

September 11, 2006

## Medicare Outpatient PPS and ASC Payment System: The Proposed Rule for 2007

### AT A GLANCE

#### **The Issue:**

On August 9, the Centers for Medicare & Medicaid Services (CMS) released the outpatient prospective payment system (PPS) proposed rule for calendar year 2007. The major proposals in the rule include:

- Linking a hospital's receipt of a full outpatient market basket update to the reporting of inpatient quality measures;
- A new coding system for hospital outpatient clinic and emergency department (ED) visits;
- A major revision of ambulatory surgical centers (ASCs) payment methodology for 2008; and,
- Expanding *inpatient* hospital quality reporting requirements for fiscal year (FY) 2008.

The proposed rule was published in the August 23 *Federal Register*, and comments on the outpatient PPS proposals are due to CMS by October 10. A final outpatient rule will be published this fall and will take effect January 1, 2007. The deadline for submitting comments on the revised ASC payment methodology is November 6, with a final rule implementing changes for 2008 released in spring 2007.

#### **Our Take:**

We are analyzing the proposed changes to the outpatient PPS, inpatient PPS quality measures and ASC payment system very closely. Any linkage of the outpatient PPS payment update to the reporting of quality measures should use measures of outpatient/ambulatory care. Linking inpatient quality measures to the outpatient PPS update is inappropriate. However, we are pleased that CMS has posted for public comment national guidelines for coding clinic and ED visits, and we will thoroughly review these guidelines as well as the new codes CMS has proposed. Finally, we also are reviewing carefully the proposed changes to ASC payment policy. We are concerned that weakening the standards that determine which services may be performed in an ASC could jeopardize patient safety and quality of care.

#### **What You Can Do:**

- ✓ Share this advisory with your senior management team, chief financial officer, billing and coding staff, nurse managers and key physician leaders.
- ✓ Model the impact of the final APC changes on your expected 2007 Medicare revenue. A spreadsheet comparing the changes in APC payment rates and weights from 2001-2007 is available on the AHA's Outpatient PPS Web page at: <http://www.aha.org/aha/issues/Medicare/OPPS/resources.html>. Please note that you must first log on as a member to view the spreadsheet.
- ✓ Given the major changes included in the proposed rule, the AHA encourages members to submit their own comments to CMS outlining how the changes will affect your facility.
- ✓ Look for an upcoming AHA advisory on expanded FY 2008 inpatient hospital quality reporting requirements.

We will provide additional information to members on this proposed rule and recommended areas for policy changes.

#### **Further Questions:**

Please contact Roslyne Schulman, AHA senior associate director for policy, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

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## **BACKGROUND**

On August 9, the Centers for Medicare & Medicaid Services (CMS) released the outpatient prospective payment system (PPS) proposed rule for 2007. The proposed rule is available at <http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/CMS1506P.pdf> and was published in the August 23 *Federal Register*.

The proposed rule includes payment policy and rate-setting proposals that apply to the outpatient PPS, it also includes proposals that are not directly related to the outpatient PPS. The rule's major provisions would:

- Link a hospital's receipt of a full outpatient market basket update to the reporting of inpatient quality measures.
- Implement a new coding system and payment policies for hospital outpatient clinic and emergency department (ED) visits.
- Revise the ambulatory surgical center (ASC) payment methodology for 2008 and an expansion in the number and type of procedures that may be provided in ASCs.
- Revise the critical access hospital (CAH) conditions of participation to allow registered nurses to conduct an Emergency Medical Treatment and Labor Act (EMTALA) medical screening examination.
- Adopt conforming and substantive changes related to the Medicare Administrative Contractors (MACs). Of particular interest, CMS would continue to allow certain national hospital chains to bill through a single MAC.
- Expand *inpatient* hospital quality reporting requirements for fiscal year (FY) 2008. (The AHA will issue a separate advisory on the expanded inpatient quality reporting requirements.)

Comments are due to CMS by October 10 on the proposals related to the outpatient PPS, the application of quality standards to the outpatient PPS update, ASC payment system in 2007, CAH conditions of participation, and MACs. A final outpatient PPS rule will be published this fall, and will take effect January 1, 2007. November 9 is the deadline for submitting comments on the revised ASC payment system to be implemented January 1, 2008. The final ASC rule implementing changes for 2008 will be released in spring 2007.

## **AT ISSUE**

### **PROPOSED CHANGES TO THE OUTPATIENT PPS FOR 2007**

#### **PPS UPDATE AND LINKAGE TO QUALITY DATA REPORTING**

To arrive at the proposed 2007 outpatient PPS conversion factor of \$61.551, CMS increased the 2006 conversion factor of \$59.511 by the rate of change in

the hospital market basket index, estimated at 3.4 percent, as required by law. In addition, CMS made adjustments to ensure budget neutrality related to changes in the wage index, pass-through spending and other policy changes in order to arrive at the proposed 2007 conversion factor.

In the rule, CMS expresses concern about the rapid growth in hospital outpatient care expenditures, which the agency projects to reach 10 percent in 2006. *(However, CMS' analysis does not attempt to account for the impact of medical advances that have enabled some services that were previously performed as inpatient services now to be performed in outpatient departments.)*

In response to the growth in outpatient expenditures, CMS is moving forward with its efforts to develop "value based purchasing." As part of that effort, the agency proposes to use its "equitable payment" authority to create an outpatient PPS quality reporting program, as of January 1, 2007. This authority allows the agency to make adjustments in a budget neutral manner that will "ensure equitable payment." For 2007, CMS proposes to link the outpatient PPS payment update to hospital reporting of inpatient quality measures in effect under the inpatient PPS quality reporting program. Any reduction in the outpatient PPS update factor resulting from the application of this new requirement would be offset by an adjustment to the conversion factor to ensure that aggregate 2007 outpatient PPS payments would be unchanged.

**Therefore, hospitals would only receive the full outpatient market basket update if they meet the inpatient reporting requirements for a full update in FY 2007. Hospitals that do not meet these inpatient reporting requirements would receive an update reduced by 2.0 percentage points – that is, a 1.4 percent update instead of the full 3.4 percent.** A reduction applied in one year would not affect a hospital's outpatient update in a subsequent year. Hospitals that are not required to participate in the inpatient quality reporting program would receive the full 2007 outpatient update.

CMS argues that the 21 inpatient quality measures reflect the quality of care provided by hospital outpatient departments. CMS also signals its intention to adopt the full set of proposed FY 2008 inpatient quality measures in the 2008 outpatient quality reporting program. The agency intends to include the reporting of outpatient-specific quality measures for purposes of determining the PPS update as early as 2009. CMS states that the future outpatient quality reporting program would apply to all hospitals, including those that are currently excluded from the inpatient quality reporting system.

**The AHA opposes linking inpatient quality measures to the outpatient PPS update. It is an inappropriate policy. Any link between quality improvement and payment for *outpatient* services should be based on *outpatient* quality measures.** The AHA does support linking outpatient quality measures to outpatient services. In fact, as a member of AQA (formerly known

as the Ambulatory Quality Alliance), the AHA is helping to develop and test quality measures for the outpatient setting. Further, the AQA and the Hospital Quality Alliance – of which the AHA also is a founder – are examining how to measure quality across an episode of care.

### **RECALIBRATION OF APC WEIGHTS**

The law requires that CMS review and revise at least annually the relative payment weights for ambulatory payment classifications (APCs). To recalibrate the relative APC weights for this proposed rule, CMS used hospital claims for services furnished during 2005. In addition, CMS has historically used APC 0601, a mid-level clinic visit, to calculate relative weights. But for 2007, CMS proposes to replace current codes with new clinic codes (described below under “Coding and Payment for Hospital and ED Visit Services”). Because of this change, CMS proposes to use APC 0606 (level III clinic visit) as the basis for calculating relative weights for 2007 rather than APC 0601 (which will no longer exist). After assigning APC 0606 a relative payment weight of 1.00, CMS determined the unscaled – not adjusted for budget neutrality – relative payment weight for each APC by dividing the median cost of the APC by the median cost for APC 0606.

The APC recalibration changes also must be budget neutral. To comply, CMS compared aggregate payments using the 2006 relative weights to aggregate payments using the proposed 2007 weights. Based on the lower expected payments in this comparison, the proposed rule *increases* the APC weights by a factor of about 1.35 (an increase of 35.4 percent), which is a much larger adjustment than in prior years. This is because the median cost of APC 0606, \$83.67, is much higher than the median cost of APC 0601, \$60.57. With a larger value, the unscaled relative weights are considerably lower and must be increased significantly by the budget neutrality adjustment.

CMS’ changes to the APC weights for 2007 continue to show significant volatility. For 59 APCs, the 2007 weights would decrease by 10 percent or more; for 27 of these, the reduction is greater than 20 percent. In total, weights would be lower for 277 APCs. Conversely, weights would increase for 360 APCs, going up 10 percent or more for 109 of them. For 26 APCs, the rate will rise by at least 30 percent.

### **REVISED COST-TO-CHARGE RATIO METHODOLOGY**

The proposed rule includes a significant change in the way the overall hospital-specific cost-to-charge ratio (CCR) is calculated. CMS uses the overall hospital CCR to set outlier thresholds and to estimate outlier and pass-through payments and in other services paid based on charges reduced to costs. The fiscal intermediaries (FIs) use overall CCRs to determine outlier payments and payments for certain other services. CMS recently discovered that it calculates the overall hospital CCR differently than the FIs. Compared with the CMS “traditional” overall CCR calculation, the FIs’ method includes allied health

education costs and adds weighting by Medicare Part B charges. In comparing these two calculations, CMS determined that, on average, the FIs' calculation resulted in higher overall CCRs (0.3309 compared to CMS' 0.3040), which the agency said resulted in higher than necessary spending in outliers, among other implications.

In the proposed rule, CMS uses features of both methods by excluding allied health education costs and adopting weighting by Medicare Part B charges. Some hospitals will experience significant changes in their hospital-specific overall CCR calculations due to this change.

### **WAGE INDEX FOR 2006**

For the outpatient proposed rule, CMS applies the FY 2007 inpatient PPS wage index as published as part of the inpatient PPS proposed rule in the April 25 *Federal Register*. This includes the wage indices proposed to be in effect through March 31, 2007 as well as those proposed to be in effect on or after April 1, 2007, to accommodate the expiring reclassification provisions under section 508 of the *Medicare Modernization Act* (MMA). CMS proposes to continue the previously established outpatient PPS policies concerning phase-in of urban-to-rural changes due to the Core-Based Statistical Areas, adoption of Medicare Geographic Classification Review Board decisions, and allowing non-inpatient PPS hospitals to apply for the out-migration wage index adjustment.

For the final outpatient rule, CMS proposes to use the revised FY 2007 inpatient PPS wage indices that will be fully adjusted for differences in occupational mix using the new survey data available in the near future. In all cases, CMS will use the final FY 2007 inpatient PPS wage indices – which include the wage indices to be in effect through March 31, 2007 and those to be in effect on or after April 1, 2007, with any subsequent corrections – for calculating outpatient PPS payment in 2007

As in prior years, the percentage of the APC payment to be adjusted by the wage index will continue to be 60 percent.

### **OUTLIER PAYMENTS**

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to set the projected target for outlier payments at 1 percent of total outpatient PPS payments – the same as 2006. CMS again is proposing to establish separate thresholds for community mental health centers (CMHCs) and hospitals. Therefore, 0.25 percent of the 1 percent projected target would be allocated to CMHCs for partial hospitalization program services.

The proposed rule continues to include both a fixed-dollar outlier threshold and a percentage threshold, but **CMS proposes to raise the fixed-dollar threshold to \$1,875 – \$625 more than in 2006 – to ensure that outlier spending does not**

**exceed the reduced outlier target.** This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology.

Thus, to be eligible for an outlier payment in 2007, the cost of a service must exceed 1.75 times the APC payment amount (the percentage threshold), *and* it must be at least \$1,875 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare will make an outlier payment that is 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate. A sample equation is on page 49547 of the proposed rule.

### **TRANSITIONAL CORRIDOR “HOLD HARMLESS” PAYMENTS**

As required by the *Deficit Reduction Act* (DRA), the proposed rule continues to phase out the transitional corridor “hold harmless” payments for rural hospitals with 100 or fewer beds that are not Sole Community Hospitals (SCHs). For 2007, CMS proposes that when the outpatient PPS payment is less than the payment that the provider would have received under the previous reasonable cost-based system, the payment amount is increased by 90 percent of the difference between those two payment systems. This represents 5 percent less in “hold harmless” payments than these hospitals received in 2006. CMS also clarifies in the proposed rule that Essential Access Community Hospitals (EACHs) are considered to be SCHs under the law and therefore are ineligible for “hold harmless” payments. Cancer and children’s hospitals receive the “hold harmless” payments on a permanent basis.

### **RURAL ADJUSTMENT FOR SOLE COMMUNITY HOSPITALS**

Consistent with current policy, CMS proposes to continue to increase payments to rural SCHs by 7.1 percent for all services paid under the outpatient PPS, with the exception of drugs, biologicals, brachytherapy seeds and services paid under the pass-through policy. The proposed rule also clarifies that EACHs are treated as SCHs for purposes of receiving the 7.1 percent adjustment, assuming these entities otherwise meet the rural adjustment criteria. The adjustment is budget-neutral and is applied before calculating outliers and coinsurance.

### **TRANSITIONAL PASS-THROUGH PAYMENTS**

In 1999, Congress created temporary additional or “transitional pass-through payments” for certain innovative medical devices, drugs and biologicals to ensure that Medicare beneficiaries had access to new technologies in outpatient care.

For 2007, CMS is projecting that pass-through payments will be 0.13 percent of total outpatient PPS payments, or \$43.2 million. Changes to the transitional pass-through pool must be budget-neutral, and, therefore, CMS proposes to return 0.04 percent – the difference between the estimated 0.17 percent pass-through payments in 2006 and the 0.13 percent pass-through payment estimate

for 2007 – to the 2007 conversion factor to fund all other outpatient PPS services.

CMS' estimate of pass-through spending represents such a small percentage of total outpatient PPS spending because there is only one remaining pass-through device category available, and the agency projects only a small expenditure for new pass-through device categories that become eligible in 2007. Additionally, pass-through payments for drugs and biologicals have been effectively eliminated due to CMS' implementation of drug payment changes stipulated in the MMA.

## **CODING AND PAYMENT FOR HOSPITAL AND ED DEPARTMENT VISIT SERVICES**

**Background.** Since April 2000, hospitals have been using evaluation and management Current Procedure Terminology (CPT) codes to report facility resources for clinic and ED visits. Recognizing that the visit code descriptors were designed to reflect the activities of physicians and did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In the past several years, different models for national coding guidelines for reporting facility services have been proposed and reviewed by CMS. In 2002, CMS specified that they would not create new codes to replace existing CPT visit codes for reporting hospital visits until national guidelines were developed, in response to the public's concern over implementing code definitions without national guidelines.

In 2003, the AHA and the American Health Information Management Association (AHIMA) submitted recommended guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience. CMS attempted to validate a modified version of the AHA/AHIMA guidelines; however, the agency's findings were inconclusive.

**Proposed Codes and Coding Policy for 2007.** For 2007, CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes.

The agency defines two different types of hospital EDs, distinguished primarily by whether or not the ED is open 24 hours a day, 7 days a week (24/7). "Type A" EDs are those that, consistent with the CPT definition of an emergency department, are open 24/7 and meet the requirements as a "dedicated emergency department" under EMTALA regulations. "Type B" EDs are those

that do not meet CPT definitions of being open 24/7 but otherwise meet EMTALA regulations as a dedicated ED.

Until national guidelines are formally proposed and finalized, CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The AHA/AHIMA proposed visit coding guidelines and a modified version of the AHA/AHIMA proposed guidelines are posted on the CMS Web site (go to: <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage> and click on the first link) for comment. The modified AHA/AHIMA guidelines contain CMS refinements based on comments it received from outside hospitals and associations, clinical review, and changing payment policies in the outpatient PPS regarding some separately payable services. CMS is seeking public comment on both versions before adopting national guidelines.

**The AHA appreciates CMS taking steps to address the important issue of hospital outpatient visit classification. In particular, we are pleased that CMS has posted for comment national guidelines for coding clinic and emergency visits, and we will thoroughly review these guidelines as well as the new codes CMS has proposed.**

The public comments received on the guidelines section of the proposed rule, along with comments on the two versions of the guidelines posted on the CMS Web site, will be publicly available. CMS is continuing to commit to provide a minimum of six-to-12 months notice prior to implementing national guidelines to provide sufficient time for hospitals to make the necessary changes and educate their staff.

***Proposed Payment Policy for 2007.*** In 2006, the five levels of visit CPT codes are assigned to three APC payment levels. Because the three APC payment rates for clinic and ED visits are based on five levels of CPT codes, the two lowest levels of CPT codes (1 and 2) are assigned to the low-level visit APCs and the two highest levels of CPT codes (4 and 5) are assigned to the high-level visit APCs, with the single middle CPT level (3) assigned to the mid-level visit APCs.

To determine appropriate payment rates for the new HCPCS G codes, CMS proposes to assign the data from the 2005 CPT visit codes and the other HCPCS codes currently assigned to the clinic visit APCs to 11 new APCs, five for clinic visits, five for emergency visits, and one for critical care services (see Table 37 in the proposed rule). CPT visit codes and other HCPCS codes were assigned to the new APCs based on median costs and clinical considerations.

CMS proposes to assign its newly proposed G codes to APCs for payment purposes as follows:

- Five new clinic visit G codes would be assigned to five new clinic visit APCs.
- Five new type A ED visit G codes assigned to five new type A emergency visit APCs. (Type A = 24/7 dedicated ED.)
- Five new type B ED visit G codes assigned to the five new clinic visit APCs. (Type B = non-24/7 dedicated ED.)
- One new critical care G code (hosp critical care, 30-74 min) assigned to the new critical care APC. The other critical care G code (hosp critical care, additional 30 min) would be packaged into other services or procedures performed during the visit.

CMS asserts that paying for type B ED visits at the clinic visit rate is consistent with the agency's current policy for services furnished in EDs that have an EMTALA obligation but do not meet the CPT definition of ED to be reported using clinic codes. In general, clinic visit APCs are paid less than emergency visit APCs.

However, CMS is seeking comments regarding this policy and states that it is concerned with ensuring that necessary ED services are available to rural Medicare beneficiaries, recognizing that rural EDs sometimes operate on a less than 24/7 basis. CMS further notes that the reporting of specific G codes for emergency visits provided in Type B EDs will permit the agency to collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a proposal of an alternative payment policy may be warranted. The earliest that such a policy could be put into place would be in the final outpatient PPS rule for 2009.

## **PAYMENT FOR MEDICAL DEVICES**

***Pass-through Devices.*** By law, devices are eligible for pass-through payments for two to three years. There are no categories of pass-through devices that will expire January 1, 2007, and only one category will continue to be available – C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system).

Of the \$43.2 million that CMS estimates will go towards device pass-through payments in 2007, CMS projects \$36.8 million to be pass-through payments for the remaining current device category continuing into 2007, and \$5.4 million represents payments for any additional categories that might become eligible in 2007.

***Policies for Device-dependent APCs in 2007.*** CMS proposes to base the payment rates for device-dependent APCs in 2007 on median costs calculated using claims with appropriate device "C" codes and which have no token charges for devices reported on the claim. Unlike previous years in which the agency

adjusted device-dependent APC payment rates in order to moderate decreases in median payment rates from one year to the next, CMS does not propose any such adjustments for 2007. Table 18 in the proposed rule displays the median costs used to set rates for device-dependent APCs.

Table 20 in the proposed rule lists the devices for which CMS will require the reporting of device codes when a claim for an associated procedure is submitted in 2007. CMS proposes to implement device-to-procedure code edits for these device codes. The devices also are posted on the CMS outpatient hospital Web site, along with a draft list of all the procedures with which they could be used appropriately and reported.

***Proposed Payment Policy when Devices are Replaced without Cost.*** CMS proposes to reduce the APC payment and beneficiary copayment for selected APCs in cases in which an implanted device is replaced without cost to the hospital or with full credit for the removed device. This is in response to device recalls and field actions that have taken place in recent years involving the failure of implantable devices. In these cases, CMS reports that manufacturers often offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient required a more expensive device.

The proposed new policy, which applies to services furnished in 2007, would only cover certain devices for which credit for the replaced device is given, or for which devices are replaced as a result of a warranty, field action, voluntary recall or involuntary recall, and certain devices which are provided free of charge. CMS proposes to calculate the amount of the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The payment adjustment would be limited to the APCs listed in Table 21 in the proposed rule when the purpose of the procedure is to replace a device identified in Table 22 and which the manufacturer furnished without cost or at full credit.

CMS proposes to implement the adjustment through the use of an appropriate modifier specific to a device that has been replaced. The presence of the modifier would trigger an adjustment in payments for the APC in Table 21. CMS acknowledges that this creates a reporting burden for hospital but believes that the reporting requirement is unavoidable since only hospitals know whether the circumstances described above have been met.

## **PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS**

### ***Drugs and Biologicals Eligible for Transitional Pass-through Payments.***

In Table 23 of the proposed rule, CMS lists 12 drugs that will lose pass-through status after December 31. CMS proposes that if there is a permanent HCPCS code available for 2007 that describes the product, then the agency will delete the C code and use the permanent HCPCS code for purposes of billing and payment.

The proposed rule also lists in Table 24 the nine drugs and biologicals with pass-through status in 2007. Current law requires that if a pass-through drug or biological is covered under a competitive acquisition program (CAP) contract, then the outpatient PPS payment rate is equal to the average price for the drug or biological under CAP, as calculated and adjusted by the Secretary. Pass-through drugs and biologicals not included in CAP are paid at the same rate as they would be if furnished in a physician office. This year, drugs and biologicals furnished in physician offices are again proposed to be paid at the rate of average sales price (ASP) plus 6 percent.

Of the nine drugs and biologicals having pass-through status in 2007, seven will be paid at ASP plus 6 percent and only two – HCPCS codes J2503 (Pegaptanib sodium injection) and J9264 (Paclitaxel injection) – will be paid at the CAP program rate. The payment rates in the proposed rule are based on fourth quarter 2005 ASP data, and updates to the ASP-based rates will be published quarterly and posted on CMS' Web site through 2007.

***Drugs, Biologicals and Radiopharmaceuticals without Pass-through Status.***

CMS currently pays for drugs, biologicals and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment and separate payment (individual APCs).

Packaging Policy for Drugs, Biologicals and Radiopharmaceuticals. The MMA required that the threshold for establishing separate APCs for drugs and biologicals be set at \$50 per administration for 2005 and 2006. Therefore, in 2006, CMS paid separately for drugs, biologicals and radiopharmaceuticals whose median cost per day exceeded \$50 and packaged those whose median cost per day was less than \$50 into the procedures with which they were billed.

This MMA-mandated packaging threshold expires January 1, 2007 and in the proposed rule, CMS evaluates four options: (1) pay all drugs separately; (2) set a high-dollar threshold; (3) continue the \$50 threshold; and (4) update the current packaging threshold for inflation. CMS settled upon the fourth option. Specifically, CMS proposes that for each year beginning with 2007, the packaging threshold would be adjusted for inflation using the Producer Price Index (PPI) for prescription drugs. Using this methodology, CMS proposes a packaging threshold of \$55.

The proposed rule continues the policy of exempting oral and injectible anti-emetic products from the packaging rule, making separate payment for all anti-emetic products. These products are listed in Table 25 of the proposed rule.

Payment for Specified Covered Outpatient Drugs (SCODs). MMA provisions require special classification and payment of certain separately paid drugs, biologicals and radiopharmaceuticals that had previously (or before December

31, 2002) received pass-through payments. In 2007, the MMA requires that payment for these SCODs be equal to the average acquisition cost for the drug, subject to adjustment for drug handling and pharmacy overhead costs.

To set the proposed 2007 rates, CMS evaluated fourth quarter 2005 ASP data on about 500 drugs and mean costs derived from 2005 outpatient PPS claims data. CMS concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be roughly equivalent to basing their payment rates at ASP plus 5 percent. The agency cites findings from a 2005 Medicare Payment Advisory Commission (MedPAC) study of pharmacy overhead costs to support its conclusion that ASP plus 5 percent is a sufficient level to cover drug acquisition as well as overhead and handling costs. The MedPAC survey results indicated that hospitals set charge levels for drugs to cover both drug acquisition and pharmacy handling costs.

Therefore, for 2007, CMS proposes to pay for the acquisition *and* pharmacy overhead and handling costs of SCODs at a *combined* rate of ASP plus 5 percent.

CMS will determine whether each SCOD will be separately paid or packaged once during the year; however, the agency will update the ASP-based payment rates on a quarterly basis as new ASP data is reported. Any SCODs with new payment rates will be posted on the CMS Web site. For the few drugs for which ASP data is not available, CMS will use the mean costs from the 2005 hospital claims data to determine payment rates until ASP data is available.

Payment for Radiopharmaceutical Agents. While CMS considers radiopharmaceuticals to be SCODs, the agency lacks ASP data on which to base the payment rates for them. Therefore, CMS proposes to pay for radiopharmaceutical agents that are separately payable (i.e., their costs exceeds the \$55 per day packaging threshold) using aggregate hospital mean costs for radiopharmaceuticals derived from the 2005 claims data. These costs are determined using CMS standard methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges (defaulting to hospital-specific overall CCRs if departmental CCRs are unavailable). As with other SCODs, payments are deemed to be inclusive of pharmacy overhead and handling costs. This is a significant change from the 2006 policy in which radiopharmaceuticals were paid on the basis of each hospital's charge reduced to cost.

Payment for New Drugs, Biologicals and Radiopharmaceuticals. For new drugs that have not yet been assigned a HCPCS code, CMS will continue applying the policy in effect since 2004. That is, according to the MMA, CMS must pay 95 percent of average wholesale price (AWP) for a new outpatient drug, biological or radiopharmaceutical for which a HCPCS code has not been assigned.

CMS also will continue to pay for new drugs, biologicals and radio-pharmaceuticals that have HCPCS codes but do not have pass-through status at the same ASP-based rate which they would receive in the physician office setting, which is proposed to be ASP plus 6 percent in 2007. For those new drugs without ASP data, CMS proposes to continue its current policy of paying at the wholesale acquisition cost.

Coding and Payment for Drug Administration. For 2007, CMS proposes to continue the 2006 drug administration coding structure, with its combination of CPT and C codes for drug administration services.

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and furnished over different lengths of time. Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However in 2005, codes used in the outpatient department distinguished between the first hour of infusion and additional hours of infusion. Using this newly available 2005 claims data, CMS is proposing that for 2007 it will assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data. The new proposed APCs are described in Tables 30-1 and 30-2.

In another change, related to the fact that CMS does not expect any changes to its coding structure for 2007, the agency is proposing that hospitals apply modifier 59 (distinct procedural service) to drug administration services using the same correct coding principles that they generally use for other outpatient PPS services.

Blood and Blood Products. For 2007, CMS proposes to set payment rates for blood and blood product APCs based on their unadjusted median costs as derived from 2005 claims data. Payment rates in 2007 would be calculated using the same simulation methodology that CMS utilized in 2006. That is, CMS will use actual or simulated hospital blood-specific CCR to convert charges to costs for blood and blood products.

### **NEW TECHNOLOGY APCs**

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. These assignments are listed in Table 10 of the proposed rule.

### **OBSERVATION SERVICES**

In 2006, CMS adopted coding changes and modified the outpatient code editor to simplify the reporting of observation services. Those changes shifted the determination of whether the observation services were separately payable or packaged from the individual provider to the outpatient PPS claims processing system.

For 2007, CMS proposes to increase payment for APC 0339 (Observation) to \$442.16 (from \$425.08 in 2006). In addition, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006 with one exception. As part of the proposed changes to the visit codes, direct admission to observation, when separately payable, will be assigned to APC 0604 (low level clinic visit) with a 2007 proposed payment rate of \$49.93. By contrast, in 2006, these services were assigned to APC 0600 with a payment rate of \$52.37.

### **INPATIENT-ONLY PROCEDURES**

CMS proposes to remove eight procedures from the inpatient-only list and to assign them to the clinically appropriate APCs, as shown in Table 40 of the rule.

### **PARTIAL HOSPITALIZATION SERVICES**

Consistent with 2006 payment policy for partial hospitalization services, CMS proposes to again reduce per-diem payment for partial hospitalization program services by another 15 percent from the 2006 per diem rate of \$246.04. This results in a proposed per-diem payment rate of \$208.80 for 2007.

Had CMS used its usual methodology to establish the payment rate for these services, the reduction in the per-diem rate would have been much greater than 15 percent due to instability in the CMHC data. However, CMS stated that it limited the reduction to 15 percent to reduce the risk of an adverse impact on access to these services.

CMS says that it will continue to monitor and work with CMHCs to improve their reporting. If CMHC data continues to be a problem, the agency would consider using data from hospital-based partial hospitalization programs only.

### **BENEFICIARY COINSURANCE**

The proposed rule would decrease beneficiary liability for coinsurance for outpatient services. As required by law, for 2007 the proposed rule maintains last year's maximum beneficiary coinsurance rate of 40 percent of the total payment to the hospital for that service. However, the average copayments for all outpatient services would drop from 27.5 percent in 2006 to 26.3 percent of total payments in 2007. Under Medicare law, the cap on coinsurance rates is to be reduced gradually until all services have a coinsurance rate of 20 percent of the total payment.

## FINANCIAL IMPACT ON HOSPITALS

CMS estimates that the proposed rule will result in the following per-case change in payment from 2006 to 2007:

<b>All Hospitals</b>	<b>3.0%</b>
Urban Hospitals	3.0%
Large Urban	3.0%
Other Urban	3.1%
Rural	3.1%
Sole Community	2.8%
Other Rural	3.3%

Payments increase less than the market basket update of 3.4 percent due largely to two factors. First, CMS projects that actual outlier payments will exceed estimated payments in 2006, and, thus, it proposes to increase the outlier threshold in 2007, accounting for a reduction in average payments of about 0.25 percent. Second, the temporary wage index increases provided by Section 508 of the MMA expired April 2006, accounting for an additional reduction of 0.17 percent.

## Proposals for Changes to the Ambulatory Surgical Center Payment System for 2007 and 2008

The proposed rule includes ASC proposed rules for 2007 and 2008. Comments on the 2007 changes to ASC payment and coverage are due October 10, the same deadline for comments on the 2007 outpatient PPS rule. However, comments on the proposals for the 2008 ASC payment system are due November 6.

### ASC PROPOSED CHANGES FOR 2007

**ASC List Update for 2007.** While CMS is not proposing any policy changes to the criteria for adding to or deleting items from the ASC list of approved procedures, the agency is proposing to add 14 procedures to the ASC list in 2007. These procedures are listed in Table 41 of the proposed rule and would be assigned to one of the current nine ASC payment groups.

**ASC Payments Capped at Outpatient PPS Rate in 2007.** The proposed rule also would implement the DRA requirement capping payment for ASC services at the outpatient PPS payment rate for surgical procedures performed at an ASC in 2007 when the ASC payment rate exceeds the outpatient PPS payment rate for the same procedure. The DRA cap applies to roughly 272 ASC procedures, which are identified in Addendum AA of the proposed rule. The majority of procedures that are subject to the DRA cap fall under ASC payment group 1, the lowest paying APC group. These DRA cap procedures largely include

procedures involving debridement, wound repair, skin grafts, fractures and dislocation treatment, and biopsies.

### **ASC PROPOSED CHANGES FOR 2008**

The MMA mandated that CMS create a new ASC reimbursement system by January 1, 2008 and that the revised system be budget neutral in 2008. Consistent with this mandate, the proposed ASC rule for 2008 includes significant revisions to the criteria for excluding services from ASC coverage and an entirely new payment structure, based primarily upon the outpatient PPS payment weights and policies. CMS intends to publish the final rule for 2008 in the spring of 2007, with the new system effective January 1, 2008.

***Changes to Criteria and List of Covered ASC Procedures in 2008.*** CMS proposes significant changes to its policy regarding which procedures Medicare will pay for if furnished in an ASC. Currently, CMS publishes a list of ASC-covered surgical procedures, which includes about 2,500 procedures.

***For 2008 and beyond, CMS proposes to exclude from coverage in an ASC only those surgical procedures that could pose a significant safety risk when performed in an ASC, procedures that require an overnight stay, and unlisted procedure codes.*** This new policy also would allow CMS to pay ASCs for procedures commonly performed in physician offices. Currently, such procedures are excluded from the ASC list.

These proposed policy changes would expand the ASC list by more than 750 procedures, of which two-thirds are procedures that are primarily performed in physician offices. Nearly 270 procedures would be excluded from the list due to safety-related concerns.

In excluding surgical procedures that require an overnight stay, CMS proposes to define an overnight stay to mean “any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure.” These procedures are identified in Table 45 in the proposed rule.

To identify procedures that pose a significant safety risk (and that therefore would be excluded from ASC payment), CMS proposes the following criteria:

- Any procedure that is currently included on the outpatient PPS inpatient-only list will be excluded (listed in Addendum E of the proposed rule).
- Any procedures that are performed 80 percent or more of the time in a hospital inpatient setting will be excluded (listed in Table 44 of the proposed rule).
- Procedures that involve major blood vessels, prolonged or extensive invasion of body cavities, extensive blood loss, or are emergency or life-threatening in nature would be excluded. CMS medical advisors would make this determination. While these criteria are similar to those currently

used by CMS to determine which procedures may be covered in ASCs, CMS does not define any of these terms in the proposed rule.

CMS proposes to no longer use certain other “time-based” criteria that are currently used to define surgical procedures that pose a significant safety risk. For instance, CMS proposes to no longer consider for purposes of excluding procedures from ASC coverage list whether the procedure exceeds 90 minutes of operating time; exceeds four hours of recovery time or exceeds 90 minutes of anesthesia.

The AHA is carefully reviewing the proposed changes to ASC coverage and payment policy, including this broad expansion in the number and types of services that may be performed in an ASC in 2007 and 2008. **We are concerned that weakening the standards that determine which services may be performed in an ASC could jeopardize patient safety and quality of care.** This is an issue because regulations and facility standards to which ASCs are subject fall far short of the requirements that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance and operating (e.g., facility, equipment, staffing, etc.) standards.

**Rate-setting Method in 2008.** The current ASC payment system consists of nine payment groups ranging from \$333 to \$1,339 and is based on 1986 ASC cost data that have been updated for inflation.

For the new ASC payment system, CMS proposes to use the APC groupings and relative payment weights for surgical procedures established under the outpatient PPS as the basis for the ASC payment groups and relative payment weights. The revised payment system in 2008 would contain 221 APC surgical procedure groups with payment amounts ranging from \$3.68 to \$16,146.03.

**Packaging Policy.** CMS proposes to continue packaging into the ASC facility payment all direct and indirect costs incurred by the facility to perform a surgical procedure. This would include payment for all drugs, biologicals, contrast agents, anesthesia materials and imaging services, as well as the other items and services that are currently packaged into the ASC facility payment. In addition, to make ASC payment policy consistent with outpatient PPS policy, CMS proposes to cease making separate payment for implantable prosthetic devices and implantable durable medical equipment (DME) inserted at an ASC.

CMS would continue to exclude from payment items and services that are paid under other Medicare Part B fee schedules (with the exception of implantables), such as physician professional fees; laboratory, x-ray or diagnostic procedures (other than those directly related to performance of surgical procedure); non-implantable prosthetic devices; ambulance services; leg/arm/back/neck braces; artificial limbs; and DME for use at a patient’s home.

**Payment for Corneal Tissue.** CMS proposes to continue to pay ASCs separately, based on their invoiced costs, for the procurement of corneal tissue.

**Payment for Office-based Procedures Performed in an ASC.** In a decision intended to eliminate the financial incentive for physicians to move office-based procedures to the higher paying ASC setting, starting in 2008, CMS proposes to cap payment for office-based surgical procedures at the lesser of the Medicare physician fee schedule non-facility practice expense payment or the ASC rate under the revised ASC payment system. Nearly 360 procedures could be subject to this payment cap. Only office-based procedures that are new to the ASC list in 2008 would be subject to the payment limit. Procedures already on the ASC list as of January 1, 2007 would be exempt from the cap.

**Payment Policy for Multiple Procedure Discounting.** Currently, CMS applies a multiple procedure discounting policy in ASCs when more than one surgical procedure is performed on the same patient in the same day. In the proposed rule, CMS would revise the ASC policy to better reflect the current outpatient PPS policy for discounting multiple surgical procedures. That is, CMS would exempt from the multiple surgical procedure discounting policy certain surgical procedures in which costly devices are implanted. Table 46 in the proposed rule lists these procedures that would be exempt from multiple procedure discounting.

**Geographic Adjustment.** CMS proposes to apply to ASCs the inpatient PPS pre-reclassification wage index values associated with the June 2003 Office of the Management and Budget geographic localities, as recognized under the inpatient and outpatient payment system, to adjust ASC payment rates for geographic wage differences.

**Inflation Adjustment.** Starting in 2008, CMS proposes to apply an annual inflation adjustment to the ASC conversion factor, based on the CPI-U. As required in the MMA, there will be no inflationary update in 2008 and 2009.

**Two-year Phase-in for ASC Payment Rates.** CMS proposes a two-year transition period that would set the 2008 payment rate using a 50/50 blend of the payment rate for procedures on the 2007 list of approved ASC procedures and the payment rate calculated under the revised payment methodology. Starting in 2009, ASC payments would be based entirely on the revised payment methodology. The 750 new ASC-covered procedures would be paid the full amount under the revised payment methodology, not the blended rate.

**Calculation of ASC Conversion Factor and Payment Rates for 2008.** The MMA requires that the new ASC payment system be implemented in a budget neutral manner. CMS calculates an estimated ASC conversion factor for 2008 at \$39.688. Thus, services performed in ASCs would be paid at 62 percent of the rate at which they would be paid if they were performed in a hospital outpatient

department under the outpatient PPS in 2008 (with an estimated 2008 conversion factor of \$64.013).

## **Other Changes Proposed for 2007**

### **EMERGENCY MEDICAL SCREENING IN CRITICAL ACCESS HOSPITALS**

CMS proposes to change the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel to screen individuals who present to the CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted by the CAH's bylaws. CMS clarifies that if the registered nurse begins the emergency medical screening and determines that the nature of the individual's condition is outside his/her scope of practice under state law, the appropriate authorized personnel must be contacted to see the patient within 30 minutes (or 60 minutes if the CAH is located in a frontier or remote area or permissible under the state's health plan) to conduct the emergency medical screening and provide stabilizing treatment.

### **MEDICARE CONTRACTING REFORM MANDATE**

The MMA included "Medicare contracting reform" provisions intended to improve Medicare's administrative services to beneficiaries and health care providers and to bring standard contracting principles to Medicare, such as competition and performance incentives. The MMA provisions will phase-in the replacement of the current Medicare FIs and carriers with new Medicare Administrative Contractors (MACs). The transition to the new contracting program must be completed by October 2011.

The MMA contracting reform provisions repealed the ability of providers to nominate their FIs. In this rule, CMS proposes conforming changes to the regulations that would assign providers to the MAC that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located. However, CMS also proposes to allow large national hospital chains that were formerly permitted by CMS to "nominate" a FI to request an opportunity for similar consideration under the new contractor program. And, qualified chain providers that were formerly granted single FI status would not need to re-request such privileges at this time.

One significant exception to the above proposal pertains to suppliers of DME, prosthetics, orthotics and supplies. CMS would continue to allow these suppliers to bill to the contractor assigned to the locale in which the beneficiary receiving the items or supplies resides.

### **HEALTH INFORMATION TECHNOLOGY**

In the proposed rule, CMS summarizes the benefits of health information technology (IT) and requests comments on the agency's statutory authority to

encourage the adoption and use of health IT, including possible inclusion in conditions of participation. A similar request was included in the inpatient proposed rule. The final inpatient rule summarized comments and did not make IT use a Medicare condition of participation, but reserved the right to revisit the issue in future rulemaking.

### **HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE**

In the proposed rule, CMS discusses its development of a transparency initiative to provide comprehensive information on the quality and costs of hospital and physician services. On June 1, CMS published on its Web site the national average Medicare payment to hospitals for 30 common inpatient conditions and elective procedures. In addition, CMS included, by county, the range of payments made to hospitals in those areas along with the number of patients each hospital treated for specific conditions. Then on August 21, CMS posted Medicare charge and payment data for 61 procedures commonly performed in ASCs, including average charge and payment data for the nation and each county and state.

The agency indicated that it intends to include more complete measures of health outcomes, patient satisfaction and volume of services, as well as more comprehensive measures of costs for an entire episode of care, and to do so in a meaningful and transparent way, to consumers and purchasers. CMS also indicated that this initiative would provide a national template for performance measures and a payment structure that aligns payment and performance.

### **NEXT STEPS**

Given the major changes included in this year's proposed rule, the AHA encourages members to submit their own comments to CMS outlining how the changes will affect your facility. Watch for more information from the AHA that may assist you in preparing your organization's comment letter.

Comments on the proposed changes to the 2007 hospital outpatient PPS policies and payment rates as well as on the proposed update to ASC payments and ASC covered procedures list for 2007 are due to CMS by October 10. Comments on the 2008 ASC payment system and payment rates are due by November 6. Comments may be submitted electronically at: <http://www.cms.hhs.gov/eRulemaking> (attachments can be in Microsoft Word, WordPerfect, or Excel; however, CMS prefers Microsoft Word).

You also may submit written comments (an original and two copies) to CMS.

#### Via regular mail

Centers for Medicare & Medicaid Services  
Department of Health and Human Services

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