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AAMC Summary and Analysis

CALENDAR YEAR 2007 MEDICARE OUTPATIENT PPS PROPOSED RULE: PROVISIONS OF INTEREST TO AAMC MEMBERS

On August 23, 2006, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register [71 Fed. Reg. 49506], its calendar year 2007 proposed rule for the Medicare hospital outpatient prospective payment system (outpatient PPS or OPSS). See “*The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates ...*” The proposed rule can be obtained on the AAMC’s web site at:
<http://www.aamc.org/advocacy/teachhosp/outptpps/start.htm>

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, device-dependent APCs, payments for drugs and devices, and outlier payment policies. The proposed rule also would make changes to the evaluation and management codes that hospitals use to report clinic and emergency department visits and clinical care services.

In addition, the rule proposes a new outpatient quality reporting program that would use the current inpatient quality measures as a proxy for the outpatient setting. Due to the link between the inpatient and outpatient programs, CMS is also proposing that the payment updates between the two settings be linked as well. The AAMC has prepared a separate document that addresses quality related issues. To access this document go to:
<http://www.aamc.org/quality>

Comments on the proposed rule are due **October 10, 2006**.

In this rule, CMS is also proposing a major revision of the Ambulatory Surgical Centers (ASCs) payment system, which would begin January 1, 2008. Comments on the proposed revised ASC payment system are due **November 6, 2006**.

If you choose to submit comments by email, please use the following link:

<http://www.cms.hhs.gov/eRulemaking>

A number of outpatient data tables are available on the CMS web site at:
<http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1185569>

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 Healthcare Common Procedure 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. Currently, there is no teaching-related adjustment under the OPSS.

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 49539)

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 2007 inpatient PPS final rule. This increase is 3.4 percent.

The rule also proposes to base payment rate increases on the reporting of quality measures. Thus, hospitals that fulfill quality reporting requirements under the inpatient prospective payment system (IPPS) would receive a full market basket update on the outpatient payments, but those that do not do so would receive 2.0 percentage points less than the market basket update, resulting in a 1.4 percent increase.

Analysis – Actual average outpatient payments will increase by only an estimated 3.0 percent for all hospitals, despite the conversion factor being increased by 3.4 percent (see Impact Table at pages 49687 – 688). This is largely due to a change in the outlier calculation as well as the expiration of the section 508 wage adjustment. Major teaching hospitals will receive an increase of only 2.6 percent compared to a 3.2 percent increase for non-teaching hospitals and a 3.0 percent increase for other teaching hospitals. According to the discussion of the impact table, it appears that the smaller increase for major teaching hospitals is due to APC recalibrations resulting in a 0.3 percent average decrease in payments for major teaching hospitals compared to a 0.1 percent increase for non-teaching hospitals.

III. EVALUATION AND MANAGEMENT CODES (E/M) (pages 49604 – 618)

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. Payment is provided at three APC payment levels such that the two lowest levels of CPT codes (1 and 2) are assigned to the low-level visit APC, the middle CPT code (3) is assigned to the mid-level visit APC and the two highest levels of CPT codes (4 and 5) are assigned to the high-level visit APC.

Providers have been reporting two CPT codes for critical care services, one code for the first 30 to 74 minutes of critical care services and one for each additional 30 minute increments of critical care services.

From the beginning of the OPSS, CMS has been instructing hospitals to code these services using the same CPT codes as physicians. However, these codes are designed to reflect the activities of physicians and therefore do not adequately describe the range and mix of services provided by hospitals during these encounters. Consequently, 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.

In response to comments presented at the APC Panel meeting in January 2002, and 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 OPSS 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 November 1, 2002 final rule included a set of principles that CMS believes any national guidelines should satisfy. For example, the coding guidelines should be based on facility resources, should be clear, usable and meet the HIPAA requirements, should only require documentation that is clinically necessary for patient care and should not facilitate upcoding or gaming. In addition, CMS suggested that the distribution of codes should result in a normal curve.

In January 2003, the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) formed an independent expert panel comprised of members with coding, health information management, documentation, billing, nursing, finance, auditing, and medical experience. CMS and the American Medical Association (AMA) (the CPT coding standards developer) were invited to observe the panel's meetings. On June 24, 2003, the panel submitted their recommended guidelines for reporting three levels of hospital clinic and emergency visits and one level of critical care services to CMS.

The guidelines were based on an intervention model in which the levels of coding are determined by the numbers and types of interventions performed by nursing or ancillary hospital staff. As the number and/or complexity of staff interventions increase, so do the levels of services. In addition, the guidelines excluded all services separately payable under the OPPS from the list of interventions. The expert panel wanted to avoid duplicate payments for these services in case some hospital resources would be attributed to both visits and separately payable services.

After making some modifications to the independent expert panel's recommendations, CMS contracted a study to test the guidelines. According to the contractor, the panel's guidelines were not helpful in establishing 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. Furthermore, modified AHA/AHIMA guidelines did not demonstrate a normal distribution of visit levels.

Proposed rule

CMS believes that over the last few years since the implementation of the OPPS, it has made progress in the development of national guidelines. However, the Agency is not ready to propose and mandate national guidelines, but continues to search for a model that would provide a set of national guidelines the Agency can implement to provide hospitals with a consistent methodology to code for E/M services. Until the national guidelines are developed, CMS is proposing to allow hospitals to continue to use their own guidelines.

Although CMS did not adopt the AHA/AHIMA guidelines, the Agency believes that the model they provide is the most thought-out of any model CMS has come across and would like to use it as a starting point. Therefore, in the proposed rule CMS addresses eight areas of concern (see pages 49616 – 49618) with the AHA/AHIMA guidelines and seeks comments from interested stakeholders.

While CMS is not implementing national coding guidelines for E/M visits in this year's proposed rule, the Agency is proposing several important changes related to E/M visits for CY 2007.

Under the current system, CMS is not able to distinguish, for payment purposes, between hospital resource costs associated with services provided at traditional emergency departments (open 24 hours) and costs associated with so-called dedicated emergency departments (not open 24 hours).

The CPT definition manual defines “emergency departments” as hospital-based facilities that are open 24 hours a day and provides unscheduled episodic services to patients who present for immediate medical attention. According to CMS, an emergency department that satisfies the CPT definition, as well as other requirements (see page 49607), is referred to as a Type A emergency department. An emergency department that does not satisfy the CPT definition, but meets other emergency department requirements, is referred to as Type B emergency department (see page 49608).

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. However, CMS recognizes that Type B emergency department visit costs may be greater than the costs hospitals incur for clinic visits, since they are more likely to treat patients that are similar clinically and in terms of resource use to those treated in Type A emergency departments. Still, because they are not open 24 hours, CMS is unsure whether their costs rise to the level of the costs incurred by Type A emergency departments. In order to collect and analyze the hospital resource costs of visits to Type B emergency departments, CMS is proposing to implement a set of five new G-codes for use by Type B emergency facilities (Table 33 at page 49608).

The proposed rule would also replace the five current CPT codes used to report clinic visits and the five CPT codes used for Type A emergency department visits with 10 new G-codes. The rationale for this change is that current CPT E/M codes do not describe hospital visit resources and there are no other CPT codes that describe clinic and emergency department visits and critical care services. Thus, CMS would create three sets of G-codes (five for each category) to distinguish among the three types of visits: clinic visits, Type A emergency department visits and Type B emergency department visits.

For critical care services, CMS is proposing two new G-codes that would replace the two current CPT E/M critical care codes.

Rather than the current three levels of payment, CMS proposes that payment be made at five payment levels based on the assignment of the codes to five clinic visit APCs and five emergency department visit APCs. In other words, for each of the five clinic visit APC payment levels there is a corresponding G-code for clinic visits and a G-code for Type B emergency department visits. For each of the five emergency department visit APC payment levels, there is a corresponding G-code representing a Type A emergency department visit.

For critical care services, the proposed rule would assign one new G-code – used for reporting the first 30 to 74 minutes of care – to a new critical care APC, while the G-code that replaces the previously packaged CPT code would be packaged into the critical care APC.

Analysis – Of the eight areas of concern with the AHA/AHIMA guidelines, one area may be of particular interest to COTH members. According to CMS, interventions listed in the guidelines do not include many of the interventions performed in specialty clinics. To the extent that members have specialty clinics, the AAMC is interested in learning how the guidelines could best reflect the services provided in these clinics.

If members have dedicated emergency departments that are not open 24 hours, 7 days a week, the AAMC is interested to find out whether CMS’s policy to pay for those visits at the same level as clinic visits is reasonable. In addition, we would like to receive your insights with regard to CMS’s proposal to pay E/M visits at five instead of three APC payment levels, the main concern being that five levels may be too specific and thus make it difficult for hospitals to precisely determine the coding level. Finally, please let us know if you have any concerns or comments about CMS’s proposal to implement the new G codes.

IV. CHANGES TO OPPTS OUTLIER POLICIES (pages 49546 – 547)

Background

As with the inpatient PPS, the OPPTS makes additional payments for outpatient services that are extremely costly (“outliers”). In CY 2005, CMS targeted these payments to be two percent of total outpatient payments, financed by a corresponding reduction in the APC conversion factor.

In its March 2004 Report, MedPAC recommended that Congress eliminate the outlier policy under the OPPTS. Since this would require a statutory change, CMS instead reduced the outlier payment for CY 2006 by reducing the size of the percentage of total outlier payments from two percent of the aggregate total payments to one percent.

Outlier eligibility is determined at the individual OPPTS 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 \$1,250 fixed-dollar threshold. The outlier payment is equal to 50 percent of the difference between the cost of the service and 1.75 times the APC payment for the service.

Proposed Rule

For CY 2007, CMS is again proposing to allocate only one percent of aggregate total payments for outlier payments. CMS would also set aside 0.25 percent of total outlier payments to Community Mental Health Centers (CMHCs) for partial hospitalization outliers.

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, to meet the one percent threshold. Thus, for CY 2007, 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 \$1,825 fixed-dollar threshold. The payment percentage would remain the same – 50 percent.

Analysis – CMS believes that due to a discrepancy between its calculation of the overall cost-to-charge ratio (CCR) and the calculation used by fiscal intermediaries (see VII below), CMS has been underestimating the outlier payment threshold and therefore has been overpaying outlier payments. However, the proposed rule contains no analyses that would indicate the amount of overpayment and/or support the magnitude of the increase in the fixed dollar threshold.

Furthermore, according to CMS, the change in the outlier threshold coupled with the change to the overall CCR that is used to estimate outlier payments (see below), are responsible for 0.25 percent of the decrease in average OPSS payments to hospitals (see discussion on page 49685). The AAMC is concerned about the impact of the CCR change, because 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 Thus, the CCR impact will likely affect major teaching hospitals' average payments. The AAMC will be examining the CCR issue and would be interested in receiving insights from COH members.

V. TRANSITIONAL PASS-THROUGH PAYMENTS (pages 49578 – 582, 49595 – 596)

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 two to three-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

¹ See 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.

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 New Devices (pages 49578 – 580)

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.

Starting in CY 2002, CMS has been deducting from the pass-through payments for the device an amount (called the offset amount) equal to the portion of the APC payment amount associated with the device that the new device is replacing.

The proposed rule would continue pass-through status for category C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system) for CY 2007, but end it in CY 2008, thereby providing a two-year pass-through status for this category. For CY 2007, CMS proposes to set the payment rate for C1820 based on CY 2005 hospital claims data when device C-code reporting was reinstated. The offset amount is 78.1 percent of the proposed payment rate for APC 0222.

B. Pass-through Payments for New Drugs, Biologicals and Radiopharmaceutical Agents (pages 49580 – 582)

CMS is proposing to continue pass-through status for nine drugs and biologicals, which received pass-through status as of April 1, 2006 (Table 24 at page 49582).

The MMA mandated that payment for drugs and biologicals be based on the competitive acquisition program methodology. The competitive acquisition program was implemented as of July 1, 2006. Only two – HCPCS codes J2503 and J9264 – of the nine drugs with pass-through status will be covered under the competitive acquisition program in CY 2007. For the other seven drugs and biologicals with pass-through status, CMS is proposing to base their payment rates at a rate that is equivalent to the payment that is being made in the physician office setting, currently set at average sales price (ASP) plus six percent.

C. Pass-through Pool (pages 49595 – 596)

Pursuant to current law, CMS is authorized to spend up to two percent of total OPPS payments for pass-through payments. CMS estimates however, that in CY 2007, only 0.13 percent of total OPPS payments will be needed for pass-through payments. This figure includes CMS's estimates for the only device category eligible for pass-through payments in CY 2007 and projections for any device categories that may become eligible for pass-through payments in CY 2006 and CY 2007. No additional pass-through payments for drugs and biologicals will be necessary.² Accordingly, the OPPS conversion factor will be reduced by only 0.13 percent.

Analysis – In contrast to the early years of OPPS, CMS seems to believe that the need for a pass-through pool is diminishing. This is due in large part to CMS's policy regarding drug payment, as well as its decision to approve only new device categories rather than individual devices. It will be important to monitor this issue to ensure that all new drugs and biologicals as well as new devices are appropriately reimbursed.

VI. OPPS PAYMENTS FOR CURRENT DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS (pages 49582 – 595)

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 payment to hospitals. The MMA provided that a threshold of \$50 be 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 exceeds \$50 per day are paid separately. However, the \$50 threshold requirement expires at the end of CY 2006.

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.

The MMA provided that for CY 2006 and subsequent years, 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. Based on its

² Under the payment methodology for pass-through drugs and biologicals, the payment pool for new drugs and biologicals is determined by the difference between the applicable fee schedule amount or the APC payment rate associated with the drug or biological and the payment for pass-through drugs and biologicals. Since the payment for drugs and biologicals for CY 2007 is set at a rate equal to the payment they would receive in the physician's office setting, and the APC payment rate for pass-through drugs and biologicals equals the payment they would receive in the physician's office setting, the difference is zero (page 49581). Thus the estimate of pass-through spending for drugs and biologicals for CY 2007 is zero.

analyses, CMS determined that the average acquisition costs for drugs and biologicals would best be represented by the average sales price. Thus, for CY 2006, certain separately payable drugs and biologicals are reimbursed at ASP plus six percent, the same amount as paid in the physician office setting. For drugs and biologicals for which CMS does not have ASP data, the Agency uses the mean costs from the CY 2004 hospital claims data as their payment rates. For radiopharmaceuticals, CMS does not have ASP data, so the Agency is using CY 2004 hospital claims data and hospital cost reports to set payment rates based on the hospital's charge for each radiopharmaceutical reduced to cost.

Proposed rule

CMS proposes to use manufacturer-submitted ASP data from the fourth quarter of CY 2005, the most current ASP data available, as well as mean costs derived from the CY 2005 hospital claims data, to set payment rates for drugs and biologicals.

Because the \$50 packaging threshold expires at the end of CY 2006, for CY 2007 and subsequent years, CMS proposes to update the threshold for inflation using an inflation adjustment factor based on the Producer Price Index (PPI) for prescription preparations. The adjusted dollar amount would be rounded to the nearest \$5 increment. Thus, for CY 2007, the proposed packaging threshold would equal \$55. Items whose cost per day is less than \$55 would be packaged with the procedures with which they are billed and those whose cost exceeds \$55 would be paid separately.

A. *Drugs and Biologicals* (pages 49582 – 586)

CMS proposes to use the same methodology used in CY 2006 to set payment rates for separately payable drugs and biologicals for CY 2007. CY 2005 claims data indicate that mean costs are equal to ASP plus five percent. Therefore CMS proposes ASP plus five percent to cover the acquisition and handling costs for drugs and biologicals.

For drugs and biologicals for which ASP data are not available, CMS is proposing to use their mean costs from the CY 2005 hospital claims data as their payment rate.

B. *Radiopharmaceuticals* (pages 49586 – 594)

In spite of CMS's continuous effort to find a proxy for the average acquisition costs for radiopharmaceuticals, the Agency states that it has not received suggestions that are specific enough or workable. Thus, CMS considered three options for setting payment rates for separately payable radiopharmaceuticals in CY 2007. Under the first option, CMS would raise the packaging threshold to an amount higher than \$55, thereby packaging a larger number of radiopharmaceuticals. The Agency is concerned however, that bundling more radiopharmaceuticals, particularly those that are relatively expensive and high volume could potentially lead to payments that are less than their costs. The second option would continue the CY 2006 methodology of paying for separately payable radiopharmaceuticals at charges reduced to costs, using the hospital's overall

CCR. CMS however, does not propose this option, because the Agency believes that paying at cost provides a disincentive for hospitals to provide radiopharmaceuticals in the most efficient manner. Furthermore, CMS states that using a hospital's overall CCR can result in an overstatement of radiopharmaceutical costs because they are likely reported in several cost centers that have lower CCRs than the hospital's overall CCR. Thus, CMS proposes another option. Under the third option, CMS would use mean costs derived from the CY 2005 claims data to establish prospective payment rates for separately payable radiopharmaceuticals. Costs would be determined by applying hospital-specific departmental CCRs to radiopharmaceutical charges. If departmental CCRs are not available, CMS would use hospital-specific overall CCRs. Because CMS believes that the third option would provide the most consistent, accurate and efficient methodology, CMS is proposing to implement it. CMS also believes this approach could become a long-term radiopharmaceutical payment policy.

Analysis – CMS is soliciting comments with regard to the options it considered for paying for separately payable radiopharmaceuticals.

VII. OTHER PROPOSED CHANGES THAT AFFECT OPPTS PAYMENTS FOR CY 2007 (pages 49514 – 548)

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 the mid-level clinic visit. CMS is required to review the APC weights at least annually.

The proposed 2007 APC rates are based on claims data from CY 2005 and hospital-specific department level and overall CCRs. CMS used 91.4 million outpatient claims, including 62.8 million multiple procedure claims that CMS converted to "pseudo" single claims, to set the proposed APC payment weights.

Revision of the Overall Cost-to-Charge Ratio (CCR) Calculation (pages 49528 – 529)

The proposed rule would change the methodology for calculating the overall CCR. The overall CCR is used to convert procedure charges from claims data to costs. The overall CCR affects many aspects of the OPPTS, including the outlier payments.

CMS has determined that the calculation of the overall CCR that the fiscal intermediaries are using to determine outlier payments and payments for those services that are paid on a cost basis differs from the calculation of the overall CCR that CMS is using. According to CMS's analyses, the fiscal intermediaries' overall cost calculation is higher on average than CMS's calculation and, as a result, CMS has been underestimating the outlier payment thresholds and overpaying outlier payments. CMS also states that spending for services paid at charges reduced to costs has also been underestimated in budget neutrality estimates. Thus, the Agency is proposing to revise the CCR calculation that

would be used by both CMS and fiscal intermediaries effective January 1, 2007. (For a more complete discussion please read pages 49528 – 529 in the 71 Federal Register)

Analysis – CMS did not include analyses that would indicate the impact of the CCR calculation on both outlier payments and budget neutrality estimates. The AAMC urges COTH members to read the CCR discussion and provide us with input on whether CMS’s proposal is a reasonable solution to address the discrepancy between CMS’s CCR calculation and the fiscal intermediaries’ calculation.

VIII. NEW TECHNOLOGY APCs (pages 49551 – 556)

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. As an alternative 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 two years or retain it in a New Technology APC for more than three 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 two years and not more than three.

Unlike other APCs, new technology APCs are defined based on “cost bands” rather than clinical descriptors. Currently, there are technology APCs in 10, 50, 100 and 500 increments, ranging from: \$0 to \$10 to \$9,500 to \$10,000. The APC payment rate is the median of the cost band (i.e. \$5 for the \$0 to \$10 cost band).

Proposed Rule

As a result of its evaluations of CY 2005 data, CMS is proposing to move certain procedures from New Technology APCs to Clinical APCs. Thus, codes for PET scans (CPT Codes 78608, 78811, 78812, and 78813) as well as CPT codes for PET/CT scans (CPT codes 78814, 78815, and 78816), would be assigned to new clinical APC 0308 (Nonmyocardial PET Imaging) with a median cost of \$865.30 for CY 2007. The proposed rule would also move HCPCS codes G0173, G0251, G0339, G0340 used to report stereotactic radiosurgery services to clinically appropriate APCs (see Table 8 at page 49554). CPT codes 95965, 95966 and 95967 describing magnetoencephalography services would be assigned to clinical APCs (Table 9 at page 49556).

In addition, 23 procedures listed on Table 10 (71 Fed. Reg. at 49556) would be moved to new or established clinical APCs that contain services exhibiting clinical and resource homogeneity.

Analysis – The movement from New Technology APCs to Clinical APCs would result in payment reductions for many of the procedures currently in New Technology APCs. For

example in CY 2006, HCPCS code G0173, used to report stereotactic radiosurgery services, receives a \$5,250 payment based on the New Technology APC 1528. In CY 2007, this code will be assigned to clinical APC 0067 and will receive a \$4,059.61 payment. The AAMC would like to get your insights as to whether CMS's proposal is reasonable.

IX. DEVICE-DEPENDENT APCs (pages 49568 – 578)

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 have been including a device code on a claim, even when a device was used. Thus, it was 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

For CY 2007, CMS proposes to set payment rates for device-dependent APCs based on median costs from CY 2005 claims, since device coding became mandatory. The Agency would only use claims that contain appropriate device codes and which have no token charges (charges less than \$1.01).

In recent years, some devices have been recalled and the manufacturers have offered replacement devices at no cost to the hospital or a credit for the device being replaced if the patient received a more expensive device. To identify devices for which the hospital incurs no expense and to set payment rates for device-dependent APCs that contain devices that have been recalled, CMS authorized hospitals to charge less than \$1.01 for these items.

The rule proposes that both APC payment and beneficiary copayment be reduced for selected APCs for which a defective implanted device is replaced at no cost to the hospital. To reflect these changes, CMS would revise the existing regulations, by adding new §419.45, Payment and Copayment Reduction for Replaced Devices.

The APCs that are subject to the adjustment can be found in Table 21 at 49577. However, the adjustment is applied only when the purpose of the procedure is to replace a device that is reported by a HCPCS code in Table 22 – a device for which the hospital incurred no cost. CMS chose the APCs in Table 21 based on three criteria:

- a) all procedures assigned to the selected APCs require implantable devices that would be reported if device replacement procedures were performed;
- b) the device that was surgically inserted or implanted remains in the patient's body at least temporarily after the procedures has been completed;
- c) the offset percent for the APC be significant – exceeds 40 percent of the cost of the APC.

In order to ensure that an adjustment is triggered only for those procedures for which a device is replaced at no cost to the hospital, CMS proposes to require hospitals to report a modifier specific to the device replacement along with the procedure associated with the device. The requirement for a modifier applies only to the procedures assigned to one of the APCs in Table 21 and only if the device is one of the devices included in Table 22.

The amount of the reduction to the APC payment rate would be calculated in the same manner as the offset amount that would be applied if the implanted device assigned to the APC had pass-through status as defined under §419.66. Specifically the offset amount would be determined by first calculating an APC median cost that includes the device cost and an APC median cost that excludes the device cost. Then, the percent of cost attributable to the device for which the hospital incurs no cost is calculated by subtracting from 100 the percentage obtained by dividing the median cost without the device by the median cost with the device. To determine the offset amount, CMS applies this percent to the payment rate of the APC. The proposed offset percent is listed in Table 21.

CMS removed APC 0080 (Diagnostic Cardiac Catherization) from the device-dependent APCs, because the codes assigned to this APC do not always require a device for which there is an appropriate HCPCS code. In addition, the Agency decided to remove the requirement for a device code for procedures assigned to a device-dependent APC that did not require the use of a device or where there were no HCPCS codes that describe all the devices that could be used in the procedure.

Because CMS has come across claims where hospitals billed a device code without billing a procedure code associated with the device, the Agency proposes to implement device-to-procedure code edits for those devices and the procedures associated with them. A list of these devices can be found in Table 20 at page 49573. CMS has provided a separate venue for comments related to this issue. Thus, hospitals wishing to submit comments that would help CMS to establish appropriate edits, should use the following email address: OutpatientPPS@cms.hhs.gov.

Analysis – The AAMC would like to receive input from members as to whether there is a sufficient number of defective devices that would justify this policy change. Moreover, would this proposal be an administrative burden? Would it be difficult to reduce the beneficiary copayment?

X. INPATIENT-ONLY PROCEDURES (page 49621)

Background

Under the OPPS, there are certain procedures that are deemed “inpatient-only” for which hospitals will not receive an OPPS 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 10, 2005 OPPS Final Rule.

Proposed Rule

Under the proposed rule, eight procedures would be taken off the “inpatient-only” list and paid under the OPPS in 2007. 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 40 (71 Fed. Reg. at 49621). 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 40, 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, should be payable under the OPPS.

XI. PROPOSED CHANGES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM (49635 – 659 and 49689 – 695)

Background

A. The Current ASC list

In 1980, Congress authorized payment to ASCs for facility services furnished in connection with certain surgical procedures under the Medicare Supplementary Medical Insurance Program (Part B). The statute requires CMS to specify surgical procedures that are appropriately and safely performed in an ASC and to update this list of procedures every two years.

CMS uses the American Medical Association’s (AMA) definition of surgery for purposes of the ASC payment. Under this definition a surgical procedure is any procedure described by a range of CPT codes (10000-69999). In the August 5, 1982 final rule, CMS established regulations (Section §416.65(a)) that set forth the following criteria for inclusion of surgical procedures on the ASC list:

- the surgical procedure is commonly performed on an inpatient basis but may be safely performed in an ASC;
- is not commonly performed or safely performed in physicians' offices;
- requires a post-operative recovery room that does not necessitate an overnight stay; and
- is not excluded from Medicare coverage.

Currently, only procedures that do not generally exceed 90 minutes operating time and a total of four hours recovery or convalescent time are included on the ASC list. In addition, for a procedure to be included on the ASC list, if anesthesia is used, it must either be local or regional or last no more than 90 minutes if it's general anesthesia (§416.65(b)). The regulations exclude procedures that result in extensive blood loss, that require major or prolonged invasion of body cavities, that directly involve major blood vessels, or that are generally emergency or life-threatening in nature (§416.65(b)(3)). Currently there are 2,500 procedures on the ASC list, but only 150 codes account for more than 90 percent of the volume in ASCs (page 49635).

B. The Current ASC Payment System

Under the current system, the ASC payment rate is a standard amount that reflects estimated ASC costs incurred in the process of providing facility services related to a procedure. Using data from a 1986 survey of ASC costs, CMS established nine ASC payment groups ranging from \$333 to \$1,339. The payment groups are heterogeneous in terms of clinical characteristics. CMS last rebased the standard amounts in 1990, using data collected in the 1986 survey. Other than adding some procedures to the ASC list in 1998, the Agency has not made any updates to the methodology or data used to set ASC payment rates since 1986.

Payment for an ASC takes into account geographic wage variations by applying the hospitals IPPS wage index value of the county in which the ASC is located to the labor portion (34.45 percent) of the standard amount.

The MMA requires that payment updates be based on the Consumer Price Index for all urban consumers (CPI-U). The MMA also mandates zero updates through CY 2009.

Proposed Rule

CY 2007 Proposed changes

CMS is proposing to add 14 surgical procedures (see Table 41 at 49629) to the ASC list for CY 2007, based on current criteria (71 Fed. Reg. at 49628). The procedures would be added to one of the nine existing payment groups.

Payment rates for ASCs would change due to the implementation of section 5103 of the Deficit Reduction Act of 2005 (DRA). Provisions in the DRA require that the payment amount for a procedure in an ASC (without application of the geographic adjustment) not

exceed the Medicare OPPS payment amount (without application of the geographic adjustment).

Analysis – CMS estimates that approximately 25 percent of the annual hospital outpatient volume for the 14 procedures proposed for inclusion on the CY 2007 list would migrate to the ASC setting (page 49689). However, CMS states that this should not have a significant impact on hospital revenues, because hospitals have a high volume of ambulatory surgeries.

CY 2008 Proposed Changes

The MMA mandates that CMS revise the ASC payment system by January 1, 2008. The statute requires that the revised system be budget neutral to result in the same aggregate amount of expenditures for surgical services furnished in ASCs in 2008 as would be made if the new system did not apply.

A. Proposed Changes to the ASC list

Citing MedPAC’s March 2004 Report to the Congress, CMS is proposing to replace the current “inclusive” list of procedures, which are the only procedures performed in an ASC that may receive payments from Medicare, with an “exclusionary” list. This change would add approximately 750 procedures that are not currently part of the ASC list.

Thus, CMS is proposing to include on the ASC list all procedures within the surgical range of CPT codes (see above) that do not pose a safety risk to Medicare beneficiaries or require an overnight stay. CMS further defines these two requirements in the following manner.

Procedures that do not pose a significant safety risk must meet the following criteria:

- a) are not included on the OPPS inpatient-only list (Addendum E at page 49952)
- b) are not performed more than 80 percent or more of the time in the hospital inpatient setting (even if they are not on the OPPS inpatient list) (see Table 44 at page 49640); or
- c) do not generally result in extensive blood loss, that require major or prolonged invasion of body cavities, that directly involve major blood vessels, or that are generally emergency or life-threatening in nature (according to CMS, many of the procedures listed in Table 45 at page 49643 satisfy this criterion).

Procedures that do not require an overnight stay refer to procedures for which active medical monitoring at midnight following the procedure would be expected, as determined by prevailing medical practice (Table 45 at page 49643).

In addition, because procedures that are commonly and safely performed in physicians' settings satisfy both criteria, CMS is proposing to no longer exclude these procedures from the ASC list. However, because payments for procedures performed in ASCs are often higher than payments for services performed in physicians' settings, CMS is concerned that including these procedures on the ASC list may lead to a migration of services that are currently performed in physicians' offices to ASCs.³ Thus, the Agency is proposing for CY 2008, to limit payment for services performed in physicians' offices to the lesser of the Medicare Physician Fee Schedule (MPFS) non-facility practice expense payment or the ASC rate.

B. Proposed Revised ASC Payment Methodology

CMS is proposing to adopt APC groups and the relative weights for surgical procedures in the OPSS as the basis for payment groups and relative weights for surgical procedures performed at ASCs. In order to comply with budget neutrality requirements, CMS would apply a budget neutrality adjustment of 62 percent of the OPSS conversion factor to obtain the APC base conversion factor.

The rule would also continue to take into account geographic wage variations by applying the hospitals' IPSS wage index value for the county in which the ASC is located to the labor portion – currently 34.45 percent – of the ASC conversion factor.

To ensure a smooth transition to the new ASC payment system and prevent any negative impacts on both providers and beneficiaries, CMS is proposing a two-year transition to the new system. Thus, for CY 2008, CMS would use transitional payments based on a blended amount equal to 50 percent of the applicable CY 2007 payment rate and 50 percent of the applicable CY 2008 payment rate. Full payment under the new methodology would be applied thereafter.

Analysis – CMS is estimating that 25 percent of hospitals' outpatient department utilization for new ASC procedures would migrate to ASCs and 15 percent of the physicians' office utilization for new ASC procedures would migrate to the ASCs (see page 49657).

CMS is asking stakeholders to weigh in on the proposal to include procedures that are currently primarily office-based or that require relatively inexpensive resources on the ASC list.

The AAMC would like to solicit members' views about the proposed revisions to the ASC payment system. In addition, we seek input on CMS's decision regarding what to "exclude" from the ASC list, specifically, which procedures pose a significant safety risk or involve an overnight stay.

³ Of the 750 procedures that CMS proposes to include on the ASC list, approximately 2/3 are currently office-based procedures.

XII. MISCELLANEOUS OPPTS ISSUES

A. Wage Index (pages 49539 – 541)

Since the inception of the OPPTS, CMS has been using the final inpatient prospective payment system (IPPS) wage indices as the wage indices for adjusting the OPPTS standard payment amounts for labor market differences. Although the FY 2007 IPPS final rule has been published, the final wage indices have not. This is due to the fact that CMS had a very short time frame to collect and calculate new occupational mix adjustment factors used in the calculating the wage index (for an in-depth discussion of the proposed changes to the Medicare wage index calculation please see the inpatient prospective payment system final rule discussion (71 Fed. Reg. at 48005)). As a result of a court mandate (*Bellevue Hosp. Ctr v. Leavitt*, April 3, 2006) that requires hospitals to apply the occupational mix adjustment to 100 percent of the wage index beginning in FY 2007 with new survey data, CMS would publish the FY 2007 occupational mix adjusted wage index tables on the CMS web site before October 1, 2006.

B. Payment for Observation Services (pages 49620 – 621)

The proposed rule would apply the same criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in CY 2006 with one exception. As a result of CMS's proposed changes to E/M coding (see II above), low level clinic visits would move from APC 0600 to APC 0604, with a CY 2007 median cost of \$49.93. In cases in which direct admission to observation is separately payable, CMS is proposing to assign HCPCS code G0379 to APC 0604.

C. Performing an "Inpatient Only" procedure on an Emergency Basis (page 49622)

Under current regulations, a hospital must use a modifier when it submits a claim, indicating that a procedure on the OPPTS 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 APC 0375. For CY 2007, the Agency is proposing to increase payment to this APC from a median cost of \$2,527 to a median cost of \$3,539.

XIII. SUMMARY

Outpatient departments and clinics are critical components of teaching hospitals. The 2007 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 Diana Mayes, at dmayes@aamc.org, 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140.