American Hospital Association

Regulatory Advisory

July 24, 2009

Medicare Outpatient PPS and ASC Proposed Rule for CY 2010

At a Glance

The Issue:

On July 1, the Centers for Medicare & Medicaid Services (CMS) released the outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule for calendar year (CY) 2010. Major proposals in the rule include:

- A market basket update of 2.1 percent for hospitals that reported data on outpatient care in 2009. Hospitals failing to report would receive a reduced update of 0.1 percent;
- No new outpatient quality measures are added for 2011; hospitals would be required to continue reporting on the 11 measures finalized for 2010 to receive a full update for OPPS services in 2011.
- Revised policies for physician supervision of outpatient services, beginning in 2010, that include allowing certain non-physician practitioners to directly supervise hospital outpatient therapeutic services. In addition, for outpatient therapeutic and diagnostic services provided in the hospital or in an on-campus provider-based department of the hospital, CMS will no longer require the supervising professional to be physically present in the department. Instead the supervisor must be present in the hospital or in an on-campus provider-based department and immediately available to assist.
- A proposal for a new methodology to pay for separately payable drugs and biologicals, which results in a proposed payment rate of average sales price (ASP) plus 4 percent.

The proposed rule also updates payments for ASCs using more recent outpatient PPS data to set the ASC payment weights, rates and conversion factor.

Comments on the OPPS and ASC proposed rule are due to CMS by August 31. A final rule will be published by November 1 and takes effect January 1, 2010.

Our Take:

CMS' proposals for 2010 related to physician supervision of outpatient therapeutic and diagnostic services offer greater flexibility, but we continue to carefully evaluate whether they fully meet the needs of hospitals and their patients. We are disappointed that CMS does not resolve the continued vulnerability for unwarranted enforcement actions that hospitals and critical access hospitals face for the years 2001 through 2009 as a result of CMS' clarifying statement on physician supervision in the 2009 rule. The AHA will continue its efforts to get CMS to acknowledge that its expectations for the previous policy were not communicated clearly and to instruct its contractors not to pursue enforcement actions.

What You Can Do:

- ✓ Share this advisory with your chief financial officer and other members of senior management, billing and coding staff, nurse managers and key physician leaders.
- ✓ Model the impact of the proposed APC changes on your expected 2010 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2008-2010 are available on the AHA's Outpatient PPS Web page: http://www.aha.org/aha/content/2009/spreadsheet/090724-adv-attach-em-composite-apc-weights-rates-2008-2010.xls.
- ✓ 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 their facility.

Further Questions: Please contact Roslyne Schulman, AHA senior associate director for policy, at rschulman@aha.org.

AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. A 19-page, in-depth examination of this issue follows.

American Hospital Association

Regulatory Advisory

July 24, 2009

Medicare Outpatient PPS and ASC Proposed Rule for CY 2010

TABLE OF CONTENTS

BACKGROUND

On July 1, the Centers for Medicare & Medicaid Services (CMS) released the outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule for calendar year (CY) 2010. The proposed rule is available at http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1224005&intNumPerPage=10 and was published in the July 20 *Federal Register.*

Comments on the OPPS and ASC proposals are due to CMS by August 31. A final rule will be published by November 1 and takes effect January 1, 2010. Watch for more information from the AHA that may assist you in preparing your organization's comment letter.

AT ISSUE

PROPOSED CHANGES TO THE 2010 OPPS SYSTEM

PPS UPDATE AND LINKAGE TO HOSPITAL QUALITY DATA REPORTING

Outpatient PPS Update. The 2010 OPPS proposed conversion factor for hospitals that report data on the 11 required outpatient quality measures in 2009 (as described below) is $67.439. To calculate the new amount, CMS increased the 2009 conversion factor of $66.059 by the rate of change in the hospital market basket index, estimated at 2.1 percent, as required by law. To ensure budget neutrality, CMS made adjustments to account for changes in the wage index and pass-through spending. Hospitals that do not report the quality data will receive a reduced market basket update via a reduced conversion factor of $66.118.

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

All Hospitals	**1.9%**
Urban Hospitals	2.0%
Large Urban	2.0%
Other Urban	1.9%
Rural	1.7%
Sole Community	1.6%
Other Rural	1.8%

Reporting of Hospital Quality Data. *The Tax Relief and Health Care Act of 2006* required CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual update to the OPPS payment rate. Hospitals failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points.

For 2010 payment update purposes, hospitals must continue to report on the 11 outpatient quality measures finalized in last year's rule. The 11 existing measures are outlined in the table below.

Aspect of Care	Measure
Heart Attack	Aspirin at arrival for patients treated in the emergency department and then transferred
	Median time from emergency department arrival to fibrinolysis for patients treated in the emergency department and then transferred
	Fibrinolytic therapy received within 30 minutes of arrival for patients treated in the emergency department and then transferred
	Median time from emergency department arrival to electrocardiogram (ECG) for patients treated in the emergency department and then transferred
	Median time from emergency department arrival to transfer for primary percutaneous coronary intervention (PCI)
Surgical Care Improvement	Timing of antibiotic prophylaxis
	Selection of prophylactic antibiotic – first or second generation cephalosporin
Imaging Efficiency	MRI lumbar spine for low back pain
	Mammography follow-up rates
	Abdomen CT – Use of contrast material
	Thorax CT – Use of contrast material

For 2011, CMS does not propose any new measures for outpatient quality reporting, but the agency will require hospitals to continue reporting on the 11 existing measures. **The AHA supports CMS' decision to refrain from adding new quality measures until hospitals gain more experience with the outpatient reporting program and any initial glitches in the new program can be addressed.**

Reporting Exception. CMS proposes to continue its reporting exception for hospitals with five or fewer patients for a quality measure in a calendar quarter. For example, if a hospital has five or fewer patients eligible for one of the heart attack transfer measures, the hospital will not have to report data for any of the five heart attack transfer measures for that quarter in order to receive its full update. Low-volume hospitals may continue to submit their quality data voluntarily.

Data Validation. In this rule, CMS proposes a temporary program for validating hospitals' outpatient quality data in 2011 and outlines a new process to validate data in 2012 and beyond. For 2011, CMS proposes to randomly select up to 20 patient cases from each hospital and validate those data. While hospitals would be required to

participate in the 2011 data validation program to fulfill their annual payment update requirements, the results of the data validation would not impact their payment. CMS would require hospitals to submit the requested medical records to a CMS contractor for validation, similar to the process used for the inpatient quality reporting program. CMS would provide feedback on the validation results to all hospitals as a learning opportunity, but hospitals would not have to meet any particular validation benchmark to receive their full annual payment update.

The validation process proposed for 2012 and beyond is similar to the one CMS included in last year's proposed rule. Unlike the current process for the inpatient reporting program, which involves the review of a small number of medical charts from all hospitals, the process proposed for the outpatient program would audit a larger number of charts from a randomly selected sample of hospitals. CMS proposes to review 48 medical charts (12 per quarter) from 800 randomly selected hospitals each year. The review would assess the accuracy of the hospital's measure rate, as opposed to the accuracy of the individual data elements. To pass validation, hospitals would have to meet a minimum of 90 percent reliability from the chart validation, which is higher than the 80 percent match rate currently used in the inpatient quality data validation program. **The AHA believes CMS' proposed process holds promise as a reasonable approach to ensure the accuracy of the quality data, but we believe a 90 percent match rate is too high an expectation in the initial years of the outpatient data validation program.**

Public Reporting. CMS proposes to publicly report outpatient quality data for the first time in 2010, beginning with data collected for services delivered in the third quarter of 2008.

Healthcare-associated Conditions. CMS discusses some of the comments received to date on whether and how it should expand its healthcare-associated conditions policy to the hospital outpatient setting, but the agency offers no new proposals.

PHYSICIAN SUPERVISION OF HOSPITAL OUTPATIENT SERVICES

Proposed Policies for Direct Supervision of Outpatient Therapeutic Services. In the 2009 OPPS final rule, CMS issued a new policy on direct physician supervision of outpatient therapeutic services that hospitals and physicians recognized as a burdensome and unnecessary policy change, but CMS characterized as a "restatement and clarification" of existing policy in place since 2001. In its attempt at clarification, CMS stated that the policy requires a physician privileged by the hospital to provide supervision and be physically present in the outpatient department at all times when outpatient therapeutic services are furnished, regardless of whether the services are furnished in the hospital, on the hospital campus or off-campus.

In response, the AHA and other national hospital and physician organizations have been working together to urge CMS to rescind or significantly modify the policy. Through multiple letters and meetings, we demonstrated that CMS' "clarification" is instead a significant change in Medicare policy that would place a considerable burden

on hospitals, requiring them to engage more physicians for direct supervisory coverage without a clear clinical need. As we made clear, the burden of this policy change is of special concern to small hospitals, critical access hospitals (CAHs) and communities in which the shortage of physicians is especially severe. The policy may lead to patient access problems if hospitals are forced to discontinue or limit the hours of certain outpatient services.

In addition, we expressed concern that CMS' language in the preamble to the 2009 OPPS rule that refers to this new policy as a "clarification" has the potential to subject hospitals to substantially heightened and unwarranted enforcement scrutiny. We recommended that CMS take immediate steps to mitigate the new and inappropriate enforcement risks that its statements have created.

In response to our efforts, CMS proposes several helpful revisions to its policy in the proposed rule that would apply beginning in 2010. However, CMS' proposals do not resolve the continued vulnerability for unwarranted potential enforcement actions for the years 2001 through 2009. In the preamble to the 2010 OPPS rule, CMS continues to explicitly assert that the "restatement and clarification" made in the 2009 OPPS rule made no change to longstanding hospital outpatient physician supervision policies, and that these policies continue to be in effect for 2009. The agency also indicates that it has not instructed contractors to delay or discontinue enforcement actions in this area. **The AHA will continue to urge CMS to rescind the 2009 policy change,** acknowledging the policy's ambiguity and uncertainty and recognizing that the agency's expectations for it were not communicated clearly in previous rulemaking. **We also will continue to urge CMS to instruct its contractors not to pursue enforcement actions.**

For the purposes of services provided in 2010, CMS proposes policy changes that would provide additional flexibility for the supervision of outpatient therapeutic services and the changes would apply to both hospitals and CAHs. **The AHA is carefully evaluating these proposals to determine whether they are sufficient and is reaching out to hospitals to determine what additional changes may be required.**

Non-physician practitioners may provide direct supervision. Starting in 2010, CMS proposes that certain non-physician practitioners, specifically physician assistants, nurse practitioners, certified nurse specialists and certified nurse-midwives, may directly supervise hospital outpatient therapeutic services that they are able to personally perform within their State's scope of practice and hospital-granted privileges. CMS has asserted that its current policy only allows physicians and clinical psychologists to provide the direct supervision of these services. However, CMS notes that due to statutory requirements, the direct supervision of cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation must be furnished by a physician, as specified in the proposed coverage policy and regulations proposed in this 2010 rule (see page 6 below).

Loosening of physical presence standard for direct supervision. Starting in 2010, CMS proposes to revise the definition of direct supervision of hospital outpatient therapeutic services for those services furnished *in a hospital or in on-campus provider-based departments (PBDs) of a hospital*. For services furnished on a hospital's main campus, direct supervision means that the supervisory physician or non-physician practitioner ("supervising professional") must be present on the same campus, in the hospital or in the on-campus PBD of the hospital, and immediately available to furnish assistance and direction throughout the performance of the procedure.

CMS also proposes to define "in the hospital" to mean areas in the main building(s) of a hospital that are under the ownership, financial and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's CMS Certification Number. Therefore, the supervising professional may not be located in any other entity, such as a physician's office, independent diagnostic testing facility (IDTF), co-located hospital, or hospital-operated provider or supplier, such as a skilled nursing facility, end-stage renal disease facility, or home health agency, or any other non-hospital space that may be co-located on the hospital's campus.

Further, while CMS does not define "immediately available," the agency does state that supervising professionals would not be considered to be immediately available if they were performing another procedure or service that could not be interrupted or so physically far away on the main campus from the location where the services are being provided that they could not intervene right away.

CMS states that its definition of direct supervision would continue to specify that supervising professionals must be available to furnish assistance and direction throughout the performance of the procedure. CMS explains that while this does not mean that they must be of the same specialty as the service or procedure being performed, the supervising professionals must have within their State's scope of practice and hospital-granted privileges the ability to perform the service or procedure.

For services furnished in an *off-campus PBD*, CMS also will allow supervision to be provided by non-physician practitioners. However in these settings, "direct supervision" would continue to mean that the physician or non-physician practitioner must be present in the off-campus PBD and immediately available to furnish assistance and direction throughout the performance of the procedure. CMS also states that it would be inappropriate to allow one physician or non-physician practitioner to supervise all services being provided at a particular off-campus remote location with multiple PBDs.

Proposed Policies for Direct Supervision of Outpatient Diagnostic Services

For 2010, CMS proposes to require that all hospital outpatient diagnostic services provided directly or under arrangement, whether provided in the hospital, in a PBD, or at a non-hospital location, follow the physician supervision requirements for individual tests as listed in the Medicare physician fee schedule Relative Value File. The existing regulatory definitions of general and personal supervision would continue to apply.

For services furnished directly or under arrangement *in the hospital or on-campus PBD*, direct supervision would mean that the physician must be present on the same campus, in the hospital or on-campus PBD of the hospital, and immediately available to furnish assistance and direction throughout the performance of the procedure. For this purpose, CMS proposes to apply the same definition of "in the hospital" as used for outpatient therapeutic services.

For diagnostic services furnished directly or under arrangement *off-campus in a PBD of the hospital*, direct supervision would mean that the physician must be present in the off-campus PBD and immediately available to furnish assistance and direction throughout the performance of the procedures.

For all hospital outpatient diagnostic services *provided under arrangement in non-hospital locations*, such as IDTFs and physicians' offices, the existing definitions of personal, direct and general supervision that apply to diagnostic tests performed in physician offices would apply.

RECALIBRATION OF APC WEIGHTS

CMS is required to review and revise at least annually the relative payment weights for ambulatory payment classifications (APCs). In the proposed rule, CMS recalibrates the relative APC weights using hospital claims for services furnished during 2008. Following the process established in 2007, CMS calculated an "unscaled" – i.e., not adjusted for budget neutrality – relative payment weight by comparing the median cost of each APC to the median cost of APC 0606 (Level III Clinic Visit)[1]. CMS used APC 0606 because it is one of the most frequently performed services in the hospital outpatient setting and represents the middle level clinic visit APC. After assigning APC 0606 a relative payment weight of 1.00, CMS determined the unscaled relative payment weight for each APC by dividing the median cost of the APC by the median cost for APC 0606.

To comply with budget neutrality requirements, CMS compared aggregate payments using the 2009 relative weights to aggregate payments using the proposed 2010 weights. Based on the lower expected payments in this comparison, the proposed rule *increases* the APC weights by a factor of 1.2863 (an increase of 28.63 percent). Similar to the adjustment made to the 2009 weights, this is a much larger adjustment than had been made in prior years. This is because the median cost of APC 0606, $86.75, is much higher than the median cost of the old mid-level clinic visit, APC 0601, of $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 payment weights for 2010 continue to show significant volatility. For 20 APCs, the proposed 2010 weights would decrease by 10 percent or more, resulting in decreased payments. For nine of these, the reduction is greater than

[1] In previous years, APC 0601 was used for this comparison.

20 percent. In total, weights would be lower for 178 APCs. Payment weights increase for 224 APCs, going up at least 10 percent for 21 of them, and 20 APCs rise by at least 20 percent.

PROPOSED PACKAGING AND BUNDLING CHANGES

In order to moderate growth in volume and spending in the OPPS, CMS in 2008 expanded the packaging of minor ancillary services associated with significant procedures into a single payment for the procedure and bundled payments for multiple significant procedures related to an outpatient encounter into a single unit of payment.

In 2008 and 2009, CMS packaged eight categories of items and services:

- Guidance services;
- Image processing services;
- Intra-operative services;
- Imaging supervision and interpretation services;
- Diagnostic radiopharmaceuticals;
- Contrast media;
- Nonpass-through implantable biologicals; and,
- Observation services.

In the same years, CMS also finalized 10 new "composite" APCs that would pay a single rate for larger bundles of major, and previously separately paid, services that are commonly performed in the same hospital outpatient encounter:

- APC 8001 (Low Dose Rate Prostate Brachytherapy Composite);
- APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite);
- APC 0034 (Mental Health Composite);
- APC 8002 (Level I Extended Assessment and Management Composite);
- APC 8003 (Level II Extended Assessment and Management Composite); and
- APCs 8004, 8005, 8006, 8007 and 8008 (Multiple Imaging Composites).

For 2010, CMS proposes to continue these established packaging and composite APC policies, but updates the payment rates using more recent OPPS claims data. In addition, consistent with the AHA's recommendations, CMS does not propose any new composite APC policies for 2010, in order to monitor the effects of existing composite APCs on utilization and payment. However, the agency continues to consider the development and implementation of larger payment bundles, such as composite APCs as a long-term policy objective for the OPPS and continues to explore other areas where this payment model may be used. In particular, CMS is evaluating the implications of creating composite APCs for cardiac resynchronization therapy services for future rulemaking.

WAGE INDEX FOR 2010

The OPPS uses the wage indices contained in the fiscal year 2010 inpatient PPS proposed rule published in the May 22 *Federal Register*. The OPPS final rule will adopt the wage indices issued in the inpatient PPS final rule expected in August. As in prior years, 60 percent of the APC payment is adjusted by the wage index.

OUTLIER PAYMENTS

Outlier Thresholds. Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2010, CMS proposes setting the projected target for outlier payments at 1 percent of total OPPS payments – the same as 2009. CMS again proposes establishing separate thresholds for community mental health centers (CMHCs) and hospitals. Therefore, 0.02 percent of the 1 percent projected target would be allocated to CMHCs for partial hospitalization program (PHP) 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 for outliers to $2,225, which is $425 more than in 2009, to ensure that outlier spending does not exceed the reduced outlier target.

Thus, to be eligible for an outlier payment in 2010, the cost of a hospital outpatient service must exceed 1.75 times the APC payment amount (the percentage threshold), *and* it must be at least $2,225 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.

Under the proposed rule, hospitals receiving reduced Medicare payment for services due to their failing to meet the outpatient quality data reporting requirements would have their costs compared to these reduced payments for the purposes of outlier eligibility and payment calculations.

In addition, CMS responds to requests from commenters, including the AHA, that the agency publish actual outlier payments made for a year once the claims data for that year are available. Consequently, in the proposed rule, CMS states that in 2008 outlier payments accounted for about 1.2 percent of total 2008 OPPS payments, which is more than the 1.0 percent set aside for outlier payments in that year. (2008 data are the most recent data available.)

TRANSITIONAL CORRIDOR "HOLD-HARMLESS" PAYMENTS

As required by the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA), CMS proposes to end the transitional corridor "hold-harmless" payments for rural hospitals with 100 or fewer beds and for sole community hospitals (SCHs) with 100 or fewer beds as of December 31. Thus, in the absence of an extension of this policy in law, no transitional hold-harmless payments will be made in 2010.

RURAL ADJUSTMENT FOR SCHS

CMS proposes to continue increasing payments to rural SCHs, including essential access community hospitals, by 7.1 percent for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy, and items paid at charges reduced to costs. The adjustment would be budget neutral to the OPPS and applied before calculating outliers and coinsurance. CMS indicates that it will reassess the 7.1 percent adjustment in the near future by examining differences between urban and rural costs using updated claims, cost and provider information.

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 2010, CMS is projecting that pass-through payments will be 0.12 percent of total OPPS payments, or $38 million.

Changes to the transitional pass-through pool must be budget neutral. Therefore, CMS proposes to remove 0.01 percent – the difference between the estimated 0.11 percent pass-through payments in 2009 and the 0.12 percent pass-through payment estimate for 2010 – from the 2010 conversion factor, which will reduce slightly all other OPPS services.

***Pass-through Devices*.** By law, devices are eligible for pass-through payments for two to three years. There are no categories that will be available for pass-through payment in 2010. However, CMS estimates $10 million in pass-through payments in 2010 for additional devices categories that could be approved for pass-through status for subsequent quarters of 2009 or 2010

***Drugs and Biologicals Eligible for Transitional Pass-through Payments*.**
In Table 21 of the proposed rule, CMS lists six drugs and biologicals that will lose pass-through status after December 31. Table 22 lists the 31 drugs and biologicals with pass-through status in 2010. CMS estimates that pass-through payment for drugs and biologicals will be $28 million in 2010.

Implantable biologicals. CMS notes that although pass-through implantable biologicals often substitute for nonpass-through implantable devices whose costs are packaged into procedural APC payments, the agency's current APC offset policies (that reduce pass-through payments to account for the costs of predecessor items packaged into APC payments) do not apply to pass-through payment for biologicals. In CMS' view, this constitutes double payment for an implanted device.

Therefore, beginning in 2010, CMS proposes that implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) would be subject to the *device* pass-through process and payment methodology only. As a result, pass-through payments for implantable biologicals would be based on hospital charges adjusted to cost (the rate used for pass-through devices), rather than the

average sales price (ASP) methodology that is applicable to pass-through drugs and biologicals. Also, it would allow CMS to appropriately offset the pass-through payment for an implantable biological using the device APC offset amounts.

Definition of pass-through payment eligibility period for new drugs and biologicals. The law allows a two- to three-year limitation on the period for which pass-through payments may be made for a new drug or biological, with the start date for this period defined in the *Social Security Act*. In the rule, CMS addresses an error in its interpretation of the act by proposing to change the start date of the pass-through payment eligibility period under its current policy, which is from the first date on which pass-through payment is made, to the date on which payment is first made for a drug or non-implantable biological as an outpatient hospital service under Medicare Part B. Because the agency cannot identify this date for each new drug in a timely way, CMS proposes to define it using a proxy – the date of first sale for a drug or non-implantable biological in the U.S. following approval from the Food and Drug Administration.

CODING AND PAYMENT FOR CLINIC AND ED VISIT SERVICES

***Guidelines*.** Since April 2000, hospitals have been using the American Medical Association's Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits using their own hospital-specific guidelines.

Since the publication of the 2008 OPPS/ASC final rule, CMS has examined the distribution of clinic and ED visit levels based upon available updated 2007 claims data. CMS continues to observe a normal and stable distribution of clinic and ED visit levels in hospital claims.

For 2010, CMS proposes that hospitals continue to report visits according to their own internal hospital guidelines to determine the different levels of clinic and ED visits until national guidelines are established. CMS notes its continued expectation that hospitals' internal guidelines would comport with the principles listed in the 2008 OPPS/ASC final rule. Hospitals with more specific questions related to the creation of internal guidelines are to contact their local fiscal intermediaries or Medicare administrative contractors.

For 2010, CMS proposes to continue recognizing the CPT and HCPCS codes describing clinic visits, Type A and B emergency department visits, critical care services, and trauma team activation provided in association with critical care services.

Clinic Visits. Hospitals use different CPT codes for clinic visits based on whether the patient being treated is a new or an established patient. Beginning in CY 2009, CMS refined the definition of new and established patients to reflect whether the patient was registered as an inpatient or outpatient of the hospital within the past three years.

For 2010, CMS proposes to continue recognizing the refined definitions of new and established patients. **The AHA will again recommend that CMS not differentiate**

hospital clinic codes between new and established patients as this adds an unnecessary level of complexity and is difficult to implement.

***ED Visits*.** In 2007, CMS introduced a distinction between two types of EDs, and referred to them as either Type A or B depending on whether the department was open 24 hours a day, seven days a week (24/7), and met the *Emergency Medical Treatment and Labor Act* (EMTALA) definition of a dedicated ED.

For 2007 and 2008, CMS paid for Type B services (open less than 24/7) at the lower hospital *clinic* rate rather than the higher ED rate, which Type A services (open 24/7) are paid. In 2009, based on claims data that show most Type B ED visits are more costly than clinic visits, but less costly than Type A ED visits, CMS established four new APCs for services provided in Type B EDs to reflect these cost differences. However, CMS used a single APC for the most intensive Type A and B ED visits because the costs were approximately the same.

For 2010, CMS' analysis of claims data shows that Type B ED visits are less expensive than Type A ED visits across all five levels of service. Therefore, CMS proposes to pay for all Type B ED visits consistent with their median costs. CMS will continue to use the same four APCs – APCs 626, 627, 628, and 629 – to pay for Level 1 through 4 Type B ED visits. The agency proposes to establish a new APC 0630 for the most intensive service, a Level 5 Type B ED visit.

PAYMENT FOR MEDICAL DEVICES WITHOUT PASS-THROUGH STATUS

***Policies for Device-dependent APCs in 2010*.** CMS proposes to revise its standard methodology to calculate payment rates for device-dependent APCs in 2010 by excluding claims that contain the "FC" modifier, as described below.

Payments for device-dependent APCs will be based on median costs calculated using single procedure claims that meet three criteria:

- the claims include the appropriate device C codes for the procedures;
- the charges for the allowed device HCPCS codes are in excess of $1.00 (thereby excluding token charges); and,
- the claims include neither the HCPCS modifier "FB" (used to identify procedures performed using an item provided without cost to the hospital or where full credit was received for a replaced device) nor the "FC" modifier (used to identify procedures performed where partial credit was received for a replaced device).

Table 5 in the proposed rule displays the median costs used to set rates for device-dependent APCs.

***Proposed Payment Policy when Devices are Replaced with Partial Credit*.** For 2010, CMS proposes to continue its policy to reduce the APC payment and beneficiary copayment for selected device-dependent APCs in cases where an implanted device is replaced without cost to the hospital or with full credit for the removed device or with

partial credit toward the replacement of the device. The APCs and devices to which this policy applies, listed in Tables 19 and 20 of the proposed rule, have not changed since 2009.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS WITHOUT PASS-THROUGH STATUS

The payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status in the proposed rule are based on fourth quarter 2008 ASP data. Updates to the ASP-based rates will be published in the final rule, quarterly thereafter and posted on CMS' Web site through 2010.

***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 or separate payment (individual APCs).

Packaging Policy for Low-cost Drugs, Biologicals and Radiopharmaceuticals. For 2010, CMS proposes to raise by $5 its packaging threshold for drugs, biological and radiopharmaceuticals, to $65 per day. Therefore, drugs costing less than $65 would have their cost packaged in the procedure with which they are billed, such as a drug administration procedure. Drugs costing more than $65 would be paid separately through their own APC.

There are a few exceptions to this packaging policy. Consistent with CMS' 2008 and 2009 packaging policy, the costs of all contrast agents, diagnostic radiopharmaceuticals and nonpass-through implantable biologicals are packaged into the procedures with which they are billed.

However, CMS proposes to no longer exempt oral and injectible anti-emetic products from its packaging policy, citing their relatively constant pricing structure and prescribing practices for these drugs that are insensitive to price. As a result, CMS proposes to package payment for all anti-emetics except for palonosetron hycrochloride, consistent with their estimated per day costs.

Payment for SCODs. CMS is required by law to use special classification and payment for certain separately paid drugs, biologicals and radiopharmaceuticals that previously (before December 31, 2002) received pass-through payments. In 2010, payment for these specified covered outpatient drugs (SCODs) must be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs. Consistent with its current policy, CMS proposes to apply the SCOD payment methodology to all separately payable drugs.

For 2010, CMS proposes to pay for the drug acquisition and pharmacy overhead costs of separately payable drugs and biologics at a combined rate of ASP plus 4 percent. This is the same amount paid for these drugs in 2009.

However, CMS calculates the 2010 rate using a revised methodology. First, the agency applies its standard drug payment methodology, using hospital claims data and cost reports, to estimate the cost of separately payable drugs, arriving at a payment rate of ASP minus 2 percent. Then, CMS proposes to make a payment adjustment that redistributes pharmacy overhead costs, in the amount of $150 million, from packaged drugs to separately payable drugs. This boosts the proposed payment rate for separately payable drugs to ASP plus 4 percent. In order to make this redistribution "budget neutral" within drugs and biologicals, and not reduce payments for other services, CMS proposes to reduce payments for packaged drugs by about 27 percent.

In explaining its decision to redistribute a portion of the pharmacy overhead from packaged to separately payable drugs, CMS describes analyses it conducted that lend support to its assumption that between one-third and one-half of the $395 million in pharmacy overhead cost currently associated with packaged drugs and biologicals is misapplied, as a function of both charge compression and the agency's choice of an annual drug packaging threshold. Based on these analyses, CMS claims its proposal offers a more appropriate allocation of pharmacy overhead cost to separately payable drugs and biologicals.

CMS further proposes that the claims data for 340B hospitals (a program that allows safety net hospitals to purchase certain outpatient drugs at a discount) be included in the calculation of payment for drugs and biologicals under the 2010 OPPS and that 340B hospitals would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program.

CMS determines annually whether each outpatient drug will be paid separately or packaged for the entire calendar year; however, the agency will update the ASP-based payment rates for separately paid drugs on a quarterly basis as new ASP data are reported. Any separately paid drugs with new payment rates would be posted on the CMS Web site.

Payment for Radiopharmaceutical Agents. While CMS considers radiopharmaceuticals to be SCODs, the agency currently lacks ASP data on which to base the payment rates for them. For 2010, CMS proposes to continue to use different payment approaches for diagnostic and therapeutic radiopharmaceuticals. CMS proposes to continue packaging payment for all *diagnostic* radiopharmaceuticals and to pay separately for *therapeutic* radiopharmaceuticals that have a mean per-day cost of more than $65.

In 2009, CMS was required by law to pay for therapeutic radiopharmaceuticals on the basis of a hospital's individual charges reduced to cost. However, because this statutory provision expires at the end of the year, for 2010 CMS proposes to allow manufacturers to submit ASP information for any separately payable therapeutic radiopharmaceutical in order for their payment to be based on ASP beginning in 2010, at ASP plus 4 percent. However, if ASP information for a particular therapeutic radiopharmaceutical is unavailable, CMS would base payment on the most recent hospital mean unit cost data available.

Payment for New Drugs, Biologicals and Radiopharmaceuticals. CMS proposes to pay for new drugs (excluding contrast agents), nonimplantable biologicals and therapeutic radiopharmaceuticals that have HCPCS codes but have neither pass-through status nor OPPS claims data at the rate of ASP plus 4 percent in 2010 – the same rate this category of drugs was paid in 2009. For new drugs without ASP data, CMS proposes to continue paying at the wholesale acquisition cost. If the wholesale acquisition cost also is unavailable, CMS proposes to make payment at 95 percent of the product's most recent average wholesale price. Table 30 of the proposed rule lists the nonpass-through drugs without claims data.

Coding and Payment for Drug Administration. For 2010, CMS proposes to continue to use the full set of CPT codes for drug administration services adopted in 2007, including the concepts of initial, sequential and concurrent administration. In addition, as part of its standard annual review, CMS analyzed the assignments of drug administration CPT codes into the five-level APC structure and, based on the results of this review, is proposing to continue a five-level APC structure put into place in 2009. Further, CMS proposes some minor reconfigurations of the APCs to account for changes in HCPCS code-specific median costs resulting from updated 2008 claims data, the most recent cost report data and the 2010 drug payment proposal.

Brachytherapy Sources. For 2009, MIPPA required CMS to continue to pay for brachytherapy on a cost basis for each individual hospital. However, this payment methodology expires December 31. Therefore for 2010, CMS proposes to pay for the brachytherapy sources listed in Table 32 at prospective payment rates based on their source-specific median costs. In addition, because brachytherapy sources are proposed to be paid on a prospective basis, they will be eligible for outlier payments and for the 7.1 percent payment increase for services provided at rural SCHs.

Blood and Blood Products. For 2010, CMS proposes to continue its current policy of setting payment rates for blood and blood product APCs based on their unadjusted median costs as derived from 2008 claims data. Payment rates in 2010 would be calculated using actual or simulated hospital blood-specific cost-to-charge ratio (CCR) to convert charges to costs for blood and blood products – the same simulation methodology that CMS used in 2009.

NEW TECHNOLOGY APCS

CMS proposes to assign one service – HCPCS code 0182T, HDR electronic brachytherapy – from a new technology APC to a clinically appropriate APC 0313.

INPATIENT-ONLY PROCEDURES

CMS proposes removing three procedures from the inpatient-only list and assigning them to the clinically appropriate APCs, as shown in Table 37 of the rule.

PARTIAL HOSPITALIZATION SERVICES

For 2010, CMS proposes to continue to use two separate APC payment rates for PHP services – one for days with three services and one for days with four or more services.

Also, consistent with recommendations from the AHA, the agency proposes to continue to use only hospital-based PHP claims data to determine the payment rates for these APCs. The proposed rates are:

- APC 0172, paid at $148 (compared to $157 in 2009), would be used for PHP days with three services.
- APC 0173, paid at $211 (compared to $200 in 2009), would be used for PHP days with four or more services.

CMS requests comments on the possibility of returning to its pre-2009 policy of using both community mental health center and hospital-based data to develop the payment rates for the final rule. **The AHA will recommend that until CMS knows the impact of the comprehensive policy and payment changes it made for PHP services in 2009, the agency should continue to use only hospital-based data to set payment rates in 2010.**

CARDIAC AND PULMONARY REHABILITATION SERVICES

In accordance with provisions in MIPPA, CMS proposes to establish a new benefit and OPPS payments for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services for beneficiaries with chronic obstructive pulmonary disease, cardiovascular disease and related conditions, effective January 1, 2010.

CMS proposes to create one new Level II HCPCS code, GXX30 (Pulmonary rehabilitation, including aerobic exercise (includes monitoring), per session, per day) for hospitals to report and bill for the services furnished under a pulmonary rehabilitation program. Given the lack of hospital OPPS cost data, CMS proposes to temporarily assign this new code to New Technology APC 1492, which is paid at $15. This rate is similar to the 2010 rate proposed for pulmonary rehabilitation under the physician fee schedule proposed rule.

Currently cardiac rehabilitation services furnished by hospitals are reported using CPT codes 93797 and 93798. For intensive cardiac rehabilitation services, CMS proposes to create two new Level II HCPCS codes, GXX28 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session) and GXX29 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session). Both cardiac rehabilitation and intensive cardiac rehabilitation would be assigned to APC 0095 at a rate of $39.

CMS will require direct physician supervision for these services, as newly defined for other outpatient therapeutic services. However, unlike other outpatient therapeutic services, CMS does not propose to allow non-physician practitioners to provide this supervision.

KIDNEY DISEASE EDUCATION

In accordance with provisions in MIPPA, CMS proposes to establish a new benefit and payments for rural providers under the Medicare physician fee schedule for kidney disease education services furnished on or after January 1, 2010 for beneficiaries diagnosed with Stage IV chronic kidney disease. Rural providers eligible to be paid for this new benefit include hospitals, critical access hospitals, skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities and hospices.

BENEFICIARY COINSURANCE

The proposed rule would decrease beneficiary liability for coinsurance for outpatient services. As required by law, 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 to 23 percent of total payments in 2010. 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.

PROPOSED CHANGES FOR THE 2010 ASC PAYMENT SYSTEM

The proposed rule includes the annual update to the ASC list of covered surgical procedures and covered ancillary procedures, as well as updated payment rates. CMS also reviews excluded surgical procedures, new procedures and procedures with revised coding to identify any that meet the criteria for designation as ASC-covered surgical procedures or covered ancillary services.

Updating these provisions in association with the annual OPPS rulemaking cycle ensures that the ASC updates occur in a regular, predictable and timely manner, and is particularly important because the OPPS relative payments weights, and in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system.

In light of a recommendation from the Medicare Payment Advisory Commission that ASCs should be required to submit cost data to the Secretary so as to allow for an effective evaluation of the adequacy of the ASC payment rates, CMS is seeking comment on the feasibility of ASCs submitting cost information. **The AHA will continue to urge CMS to seek congressional authority to require ASCs to report cost data in order to allow for future validation of the relative appropriateness of ASC payment weights and rates.**

Updating the ASC Relative Payment Weights for 2010 and Future Years. CMS updates the ASC relative payment weights in the revised ASC payment system each year using the national OPPS relative payment weights (and physician fee schedule non-facility practice expense amounts, as applicable) for that same calendar year and

uniformly scales the ASC relative payment weights for each year to make them budget neutral. For 2010, CMS proposes an ASC scaler of 0.9514.

Updating the ASC Conversion Factor. For the 2010 ASC payment system, CMS calculates and applies the pre-floor and pre-reclassified hospital wage index used for the payment adjustment to the ASC conversion factor, just as the OPPS wage index adjustment is calculated and applied to the OPPS conversion factor. In addition, for the first time since the new ASC payment system was implemented, CMS proposes to apply an inflation update to the ASC conversion factor, a 0.6 percent increase based on the Consumer Price Index for All Urban Consumers (CPI-U). This results in a proposed ASC conversion factor of $41.625. By contrast, the proposed OPPS conversion factor is $67.439.

ASC-covered Surgical Procedure Payment Rate Update. For procedures that were on the ASC list of covered surgical procedures prior to 2008, CMS proposes continuing the ASC payment transition for 2010 using a blend of 75 percent of the proposed 2010 ASC rate (based on the OPPS) calculated according to the standard or device-intensive methodology, respectively, and 25 percent of the 2007 ASC payment rate. Procedures added to the ASC list for 2008 and beyond are not subject to transitional payment and are instead paid at 100 percent of the proposed 2010 ASC rate. CMS also proposes updating the payment amounts for office-based procedures at the lesser of the proposed 2010 physician fee schedule non-facility practice expense amount or the 2010 ASC payment amount calculated according to the standard methodology.

ASC-covered Surgical Procedures. CMS proposes adding 28 procedures to the list of ASC-covered surgical procedures (see Table 41 of the proposed rule). Procedures added to the ASC list after 2008 are paid at 100 percent of the 2010 ASC payment rate, and are not subject to the transitional blended payment.

Surgical Procedures Designated as Office-based**.** Office-based procedures are procedures that CMS determines are performed predominantly (more than 50 percent of the time) in physicians' offices. They are paid at the lower of the Medicare physician fee schedule (PFS) non-facility practice expense relative value unit amount or the amount calculated using the ASC standard rate-setting methodology for the procedure.

For 2010, CMS proposes designating six procedures as "office-based" procedures (see Table 43 of the proposed rule). In addition, CMS proposes to make permanent the office-based designation of four surgical procedures that have temporary office-based designations in 2009 (see Table 44 of the proposed rule).

ASCs not Subject to Quality Data Reporting. CMS does not propose implementing an ASC quality reporting program for 2010 despite having statutory authority to do so. **The AHA will continue to encourage CMS to implement a quality reporting system for ASCs as soon as possible**. As we have stated previously, providers that perform the same services should be held to the same accountability standards with respect to

the quality of the care they deliver and that patients deserve the same transparency about the quality of care from all facilities where they may seek a particular service.

Proposed Revision to Terms of Agreements for Hospital-operated ASCs. ASCs operated by hospitals, like other ASCs, must meet the applicable conditions for coverage and enter into an agreement with CMS in which the agency accepts the ASC as qualified to furnish ambulatory surgical services. In addition, there are other terms of agreement for an ASC operated by a hospital. In an effort to reduce hospital administrative burden, CMS proposes to remove language from the regulations that currently requires a hospital-operated ASC to satisfy CMS that there is "good cause" for its request to become a provider-based department of a hospital prior to being recognized as such.

NEXT STEPS

The AHA encourages members to submit comments to CMS outlining how the agency's proposals will affect their facilities. Watch for more information from the AHA that may assist you in preparing your organization's comment letter.

Comments are due to CMS by August 31 and may be submitted electronically at: http://www.regulations.gov. Follow the instructions for "Comment or Submission." Attachments can be in Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word.

CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

Via regular mail
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1414-P
P.O. Box 8013
Baltimore, MD 21244-1850

Via overnight or express mail
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1414-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244