



**Association of
American Medical Colleges**
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0460 F 202 862 6161
www.aamc.org

Darrell G. Kirch, M.D.
President

VIA HAND DELIVERY

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Attention: CMS-1506-P

Dear Dr. McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*The Hospital Outpatient Prospective Payment System[OPPS] and CY 2007 Payment Rates ...*" 71 Fed. Reg. 49506 (August 23, 2006). The AAMC represents approximately 400 major teaching hospitals and health systems; all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our comments focus on the following areas: the proposal to link the inpatient quality reporting requirements to the OPPS payment update; the proposed changes to the evaluation and management codes that hospitals use to report clinic and emergency department visits and critical care services; the proposal to reduce the ambulatory payment classification (APC) payment for procedures involving replacement of a defective device; the outlier payment policy; payment for acquisition and handling costs of separately payable drugs and biologicals; and new technology APCs.

QUALITY REPORTING UNDER THE OPPS

The AAMC is a founding member of the Hospital Quality Alliance (HQA) which has, among its many purposes, fostering accountability among the nation's hospitals for the care provided to patients. The AAMC has been, and continues to be, a proponent of measuring quality and providing incentives for the improvement of care. However, we

are not in support of the proposed outpatient payment update program and the linkage between the inpatient and outpatient programs.

The National Quality Forum has served as a consensus organization that endorses measures for public accountability and quality improvement. The measures endorsed by NQF cover many settings in the healthcare continuum. A significant amount of research, testing and resources are used to ensure that appropriate and valid measures are approved for specific conditions and care settings.

It is inappropriate to assume that the measures used in the inpatient setting can serve as a proxy for measuring the quality of care in the outpatient setting. This is completely contrary to the performance measurement philosophy subscribed to by the NQF and its membership. One cannot assume that the care processes in the outpatient setting are the same as the inpatient setting and that the only difference between the two is the level of acuity. As currently articulated in the proposed rule, measures do not currently exist for the outpatient setting. Therefore, we believe quality reporting requirement for the outpatient payment update program should be postponed until proper measures are developed through the established NQF process.

The HQA has played the primary role in selecting measures that are publicly reported on the Hospital Compare website. As a result, it has been the case that the measures required for the inpatient payment update have been selected from those measures approved for reporting. We believe that the HQA and the Ambulatory Quality Alliance (AQA), when appropriate, should be the organizations that select the measures to be publicly reported. CMS can then utilize those measures for the appropriate inpatient and or outpatient payment update programs.

Another reason these payment systems should not be linked at this time is that while most hospitals have complied with the inpatient quality reporting requirement and will receive a full inpatient payment update in fiscal year 2007, there are still many technical issues that remain that can put hospital updates at risk. This is the second year that hospitals' data have been required to pass validation screens in order for the hospital to receive their updates. However, it is recognized that this process needs to be improved. Given that the system still needs improvements, it is unreasonable to put hospitals at risk for losing not only their inpatient update but their outpatient update as well.

EVALUATION AND MANAGEMEN (E/M) CODING AND GUIDELINES

Background

Since the implementation of the OPSS, hospitals have been reporting five resource-based coding levels for clinic visits and five coding levels for emergency department visits using CPT E/M codes. The least and most resource intensive codes are combined resulting in three APC payment levels.

Because the CPT E/M codes are designed to reflect the activities of physicians, they do not adequately describe the range and mix of services provided by hospitals during these encounters. Thus, CMS has instructed hospitals to use their own internal guidelines – based on hospital resource use – to determine which CPT level code to report. As a result, there is no consistency in the coding methodology used by various hospitals.

To address concerns that the use of E/M codes with different reporting rules and meanings would violate Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) requirements, CMS recommended in its November 1, 2002 OPPS final rule that an independent expert panel charged with the task of recommending to CMS definitions and guidelines for clinic and emergency E/M codes be convened. The final rule also specified that CMS would not create new codes to replace existing CPT E/M codes for reporting hospitals visits until national guidelines have been developed.

In January 2003, the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) formed an independent expert panel charged with the task of developing E/M coding guidelines. In June 2003, the panel submitted a set of guidelines to CMS.

After making some modifications to the independent expert panel's recommendations, CMS contracted a study to test the guidelines. According to CMS, the contractor's findings indicated that the AHA/AHIMA model did not establish a relationship between the distribution of current hospital reporting of visits using CPT E/M codes that are assigned according to each hospital's internal guidelines and the distribution of code levels under the panel's guidelines. CMS did not adopt the recommendations, but stated that the AHA/AHIMA model should serve as a starting point for national guidelines development.

Proposed Rule

Although the November 1, 2002 OPPS final rule, specified that CMS would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines have been developed, the Agency is proposing for CY 2007 to create new Health Care Procedure Coding System (HCPCS) level II G codes for hospital clinic visits, emergency department (ED) visits and critical care services. Specifically, CMS would create five G codes to replace the current CPT codes currently used to report clinic visits, five G codes for emergency departments that are open 24 hours (Type A emergency departments), five G codes for emergency departments that satisfy other requirements, but are not open 24 hours (Type B emergency departments), and two G codes to replace the two current CPT codes used to report critical care services. Because Type B emergency departments do not meet the CPT definition of emergency departments, CMS has been instructing hospitals to report services furnished in these

departments using CPT clinic visit E/M codes rather than the emergency department visit codes used by Type A emergency departments.

For clinic and emergency department visit services, CMS proposes that payment be made at five payment levels instead of the current three levels of payment, based on the assignment of the codes to the five clinic visit APCs and the five emergency department visit APCs. Both clinic visit codes and Type B emergency department visit codes would be mapped to the corresponding clinic visit APC payment level, while Type A emergency department visit codes would be mapped to the appropriate emergency department visit APC payment level.

CMS's rationale for creating a separate set of codes for visits to emergency departments that are not open 24 hours is that the codes would help CMS collect and analyze hospital resource costs of visits to Type B EDs. The Agency proposes to continue to pay for Type B ED visits based on clinic visit APCs until it collects and analyzes the data.

The proposed rule would give hospitals the option to continue to use their own internal guidelines to determine the visit levels to be reported with the new G codes or to adjust their guidelines to reflect the new codes and policies.

Comments

The AAMC urges CMS to rescind the proposal to implement new G codes for hospital clinic and emergency department visits before the adoption of national code definitions and national guidelines. The proposal would impose an administrative burden on hospitals for several reasons. First, since G codes are not recognized by other payers, hospitals would need to use two sets of codes to report clinic and emergency department visits: G codes for Medicare and CPT codes for non-Medicare payers. Second, since the G codes are temporary, hospitals would likely need to change their coding processes twice, once with the implementation of G codes and again when national guidelines have been developed. Furthermore, without a standardized methodology to determine the visit levels to be reported with the new G codes, there will continue to be considerable variability in the levels of service and a lack of stability in terms of coding and payment policy. Finally, the proposal to pay E/M visits at five rather than three levels introduces a degree of specificity that would make it very difficult for hospitals to precisely determine the level payment a particular intervention should be assigned to.

In addition, we urge CMS to consider paying for services provided at satellite emergency departments at the Type A emergency department payment rate. Satellite EDs are facilities that are located at a different location than the main campus and, although they are not open 24 hours, they satisfy other emergency department requirements. Because they are an extension of the main campus, they are likely to treat patients that are similar clinically and in terms of resource use to those treated in the emergency department located on the main campus. Therefore, these facilities enhance beneficiary access. We

are concerned that providing payment at the clinic level until such time as CMS gathers sufficient data to determine costs of Type B emergency departments could hurt satellite emergency departments and hinder access to care.

DEVICE-DEPENDENT APCs

The rule proposes that both the APC payment and beneficiary copayment be reduced for selected “device-dependent” procedures that involve replacing a defective implanted device with a new device that was provided to the hospital at no cost or the hospital received full credit for the removed device. The payment reduction would be based on an estimate of the device cost.

CMS provided no information as to how many procedures involve defective device replacement, so it is not possible to know the magnitude of the problem or the impact of this proposal. However, on its face, it seems reasonable that payment for defective devices that are replaced should be taken out of the APC payment rate when the device has been replaced at no cost to the hospital. However, the methodology used to calculate the amount of the APC reduction raises two concerns.

First, even though the hospital may incur no cost for the device that replaces the defective device, the hospital often still incurs administrative costs related to processing the “no charge” status of the device. For example, the hospital needs to record the “no charge” status of the device when it is received; it needs to instruct the finance and patient accounting departments to charge differently for the device/procedure; and the hospital must report to Medicare that the procedure involves the replacement of a defective. Consequently, if CMS does not take into consideration the administrative costs related to the replacement of a defective device, even when the hospital incurs no cost for the device, reducing the APC payment by an amount that equals the full device cost would lead to payment that is lower than the total cost incurred.

Second, reducing the APC payment by the full device cost may result in further underpayment if the replacement device is an upgrade from the device that is removed from the patient. In these cases, hospitals generally must pay the difference between the upgraded device and the replaced device.

In light of these concerns, we urge CMS to reduce the APC payment amount for devices that are replaced at no cost to the hospital by a percentage that is lower than the percentage associated with the full cost of the defective device. In addition, for upgraded devices, we urge CMS to apply a smaller offset amount to the APC associated with the upgraded device than the offset applied to an APC associated with a device that is replaced at no cost to the hospital.

CMS is proposing that hospitals use a modifier to identify those devices that have been replaced without cost to the hospital or where full credit was given by the manufacturer.

The Agency recognizes that the “the current FB modifier may not be appropriate in cases in which the replacement device is a more expensive device than the device being removed and may need to be changed to expand its use for all potential APC payment adjustment scenarios.” (71 Fed. Reg. at 49577). It is unclear whether CMS proposes to continue using the FB modifier or whether another modifier would be required for the purpose of identifying devices that have been replaced without cost to the hospital or where full credit was given by the manufacturer. We urge CMS to clarify how the modifier would be used in order to identify devices that are more expensive than the removed device.

OUTLIER PAYMENTS

Outlier payments are an important component of the OPSS, because they provide some financial cushion when hospitals provide high cost services. In 2006, CMS reduced the percentage of the total outlier payments from two percent of total expenditures to one percent. For 2007, CMS is proposing to continue to allocate one percent of total payments for outlier payments.

A hospital receives an outlier payment for a service if the hospital’s cost for that service exceeds 1.75 times the APC payment rate and the cost exceeds the APC payment rate plus a fixed dollar threshold of \$1,175. CMS proposes to increase the fixed-dollar threshold by \$575 (from \$1,250 to \$1,825), while keeping the multiplier threshold at its current level of 1.75. CMS states that the increase in the outlier threshold is the result of applying a new methodology for calculating the cost-to-charge ratios (CCR) as well as targeting the outlier pool to account for one percent of total payments. According to CMS changes to outlier payments are estimated to result in a 0.25 percent loss in total payments for hospitals.

As we have noted in the past, major teaching hospitals tend to treat a larger proportion of complex and costly cases, thereby relying more heavily on outlier payments. For instance, data from CY 2004 and CY 2005 show that outlier payments as a percent of total payments are greater for major teaching hospitals (3.0 percent and 3.2 percent respectively) than for non-teaching (1.8 percent and 1.5 percent respectively) and other teaching (1.7 percent and 1.8 percent respectively).¹ Furthermore, according to CMS’s analyses published in the November 10, 2005 final rule, non-teaching and minor teaching hospitals were estimated to experience a slight positive impact due to the outlier pool reduction (0.2 percent), while major teaching hospitals were estimated to see a 0.7 percent decrease in total payments in CY 2006.²

¹See Table 16 (CY 2004 OPSS final rule) and Table 42 (CY 2005 OPSS final rule) in 68 Fed. Reg. at 63475 (Nov. 7, 2003), and 69 Fed. Reg. at 65857 (Nov. 15, 2004), respectively.

² See Table 40 in 70 Fed. Reg. at 68725 (Nov.10,2005).

In the proposed rule, CMS did not include any analyses that would specifically show the impact of the revised CCR calculation on outlier payments and has provided no data to support the proposed reduction or its impact on various classes of hospitals. Even more important, unlike the inpatient proposed rule, the OPPS rule contains no information about whether historical outlier payments were more or less than the outlier pool. We believe these data must be made available to allow providers to make meaningful comments as to whether increasing the outlier threshold is appropriate.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Relying on hospital cost reports and outpatient claims data to estimate costs, CMS is proposing to pay for separately payable drugs and biologicals at the average sales price (ASP) plus five percent. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2006. It also is lower than the physician office setting payment rate of ASP plus six percent.

We appreciate CMS's request for comments on hospitals' overhead costs associated with these drugs (71 Fed. Reg. at 49585). We believe that both the current and proposed payment rates may be too low for certain drugs and biologicals with very high overhead and handling costs. According to CMS's analyses, paying hospitals at ASP plus five percent would cover both the acquisition and the handling costs for drugs and biologicals. We have heard from several of our hospitals, however, that some of their acquisition and handling costs exceed even the current payment rate of ASP plus six percent.

There may be two potential explanations that can account for the discrepancy between the payment that CMS believes would cover the acquisition and handling costs of certain separately payable drugs and biologicals and what would constitute sufficient payment to cover their costs.

First, there is the issue of "charge compression." Studies have shown that hospitals usually use a lower markup for high cost items than they do for lower cost items. CMS however, applies one department level cost-to-charge ratio to all services reflected in that department. Because this methodology does not take into account hospitals' variability in setting charges, it invariably results in what is referred to as "charge compression", which is the under-estimation of costs associated with low markup services and over-estimation of costs associated with high-markup items.³ Recognizing the likelihood of this phenomenon on the inpatient side, CMS has awarded a one-year study to RTI International to study methods of improving the accuracy of the adjustment of charges to costs for inpatient services. Since hospitals use the same practice on the outpatient side, it is likely that outpatient services are also affected by the charge compression. Thus, the more expensive the drug or biological, and the lower the markup, the more likely that its

³ Note: This issue also applies to device-related APCs.

cost derived from the application of a department level cost-to-charge ratio is underestimated.

Second, in its June 2005 Report to the Congress, the Medicare Payment Advisory Commission (MedPAC) found that drug handling costs are not negligible and vary greatly depending upon the type of drug involved. The report further noted that some classes of hospitals, including teaching hospitals, provide many services that include separately payable drugs and biologicals and a payment system based on acquisition costs could have redistributive effects among facilities.⁴ We are concerned that CMS uses a methodology based on averages that may mask the high handling costs of certain drugs and biologicals.

We urge CMS to clarify in the final rule the methodology used to arrive at the ASP plus five percent payment proposal. The proposed rule does not fully explain how the claims data analyses were translated into the ASP methodology. The preamble discussion merely states that “using mean unit cost [from the CY 2005 hospital claims data] . . . would be equivalent to basing their payment rates, on average, at ASP + 5 percent.” (71 Fed. Reg. at 49585). Given that the ASP methodology is drug-specific, it is unclear what “crosswalk” CMS used to connect the claims data and the ASP data. We urge CMS to provide further explanation of its methodology in the final rule. We further respectfully request that CMS provide information as to what variables from the claims data the Agency is using to arrive at the proposed payment rates, how many hospitals are included in the data analysis, and the trimming procedures utilized.

In light of these concerns, and until such time as these data have been provided and hospitals have had the opportunity to review and comment on the methodology used to determine payment rates for drugs and biologicals, we urge CMS to continue paying for separately payable drugs and biologicals at ASP plus six percent.

NEW TECHNOLOGY APCs

CMS is proposing to move certain procedures from “new technology APCs” to clinical APCs in less than two years. A number of these procedures will experience payment reductions due to these new assignments. Although it is the purview of CMS to move services from new technology APCs to clinical APCs in less than two years, we are concerned that the data that CMS obtains in the first two years after services are approved may not be accurate because diffusion of new technologies can be slow and hospitals need time to update their charge masters to appropriately reflect charges that reflect the actual costs of the new services. We ask CMS to consider maintaining procedures in the new technology APC categories for a minimum of two years before assigning them to a clinical APC.

⁴ See MedPAC’s June 2005 Report to the Congress: *Issues in a modernized Medicare program*, page 140.

Administrator McClellan

October 10, 2006

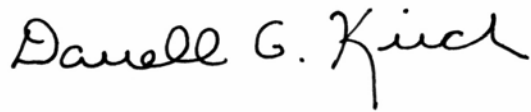
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Teaching hospital's outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission of teaching hospitals. Medicare outpatient payments are critical for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be pleased to work with CMS as it continues to refine and improve this important Medicare payment system.

If you have questions concerning these comments, please contact Diana Mayes, at dmayes@aamc.org, or 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive, slightly slanted style.

Darrell G. Kirch, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC
Diana Mayes, AAMC