American Hospital Association

Regulatory Advisory

July 21, 2011

Medicare Outpatient PPS and ASC Proposed Rule for CY 2012

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) 2012. In addition to updating OPPS and ASC payment weights and rates, the proposed rule includes the implementation of an ASC quality reporting program, inpatient value-based purchasing (VBP) changes, quality reporting through electronic health records (EHRs) and physician self-referral rule changes. Major OPPS proposals include:

- A mandated 1.3 percentage point reduction to the CY 2012 market basket update of 2.8 percent, resulting in an adjusted market basket update of 1.5 percent.
- No enforcement in CY 2012 of the direct supervision policy for outpatient therapeutic services provided in critical access hospitals (CAHs) and in small rural PPS hospitals with 100 or fewer beds.
- Using an existing federal outpatient advisory committee as an independent review body to evaluate individual outpatient therapeutic services for potential changes in supervision level.
- The addition of nine new quality measures for 2014 and one in 2015.
- A voluntary Electronic Reporting Pilot in 2012 to test automated reporting from the EHR for the quality measures required under the EHR incentive program.
- A payment adjustment for 11 cancer hospitals.
- Significant payment reductions for hospital-based partial hospitalization program services.

Comments on the OPPS and ASC proposed rule are due to CMS by August 30. The final rule, expected in November, takes effect January 1, 2012.

Our Take:

The AHA appreciates the steps that CMS has taken over the last several years to address some hospital issues and concerns around its direct supervision policy, particularly the extended delay in enforcement of direct supervision requirements in CAHs and small rural PPS hospitals. We continue to believe that there are many procedures that can be, and are, safely furnished in hospital outpatient departments under the general supervision of a physician. Therefore, we are encouraged by the proposed implementation of an independent review process that will be used to consider and revise supervision levels for certain outpatient therapeutic services. However, we are concerned that the proposal will not fairly represent the interests of small rural PPS hospitals, could result in more burdensome supervision requirements for services without justification, and does not allow for formal public notice and comment on CMS' decisions. In addition, the AHA continues to disagree with CMS' repeated assertion that it has required direct supervision of outpatient therapeutic services since 2001. We will continue to advocate for changes to meet the needs of hospitals and their patients.

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. A 115-page summary also is available.
- ✓ Model the impact of the APC changes on your expected 2012 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2011-2012 are available on the AHA's Outpatient PPS Web page under "Resources." Please note: AHA members must be logged on to the website to access the spreadsheets.

Further Questions:

Please contact Roslyne Schulman at rschulman@aha.org for OPPS issues; Lisa Grabert at lgrabert@aha.org for quality reporting issues; Joanna Kim at jkim@aha.org for VBP issues; Ellen Pryga at epryga@aha.org for self-referral issues.

AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. A 25-page, in-depth examination of this issue follows.

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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) 2012. In addition to the regular updating of the OPPS and ASC payment weights, rates and policies, this year's proposed rule also proposes changes to the regulations governing the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs and the inpatient prospective payment system (IPPS) hospital value-based purchasing (VBP) program. The rule also would establish a quality reporting program for ASCs and establishes criteria and a process to obtain an exception to the ban on growth by grandfathered hospitals under the physician self-referral prohibition. CMS projects that total payment for services furnished in hospital outpatient departments will be approximately $41.9 billion in CY 2012.

The rule, published in the July 18 *Federal Register*, is available at: http://www.ofr.gov/OFRUpload/OFRData/2011-16949_PI.pdf. A final rule will be released in November, which will take effect January 1, 2012. Comments on the provisions of the OPPS and ASC proposed rule are due to CMS by August 30.

This *Regulatory Advisory* highlights many of the rule's proposals. In addition, the AHA offers members a more detailed summary, prepared by Health Policy Alternatives. This members-only resource is available at http://www.aha.org/aha/issues/Medicare/OPPS/resources.html.

AT ISSUE

PROPOSED CHANGES TO THE 2012 OPPS

PPS UPDATE AND LINKAGE TO HOSPITAL QUALITY DATA REPORTING

Outpatient PPS Update. The proposed rule includes a *Patient Protection and Affordable Care Act* (ACA)-required productivity reduction of 1.2 percentage points and an additional reduction of 0.1 percentage point to the CY 2012 market basket update of 2.8 percent. This results in a proposed market basket update of 1.5 percent for those hospitals that publicly report data on 15 quality measures. The 2012 update for hospitals that do not meet quality reporting requirements would be -0.5 percent.

CMS proposes a CY 2012 OPPS conversion factor for hospitals meeting quality data reporting requirements of $69.420. To calculate the new amount, CMS increased the CY 2011 conversion factor of $68.876 by the adjusted hospital market basket update of 1.5 percent, as required by law. To ensure budget neutrality, CMS made adjustments to account for changes in the wage index, the cancer hospital adjustment and pass-through spending. Hospitals that do not report the quality data will receive a reduced conversion factor of $68.052.

CMS estimates that the market basket update and other policies in the proposed rule will result in the following per-case change in payment:

All Hospitals	**1.1%**
Urban Hospitals	1.2%
Large Urban	1.1%
Other Urban	1.2%
Rural	0.9%
Sole Community	0.9%
Other Rural	0.9%
Exempt Cancer Hospitals[1]	37.8%

Hospital Outpatient Quality Reporting Program. *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.

CMS proposes to add 10 new quality measures to the Hospital Outpatient Quality Reporting (OQR) program. Nine of these new measures would be required for CY 2014 payment determination, bringing the total number of measures required to be reported for a full payment update in that year to 32. One additional measure would be required for CY 2015 payment determination, bringing the total number of measures required to be reported for a full payment update in that year to 33. A table of all 10 proposed new measures, reporting periods and due dates is included below.

Proposed Measures for CY 2014 Payment Determination. Among the nine measures proposed for CY 2014 payment determination, one would be submitted using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), six measures would be submitted quarterly through medical record abstraction and two measures would be reported annually through a web portal available on CMS's QualityNet website.

Hospital Outpatient Quality Reporting Program Proposed New Measures		
Measure	**Reporting Period**	**Reporting Due Date**
Calendar Year 2014		
Surgical Site Infection	Jan 1 – Mar 31, 2013	Aug 1, 2013
	Apr 1 – Jun 30, 2013	Nov 1, 2013
Hemoglobin A1c Management	Jan 1 – Mar 31, 2013	TBD
Diabetes: Low Density Lipoprotein Cholesterol < 130 and Lipid Management < 100		
Diabetes: Blood Pressure Management		
Diabetes: Eye Exam	Apr 1 – Jun 30, 2013	
Diabetes: Urine Protein Screening		
Cardiac Rehabilitation Patient Referral From an		

[1] This estimate reflects the impact of the cancer hospital adjustment on APC payments only. However, after accounting for the hold harmless TOPs payments that CMS estimates cancer hospitals would no longer receive, the proposed net increase in payment to cancer hospitals would be about nine percent.

Outpatient Setting		
Safe Surgery Checklist	Jan 1 – Dec 31, 2012	July 1 – Aug 31, 2013
Hospital Outpatient Volume for Selected Outpatient Surgical Procedures • Cardiovascular • Eye • Gastrointestinal • Genitourinary • Musculoskeletal • Nervous System • Respiratory • Skin		
Calendar Year 2015		
Influenza Vaccination Coverage among Healthcare Personnel	Oct 1, 2013 – Mar 31, 2014	TBD

Surgical Site Infection
Hospital outpatient departments would be required to submit a surgical site infection measure to NHSN for performance beginning January 1, 2013. This measure assesses the percentage of surgical site infections occurring within 30 days after a specified procedure if no implant is left in place or within one year if an implant is in place. The regulation did not specify which procedures this measure would apply to, however we understand that CDC is currently targeting colon surgery and abdominal hysterectomies. This measure is endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA).

Diabetes Measures
CMS is proposing five diabetes measures that would be submitted from medical record abstraction for performance beginning January 1, 2013. Four of the five measures pertain to patients with a diagnosis of diabetes for ages 18-75 years. The first measure addresses management of hemoglobin Alc levels with the most recent level greater than 9 percent. CMS also proposed a paired measure of lipid management for patients with low density lipoprotein cholesterol (LDL-C) greater than 130 and a LDL-C greater than 100. There are proposals for two process measures for the percentage of patients who received an eye exam during the reporting year or during the prior year if the patient is low risk for retinopathy and the percentage of patients who received a urine protein screening with at least one test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy. The final measure proposed applies to patients 18-years and older with a diagnosis of hypertension for the percentage of patient visits with blood pressure measurement recorded. These five measures are NQF-endorsed.

Cardiac Rehabilitation Referrals from Outpatient Settings
CMS is proposing one cardiovascular disease measure that would be submitted from medical record abstraction for performance beginning January 1, 2013. This measure calculates the percentage of patients evaluated in an outpatient setting who in the previous 12 months experienced any of the following:

- Acute myocardial infarction;
- Chronic stable angina;

- Coronary artery bypass graft (CABG) surgery;
- Percutaneous coronary intervention (PCI);
- Cardiac valve surgery (CVS); or
- Cardiac transplantation who have not already participated in an early outpatient cardiac rehabilitation/secondary prevention program for the qualifying event and who are referred to early outpatient cardiac rehabilitation/secondary prevention program unless there is a documented medical or patient oriented reason why a referral was not made.

While this measure is NQF-endorsed, it is not HQA-adopted.

Safe Surgical Checklist
CMS proposes this "structural" measure to identify whether a hospital outpatient department utilizes a safe surgery checklist to assess effective communication and safe practices performed during three distinct perioperative periods:

1. Prior to the administration of anesthesia;
2. Prior to skin incision; and
3. Closure of incision and prior to the patient leaving the operating room.

CMS also includes an example chart of safe surgery practices that may be performed during these perioperative periods:

First critical point (period prior to administering anesthesia)	Second critical point (period prior to skin incision)	Third critical point (period of closure of incision and prior to patient leaving the operating room)
• Verbal confirmation of patient identity • Mark surgical site • Check anesthesia machine/medication • Assessment of allergies, airway and aspiration risk	• Confirm surgical team members and roles • Confirm patient identity, procedure, and surgical incision site • Administration of antibiotic prophylaxis within 60 minutes before incision • Communication among surgical team members of anticipated critical events • Display of essential imaging as appropriate	• Confirm the procedure • Complete count of surgical instruments and accessories • Identify key patient concerns for recovery and management of the patient

This measure is proposed to be reported on the Quality Net website from July 1 – Aug 31, 2013 for performance from January 1 – December 31, 2012. This measure is neither NQF-endorsed nor HQA-adopted.

Volume of Outpatient Surgical Procedures for Performance in CY 2012
Similar to the surgical checklist, CMS proposes volume of surgical procedures as a structural measure to be collected over the same timeframe as the surgical checklist measure. CMS states that there is substantial evidence that volume of surgical procedures is related to better outcomes. Further, CMS purports that most hospital outpatient procedures fall into one of eight categories: cardiovascular, eye,

gastrointestinal, genitourinary, musculoskeletal, nervous system, respiratory and skin. CMS is therefore proposing to collect volume data on procedures for these eight categories.

Proposed Measures for CY 2015 Payment Determination. CMS proposes one measure for CY 2015 payment determination on influenza vaccination of healthcare personnel. Data for this measure would be submitted to NHSN for performance from October 1, 2013 through March 31, 2014. The measure assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. This measure is NQF-endorsed; however it is not HQA-adopted.

SUPERVISION OF HOSPITAL OUTPATIENT THERAPEUTIC SERVICES

Background. In the CY 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 the change as a "restatement and clarification" of existing policy in place since CY 2001. In its attempt at clarification, CMS retroactively interpreted the policy to require that a physician privileged by the hospital provide supervision and be physically present in the same 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.

Through multiple letters and meetings, the AHA and other national hospital and physician organizations demonstrated that CMS's "clarification" is instead a significant change in Medicare policy that would place considerable burden on hospitals. In response to our efforts, the final rule for CY 2010 added a marginal level of additional flexibility to its policy for CY 2010. However, the AHA continued to disagree with CMS's repeated assertion that the agency was merely restating and clarifying its existing direct supervision policy dating back to CY 2000 and the application of this policy to outpatient therapeutic services furnished in CYs 2001 through CY 2009.

For CY 2010, CMS revised the regulations to permit certain non-physician practitioners (NPPs) to provide direct supervision for outpatient therapeutic services. In addition, for outpatient services *furnished on a hospital's or CAH's main campus*, starting in CY 2010, CMS modified its proposed definition of "direct supervision" to allow the supervising professional to be *anywhere* on the hospital campus, including a physician's office, an on-campus skilled nursing facility, rural health clinic, or other non-hospital space, as long as they were "immediately available" to redirect patient care if it became necessary. While these changes provided some marginal assistance for hospitals struggling to comply, hospitals remained concerned about physician and NPP shortages, particularly in rural areas and were confused about certain inconsistencies and ambiguities regarding CMS policy.

In CY 2010, increasing concern voiced by CAHs on the impact of the direct supervision requirements on access to services in rural communities, led CMS to issue a temporary delay in enforcement of the direct supervision regulations for outpatient therapeutic services furnished in CAHs during CY 2010.

For CY 2011, CMS extended the enforcement delay for CAHs through CY 2011 and expanded it to include small rural PPS hospitals with 100 or fewer beds. CMS also revised the definition of "direct supervision" to remove all references to the physical boundaries within which the supervising physician or NPP must be located, but retained the requirement that they be "immediately available to furnish assistance and direction throughout the performance of the procedure." Further, CMS identified a set of 16 "nonsurgical extended duration therapeutic services," including observation services, various intravenous and subcutaneous infusions and various therapeutic, prophylactic or diagnostic injections, which require direct supervision only for the initiation of the service, followed by general supervision for the remainder of the service.

Finally, in the CY 2011 final rule, largely consistent with recommendations from the AHA and others, the agency noted its intention to propose in the CY 2012 rule the establishment of an independent review process that would allow for an assessment of the appropriate supervision levels for individual hospital outpatient therapeutic services. In comments to CMS, the AHA stated disagreement with the agency's intention to allow the process to assign a level of supervision to individual services higher than direct supervision (i.e., personal supervision) in the absence of clinical evidence and documentation that demonstrates that there is a need for personal supervision. Further, we expressed concern about CMS's proposal to use the federal Advisory Panel on APC Groups (APC Panel) as the independent technical committee that would review requests for revised levels of supervision, stating that the Panel membership lacks representatives from rural hospitals or CAHs. Finally, we urged CMS to subject the recommendations of the independent technical committee to a public notice-and-comment rulemaking process prior to making final decisions about the level of supervision for individual services.

Proposed CY 2012 Supervision Policy for Outpatient Therapeutic Services. CMS proposes a number of changes consistent with its stated intentions described in the CY 2011 OPPS final rule.

Selection of a Review Body. CMS proposes to establish the APC Panel as an independent review body that would evaluate individual services for potential re-assignment by CMS to lower (general supervision) or higher (personal supervision) levels of supervision. CMS would amend the APC Panel charter to reflect this new role, including adding two to four new CAH representatives as Panel members. The agency would create a supervision subcommittee on the APC Panel that is charged to evaluate appropriate supervision standards for individual services and present its deliberations to the full Panel. Each member of the full Panel would then vote to determine the Panel's recommendations to CMS.

Review Process. CMS proposes to diverge from its standard practice with regard to how the agency makes decisions based on APC Panel recommendations. That is, CMS proposes not to subject its decisions on Panel recommendations regarding supervision levels to formal public notice-and-comment rulemaking. Rather, CMS would use a sub-regulatory process in which its decisions would be posted on the OPPS website for informal public review and comment, and decisions would be effective either in July or January following the most recent APC Panel meeting. CMS

notes that this process is similar to the way in which it sets supervision levels for diagnostic services under the Medicare physician fee schedule (PFS).

Evaluation Criteria. Requests for the Panel to revise the supervision level for specific services would be submitted through a standard APC Panel process and CMS could also independently request review of specific services. If CMS receives an unmanageable number of requests, the agency proposes to prioritize requests by service volume, total expenditures and/or frequency of requests. CMS also will prioritize services requested for review through public comment on the CY 2010 and 2011 OPPS proposed rules. CMS would require that requests include justification for the change in supervision level that is sought, supported, to the extent possible, with clinical evidence.

CMS proposes to charge the APC Panel with recommending a supervision level – general, direct or personal – to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a CPT code. The Panel would be instructed to consider the clinical, payment and quality context of a patient encounter as well as the likelihood that a patient's care would need to be reassessed or modified by a supervisory practitioner during the therapeutic intervention or whether guidance or advice to the hospital staff furnishing the services would be needed. In addressing these issues, the Panel would be directed to consider the service's complexity, the acuity of patients receiving the services, the probability of an unexpected or adverse patient event occurring and the expectation of rapid clinical changes during the service or procedure.

In the event there has been a previous consideration and decision on the supervision level for a service, CMS would consider the request and, as warranted, forward the request to the APC Panel for its review. For such requests, CMS proposes to require the requestor to submit new evidence to support a change in policy, for example, evidence of a change in clinical practice patterns due to new techniques or new technology. If sufficient new information was provided with the request, CMS would send the request to the APC Panel, and the Panel would reconsider the service and make another recommendation to CMS.

Further Delay of Enforcement for CAHs and Small Rural Hospitals. CMS estimates that policy decisions on many key services would not be completed until sometime in 2012. In the interim period, **the agency proposes to extend for an additional year – through CY 2012 – its decision not to enforce the direct supervision policy for outpatient therapeutic services provided in CAHs and small rural hospitals with 100 or fewer beds.** CMS notes that this extension is intended to allow these hospitals time to meet the direct supervision standard while the agency continues its deliberation on policy alternatives.

Conditions of Payment for Hospital Outpatient Therapeutic Services Described by Different Benefit Categories. CMS proposes to revise the regulations to clarify that therapeutic services and supplies that are covered by Medicare through a *Social Security Act* statutory benefit category other than "incident to" services are nevertheless subject to the supervision and other regulatory requirements under 42 CFR 410.27 when they are furnished to hospital outpatients and paid under the OPPS or in CAHs.

This is intended to answer questions that have been raised regarding whether hospitals are required to comply with supervision requirements when they furnish services, such as radiation therapy, that have a separate statutory benefit category.

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 CY 2010. 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). CMS uses 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 determines 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 compares aggregate payment weights using the CY 2011 scaled relative weights to the estimated aggregate weights using the 2012 proposed unscaled relative weights. Based on the lower expected payments in this comparison, the final rule *increases* the CY 2012 APC weights by a factor of 1.4647 (an increase of 46.47 percent). Similar to the adjustment made to the CY 2011 weights, this is a much larger adjustment than had been made in prior years. This is because the median cost of APC 0606, $105.34, 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's changes to the APC payment weights for CY 2012 continue to show significant volatility. For 25 APCs, the proposed CY 2012 weights decrease by 10 percent or more, resulting in decreased payments. For eight of these, the reduction is greater than 20 percent and for two APCs the reduction exceeds 30 percent. In total, weights are lower for 183 APCs. Payment weights increase for 189 APCs, going up at least 10 percent for 20 of them; six APCs rise by at least 20 percent, and three APCs increase more than 30 percent. These comparisons are based on 413 APCs and do not include drugs, biologicals and radiopharmaceuticals, brachytherapy sources, blood/blood products or new technology APCs. No comparison could be made for five APCs because they are new or lacked values for CY 2012.

PACKAGING AND BUNDLING CHANGES

In order to moderate growth in volume and spending in the OPPS, CMS in CY 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. Over the same years, CMS also finalized 10 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. For CY 2012, CMS

continues these established packaging and composite APC policies, but updates the payment rates using more recent OPPS claims data.

Proposed Composite APC for Cardiac Resynchronization Therapy with Defibrillator. CMS proposes to create a new composite APC 8009, Cardiac Resynchronization Therapy with Defibrillator Composite (CRT-D). CRT-D uses a pacing electrode implanted in combination with an implantable cardioverter defibrillator.

CMS proposes a significant policy precedent in the proposed rule by proposing to use its "equitable adjustment authority" outlined in the *Social Security Act* to cap the payment rate for composite APC 8009 at the most comparable *inpatient* Medicare-severity diagnosis-related group (MS-DRG) payment rate that would be provided to acute care hospitals for providing CRT-D services to hospital inpatients. Specifically, the agency proposes to pay for the new composite APC at the lesser of the APC's median cost or the IPPS payment rate for MS-DRG 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without Major Complication or Comorbidity). Because the APC's median cost, estimated by CMS at $38,854, is higher than the MS-DRG rate, CMS proposes to establish the rate for composite APC 8009 at the median MS-DRG rate of $26,364.93. Unlike other inpatient payments, CMSs' proposed payment rate does not include adjustments for capital costs, indirect medical education or disproportionate share.

WAGE INDEX CHANGES FOR 2012

The OPPS uses the wage indices contained in the fiscal year (FY) 2012 IPPS proposed rule, published in the May 5 *Federal Register*. As in prior years, 60 percent of the APC payment is adjusted by the wage index.

Wage Index Floor. CMS raises concerns about hospital actions involving the IPPS wage index rural floor that have resulted in significant wage index disparities. CMS notes that the law does not require it to use the IPPS wage indexes in the outpatient OPPS, and as such, is considering using a modified version of the IPPS wage indexes instead, which would address its concerns about the rural floor. Therefore, CMS requests public comment on whether to:

- adopt the IPPS wage index for the OPPS in its entirety including the rural floor, geographic reclassifications and all other wage index adjustments;
- adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the State;
- adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each State instead of nationally; or
- adopt another decision rule for when the rural floor should not be applied in the OPPS when CMS has concerns about disproportionate impact.

In addition, CMS also seeks public comment on an option being considered for both the IPPS and the OPPS, where the applicable rural wage index floor would be determined using only data from those hospitals geographically rural under Office of Management and Budget and the U.S. Census Bureau's Metropolitan Statistical Area designations, and without including wage data associated with hospitals reclassified from urban to rural status. CMS believes that such a policy would eliminate the incentive to reclassify

from urban to rural status primarily to increase rural floors across a State, and would ensure that the rural floor is based upon hospitals geographically located in rural areas.

OUTLIER PAYMENTS

Outlier Thresholds. Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For CY 2012, CMS proposes to set the projected target for outlier payments at 1 percent of total OPPS payments – the same as CY 2011. CMS again proposes to establish separate thresholds for community mental health centers (CMHCs) and hospitals. Therefore, 0.14 percent of the 1 percent projected target is proposed to be allocated to CMHCs for partial hospitalization program (PHP) services.

The rule continues to include both a fixed-dollar outlier threshold and a percentage threshold, but in CY 2012 CMS proposes to increase the fixed-dollar threshold for outliers to $2,100, which is $75 more than in CY 2011, to ensure that outlier spending does not exceed the reduced outlier target.

Thus, to be eligible for an outlier payment in CY 2012, the cost of a hospital outpatient service would have to exceed 1.75 times the APC payment amount (the percentage threshold), ***and*** it would have to be at least $2,100 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare would 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.

TRANSITIONAL CORRIDOR "HOLD-HARMLESS" PAYMENTS

As required by the *Medicare and Medicaid Extenders Act of 2010*, CMS proposes to end the transitional outpatient payments (TOPs), also known as the "hold-harmless" payments, for rural hospitals with 100 or fewer beds and for sole community hospitals (SCHs) as of December 31. Thus, in the absence of an extension of this policy in law, no hold-harmless payments are expected to be made for these hospitals in CY 2012. As part of its advocacy agenda, the AHA continues to press Congress to extend the outpatient hold-harmless policy and a number of other measures of importance to rural and other hospitals that are set to expire at the end of this year.

RURAL ADJUSTMENT FOR SOLE COMMUNITY HOSPITAL

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 is budget neutral to the OPPS and applied before calculating outliers and coinsurance.

CANCER HOSPITAL ADJUSTMENT

CMS proposes increasing payments for the 11 "exempt" cancer hospitals based upon updated data from a study mandated by the ACA and conducted by CMS, which concluded that these hospitals have significantly higher outpatient costs than other hospitals paid under the OPPS. The ACA requires CMS to make an "appropriate adjustment" to reflect these higher costs. Specifically, CMS proposes to increase each of the cancer hospitals' OPPS payments by the percentage difference between their

individual payment-to-cost ratio (PCR) and the weighted average PCR of the other hospitals paid under the OPPS (0.901). This hospital-specific payment adjustment would be applied to most OPPS-covered items and services. This adjustment would increase base OPPS payments to cancer hospitals by an average of 39 percent for CY 2012, and reduce OPPS payments to all other hospitals by 0.6 percent to maintain budget neutrality. However, since "hold harmless" payments for cancer hospitals are calculated annually based on the difference between aggregate OPPS payments – which will now include the cancer adjustment amount – and the payment they would have received before implementation of the OPPS, CMS predicts that no cancer hospitals will continue to qualify for hold-harmless payments. Therefore, CMS estimates that although the gross increase in OPPS payments for cancer hospitals is 39 percent, their *net increase* in payments, taking into consideration the absence of hold-harmless payments, would be 9 percent.

In CY 2011, CMS had proposed but did not finalize a similar payment adjustment for cancer hospitals based on concerns raised by the AHA and others regarding flaws in CMS's methodology and interpretation of the statute. CMS has issued the same proposal for CY 2012 because no changes were made to the ACA requirements since CY 2011.

TRANSITIONAL PASS-THROUGH PAYMENTS

Congress created temporary additional, or "transitional pass-through payments," for certain innovative medical devices, drugs and biologicals to ensure that Medicare beneficiaries have access to new technologies in outpatient care. For CY 2012, CMS projects that pass-through payments will be 0.15 percent of total OPPS payments, or $64.5 million, which includes $45 million in pass-through payments for devices and $19.5 million for drugs and biologicals.

Changes to the transitional pass-through pool must be budget neutral and, as a result, CMS usually proposes to adjust the conversion factor by the differences in projected pass-through spending to reflect differences in consecutive years. However, because CMS estimates that pass-through payments will be 0.15 percent of total projected OPPS spending for both CY 2011 and CY 2012, the agency does not propose any change in the CY 2012 conversion factor for pass-through spending.

CODING AND PAYMENT FOR CLINIC AND ED VISIT SERVICES

In its analysis of CY 2010 data, CMS continues to observe a normal and relatively stable distribution of clinic and emergency department (ED) visit levels in hospital claims compared to CY 2009 data. CMS continues to encourage hospitals to report visits according to their own internal hospital guidelines. However, for Type A ED visits, the agency has noted a slight shift over time toward higher numbers of level 4 and level 5 visits relative to the lower level visits. Also, CMS observes that, in aggregate, hospitals' charges for these higher-level ED visits are trending upward in recent years. As a result, the agency restates its expectation that hospitals not purposely change their visit guidelines or otherwise increase the level of coding of clinic and ED visits for purposes of meeting the criteria for payment of the extended assessment and management composite APC.

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

The proposed payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status in the proposed rule are based on April 2011 ASP data. Updates to the ASP-based rates will be published quarterly and posted on CMS website through CY 2012.

***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 CY 2012, CMS proposes to raise by $10 its packaging threshold for drugs, biological and radiopharmaceuticals, to $80 per day. Therefore, drugs costing less than $80 would have their cost packaged in the procedure with which they are billed, such as a drug administration procedure. Drugs costing more than $80 would be paid separately through their own APC.

There are a few exceptions to this packaging policy. Consistent with CMS current packaging policy, the agency proposes that the costs of all contrast agents and non-pass-through diagnostic radiopharmaceuticals are packaged into the procedures with which they are billed.

Payment for Specified Covered Outpatient Drugs. CMS is required by law to use special classification and payment for certain separately paid drugs and biologicals that previously (before December 31, 2002) received pass-through payments. In CY 2012, 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 and biologicals.

For CY 2012, CMS proposes to pay for the drug acquisition and pharmacy overhead costs of separately payable drugs and biologicals at a combined rate of average sales price (ASP) plus 4 percent. This rate is lower than the ASP plus 5 percent rate paid for drugs in CY 2011.

CMS calculated this CY 2012 payment rate using a revised methodology finalized in the CY 2010 final OPPS rule. First, the agency applies its standard drug payment methodology, using hospital claims data and cost reports to estimate the cost of separately payable drugs and biologicals, which resulted in a payment rate of ASP minus 2 percent. The agency notes that payment at ASP minus 2 percent understates the cost of separately payable drugs and biologicals and their related pharmacy overhead. Therefore, CMS made a payment adjustment that redistributes pharmacy overhead costs, in the amount of $215 million, from packaged coded and uncoded drugs and biologicals to separately payable drugs and biologicals. This amount includes an inflation allowance (calculated using the Producer Price Index for Pharmaceuticals for Human Use) to account for inflation and changes in the prices of pharmaceuticals in the overall economy since CY 2011. The $215 million consists of

$161 million (approximately 35 percent of their pharmacy overhead cost) from the coded packaged drug cost and $54 million from the uncoded packaged drug and biological cost (about 11 percent of their pharmacy overhead cost). This boosts the proposed payment rate for separately payable drugs and biologicals to ASP plus 4 percent.

In explaining its decision to continue to redistribute $161 million of the pharmacy overhead from packaged drugs with an ASP to separately payable drugs, CMS describes analyses it conducted that support its assumption that between one-third and one-half of the $544 million in pharmacy overhead cost currently associated with coded packaged drugs and biologicals is misapplied, as a function of both charge compression and the agency's choice of an annual drug packaging threshold. In addition, in redistributing $54 million, or 11 percent of the total cost of uncoded packaged drugs and biologicals, CMS makes the conservative assumption that whatever pharmacy overhead cost is not accurately associated with uncoded packaged drugs, it would not be less than 8 percent of total uncoded drug costs. Based on these analyses, CMS claims its payment methodology offers a more appropriate allocation of pharmacy overhead cost to separately payable drugs and biologicals.

CMS further proposes to continue to include the claims data for 340B hospitals (a program that allows safety net hospitals to purchase certain outpatient drugs at a discount) in the calculation of payment for drugs and biologicals under the CY 2012 OPPS and that 340B hospitals would be paid the same amounts as hospitals that do not participate in the 340B program for separately payable drugs and biologicals.

While CMS determines annually whether each outpatient drug will be paid separately or packaged for the entire calendar year, the agency proposes to continue to 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 will be posted on the CMS website.

PARTIAL HOSPITALIZATION PROGRAM

Background. In CY 2011, CMS finalized a significant payment policy change for PHP services. The agency established a policy in which it would calculate four separate PHP APCs per diem payment rates – two for CMHC PHPs and two for hospital-based PHPs – based on each provider's own unique cost data. CMS stated that creating the four payment rates would support continued access to the PHP benefit, including a more intensive level of care furnished in hospital-based PHPs, while also providing appropriate payment based on the unique cost structures of CMHC PHPs and hospital-based PHPs.

Further, consistent with recommendation from the AHA, CMS agreed to mitigate the rate reduction for CMHCs by instituting a two-year transition to rates based solely on CMHC data. For CY 2011, CMS calculated a blended payment rate for CMHC PHP APCs services using both hospital and CMHC data.

Proposed PHP Payment for CY 2012. CMS proposes to continue to use four separate APCs to pay for Medicare services, including two APCs for services furnished in CMHC, and two APCs for services furnished in hospital-based PHPs. Payments for hospital-

based PHP services would be calculated using only hospital data. Concluding the two-year transition described above for CMHC payments, CMS proposes to calculate payments for CMHC PHP services using only CMHC claims data.

CMS proposed payment rates for both hospital-based and CMHC PHP services would decline significantly. The proposed rates for CMHC Level I and Level II services would decline 27 and 33 percent, respectively. The proposed CY 2012 payment rates for hospital-based PHP services would decline 23 percent for both Level I and Level II services. The proposed rates for hospital-based PHP services are:

- APC 0175, Level I Partial Hospitalization (three services) for Hospital-Based PHPs paid at $156.69 (compared to the 2011 rate of $204.89); and
- APC 0176, Level II Partial Hospitalization (four or more services) for Hospital-Based PHPs paid at $183.27 (compared to the 2011 rate of $238.33).

CMS attributes the CMHC decline to targeted fraud and abuse efforts implemented by various federal agencies. By contrast, CMS says the decrease in the hospital-based payment rate is the result of one provider with higher cost data no longer billing Medicare for PHP services. The AHA will work with CMS to better understand what is causing such onerous payment reductions and will urge CMS not to finalize these rates.

COMPUTED TOMOGRAPHY (CT) OF ABDOMEN AND PELVIS

In our comments to CMS for its CY 2011 OPPS final rule, the AHA expressed concern about the way in which CMS had decided to handle payment for three new CPT codes that are combination codes describing CT of the abdomen and pelvis:

- CPT 74176 (CT, Abdomen and Pelvis; Without Contrast Material);
- Cpt 74177 (CT, Abdomen and Pelvis; With Contrast Material(s)); and,
- Cpt 74178 (CT, Abdomen and Pelvis; Without Contrast Material In One or Both Body Regions, Followed by Contrast Material(s) and Further Sections in One or Both Body Regions).

CMS had assigned the new combination service codes to APC groups that describe *single* services. The AHA cautioned that, unless corrected, this decision would result in a significant underpayment for hospital CT services. We urged CMS instead to establish two new APCs into which CPT codes 74176, 74177 and 74178 would be placed, depending on whether or not contrast is used in the performance of the service and that the payment should account for two services not one. While CMS declined to correct the payment rate for CY 2011, the agency did promise to reconsider for CY 2012.

In the CY 2012 proposed rule, CMS agrees that accurate and appropriate payment rates for these services should be based on historic claims data for the combinations of predecessor codes, because it would take into account the full cost of both services that are now reported by a single CPT code. CMS proposes to establish two new APCs:

- APC 0331 (Combined Abdominal and Pelvis CT Without Contrast), to which CMS proposes to assign CPT code 74176 and for which the CY 2012 OPPS payment rate would be based on a median cost of approximately $417.

- APC 0334 (Combined Abdominal and Pelvis CT With Contrast), to which CMS proposes to assign CPT codes 74177 and 74178 and for which the CY 2012 payment rate would be based on a median cost of approximately $592.

BENEFICIARY COINSURANCE

CMS proposes to decrease beneficiary liability for coinsurance for outpatient services. As required by law, CMS maintains last year's maximum beneficiary coinsurance rate of 40 percent of the total payment to the hospital for that service. However, CMS estimates that the average copayments for all outpatient services would drop to 22.1 percent of total payments in CY 2012. 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.

OTHER UPDATES TO OPPS PAYMENT POLICY

CMS proposes to use its standard policy and methodology to update payments for medical devices without pass-through status, including payment for device-dependent APCs and payments for device-dependent procedures when devices are replaced with a full or partial credit. Similarly, CMS proposes to use its standard policy and methodology to update its CY 2012 payments for therapeutic radiopharmaceutical agents; brachytherapy sources; blood and blood products; and new drugs, biologicals and radiopharmaceuticals. In addition, CMS conducted its usual analysis of pass-through drugs and biologicals and pass-through devices; new technology APCs and inpatient-only procedures and proposes changes in the proposed rule.

A more detailed explanation and discussion of these and other OPPS provisions can be found in a 115-page summary, prepared by Health Policy Alternatives. This resource is available on the AHA's Outpatient PPS Web page under "Resources."

PROPOSED CHANGES FOR THE 2012 ASC PAYMENT SYSTEM

The proposed rule includes the annual review and 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. The proposed rule also implements the ACA requirement that the annual update under the ASC payment system be reduced by a productivity adjustment.

UPDATES AND CHANGES TO ASC PAYMENT POLICY

Updating the ASC Relative Payment Weights for CY 2012. CMS updates the ASC relative payment weights in the revised ASC payment system each year using the national OPPS relative payment weights (and PFS 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 CY 2012, CMS proposes to use an ASC scaler of 0.9373.

Updating the ASC Conversion Factor. For the 2012 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. For CY 2012, CMS proposes to apply a 1.0003 ASC wage index budget neutrality adjustment to calculate the 2012 ASC conversion factor.

In addition, the ACA requires that effective in CY 2011, the annual inflation update under the ASC payment system (the Consumer Price Index for all Urban Consumers (CPI-U)) must be reduced by a productivity adjustment (defined as the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity), which CMS refers to as the "MFP adjustment." For CY 2012, CMS estimates the CPI-U to be 2.3 percent and the MFP adjustment to be 1.4 percentage points. Therefore, CMS proposes to apply to the ASC conversion factor a 0.9 percent MFP-adjusted update. This update, together with the wage adjustment for budget neutrality discussed above, results in a proposed CY 2012 ASC conversion factor of $42.329. By contrast, the proposed CY 2012 OPPS conversion factor is $69.420.

ASC-covered Surgical Procedure Payment Rate Update. CMS proposes to update ASC payment rates for CY 2012 using the established rate calculation methodology for ASC-covered surgical procedures. CMS also proposes to update the payment amounts for office-based procedures at the lesser of the proposed CY 2012 PFS non-facility practice expense amount or the CY 2012 ASC payment amount calculated according to the standard methodology.

ASC-covered Surgical Procedures. CMS does not propose to add any procedures to the list of ASC-covered surgical procedures.

***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 PFS non-facility practice expense relative value unit amount or the amount calculated using the ASC standard rate-setting methodology for the procedure.

For CY 2012, CMS proposes to designate 10 procedures as "office-based" procedures (see Table 45 of the proposed rule). In addition, CMS proposes to remove the office-based designation of 15 surgical procedures that have temporary office-based designations in CY 2011 (see Table 46 of the proposed rule).

PROPOSED ASC QUALITY REPORTING PROGRAM

The Tax Relief and Health Care Act of 2006 authorizes CMS to implement a program under which ASCs must report data on the quality of care in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points.

For the first time, CMS proposes 11 quality measures to begin the ASC Quality Reporting Program. Eight measures would be required for CY 2014 payment determination. Among the eight measures proposed for CY 2014 payment determination, seven measures would be submitted as quality data codes along with

claims data submitted by ASCs. These seven measures would be submitted in a similar method to the one used in CMS Physician Quality Reporting System, from January 1 through December 31, 2012. The remaining measure, surgical site infection, would be submitted using the CDC's NHSN. ASCs would be required to submit a surgical site infection measure to NHSN beginning January 1, 2013.

CMS proposes two quality measures for CY 2015 payment determination, including a safe surgical checklist and volume of ASC surgical procedures for: gastrointestinal, eye, nervous system, musculoskeletal, skin and genitourinary. These measures would be reported through a web-based portal for performance in CY 2012.

Finally, CMS proposes one measure for CY 2016 payment determination on influenza vaccination of health care personnel. Data for this measure would be submitted to NHSN for October 1, 2013 through March 31, 2014. A table of all 11 measures, reporting periods and due dates is included below.

Ambulatory Surgical Center Quality Reporting Program Proposed Measures		
Measure	**Reporting Period**	**Reporting Due Date**
Calendar Year 2014		
Patient Burn	Jan 1 – Dec 31, 2012	Ongoing claims data submission
Patient Fall		
Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant		
Hospital Transfer/Admission		
Prophylactic Intravenous Antibiotic Timing		
Ambulatory Surgery Patients with Appropriate Method of Hair Removal		
Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin		
Surgical Site Infection Rate	Jan 1 – Mar 31, 2013	Aug 1, 2013
	Apr 1 – Jun 30, 2013	Nov 1, 2013
Calendar Year 2015		
Safe Surgery Checklist	Jan 1 – Dec 31, 2012	July 1 – Aug 31, 2013
ASC Facility Volume Data for Selected ASC Surgical Procedures • Gastrointestinal • Eye • Nervous System • Musculoskeletal • Skin • Genitourinary		
Calendar Year 2016		
Influenza Vaccination Coverage among Healthcare Personnel	Oct 1, 2013 – Mar 31, 2014	TBD

OTHER CHANGES FOR CY 2012

PROPOSED CHANGES FOR HOSPITAL VALUE-BASED PURCHASING

The ACA requires the Secretary of Health and Human Services (HHS) to establish a VBP program to pay hospitals for their actual performance on quality measures, rather than just the reporting of those measures, beginning in FY 2013. See the AHA hospital VBP final rule *Regulatory Advisory* at www.aha.org/aha/advisory/2011/110524-regulatory-adv.pdf for more information on policies related to this program that have been finalized in previous rules.

Additional Measure for FY 2014. For FY 2013, the first year of the VBP program, CMS had previously finalized 12 measures for the clinical process domain. In this rule, it proposes to retain these 12 measures in the second year of the program, FY 2014, as well as add a 13th clinical process measure: Surgical Care Improvement Process (SCIP)-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2.

CMS will monitor all clinical process measures to ensure that they are not "topped-out." If it finds that certain measures are topped-out, the agency may choose not to finalize inclusion in the program. However, CMS notes that its topped-out policy will not apply to the hospital-acquired conditions, which it previously finalized for inclusion in the VBP program beginning in FY 2014.

Also, in the FY 2012 IPPS proposed rule, CMS proposed adding an efficiency measure of Medicare per-beneficiary spending to the VBP program beginning in FY 2014. See the AHA FY 2012 IPPS proposed rule *Regulatory Advisory* at http://www.aha.org/aha/advisory/2011/110503-regulatory-adv.pdf for more information on the proposed efficiency measure.

Hospitals Excluded from the Program. The ACA excludes from the VBP program hospitals with small numbers of applicable patient cases or measures, as defined by the Secretary. For the clinical process measures domain, CMS had previously finalized a policy to exclude from hospitals' scores any measures for which they report fewer than 10 cases. For FY 2013, the agency also will exclude from the VBP program any hospitals for which fewer than four of the 12 clinical process measures apply. For the patient experiences of care domain, CMS will exclude any hospital that reports fewer than 100 Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys during the performance period.

CMS had previously finalized that an outcomes domain would begin in FY 2014 and consist of three mortality measures, two Agency for Healthcare Research and Quality (AHRQ) patient-safety indicator measures, and eight hospital-acquired conditions, but it did not set minimums for these measures. In this rule, CMS proposes a hospital would need 10 cases to be eligible for a mortality measure and three cases to be eligible for a patient-safety indicator. In addition, CMS proposes that all hospitals that submit at least one Medicare claim during the performance period will be eligible for all hospital-acquired conditions except "Foreign Object Retained After Surgery." The agency notes that the Foreign Object hospital-acquired condition will not apply to all hospitals, but does not state how it will determine whether a hospital is eligible for this condition.

In addition, for FY 2014, the agency proposes to exclude from the VBP program any hospitals for which fewer than 10 of the 13 outcomes measures apply. These 10 measures would need to be comprised of at least seven of the eight hospital-acquired conditions and any other three outcomes measures.

Finally, CMS proposes to exclude from the VBP program any hospital that does not have enough cases and measures to receive scores on all finalized domains.

Baseline and Performance Periods for FY 2014. For FY 2014, for both the clinical process and HCAHPS measures, CMS proposes a nine-month baseline period of April 1, 2010 through December 31, 2010, and a nine-month performance period of April 1, 2012 through December 31, 2012. This nine-month performance period would allow CMS to notify hospitals of their final FY 2014 performance scores by the beginning of that fiscal year, as well as consider selecting CY 2013 as the performance period for the FY 2015 VBP program.

For the mortality measures that CMS will include in the VBP program beginning in FY 2014, the agency previously finalized a 12-month performance period of July 1, 2011 through June 30, 2012, with a baseline period of July 1, 2009 through June 30, 2010. For the AHRQ measures and the hospital-acquired conditions that CMS will include in the VBP program beginning in FY 2014, the agency proposes a nearly seven-month performance period of March 3, 2012 (one year after the date the agency contends these measures were first included on *Hospital Compare*, as is required by statute) through September 30, 2012. CMS proposes these dates because it states that, in order to be able to score these measures in time for use in the FY 2014 VBP program, the performance period would need to end by the fourth quarter of FY 2012. The agency proposes that the baseline period for these measures be exactly two years prior: March 3, 2010 through September 30, 2010.

The following tables illustrate all proposed and finalized baseline and performance periods for the FY 2013 and FY 2014 program years.

Table 1: FY 2013 Hospital VBP Program Baseline and Performance Periods

Domain	Baseline Period	Performance Period
Clinical Process	July 1, 2009 – Mar 31, 2010	July 1, 2011 – Mar 31, 2012
Patient Experience (HCAHPS)	July 1, 2009 – Mar 31, 2010	July 1, 2011 – Mar 31, 2012

Table 2: FY 2014 Hospital VBP Program Baseline and Performance Periods

Domain	Baseline Period	Performance Period
Clinical Process	April 1, 2010 – Dec 31, 2010*	April 1, 2012 – Dec 31, 2012*
Patient Experience (HCAHPS)	April 1, 2010 – Dec 31, 2010*	April 1, 2012 – Dec 31, 2012*
Efficiency**	May 15, 2010 – 90 days prior to Feb 14, 2011*	May 15, 2012 – Feb 14, 2013*

Outcomes • Mortality • Hospital-acquired conditions • AHRQ	• July 1, 2009 – June 30, 2010 • Mar 3, 2010 – Sept. 30, 2010* • Mar 3, 2010 – Sept. 30, 2010*	• July 1, 2011 – June 30, 2012 • Mar 3, 2012 – Sept. 30, 2012* • Mar 3, 2010 – Sept 30, 2012*

* Proposed dates
** Proposed domain

Determining Performance Standards. For FY 2014, CMS proposes to use the same methodology for determining the clinical process measure and HCAHPS performance standards as it will use for FY 2013. In addition, CMS had previously finalized using this methodology for the mortality measure standards. Specifically, CMS would establish a minimum "achievement threshold" that hospitals must meet to receive any points for achievement. The agency proposes that, for each measure, the achievement threshold would be the median score among all hospitals during the baseline period. CMS also proposes a "benchmark" score of the mean of the top decile of all hospitals' scores. All hospitals that meet or exceed the benchmark score during the performance period would receive maximum points for that measure.

CMS also proposes to use these methodologies to set the AHRQ and hospital-acquired condition achievement thresholds and benchmark scores. For the hospital-acquired conditions, the agency proposes to treat the individual conditions as a single aggregate condition for purposes of setting performance standards and scoring. A hospital's single aggregate score would be the equally-weighted average of the rates of all the hospital-acquired conditions for which the hospital is eligible. CMS also proposes to separately calculate and apply standards for hospitals that are eligible for seven of the eight conditions (because "Foreign Object Retained After Surgery" does not apply to them) and hospitals that are eligible for all eight of the conditions.

Calculating Hospital Scores. Once the performance standards are established each year, CMS will calculate hospitals' VBP scores on the individual measures. To calculate achievement scores for each measure, CMS previously finalized that it will assign a hospital points along a range between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the standard at which a hospital will receive the maximum number of points). To calculate improvement scores for each measure, CMS will assign a hospital points along a range between the hospital's score during the baseline period and the benchmark score. The final score for a measure will be the higher of achievement or improvement.

CMS also previously finalized that it will calculate a score for each domain by summing the individual measure scores within that domain, weighting each measure equally. The score for each domain will be based only on the measures that apply to that hospital. The hospital's total points for the domain will then be divided by that hospital's total points possible.

The agency proposes to use this same scoring methodology for the FY 2014 VBP program, with certain modifications for hospital-acquired condition scoring. Specifically, as noted above, it proposes to treat the individual hospital-acquired conditions as a single aggregate condition for purposes of setting performance standards and scoring. The aggregate condition rate would be used to assign points in accordance with the proposed performance standards discussed above and calculate the greater of the hospital's achievement and improvement scores. The hospital's final aggregate hospital-acquired condition score would be combined with the hospital's score on the other outcomes measures to derive the outcomes domain score, with the aggregate condition score weighted equally with the other outcomes measures in the domain.

CMS will then combine the scores of the different domains to determine a total performance score. For FY 2013, the first year of the VBP program, CMS previously finalized that the clinical process of care domain would account for 70 percent of a hospital's total performance score, and the patient experience of care domain would account for 30 percent of the total performance score. However, for FY 2014, this weighting must be revised, as the agency is adding an outcomes domain and has proposed to add an efficiency of care domain. Accordingly, CMS proposes to weight the domains as: clinical process of care domain weight 20 percent; patient experience of care domain weight 30 percent; outcomes domain weight 30 percent; and efficiency domain weight 20 percent.

Ensuring Hospital-acquired Condition Reporting Accuracy. CMS previously finalized a policy to apply the existing Medicare pay-for-reporting program data validation process to both the pay-for-reporting and VBP programs. Under this process, 800 hospitals are selected each year and asked to submit medical records for data validation. In this rule, CMS notes that Medicare Administrative Contractors review hospital-acquired condition data on the claims to ensure they are accurately reported. The agency states that it also is considering proposing additional review of the accuracy of hospital-acquired condition data. Specifically, it is considering targeting a subset of hospitals that report zero or an aberrantly low percentage of hospital-acquired conditions relative to the overall national average. CMS intends to take appropriate action if it discovers systematic underreporting of hospital-acquired condition or other adverse event information, including, where appropriate, reporting such instances to the Office of the Inspector General.

Data Review and Corrections Process. Under the ACA, CMS must ensure that each hospital has the opportunity to review (and submit corrections) for its public VBP information. For chart-abstracted measures, CMS proposes that the review and correction process utilized for the hospital inpatient quality reporting (IQR) program also be used to allow hospitals to correct data and measure rates for the hospital VBP program. Under this process, hospitals would continue to have the opportunity to review and correct data they submit on all IQR program chart-abstracted measures, whether or not the measure is adopted as a measure for the hospital VBP program. The agency also proposes to use the IQR program's data submission, review and correction processes, which will allow for review and correction of data on a continuous basis, which would, in turn, allow hospitals to correct data and measure rates used to calculate the VBP program Total Performance Score.

For HCAHPS data, CMS proposes a two-phase process. In the first phase, hospitals would have the opportunity to review and correct data on all HCAHPS IQR program dimensions, whether or not such dimensions are adopted for the VBP program. In the second phase, hospitals would have the opportunity to review the patient-mix and mode-adjusted HCAHPS scores on dimensions that are adopted for the VBP program to determine whether they believe CMS calculated their scores on these dimensions correctly.

PHYSICIAN SELF-REFERRAL AND PATIENT NOTIFICATION

The ACA limited the use of the physician self-referral exceptions for hospitals with physician ownership or investment. Only existing physician-owned hospitals may use the "whole hospital" and rural exceptions to the ban on self-referral subject to certain conditions. Most of the implementing rules and conditions were published last year through the OPPS/ASC payment notices.

This year's proposed rule contains the remaining required regulations. CMS proposes the criteria and process to obtain an exception to the ban on growth by grandfathered hospitals. The criteria for granting a request to expand closely mirror the statute. They relate to whether:

- There is significant growth in the area population;
- Hospital bed capacity is low and bed occupancy is high in the area;
- Medicaid inpatient admissions at the requesting hospital are at or above the annual percent level in other hospitals in the county; and
- The requesting hospital does not discriminate against federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

A simplified set of criteria are proposed for high Medicaid facilities. Required data sources for the various calculations required by the criteria must be drawn from Medicare cost reports and U.S. Census Bureau data.

The proposed process for requesting permission to grow is straightforward and, consistent with the statute, provides opportunity for community and public notice and written comment. It applies to all hospitals requesting permission, including high Medicaid hospitals, and includes:

- Notice of a request to expand must be posted on the hospital's website from the point of request through a final decision by CMS.
- Notice of a request also will be posted on CMS's website, announced through its hospital listserv, and a notice published in the *Federal Register* with a 30-day comment period.
- The requesting hospital's application will be considered complete at the end of the 30 days if no comments are received. If comments are received, CMS will provide them to the requesting hospital which then has 30 days to provide documentation and information to CMS to rebut the comments.
- Once the application is certified as complete, CMS must render a decision no later than 60 days after that certification. Decisions will be posted on CMS's website, including the identification of the hospital and the size expansion approved.

The proposal also reduces the requirement for provision of patient notices regarding lack of 24 hours-a-day/7 days-a-week (24/7) availability of doctors at inpatient facilities. The notice requirement was added to the Medicare provider agreement rules by the FY 2008 IPPS notice and currently applies to all inpatients and outpatients at inpatient facilities that do not have 24/7 physician onsite availability. The proposed rule would roll back the outpatient notice procedure to apply only to those outpatient visits that involve observation, surgery or any other procedure requiring anesthesia — a recommendation long supported by the AHA.

QUALITY REPORTING THROUGH EHRS

The rule proposes changes to the regulations governing the Medicare and Medicaid EHR Incentive Programs, particularly requirements on hospitals to report on 15 specific clinical quality measures. Specifically, CMS proposes to require hospitals to continue using web-based attestation for reporting of the quality data required for the Medicare EHR Incentive Program in FY 2012, rather than requiring electronic submission directly from the EHR. The required measures would not change (see the AHA's August 13, 2010 *Regulatory Advisory* on the EHR incentive programs for a list of quality measures).

In addition, CMS proposes to begin a voluntary Electronic Reporting Pilot in 2012 to test automated reporting of the quality measures required under the EHR incentive programs. While the same 15 quality measures would be used in the pilot, the actual data submitted to CMS would be different. CMS proposes that rather than submitting summary data (numerator, denominator and exclusions), as currently required, hospitals participating in the pilot would:

- Submit clinical quality measures (CQM) data on Medicare patients only;
- Submit Medicare patient-level data from which CMS may calculate CQM results using a uniform calculation process;
- Submit one full fiscal year of CQM data, regardless of the year of participation in the EHR incentive program (CMS only requires a 90-day reporting period for the first year of participation in the EHR incentive program), and
- Use new CMS-specified data standards.

CMS proposes that participating hospitals could choose whether to rely on the pilot test submission to meet the quality reporting requirements under the EHR incentive program, or follow the web-based attestation process currently in place. The pilot test would involve use of data transmission standards other than those currently supported by certified EHRs because CMS has concluded that "it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry content exchange standards as required for certified EHR technology." CMS anticipates that the pilot will instead test use of the Health Level Seven (HL7) standard Level 1 Quality Report Document Architecture (QRDA). This standard has been developed to support transmission of quality data.

CMS also states in the proposed rule its future intention that hospital quality reporting under the OPPS, IPPS, and EHR incentive program would be based largely on EHR submission, as soon as FY 2015. Thus, the pilot test for submitting data on the measures required for the EHR incentive program also could inform future mechanisms

for reporting quality data under other programs. Additional information about the pilot would be provided on CMS's QualityNet website (qualitynet.org).

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 30 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.

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