

August 26, 2005

## AAMC Summary and Analysis

### **CALENDAR YEAR 2006 MEDICARE OUTPATIENT PPS PROPOSED RULE: PROVISIONS OF INTEREST TO AAMC MEMBERS**

On July 25, 2005, the Centers for Medicare and Medicaid Services (CMS) published its calendar year 2006 proposed rule for the Medicare hospital outpatient prospective payment system (outpatient PPS or OPSS). See *Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule*. 70 Fed. Reg. 42674. A correction notice which slightly decreased the conversion factor was published on August 26, 2005 (70 Fed. Reg. 50680). The proposed rule can be obtained by accessing the AAMC's issue brief on this topic at: <http://www.aamc.org/advocacy/library/teachhosp/hosp0055.htm>.

Among other items, the proposed rule contains the level of the payment increase (known as the "update factor") for OPSS base payment rates, as well as changes and discussions related to: ambulatory payment classification (APC) groups and relative weights, transitional payments for new drugs and devices, and outlier payment policies.

Comments on the proposed rule are due **September 16, 2005**. If you choose to submit comments by mail, send the original and two copies to:

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

A number of outpatient data tables are available on the CMS web site at:  
<http://www.cms.hhs.gov/providers/hoppps/2006p/1501p.asp>

#### **I. GENERAL BACKGROUND**

On August 1, 2000, Medicare implemented a prospective payment system for hospital outpatient services. The outpatient PPS does not affect Medicare physician payments.

The major categories of services subject to the OPSS are:

- clinic visits,
- emergency room visits,
- diagnostic services,
- surgical procedures,
- radiology services, and
- cancer chemotherapy.

In general, the outpatient services excluded from the OPSS are those that already are subject to an existing fee schedule or payment system, for example laboratory services. Payments under the OPSS are for individual services (as identified by HCFA's Common Procedural Coding System (HCPCS) or Physicians' Current Procedural Terminology (CPT)).

Ambulatory Payment Classification (APC) groups are the foundation of the OPSS. In general, hospital outpatient services (as identified by HCPCS/CPT codes) are grouped together according to their similarity in terms of resource costs and clinical indications. In some cases there may be only a few services under a given APC, while in others there may be 50 or more.

In general, each APC is assigned a relative weight based on the median costs of the services in the APC. The relative weight is multiplied by the OPSS "conversion" factor to arrive at a base APC amount. This amount is then adjusted by the hospital wage index, which reflects differences in labor costs across geographic areas.

Certain outpatient services have unique payment methodologies. This is true particularly for new outpatient services, and certain drugs and devices.

## **II. OPSS CONVERSION FACTOR UPDATE AND PAYMENT RATES (page 42694)**

The proposed rule implements the current law requirement that the base payment rate under the OPSS (known as the "conversion factor") be increased to reflect the full increase in the hospital inpatient market basket, as published in the FY 2006 inpatient PPS final rule. This increase is 3.7 percent.<sup>1</sup>

*Analysis* -- It is beneficial that the conversion factor update will reflect the full market basket increase. The actual increase to the 2005 conversion factor will be approximately 4.14 percent, from \$56.983 to \$59.343. This is because budget neutrality policies, such as the wage index budget neutrality adjustment, a 1 percent rather than a 2 percent outlier pool, the transitional pass-through pool and a proposed sole community hospital adjustment, are applied to the conversion factor.

Actual average outpatient payments will increase only an estimated 1.9 percent for all hospitals, largely due to the expiration of several MMA provisions (see Correction Notice Impact Table at page 70 Fed. Reg. at 50682). Major teaching hospitals will receive an increase of only 0.6 percent compared to a 2.3 increase for other teaching and non-teaching hospitals. According to the discussion of the impact table, it seems that the much smaller increase for major teaching hospitals is due to the expiration of payments for certain drugs, as well as changes to the wage index that will reduce payments, on average, for major teaching hospitals in 2006. The average for the other hospital

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<sup>1</sup> Note that the proposed rule stated that the market basket (MB) increase is 3.2 percent, but this was published before the Inpatient Final Rule was published, which states that the MB update is 3.7 percent.

categories also is higher in part because of a proposal to give rural sole community hospitals a payment increase (see below). The AAMC will be asking CMS to provide further information regarding how the Agency derived its impact estimates.

### **III. ADJUSTMENTS FOR CERTAIN HOSPITAL CATEGORIES (pages 42698--701)**

Current law permits CMS to make adjustments in a budget neutral manner to the OPPS payments for certain hospital categories if the Agency determines such adjustments are “necessary to ensure equitable payments.” (BBA sec. 4523). Pursuant to a mandate in the 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.

*Analysis* -- Despite past pronouncements that it would study teaching hospitals’ outpatient costs, the proposed rule includes no such discussion. The AAMC will urge CMS to conduct an analysis to determine whether a teaching adjustment is appropriate.

### **IV. CHANGES TO OPPS OUTLIER POLICIES (pages 42701--702)**

#### Background

As with the inpatient PPS, the OPPS makes additional payments for outpatient services that are extremely costly (“outliers”). CMS targeted these payments to be 2.0 percent of total outpatient payments, financed by a corresponding reduction in the APC conversion factor.

Outlier eligibility is determined at the individual OPPS service level. In CY 2005, CMS introduced a fixed dollar threshold in addition to the traditional multiplier threshold to better target outliers to those high cost and complex procedures where a very costly case could present a hospital with significant financial loss. Thus, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment rate and exceeds the APC payment rate plus a \$1,175 fixed dollar threshold. The outlier payment is equal to 50% of the difference between the cost of the service and 1.75 times the APC payment for the service.

amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate plus \$1,175.

#### Proposed Rule

In its March 2004 Report, MedPAC recommended that Congress eliminate the outlier policy under the OPPS. Since this would require a statutory change, CMS proposes to, instead, decrease the outlier payment for CY 2006, by reducing the size of the percentage

of total outlier payments from 2% of the aggregate total payments to 1%. In order to achieve this reduction, CMS would increase the fixed dollar threshold by \$400 (from \$1,175 to \$1,575), while keeping the multiplier threshold at its current level of 1.75. 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 exceeds the APC payment rate plus a \$1,575 fixed dollar threshold. The payment percentage would remain the same -- 50 percent.

*Analysis* -- According to CMS, the change in the outlier threshold has a minimal redistributive impact by class of hospital. However, the proposed rule contains no analyses that support its proposal to reduce the outlier pool. Furthermore, it is unclear whether the outlier pool has been overspent or underspent. The AAMC will urge CMS to publish data on outlier payments before making changes to the outlier payments.

## **V. TRANSITIONAL PASS-THROUGH PAYMENTS (pages 42717--723, 42735)**

### Background

The OPSS provides that hospitals may receive “pass-through” payments for a limited period of time, from two to three years, for specific items, including new drugs and devices that meet specified criteria.

After the 2-3 year period, the device/drug/biological and its associated costs are “packaged into” a current APC or a new APC is created. The two-to three year time frame was established because it generally takes CMS this amount of time to collect the claims data and allow Agency staff to analyze the device/drug/biological costs and incorporate those costs into the APC rate calculations.

### ***A. Pass-through payments for Devices (pages 42717--718)***

As mandated by law, in April 2001, CMS established “categories” to determine whether a specific device qualifies for transitional payments (the category designation does not apply to drugs and biologicals). If a category qualifies for pass-through status, then all devices that fall within that category receive transitional payments; individual devices cannot independently qualify for these payments.

The criteria for determining whether a device category is eligible for pass-through payments are set forth at 42 CFR §419.66. One of the criteria used to establish a new category of devices for pass-through payment is that the item be surgically inserted or implanted through a surgically created incision.

In CY 2005, three device categories are eligible for pass-through payments: C1814, C1818 and C1819 (70 Fed. Reg. at 42718).

## Proposed Rule

The proposed rule states that pass-through payments for the 3 current device categories will expire at the end of December 2005. The costs of these devices will be packaged with the costs of the procedures with which the devices were billed in 2004 (70 Fed. Reg. at 42718). CMS proposes no new device categories for pass-through payments for CY 2006.

In response to comments from past rulemakings CMS is proposing to modify the criterion concerning surgical implantation to consider eligible “those items that are surgically inserted or implanted either through a natural orifice or a surgically created orifice (such as through an ostomy), as well as those that are inserted or implanted through a surgically created incision.” (70 Fed. Reg. at 42721)

In addition, CMS is proposing to create a new device category for those instances where an existing or previously existing category descriptor does not appropriately describe the new type of device. This proposal is in response to concerns that current device category descriptors are too broad and preclude some new technologies from qualifying for establishment of a new device category for pass-through payment.

### ***B. Pass-through Payments for Drugs, Biologicals and Radiopharmaceutical Agents (pages 42721--723)***

CMS is proposing to continue pass-through status for 14 drugs and biologicals and end pass-through status for 10 drugs and biologicals in CY 2006.

Payments for the pass-through items are equivalent to the payment that is made in the physician office setting, which is based on average sales price (see below). Since this payment methodology is the same as the payment methodology for drugs and biologicals without pass-through status, there essentially is no payment made from the pass-through “pool”(see below).

### ***C. Pass-through Pool (page 42735)***

Pursuant to current law, CMS is authorized to spend up to 2 percent of total OPPS payments for pass-through payments. CMS estimates however, that in CY 2006, only 0.05 percent of total OPPS payments will be needed for pass-through payments. This is because currently there are no device categories eligible for pass-through payments in 2006 and all pass-through drugs will be paid the same as all other drugs, so no additional pass-through payments will be necessary. The 0.05 percent is based on CMS’s estimate of any device categories that would become eligible for pass-through payments in 2006. Accordingly, the OPPS conversion factor will be reduced by only 0.05 percent.

*Analysis* -- In stark contrast to the early years of OPDS, it appears that the need for a pass-through pool is diminishing. This is due in large part to CMS's new policy regarding drug payment, as well as its decision to approve only new device categories rather than individual devices. CMS's proposal to broaden the criteria for approving new device categories may result in additional devices being approved for pass-through payments.

## **VI. OPDS PAYMENTS FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS (pages 42723--732)**

### Background

Items that do not have pass-through status, are paid in one of two ways: packaged payment and separate payment. While packaging the costs of items into the payment for the procedure with which they are associated encourages hospital efficiencies, CMS recognizes that expensive and rarely used drugs, biologicals and radiopharmaceuticals need to be paid separately in order to prevent insufficient payments to hospitals. Thus, under current law, a threshold of \$50 per day is applied, so that items whose cost per day is less than \$50 are packaged with the procedures with which they are billed and those whose cost exceed \$50 per day are paid separately. In CY 2005, an exception to the packaging rule was made for one class of drugs, the oral and injectable 5HT3 forms of anti-emetic treatments, which CMS is paying for separately.

Under current law, for CYs 2004 and 2005, hospitals were reimbursed at the following rates:

- 1) A sole source drug was paid no less than 83 percent and no more than 95 percent of the average wholesale price (AWP)
- 2) An innovator (brand) multiple source drug was paid no more than 68 percent of the AWP
- 3) A non-innovator (generic) multiple source drug was paid no more than 46 percent of the AWP

CMS has also created APCs for certain products, rather than packaging them with their associated outpatient procedure. These items include: orphan drugs, blood and blood products, certain vaccines and devices of brachytherapy consisting of a seed or seeds.

### Proposed rule

CMS proposes to continue to pay separately for drugs, biologicals and radiopharmaceuticals whose per day cost exceeds \$50 and packaging into the appropriate procedure code those drugs whose cost is below \$50.

The MMA provided that for CY 2006, payment for separately payable drugs, biologicals and radiopharmaceuticals be equal to the average acquisition cost for the drug for that year, subject to any adjustment for overhead costs. This is in contrast to the current payment methodology, which is based on average wholesale price.

### ***A. Drugs and Biologicals***

Based on its analyses, CMS has decided that the “average” acquisition cost for drugs, and biologicals would be best represented by the average sales price (ASP). Thus, CMS is proposing to pay ASP plus 6 percent to cover the acquisition costs for drugs and biologicals. This payment is the same amount as paid in the physician office setting. Furthermore, CMS is proposing to add an additional 2 percent to cover handling costs incurred by hospitals’ pharmacy departments when administering separately payable drugs and biologicals.

For drugs and biologicals for which CMS does not have ASP data, CMS is proposing to use the mean costs from the CY 2004 hospital claims data as their payment rate.

### ***B. Radiopharmaceuticals***

Because CMS does not have ASP data on radiopharmaceuticals, the Agency proposes to use the same methodology to calculate per day costs as it does for drugs and biologicals with no ASP data. Thus, CMS would use the mean costs from the CY 2004 hospital claims data to determine the item’s packaging status.

For separately payable radiopharmaceuticals, CMS is proposing to pay based on the hospital’s charge for each radiopharmaceutical agent adjusted to costs. However, unlike drugs and biologicals, radiopharmaceuticals would not be subject to an additional payment that would cover handling costs, since CMS believes these costs are included in the hospital’s charge for the radiopharmaceutical.

*Analysis* -- CMS is proposing to use the ASP data from the fourth quarter of 2004 to set payment rates for drugs and biologicals paid under the OPPS. These are the same data that were used to set payment rates for drugs and biologicals in the physician office setting effective April 1, 2005. CMS believes that the new methodology would better reflect the cost of drugs as administered in the physician office setting.

Note that under the proposed rule, for CY 2006 brand and generic drugs will be paid similarly, with a single ASP-based payment rate that considers the prices for both forms of the drug. CMS is specifically seeking comments on the adequacy of the ASP plus 8 percent payment rate. CMS states that if it used claims data to set the payment rate at mean costs, it would be equivalent to ASP plus 8 percent.

Both the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) did studies of drug handling costs. Their results showed wide variation in handling costs, depending upon the type of drug involved (example: oral tablet vs. compounded preparation).

The AAMC is interested in members’ views on drug handling costs.

## **VII. PROPOSED CY 2006 APC GROUPINGS AND PAYMENT RATES (pages 42680--692 and 42703--705)**

### Background

Pursuant to current law, services within an APC group cannot be considered comparable with respect to the use of resources if the highest median for a service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group. This is called the 2 times rule. Some exceptions are made in unusual cases such as low volume services.

An APC payment for a particular outpatient service results from multiplying the APC conversion factor by the relevant APC's payment "weight." This amount is then multiplied by the relevant geographic wage index value. The APC weight represents the median cost of the services included in that APC relative to the median cost amount of the services included in APC 0601, mid-level clinic visit. CMS is required to review the APC weights at least annually.

### Proposed Rule

The proposed 2006 APC rates are based on claims data from CY 2004 and hospital specific department level and overall cost-to-charge ratios (CCRs).<sup>2</sup> Payment rates are based on the following factors:

- 81 million outpatient claims, including 50 million multiple procedure claims that CMS converted to "pseudo" single claims, in order to increase the number of claims that could be used to determine payment weights;
- The incorporation of device costs into APC rates for those devices that are no longer eligible for transitional pass-through payments (see below); and
- Changes in APC assignments (including 58 HCPCS reassignments) for a number of outpatient services (see Table 7 on page 42703); these changes would resolve some of the APC 2 times rule violations.

*Analysis* -- As they have done in the past, CMS staff has proposed a number of coding and APC assignment changes. AAMC hospitals may want to review the proposed rule table to assess any changes affecting high volume or costly outpatient services. Also, as in past years, CMS continues to try and increase the number of outpatient claims that are used to determine payment weights. Single procedure claims are the most ideal, because all of the costs on the claim are associated with a single procedure. This is not the case in which multiple procedures are billed on the same claim. CMS has developed several ways of creating "pseudo single claims" from some of these multiple procedure claims in order to increase the claims available for payment calculations.

## **VIII. NEW TECHNOLOGY APCs (pages 42706--710)**

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<sup>2</sup>Procedure charges from claims data are converted to costs using the CCRs.

## Background

CMS makes special temporary additional payments for new technology items and services until it gathers sufficient data to be able to assign the services to a clinically appropriate APC. In addition to granting pass-through status, CMS may decide to assign a new technology to a “new technology” APC. The policy allows CMS to move a service from the New Technology APC and place it with a procedure under a clinical APC in less than 2 years or retain it in a New Technology APC for more than 3 years depending on whether it has sufficient data to be able to make a decision for reassignment. By contrast, devices with a pass-through status are required to retain that status for at least 2 years and not more than 3.

Unlike other APCs, new technology APCs are defined based on “cost bands” rather than clinical descriptors. Currently, there are technology APCs in 50, 100 and 500 increments, ranging from: \$0 to \$50 to \$9,500 to \$10,000. The APC payment rate is the median of the cost band (i.e. \$25 for the \$0 to \$50 cost band).

## Proposed Rule

As the number of procedures that qualify for placement in the new technology APCs has continued to increase over the past 2 years, CMS believes that the \$0 to \$50 cost band spans too broad of a cost interval to accurately represent the lower costs of an ever-increasing number of procedures that qualify for new technology payment. Therefore, CMS is proposing to refine this cost band by adding five new \$10 cost bands, so that there will now be a \$0-\$10 APC, \$10-\$20 APC, etc.

CMS is also proposing to make changes in its requirements for assigning services to New Technology APCs by requiring that an application for a code for a new technology service be submitted to the American Medical Association’s (AMA’s) CPT Editorial Panel before CMS accepts a New Technology APC application for review.

As a result of its evaluations of CY 2004 data, CMS is proposing to move certain procedures from New Technology APCs to Clinical APCs. Thus, CPT Codes 77523 and 77525 would be moved from new technology APC 1510 to clinical APC 0667 (Level II Proton Beam Radiation Therapy) based on a median cost of \$934.46 (see in-depth discussion at page 42707). In addition, 10 procedures listed on Table 11 (70 Fed. Reg. at 50681) would also be moved to new or established clinical APCs that contain services exhibiting clinical and resource homogeneity.

## **IX. DEVICE-DEPENDENT APCs (pages 42713--716)**

### Background

Certain APCs are populated by codes that usually, but not always, require that a device be implanted or used to perform the procedure. Over the years, CMS has used both

external data and Medicare claims data to establish APC median costs for APCs that contain outpatient services that involve devices, largely because of variation in hospitals' coding of devices. That is, not all hospitals include a device code on a claim, even when a device was used. Thus, it is often unclear whether a hospital's cost for an outpatient procedure on a claim included a device or not, making it difficult to determine accurate costs for procedures that include devices, solely from Medicare claims data. This issue became further complicated when CMS made the use of device codes optional prior to CY 2005. CMS reinstated mandatory device coding in CY 2005.

### Proposal

CMS is proposing to base the CY 2006 OPSS device-dependent median costs on 2004 claims data, the most current data available. Because hospital device code reporting was optional in CY 2004, claims for that year do not reflect the costs of devices used to provide services. Thus, in order to set payment rates, CMS adjusted CY 2006 median costs by comparing them with median costs that were used to set the payment rates for the CY 2005 OPSS. Based on its analysis of the data, the Agency found that 21 APCs experienced increases in median cost compared to the CY 2005 adjusted median costs, 1 APC median was unchanged, 16 APCs experienced decreases in median costs, and 8 APCs are proposed to be reconfigured in such a way that no valid comparison is possible. CMS is proposing to adjust median costs to the greater of the 2006 unadjusted APC median cost from 2004 claims data or 85 percent of the CY 2005 median used to set the payment rate in CY 2005. The Agency does not want to impose a limit on the extent to which a median cost can increase, because it does not believe that setting a corridor to control both increases and decreases in median costs is consistent with the use of adjusted medians.

## **X. INPATIENT-ONLY PROCEDURES (pages 42745--746)**

### Background

Under the OPSS, there are certain procedures that are deemed "inpatient-only" for which hospitals will not receive an OPSS payment if they are performed in the hospital outpatient department. CMS updates the list periodically, in large part to remove procedures from the list that staff determine can now be safely performed on an outpatient basis. The inpatient-only list was updated most recently in the November 15, 2004 OPSS Final Rule.

### Proposed Rule

Under the proposed rule, 25 procedures would be taken off the "inpatient-only" list and paid under the OPSS in 2006. CMS relied on recommendations from its APC Advisory Panel to develop this list. The Agency also looked at physician outpatient claims and the list of procedures that are paid by Medicare when performed in ambulatory surgical centers. The list of procedures proposed to be taken off the "inpatient-only" list is

published in Table 31 (70 Fed. Reg. at 42746). This table also contains the APC to which the service will be assigned for payment purposes.

*Analysis* -- AAMC teaching hospitals should review the list in Table 31, in particular to determine the appropriateness of the APCs to which CMS is assigning the previously “inpatient-only” services. Hospitals also should review the list of services that remain on the “inpatient-only” list (Addendum E) to determine whether any of these can safely be performed in an outpatient setting and, therefore, also should be payable under the OPSS.

The AAMC is particularly interested in whether any teaching hospitals are performing valvotomy, mitral valve, closed heart procedures (CPT code 33420) on an outpatient basis. While CMS originally considered removing it from the inpatient-only list, it decided not to remove it because its data indicates that it continues to be performed on an inpatient basis. If this procedure can safely be performed on an outpatient basis, we will urge CMS to remove it from the inpatient-only list.

## **XI. MISCELLANEOUS ISSUES**

### ***A. Payment for Observation Services (pages 42742--745)***

The proposed rule would make two changes in payment policy for observation services, intended to reduce the administrative burden on hospitals that arises when they attempt to differentiate between packaged and separately payable observation services. As a result of these changes, hospitals will no longer need to determine, prior to claims submission, whether patient condition and the services furnished meet the criteria for separately payable services; instead that determination will be made by CMS’s OPSS claims processing logic.

### ***B. Performing an “Inpatient Only” procedure on an Emergency Basis (page 42747)***

Under current regulations, a hospital must use a modifier when it submits a claim, indicating that a procedure on the OPSS inpatient list was performed in order to resuscitate or stabilize a patient with a life-threatening condition and the patient died before being admitted as an inpatient. CMS then assigns the service to the appropriate APC. For CY 2006, the Agency is proposing to pay based on a median cost of \$2,528.61.

CMS is concerned about the very large increase in the volume of hospital claims billed with the modifier over a one year period (from 18 to 300 claims). The Agency states that it will closely monitor hospital use of the modifier to determine whether it needs to change its policy regarding payment for this service or whether it should further educate hospitals on the correct use of the modifier.

*Analysis* -- Hospitals should review CMS’s criteria regarding the use of the modifier and comment if it seems unclear.

### ***C. Multiple Diagnostic Imaging Procedures (pages 42748--751)***

*Analysis* -- If CMS's proposed policy is finalized, hospitals will see a decrease in payments for some diagnostic imaging procedures that are performed in the same session with the patient. Currently, hospitals receive full payments for each diagnostic imaging procedure, even if they occur during the same operative session. CMS proposes that when two or more procedures in the same family are performed in the same session, the first procedure would be paid in full, but any subsequent procedure will be paid at a discount of 50 percent. CMS has identified 11 families of imaging procedures, based on the type of imaging modality used and contiguous body area that will be affected by the proposed policy.

## **XII. SUMMARY**

Outpatient departments and clinics are critical components of teaching hospitals. The 2006 Medicare outpatient proposed rule has a number of important changes that could have a significant impact on teaching hospitals' Medicare outpatient payments and decision-making.

If you have any questions regarding the proposed rule or this summary, or have concerns that you would like to discuss for possible inclusion in the Association's comment letter, please contact Karen Fisher at [kfisher@aamc.org](mailto:kfisher@aamc.org), or 202-862-6140 or Diana Mayes, at [dmayes@aamc.org](mailto:dmayes@aamc.org), 202-828-0498.