Currently, the administrative data derived from claims can only indicate whether a particular test has been performed. For example, current administrative data can indicate whether a diabetic patients' hemoglobin A1c (HbA1c) level has been tested. By performing the test, the physician is adhering to the evidence base that indicates this test is important for diabetic patients. Conducting the test, however, is only means to an end: in this case, the goal is to lower patients' HbA1c levels to a healthy level. Though the process of conducting the test is necessary to determine whether control has been achieved, strong evidence shows that actually achieving the intermediate outcome of controlling the HbA1c level leads to the best ultimate outcomes, namely, decreased mortality and morbidity among patients with diabetes.

Many private sector performance measurement systems have moved away from measuring whether the test has been done to measuring whether control has been achieved. For example, the Integrated Healthcare Association's physician pay for performance program included measures for testing diabetic patients' HbA1c and low-density lipoprotein (LDL) in their first year and introduced measures of control of HbA1c and LDL in their second and subsequent years. The Bridges to Excellence physician recognition program also has indicators of both testing and control in its physician quality measurement program. Measures of HbA1c and LDL control are also included in Medicare's physician voluntary reporting program (PVRP).

Requiring labs to report clinical values would allow Medicare's quality measurement to evolve in three ways. First, gathering clinical data from the labs that perform the tests—rather than requiring physicians to collect and report the lab value data—would allow quality measurement efforts to include the substantial number of physicians who would be excluded from measurement because they do not or cannot collect and report clinical lab values. So far, only about 6,000 physicians have participated in Medicare's PVRP which requires lab values. Second, the measures themselves could evolve from process to intermediate outcomes, thus improving the measures by moving them closer toward the goal of measuring whether patients' health is better. Finally, other important measures of control for other clinical conditions—such as the serum albumin level of elders at risk for

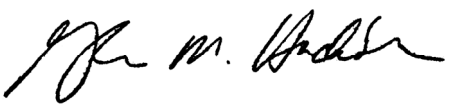
malnutrition or the hemoglobin levels for chemotherapy patients who use erythroid growth factors—could be added to the measure set without creating a new data burden on physicians. Reporting laboratory information as part of claims is not without burden. Industry representatives say that clinical and financial systems are often separated; it would take work to link them. It may be difficult to design fields to capture the variety of clinical lab results, including numeric results, codes, and narratives. However, because of the important role this information could play in the evolution of quality measurement, the changes needed to implement this new reporting function for clinical labs should be required as soon as possible.

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

GMH/aw/w