



VIA HAND DELIVERY

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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-1501-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 "*Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (outpatient PPS or OPPS) and Calendar Year 2005 Payment Rates.*" 70 Fed. Reg. 42674 (July 25, 2005).¹ 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 financial impact of the OPPS on major teaching hospitals, the outlier payment policy, the multiple imaging discount, the proposed payment for overhead and handling costs of separately payable drugs, and the "inpatient-only" list.

I. CMS Should Study the Impact of OPPS on Teaching Hospitals

The outpatient PPS is the only major Medicare payment system that does not include a teaching adjustment. Teaching adjustments are included in the inpatient, psychiatric and rehabilitation facilities prospective payment systems. We urge CMS to conduct a study to determine whether teaching hospitals incur higher outpatient service costs compared to other hospital types, thereby supporting the addition of a teaching adjustment to the OPPS.

¹ I also will be referring to the correction notice for the proposed rule, which was published on August 26, 2005 (70 Fed. Reg. 50680).

The outpatient department is critical to fulfilling the missions of teaching hospitals. In addition to providing a site for clinical education for all types of health professional trainees, teaching hospital outpatient departments provide an environment in which clinical research can flourish, and are a source for specialized, unique, and referral/standby services. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and care for the nation's sickest patients. In addition, teaching hospital outpatient departments often serve as a primary source of health care for low-income Medicare beneficiaries and other individuals.

Medicare payments for hospital outpatient services represent an important source of reimbursement for teaching hospitals. Yet, according to the financial impact table contained in the correction notice of the proposed rule (70 Fed. Reg. at 50682), CMS estimates that average payment increases for major teaching hospitals in calendar year 2006 will lag significantly behind those of other hospital groups: 0.6 percent compared to 2.3 percent for non-teaching and other teaching hospitals.

The 2006 figure represents the fourth consecutive year exhibiting this disturbing disparity.² These financial impacts are particularly troublesome because teaching hospitals are more dependent on outlier, pass-through, and device-dependent APC payments, yet these payments are not stable, predictable funding sources. Through 2003, teaching hospitals could depend on transitional corridor payments to help protect against significant financial losses, but the availability of these payments expired at the end of 2003.

In the initial OPPS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments . . . for certain classes of hospitals." (Section 4523 of the BBA). Pursuant to a mandate in the Medicare Modernization Act (MMA), CMS has conducted an analysis to determine whether rural hospital outpatient costs exceed those of urban hospitals. Although the regression analysis did not support an adjustment for all rural hospitals, it did support an adjustment for sole community hospitals. As a result, CMS is proposing that sole community hospitals receive a payment adjustment of 6.6 percent.

² CMS also estimated that the OPPS payment increase for major teaching hospitals would be less than that of other hospital categories in 2003, 2004 and 2005. See OPPS final rules in 67 Fed. Reg. at 66810 (Nov. 1, 2002), 68 Fed. Reg. at 63475 (Nov. 7, 2003), and 69 Fed. Reg. at 65857 (Nov. 15, 2004).

We are unaware whether CMS has done an analysis of teaching hospital costs. In the discussion accompanying the financial impact table, the Agency seems to state that the expiration of pass-through drug payments is a key factor in the low payment increases for major teaching hospitals. If the expiration of pass-through payments for drugs does play such a major role in decreased payments for teaching hospitals, we believe it is incumbent upon CMS to provide a more in-depth analysis of how the drug payment policy affects teaching hospitals.

In addition, since CMS has estimated that OPPS payments for teaching hospitals are lagging behind those of other teaching and non-teaching hospitals, we believe a comprehensive analysis is overdue. Such an analysis should not only examine the impact of other payments, such as outlier, transitional corridor and device-dependent APC payments, but also the impact of the costs associated with teaching hospitals' teaching and research missions on their outpatient cost structure. If such an analysis concludes that teaching hospitals have higher costs, like sole community hospitals, we believe a teaching adjustment would be warranted.

II. CMS Should Not Reduce the Outlier Payment Pool

Outlier payments are an important component of the OPPS because they provide some financial cushion when hospitals provide high cost services. Currently, CMS targets these payments to be 2 percent of total outpatient payments, financed by a corresponding reduction in the APC conversion factor. 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 decrease the outlier pool from 2 percent of total payments to 1 percent. In order to achieve this reduction, CMS would increase the fixed dollar threshold by \$400 (from \$1,175 to \$1,575). Thus, for CY 2006, payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and the cost exceeds the APC payment rate plus a \$1,575 fixed dollar threshold. The outlier payment would remain the same -- 50 percent of the service cost is above the threshold.

We oppose the reduction of the outlier pool. First, the APC payment rates continue to fluctuate, widely in some cases. We believe there should not be changes to the outlier pool until there is more stability among and across APC payment rates. Secondly, CMS has provided no data to support the proposed reduction or its impact on various classes of hospitals; the only rationale provided is a MedPAC recommendation to eliminate the outlier pool. We believe these data must be made available to allow providers to make meaningful comments as to whether the outlier pool should be increased or decreased. It is only fair to ask that if payment reductions are made, there are data to support the hypothesis that the outlier pool has been underspent and that this information is made available to the public.

As we have written in the past, we continue to believe that outpatient services that qualify for outlier payments should receive 80 percent of their costs above the threshold, rather than the current level of 50 percent. While teaching hospitals would still incur significant unreimbursed costs, increasing the payment level would help ameliorate the level of these losses for hospitals, such as teaching hospitals, that provide complex outpatient services. Increasing the payment level would also make the OPSS consistent with the policy under the inpatient PPS.

III. CMS Should Rescind the Proposal To Discount Multiple Diagnostic Imaging Procedures

Under the OPSS, hospitals receive a full APC payment per imaging procedure, regardless of how many scans the patient may have during a single episode (one day) of care.

CMS is proposing to reduce the payments for multiple imaging procedures within the same “imaging family” provided to a patient in the same encounter. Specifically, a hospital would receive full payment for the highest APC-weighted imaging procedure and then 50 percent of the APC payment for subsequent procedures.

We urge CMS to rescind this proposal pending further study. Two issues in particular highlight the need for an in-depth analysis of the proposed pricing methodology before it becomes part of the payment system. First, CMS’s rationale for this proposal is that this payment would be consistent with the pricing methodology already used for multiple imaging procedures in the physician’s office. However, it is unclear whether the cost structure and practice pattern (i.e. complexity of cases and imaging procedures) in the hospital setting are the same as those in the physician’s office.

Secondly, even if additional procedures performed in the same encounter are less costly, CMS’s proposal misses an important point: this cost efficiency is already built into each hospital’s cost structure and therefore already accounted for in CMS’s rate determination.

As the Agency knows, outpatient service costs, which are the basis for the APC rate determinations, are calculated by multiplying the charges on the claim by the appropriate hospital department’s cost-to-charge ratio (CCR). We understand that most hospitals charge the same for single procedures as they charge for any additional procedure performed during a multiple procedure test. To the extent this is the case, then the hospital’s departmental CCR is lower than it should be because the denominator is higher than it otherwise would be if the hospitals had charged less for the subsequent services. This results in a cost determination at the individual service level that is likely too low for single scans, and possibly too high for subsequent scans. As a result, the APC payment rate also is likely too low for single scans, and too high for multiple scans. However, since most hospitals do both single and multiple scans, the overall payments may be adequate.

By discounting subsequent tests performed during multiple procedures, the proposed rule essentially eliminates the amount that it possibly is overpaying for subsequent scans. However, it is still underpaying when only a single imaging procedure is performed, as well as underpaying the procedure that receive the full APC payment when it occurs in the same session with other imaging procedures. Consequently, if finalized, the proposed rule methodology would underpay all procedures, whether single procedures or multiple procedures.

We believe these issues need to be studied in more detail before any type of discounting policy is contemplated. Depending on the results of these analyses, CMS may decide that it is suitable to have no discount or a discount less than 50 percent for subsequent tests performed during multiple imaging procedures.

IV. CMS Should Reconsider Its Proposal for Drug Handling Costs

Currently under the OPDS, payments for certain separately payable drugs, biologicals and radiopharmaceuticals are based on the average wholesale price (AWP).

For 2006, CMS proposes to end payments based on the average wholesale price. Instead, it proposes to pay based on the average sales price (ASP). To cover acquisition costs, the Agency proposes to pay hospitals ASP plus 6 percent -- the same as what is paid when the drug is provided in the physician's office setting.

To cover overhead and handling costs, CMS is proposing to pay an additional amount equal to ASP plus two percent. This amount appears to be an estimate based on an analysis of overall drug costs since CMS does not have hospital charge data on handling costs incurred by hospitals' pharmacy departments when administering separately payable drugs and biologicals. In order to acquire data on drug handling and overhead costs, CMS is proposing to establish C-codes for drug handling categories and to instruct hospitals to charge the appropriate handling C-code for handling costs associated with each administration of each drug and biological.

We appreciate CMS's effort to establish accurate payment to cover drug handling and overhead costs. However, we strongly oppose the proposal to mandate the use of C-codes. According to our members, such a requirement is unduly burdensome and would create organizational "chaos" in outpatient departments. Among the many complex administrative obstacles to implementing the proposal, three issues stand out. First, implementing the C-codes would force hospitals to change their billing systems to separate out handling charges for separately payable drugs, while retaining these charges within the overall charge for those items in which the drug cost is packaged. Second, the new C-codes would be recognized by and acceptable only to Medicare, thus requiring hospitals to modify their systems to separate out these costs for Medicare, but continue to combine them with acquisition costs and bill them as a single item for other payers. Third, many hospitals use the same charge master for inpatient and outpatient services. Implementing this proposal, which is specific to the outpatient payment system, would

seemingly require modifications to the charge master to recognize drug delivery in the inpatient versus outpatient setting.

For these reasons, we strongly recommend that CMS look into other methods of gathering data for the purpose of studying handling costs. We would be eager to assist the Agency in this endeavor.

With regard to CMS's specific proposal to pay two percent of ASP to cover handling costs, we believe that this payment rate may not be adequate to cover the overhead and handling costs of drugs and biologicals, particularly those that require more intricate preparation. As the two studies conducted by the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) demonstrated, handling costs vary greatly depending upon the type of drug involved (example: oral tablet versus compounded preparation). If a hospital has a higher utilization of drugs whose handling costs are at the high end of the spectrum, two percent of ASP would not cover those costs. Given the lack of sound handling cost data and the consequent uncertainty associated with any payment methodology ultimately adopted by the Agency, we urge CMS to compare the payment rates under the payment methodology it ultimately finalizes to the 2005 payment rates and provide an appropriate adjustment for those drugs that experience significant payment reductions.

V. "Inpatient-Only" List

Under current OPSS policy, CMS deems certain procedures as "inpatient-only" for which hospitals will not receive an OPSS payment if these procedures are performed in the hospital outpatient department. Under the proposed rule, 25 procedures would be taken off the "inpatient-only" list and paid under the OPSS in 2006.

While we appreciate that CMS has removed a significant number of procedures, we also urge CMS (as we have in the past) to accept the recommendation made by the APC Advisory Panel at the February 2004 meeting, and eliminate the "inpatient-only" list altogether. The determination of whether a patient should be admitted as an inpatient or treated as an outpatient should not be made by CMS, but rather be based on the professional judgment of the physician overseeing the patient.

If the Agency decides to retain an "inpatient-only" list, we also believe CMS must revise the criteria to determine when a procedure is removed from that list. Two of these criteria require that the procedure is being performed in "most outpatient departments" or that "most outpatient departments" are equipped to provide the service. Major teaching hospital outpatient departments often are the first places to perform services that heretofore had been performed only in an inpatient setting. Thus, there likely will be a time gap between when these services are performed safely in teaching hospital outpatient departments and "most" hospitals' outpatient departments. The criterion should be whether a procedure can be performed safely in an outpatient department, *not*

the number of outpatient departments in which the procedure is performed. We urge CMS to reconsider its current policy on this issue.

We also agree with the comments of the American Hospital Association that if the “inpatient-only” list is not eliminated, there should be an appeals process to address those circumstances in which an OPPS payment for a service provided in an outpatient setting is denied because it is on the “inpatient-only” list. These hospitals are not eligible to receive payments under the inpatient PPS, because the service was not provided in that setting. Consequently, unless hospitals have an opportunity for reconsideration, they will continue to receive no reimbursement for these services. As a result of this policy and because teaching hospitals are the first places to perform services that had previously only been performed in an inpatient setting, they will continue to be denied payment until these services are performed by “most” hospitals’ outpatient departments. An appeals process could provide payments to hospitals, such as teaching hospitals, whose cutting edge technology permits them to be on the front lines of performing procedures previously considered inpatient-only, in an outpatient setting.

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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 happy 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 Karen Fisher at kfisher@aamc.org, or 202-862-6140 or Diana Mayes, at dmayes@aamc.org, 202-828-0498.

Sincerely,

Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC
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