American Hospital Association

Regulatory Advisory

August 18, 2008

MEDICARE INPATIENT PPS: THE FINAL RULE FOR FISCAL YEAR 2009

AT A GLANCE

The Issue:

On July 31, the Centers for Medicare & Medicaid Services (CMS) released its fiscal year (FY) 2009 final rule for the hospital inpatient prospective payment system (PPS). The final rule, available at http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp, was published in the August 19 *Federal Register* and will take effect October 1. The rule affects the inpatient PPS, long-term care and critical access hospitals. Major changes in the rule include:

Operating Payment Update: Hospitals that submit data on 30 quality measures will receive a 3.6 percent market-basket update, while hospitals not submitting data will receive a 1.6 percent update.

Quality Reporting: To receive a full payment update in FY 2009, hospitals must report on 30 measures. To receive a full payment update in FY 2010, CMS added 13 new measures for reporting and retired one current measure for a total of 42 measures on which hospitals must report. While the AHA is pleased that CMS reduced the number of new measures from 43 in its proposal to 13, and that all 13 are endorsed by the National Quality Forum, we are disappointed that CMS chose only four measures that have been adopted by the Hospital Quality Alliance.

Hospital-acquired Conditions: CMS finalized two additional hospital-acquired conditions for which it will no longer pay a higher diagnosis-related group (DRG) rate beginning in FY 2009 if they are not present on admission. It also expanded one of the eight conditions adopted in last year's final rule.

DRGs: FY 2009 marks the end of the transition to the new Medicare-Severity DRG system. Beginning October 1, the Medicare-Severity DRGs and the cost-based relative weights will be fully phased in. As mandated by Congress, the rule includes a prospective 0.9 percent cut to the standardized amount to eliminate the effects of documentation and coding that CMS says do not reflect real changes in case mix.

AT A GLANCE (CONTINUED)

Wage Index: CMS made it more difficult for hospitals to qualify for reclassification and also changed the manner in which budget neutrality related to the rural floor is applied.

Indirect Medical Education (IME) Payment Cuts: The rule cuts payments to teaching hospitals by eliminating the IME adjustment to capital payments.

What You Can Do:

- ✓ Watch for more information on what you can do to help prevent the IME cut when Congress returns in September.

- ✓ CMS is still implementing Section 508 reclassification extensions contained in the *Medicare Improvements for Patients and Providers Act of 2008*. Therefore, final wage index data are not available. CMS will publish final data in a separate notice prior to October 1. For hospitals in labor markets affected by the section 508 extension, CMS stated that it will assign the hospital a wage index that it believes results in the highest FY 2009 wage index for which the hospital is eligible. **A hospital will have 15 days from the date of publication of the separate notice to inform CMS if it wishes to revise the decision CMS made on its behalf.**

- ✓ Share this advisory with your senior management team and ask your chief financial officer to examine the impact of the payment changes on your Medicare revenue for FYs 2009 to 2011. Tentative wage data are posted on the CMS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp; the tentative impact file can be found at http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp.

- ✓ Share this advisory with your billing, medical records and quality improvement departments, as well as your clinical leadership team – including the quality improvement committee and infection control officer – to apprise them of the changes to the DRGs and quality measurement requirements.

Further Questions:

Contact Joanna Hiatt, senior associate director of policy, at (202) 626-2340 or IPPSQuestions@aha.org.

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TABLE OF CONTENTS

BACKGROUND

On July 31, the Centers for Medicare & Medicaid Services (CMS) released its final rule for the fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS). The final rule is available at http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp and was published in the August 19 *Federal Register*.

According to CMS' impact assessment, the overall changes will provide, on average, a 4.7 percent payment increase to hospitals. Urban hospitals will receive a 4.8 percent average increase, while rural hospitals will receive a 3.9 percent average increase. However, this is misleading because CMS assumes that all hospitals will alter their coding based on the diagnosis-related group (DRG) changes in a way that will increase payments by 1.8 percent without a commensurate increase in patient severity. If this increase does not materialize, the overall changes in this final rule will provide, on average, only a 3.0 percent payment increase to urban hospitals, and only a 2.1 percent increase to rural hospitals. .

CMS is still implementing certain provisions of the *Medicare Improvements for Patients and Providers Act of 2008*, which extended certain wage index reclassifications and affects the rule's budget neutrality adjustments. Therefore, CMS is able to provide only tentative FY 2009 wage index values for hospitals, as well as tentative standardized amounts, relative weights and thresholds for outliers and new technology add-on payments. CMS indicated it will publish final figures in a subsequent notice issued before October 1.

A detailed summary of the final rule is provided below.

AT ISSUE

Operating PPS Rate Update

The market basket is an input price index that measures price changes over a fixed period of time. To construct the market-basket index, price proxies, such as the U.S Consumer Price Index, are used to estimate the price changes for a mix of goods and services purchased by hospitals. The rate increase in the hospital market basket for FY 2009 operating PPS payments is 3.6 percent. This also applies to the sole community hospital (SCH) and Medicare-dependent hospital (MDH) hospital-specific rates, as well as the rate-of-increase limits for children's hospitals and cancer hospitals.

As required by law, hospitals that do not report the 30 quality measures established in the 2008 outpatient PPS final rule will receive an update of the

market basket minus 2.0 percentage points, or 1.6 percent for FY 2009. (See "Hospital Quality Reporting" for more information.)

Also by law, CMS must adjust the proportion of the standardized amount that is attributable to wages and wage-related costs (known as the labor-related share) by a factor that reflects the relative difference in labor costs among geographic areas (known as the area wage index). For FY 2009, CMS maintained labor-related shares of 62 percent for those hospitals with wage indices less than 1.0 and 69.7 percent for those hospitals with wage indices greater than 1.0. CMS also maintained the labor-related share for Puerto Rico at 58.7 percent.

The tentative operating standardized amounts for FY 2009 are as follows:

Area Wage Index Greater Than 1.0

Full Update (3.6%)		**Reduced Update (1.6%)**	
Labor-related	Non-labor-related	Labor-related	Non-labor-related
$3,571.82	$1,552.74	$3,502.87	$1,522.76

Area Wage Index Less Than 1.0

Full Update (3.6%)		**Reduced Update (1.6%)**	
Labor-related	Non-labor-related	Labor-related	Non-labor-related
$3,177.23	$1,947.33	$3,115.89	$1,909.74

For Puerto Rico hospitals, the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) mandated that the payment per discharge equal the sum of 25 percent of a Puerto Rico-specific rate, which reflects the base year average costs per case of Puerto Rico hospitals, and 75 percent of the federal national rate.

The tentative operating standardized amounts for Puerto Rico for FY 2009 are as follows:

For Hospitals in Puerto Rico

	Rates if wage index is greater than 1.0		**Rates if wage index is less than or equal to 1.0**	
	Labor-related	Non-labor-related	Labor-related	Non-labor-related
National	$3,571.82	$1,552.74	$3,177.23	$1,947.33
Puerto Rico	$1,507.09	$923.69	$1,426.87	$1,003.91

Capital PPS Rate Update

CMS is required to pay for a portion of the capital-related costs of inpatient hospital services. These costs include depreciation, interest, taxes, insurance and similar expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (e.g., MRIs and CAT scanners). This is done through a separate capital PPS, which is structured similarly to the operating PPS. Under the capital inpatient PPS, there is a standard federal payment rate that is adjusted by the DRG for each discharge, with additional payment adjustments for teaching hospitals and disproportionate share hospitals.

The tentative capital standard federal payment rate for FY 2009 is $423.96. Capital payments to hospitals in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the federal capital rate. The tentative FY 2009 capital rate for Puerto Rico is $198.84.

In the FY 2008 final rule, CMS made two changes to the structure of payments under the capital PPS, claiming that payments exceeded what was required for hospitals to provide inpatient services. First, the agency eliminated the 3.0 percent additional payment that had been provided to hospitals located in large urban areas. Second, the agency adopted a policy to phase out the indirect medical education (IME) adjustment to teaching hospitals starting in FY 2009. Given that the impact of phasing out the IME adjustment to capital payments is significant – a reduction of $1.3 billion over five years – CMS provided the public with an additional opportunity to comment in the FY 2009 proposed rule. Although many commenters, including the AHA, 210 representatives and 51 senators, urged CMS not to proceed with these cuts, the agency announced that it is moving forward with its plans. Therefore, in FY 2009 hospitals will receive half their IME adjustment; in FY 2010 and beyond, the adjustment will be eliminated. **The AHA opposes these unnecessary cuts, which ignore how vital these capital payments are to investment in the latest medical technology, ongoing maintenance and improvement of hospital facilities and importance of medical education. We will continue to work with Congress to reverse these cuts.**

Hospital Quality Reporting

To be eligible for a full market-basket update in FY 2009, hospitals must report on 30 measures of care. These 30 measures include all of the previously reported measures, as well as three additional measures adopted last fall. The new measures include one new outcome measure of pneumonia care and two measures of surgical care, including:

- Pneumonia 30-day mortality;
- Cardiac surgery patients with controlled 6 a.m. postoperative serum glucose; and
- Surgery patients with appropriate hair removal.

Hospitals began submitting quality data on the two new surgical care measures for discharges in January 2008. For the new pneumonia mortality measure, as with the heart attack and heart failure mortality measures, CMS is calculating hospitals' mortality rates from claims data. Hospitals do not have to collect or submit any data for this measure. For FY 2009, hospitals also will have to meet the requirements of the previously established data validation process. More information on the data submission and validation process can be found on the QualityNet Web site at http://www.qualitynet.org.

In the proposed rule, CMS suggested adding 43 new measures for FY 2010. The proposed measures included:

- One surgical care measure;
- Four nursing sensitive measures;
- Three readmission measures;
- Six venous thromboembolism measures;
- Five stroke measures;
- Nine patient safety and quality indicators from the Agency for Healthcare Research and Quality; and
- Fifteen cardiac surgery measures from the Society of Thoracic Surgeons registry.

Most of the proposed measures were not endorsed by the National Quality Forum (NQF), nor adopted by the Hospital Quality Alliance (HQA). **In our comments to CMS, we emphasized that any measures added to the pay-for-reporting program must first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA**. We also urged CMS to take a more focused approach as it increases the number of quality measures to enable hospitals to concentrate efforts on important quality areas and make improvements.

We are pleased that CMS significantly scaled back the number of new measures that will be required for hospitals for FY 2010 payment purposes and adopted only 13 of the 43 proposed measures in the final rule. The new measures include:

- Surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period;
- Heart failure 30-day readmission;
- Death among surgical patients with treatable serious complications;
- Iatrogenic pneumothorax;
- Postoperative wound dehiscence;
- Accidental puncture or laceration;
- Abdominal aortic aneurysm mortality rate;
- Hip fracture mortality rate;
- Mortality for selected surgical procedures (composite measure);

- Mortality for selected medical conditions (composite measure);
- Complication/patient safety for selected indicators (composite measure);
- Nursing sensitive measure: Failure to rescue; and
- Participation in a systematic database for cardiac surgery.

While CMS finalized only measures that have been endorsed by the NQF, we are disappointed that it chose only four measures that have been adopted by the HQA: surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period; postoperative wound dehiscence; accidental puncture or laceration; and abdominal aortic aneurysm mortality rate.

Hospitals must begin collecting data on the perioperative beta blocker measure for discharges occurring on or after January 1, 2009; first quarter 2009 data are due to CMS' data warehouse by August 15, 2009. The measure of participation in a systematic database for cardiac surgery will not require hospitals to participate in a registry, but rather report on whether or not they do participate. To fulfill the requirements for this measure, hospitals will be required to report to CMS between July 1 and August 15, 2009 on whether or not they participate in a cardiac surgery database. More information on how to report this information will be available at http://www.qualitynet.org.

All of the other new measures will be calculated by CMS using Medicare claims data. This will lessen the data collection and reporting burden to hospitals. But by excluding all other patients, CMS will be painting an incomplete picture of hospital quality improvement efforts.

CMS has chosen to retire the pneumonia oxygenation assessment measure and will no longer require hospitals to report on it. Almost all hospitals have been consistently performing at or near 100 percent on this measure, and CMS believes the benefits of reporting on this measure no longer outweigh the burden on hospitals of data collection. Therefore, hospitals will have to report on 42 quality measures to receive their full payment update in FY 2010. However, CMS expects two other readmission measures for heart attack and pneumonia to be endorsed by the NQF this fall and plans to adopt them in the final outpatient PPS rule for inpatient PPS implementation in FY 2010.

Appendix A to this advisory lists the current reporting measures, including those adopted in the final rule.

Quality Reporting for Low-volume Hospitals

Beginning on January 1, discharges, hospitals with a low volume of certain patients will not be required to submit data for those patients. Specifically, hospitals that have fewer than five heart attack, heart failure, pneumonia or surgical care patients in a calendar quarter will not be required to submit data for those patients. Hospitals that have fewer than five HCAHPS-eligible patients in

any month will not be required to submit HCAHPS surveys for that month. All hospitals must continue to submit to CMS their total numbers of eligible patients for each condition and their sample sizes, if they choose to sample their patient populations for quality reporting.

Hospital-acquired Conditions

In the inpatient PPS, potentially preventable complications in care, such as infections acquired in the hospital, can sometimes trigger higher payments – either as payment outliers or by assignment to a higher-paying complication or comorbidity (CC) or major CC (MCC) DRG. *The Deficit Reduction Act of 2005* (DRA) required CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a higher-paying DRG. The statute required that the conditions be either high-cost, high-volume or both; result in the assignment of a case to a DRG that has a higher payment when the condition is present as a secondary diagnosis; and be reasonably preventable through the application of evidence-based guidelines. The DRA also mandated that for discharges occurring on or after October 1, 2008, the presence of one or more of these conditions would not lead to the patient being assigned to a higher-paying DRG. That is, the case would be paid as though the secondary diagnosis were not present. Finally, the DRA required hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007.

In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher DRG rate beginning in FY 2009 if the conditions occur while a patient is under the hospital's care. Those eight conditions are:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility;
- Pressure ulcers;
- Falls and trauma;
- Catheter-associated urinary tract infections;
- Vascular catheter-associated infections; and
- Surgical site infection – Mediastinitis after coronary artery bypass surgery.

This year, CMS proposed to expand the list and include an additional nine conditions when the payment policy takes effect on October 1. The nine proposed conditions were:

- Surgical site infections following elective procedures;
- Legionnaires' disease;
- Glycemic control;
- Iatrogenic pneumothorax;
- Delirium;
- Ventilator-associated pneumonia;

- Deep-vein thrombosis/pulmonary embolism;
- Staphylococcus aureus septicemia; and
- Clostridium difficile-associated disease.

In the final rule, CMS added two of its nine proposed hospital-acquired conditions – certain conditions of poor glycemic control and deep vein thrombosis/ pulmonary embolism after certain orthopedic surgical procedures – to the list of eight conditions finalized in last year's rule. CMS did not finalize the other seven hospital-acquired conditions, acknowledging commenters', including AHA's, input that they were not reasonably preventable. In addition, CMS expanded the surgical site infection condition to include infections occurring after certain orthopedic surgeries and bariatric surgery. **Therefore, the final list for FY 2009 contains 10 hospital-acquired conditions.** CMS also refined two of the conditions adopted last year, by including an additional ICD-9 code (998.7) under the condition of object left in during surgery and using new codes for the identification of stage III and stage IV pressure ulcers.

While we are pleased that CMS has scaled back the number of conditions and the patient populations to which the policy will be applied, **we still have strong concerns that most of the selected conditions are not always preventable. In addition, it will not always be possible for hospitals to accurately capture present-on-admission information for all conditions and all patients.**

The payment changes for hospital-acquired conditions will apply only when the selected conditions are the only CCs or MCCs present on a claim. CMS finalized its policy to not make higher payments for the selected conditions if they are coded as not present on admission, or if the medical record documentation is insufficient to determine whether the condition was present on admission.

National Coverage Determination

When it released the final rule, CMS also announced that it was initiating a national coverage determination (NCD) process that would address Medicare coverage of certain surgical procedures, including:

- Surgery on the wrong patient;
- Wrong surgery on the patient; and
- Surgery on the wrong body part.

Medicare NCDs set national policy on whether Medicare will cover an item or service and under what conditions. The NCD process begins with a CMS internal national coverage analysis that includes a 30-day public comment period. The comment period will be open until August 30 and AHA plans to submit comments. CMS expects to release a proposed decision memorandum on or before February 1, followed by another round of public comments, and publish a finalized NCD policy by April 30.

Value-based Purchasing

The DRA mandated that CMS develop a plan to implement value-based purchasing for hospitals under the Medicare program. CMS submitted its plan to Congress on November 21, 2007. In the rule, CMS outlined its development of the plan and discussed the plan's components. For more information on the plan, see the AHA's December 5, 2007 Quality Advisory at http://www.aha.org.

Implementation of value-based purchasing requires action by Congress. CMS intends to test the potential impact of its value-based purchasing plan by conducting a simulation of hospitals' performance under the program and assessing the performance scores and the financial impact of the proposal. Interest in value-based purchasing among Congressional committees remains high and legislative proposals are likely to be made next year.

Wage Index

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. The final rule bases the FY 2009 wage index on data from hospitals' FY 2005 cost reports. According to CMS, the national average hourly wage increased 4.3 percent compared to the FY 2008 index. As a result, a number of hospitals may see their wage index decline relative to last year because, even though their wages rose, they did not rise as quickly as those at other hospitals. **We recommend that you verify that the wage data used for your hospital is accurate.** It can be found on CMS' Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp or in the Addendum to the rule.

MedPAC Recommendations. In the *Tax Relief and Health Care Act of 2006*, Congress required the Medicare Payment Advisory Commission (MedPAC) to develop a report by June 2007 with recommendations and alternatives to improve the area wage index. Additionally, the act required CMS to consider MedPAC's recommendations and propose changes to the wage index in the FY 2009 proposed rule. CMS is still reviewing MedPAC's recommendations, however, and is using an external contractor to analyze their impact. Results from CMS' research of the MedPAC recommendations and other proposals to address the wage index will be published in the FY 2010 inpatient PPS proposed rule.

Individual and Group Reclassifications. Many hospitals apply each year to the Medicare Geographic Classification Review Board for reclassification to another area to receive a higher area wage index. CMS' current criteria for reclassification require an urban hospital to demonstrate that its average hourly wage is at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation, and at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located. For rural hospitals, the thresholds are 82 percent and 106 percent, respectively.

CMS developed the methodology for these criteria in its FY 1993 inpatient PPS final rule by calculating one standard deviation above (108 percent) and below (84 percent) the national average hourly wage. In the FY 2000 inpatient PPS final rule, the wage comparison criteria for rural hospitals seeking individual hospital reclassifications were reduced to 82 percent and 106 percent to compensate for the historic economic underperformance of rural hospitals.

CMS had not evaluated or recalibrated the average hourly wage criteria for geographic reclassification since they were established in FY 1993. As part of its effort to implement wage index changes, CMS re-evaluated the average hourly wage criteria for geographic reclassification using the 1993 methodology and wage data for FYs 2006, 2007 and 2008. Based on these new data, CMS is increasing the threshold necessary for a hospital to reclassify to another wage area, with a two-year transition.

- Currently, an urban hospital needs an average hourly wage that is 84 percent of the area to which they want to reclassify. In FY 2010, this percentage will increase to 86 percent and beginning in FY 2011, it will reach 88 percent (fully phased-in).
- A rural hospital currently needs an average hourly wage that is 82 percent of the area to which they want to reclassify. In FY 2010, this percentage will increase to 84 percent and beginning in FY 2011, it will reach 86 percent (fully phased-in).
- Rural and urban county groups currently need an average hourly wage that is 85 percent of the area to which they want to reclassify. In FY 2010, this percentage will increase to 86 percent and beginning in FY 2011, it will reach 88 percent (fully phased-in).

CMS estimated that approximately 15 percent of hospitals with individual reclassifications and approximately 9 percent of hospitals with group reclassifications in 2008 would not have qualified for reclassification under its new criteria. **The new criteria will apply only to new reclassifications beginning in FY 2010.** Any hospitals or county group in the midst of a three-year reclassification in FY 2010 will not be affected by the change until they reapply for reclassification. The effective date for these changes is September 2 – the deadline for hospitals to submit applications for reclassification for the FY 2010 wage index.

Budget Neutrality Related to the Rural Floor. *The Balanced Budget Act of 1997* established the rural floor by requiring that the wage index for a hospital in an urban area of a state cannot be less than the area wage index determined for that state's rural area. Additionally, in 2006, CMS temporarily adopted an "imputed" rural floor measure by establishing a wage index floor for those states that did not have rural hospitals. Both the rural floor and the imputed rural floor have been funded through a nationwide budget neutrality adjustment. For FY 2009, CMS found that, tentatively, 277 hospitals in 28 states will benefit from the

rural floor. An additional 26 hospitals in New Jersey will receive the imputed rural floor.

Beginning in FY 2009, CMS will apply a statewide (rather than a nationwide) rural floor budget neutrality adjustment to the wage index. Therefore, states with no hospitals receiving a rural floor wage index will no longer have a negative budget neutrality adjustment applied to their rates. Conversely, hospitals within each state with hospitals receiving a rural floor will fund the higher payments for those hospitals. The budget neutrality adjustment for the imputed floor also will be applied at the state level.

The imputed floor was a temporary three-year provision CMS created in 2006; in this rule, the agency extended this floor through 2011.

Section 508 Reclassifications. The *Medicare Improvements for Patients and Providers Act of 2008* extended wage index reclassifications under section 508, as well as under certain special exceptions, through September 30, 2009. Due to the timing of the enactment of the law, however, CMS could not finalize wage index values for hospitals that would be reclassified under section 508 or special exceptions. The agency will issue the final wage index values and other related tables in a separate *Federal Register* notice before October 1. For hospitals in labor markets affected by the section 508 and special exceptions extension, CMS will assign the hospital a wage index that it believes results in the highest FY 2009 wage index for which the hospital is eligible. **A hospital will have 15 days from the date of publication of the separate notice to inform CMS if it wishes to revise the decision CMS made on its behalf.**

Documentation and Coding Adjustment for DRG Changes

In FY 2009, both the two-year transition to Medicare-Severity DRGs (MS-DRGs) and the three-year transition to cost-based relative weights will be completed. Beginning in FY 2009, the relative weights will be based on 100 percent cost weights using the MS-DRGs.

CMS believes that adopting the MS-DRGs will lead to coding and classification changes that will increase aggregate hospital payments without a corresponding increase in actual patient severity of illness. As a result, CMS, in the FY 2008 inpatient PPS final rule, established a prospective documentation and coding adjustment of negative 1.2 percent for FY 2008, negative 1.8 percent for FY 2009 and negative 1.8 percent for FY 2010. Congress, in P.L. 110-90, lowered this prospective adjustment to negative 0.6 percent in FY 2008 and negative 0.9 percent in FY 2009. The final rule applies the mandated documentation and coding adjustment of negative 0.9 percent to the FY 2009 inpatient PPS national standardized amount.

Last November, CMS reversed its earlier decision to apply the documentation and coding adjustment to SCHs and MDHs. While CMS stated its belief that the

adjustment should apply to these facilities, it expressed a concern that applying the adjustment to hospital-specific rates was not consistent with the plain meaning of the statute, which only mentions adjusting "the standardized amount" and does not mention adjusting hospital-specific rates. Thus, for FY 2008, the documentation and coding adjustment was not applied to SCHs or MDHs. For FY 2009, CMS continues this policy and does not apply the negative 0.9 percent adjustment to SCHs or MDHs.

In addition, CMS does not to apply the negative 0.9 percent adjustment to the Puerto Rico-specific standardized amount (25 percent of the total Puerto Rico-specific rate) in FY 2009. After examining the statute further, CMS believes that the documentation and coding adjustment applies to the *national* standardized amounts, but not the Puerto Rico-specific standardized amount.

CMS indicates, however, that it continues to have concerns about implementation of the documentation and coding adjustment. The agency stated that it now believes that it does have authority to apply the adjustment to the hospital- and Puerto Rico-specific rates; thus, payments to SCHs, MDHs and Puerto Rico hospitals should be lowered. CMS asserts that it has the authority to do this using its special exceptions and adjustment authority, which authorizes the agency to provide "for such other exceptions and adjustments to [inpatient PPS] payment amounts… as the Secretary deems appropriate." While not applying the adjustment to these three types of hospitals at this time, CMS stated that it will examine FY 2008 claims data for hospitals paid based on the hospital- and Puerto Rico-specific rates; if CMS finds evidence of significant increases in case-mix for patients treated in these facilities, it will consider applying a cumulative documentation and coding adjustment to the FY 2010 rates.

Refinement of the MS-DRG Relative Weight Calculation

To calculate the cost-based MS-DRG relative weights for FY 2009, CMS is using the same methodology that it used for FY 2008. In FY 2009, CMS will complete the three-year transition to cost-based weights, moving from a blend of cost- and charge-based weights in FY 2008 to full implementation. In addition, as discussed below, CMS has made changes to the cost report to improve the accuracy of cost-based weights.

CMS continues to respond to concerns about potential bias in the weights due to "charge compression" – applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over cost to higher cost items and services. This practice can potentially lead to undervaluing high-cost items and overvaluing low-cost items in calculating the cost-based weights. Research indicates that this occurs most often in the area of medical supplies.

In response to public comments and research concluding that more precise cost reporting is the best way to minimize charge compression and improve the

accuracy of cost-based weights, CMS is changing the cost report. Specifically, CMS is splitting the current cost center of "Medical Supplies Charged to Patients" into two cost centers – one for relatively inexpensive medical supplies and another for more expensive devices (such as pacemakers and other implantable devices). These changes will affect the inpatient and outpatient PPS relative weights and, by extension, the ambulatory surgery center rates.

However, CMS revised its proposal for assigning devices to these two cost centers based on the AHA's recommendation to use revenue center codes, which is less burdensome to hospitals. Specifically, revenue codes 0275 (pacemaker), 276 (intraocular lens), 278 (other implants) and 0624 (FDA investigational devices) should be reported in the "Implantable Devices Charged to Patients" cost center. All other supply revenue codes should be reported in the "Medical Supplies Charged to Patients" cost center.

CMS made the cost report change outlined above as part of its larger effort to update the Medicare hospital cost report. The agency expects a larger proposed revision of the cost report, which will include the change above, to be issued after the publication of this inpatient PPS final rule. The revised cost report would be available for cost reporting periods beginning after Spring 2009, and these changes would affect the relative weights beginning in FY 2012 or FY 2013.

Changes to DRG Classifications

Artificial Heart Devices. CMS removed procedure code 37.52 (Implantation of total internal biventricular heart replacement system) from MS-DRG 215 (Other Heart Assist System Implant) and assigned it to MS-DRG 001 (Heart Transplant or Implant of Heart Assist System With Major Comorbidity or Complication) and MS-DRG 002 (Heart Transplant or Implant of Heart Assist System Without Major Comorbidity or Complication). In addition, CMS removed code 37.52 from the "Non-covered Procedure" edit and assigned it to the "Limited Coverage" edit. This procedure will be covered when the implanting facility has met the criteria set forth by CMS. Procedure code 37.52 must be present on the claim with diagnosis code V70.7 (Examination of participant in clinical trial) in order for the claim to be a covered Medicare service.

Automatic Implantable Cardioverter-Defibrillators (AICD) Lead and Generator Procedures. CMS revised the title of MS-DRG 245 to read "AICD Generator Procedures," which includes procedure codes capturing the implantation or replacement of AICD pulse generators (codes 37.96, 37.98, and 00.54). In addition, CMS created a new MS-DRG 265 titled "AICD Lead Procedures" to include procedure codes that identify the implantation or replacement of AICD leads (codes 37.95, 37.97 and 00.52).

Severe Sepsis. CMS revised the titles for MS-DRGs 870, 871 and 872 to incorporate the term "severe sepsis" as follows:

- MS-DRG 870: Septicemia or Severe Sepsis With Mechanical Ventilation 96+ Hours.
- MS-DRG 871: Septicemia or Severe Sepsis Without Mechanical Ventilation 96+ Hours With MCC.
- MS-DRG 872: Septicemia or Severe Sepsis Without Mechanical Ventilation 96+ Hours Without MCC.

The change is believed to better assist in the recognition and identification of severe sepsis, which would lead to better clinical outcomes and quality improvement efforts. Both severe sepsis (code 995.92) and septic shock (code 785.52) are already assigned to these three MS-DRGs.

Traumatic Compartment Syndrome. CMS added traumatic compartment syndrome codes 958.90 through 958.99 to MS-DRGs 963 (Other Multiple Significant Trauma With MCC), and MS-DRG 965 (Other Multiple Significant Trauma Without CC/MCC) in MDC 24 (Multiple Significant Trauma). Codes 958.90 through 958.99 were added to the list of principal diagnosis of significant trauma. In addition, code 958.91 was added to the list of significant trauma of upper limb, code 958.92 was added to the list of significant trauma of lower limb, and code 958.93 was added to the list of significant abdominal trauma.

MCE Changes. CMS finalized the following changes to the Medicare Code Editor (MCE) edits:

- List of unacceptable principal diagnoses in MCE – CMS removed code V62.84 (Suicidal ideation) from the MCE list of Unacceptable Principal Diagnoses.
- Diagnoses allowed for males only edit – CMS added the following four codes located in the ICD-9-CM Chapter Diseases of Male Genital Organs:
    - 603.0 Encysted hydrocele
    - 603.1 Infected hydrocele
    - 603.8 Other specified types of hydrocele
    - 603.9 Hydrocele
- Limited coverage edit – CMS removed procedure code 37.52 (Implantation of internal biventricular heart replacement system) from the MCE "non-covered procedure" edit and assigned it to the "limited coverage" edit. In addition, this edit will require both ICD-9-CM diagnosis code V70.7 (Examination of participant in clinical trial) and procedure code 37.52 on the same claim to comply with the coverage policy.

Surgical Hierarchies. CMS revised the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) by placing MS-DRG 245 (AICD Generator Procedures) above the new MS-DRG 265 (AICD Lead Procedures).

CC Exclusion List. CMS implemented limited revisions to the CC Exclusions List to take into account the changes that will be made in the ICD-9-CM diagnosis

coding system effective October 1. The agency's changes are in accordance with the principles established when the CC exclusions list was created in 1987.

Review of Procedure Codes in MS-DRGs 981. MS-DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476 and 477, respectively) are reserved for those cases in which none of the operating room procedures performed are related to the principal diagnosis. These DRGs are intended to capture atypical cases – those not occurring with sufficient frequency to represent a distinct, recognizable clinical group. Each year, CMS reviews cases assigned to these DRGs to determine whether it would be appropriate to change the procedures assigned among these DRGs. CMS did not change any procedures assigned among these DRGs.

Post-acute Care Transfers

Since FY 1999, certain Medicare patients discharged to a post-acute care setting – including inpatient rehabilitation hospitals and units, long-term care hospitals, cancer hospitals, psychiatric hospitals, children's hospitals and skilled nursing facilities – or discharged within three days to home health services, are defined as transfer cases and are paid a daily (per diem) rate, rather than a fixed DRG amount, up to the full PPS rate.

CMS had proposed to expand this provision to patients receiving home health care services within seven days of discharge, which would have reduced payments to hospitals by $50 million in FY 2009, and $330 million over five years. However, in the final rule, the agency agreed with the AHA's critique that its analysis of the proposal was not adequate and, therefore, did not finalize the post-acute care transfer policy expansion. CMS indicated that it will continue to monitor this policy to track changes in practice that may indicate a need for revisions.

Graduate Medical Education

On April 12, 2006, and November 27, 2007, CMS issued two interim final rules with comment period that modified graduate medical education (GME) regulations to provide greater flexibility in training residents during times of disaster. In this final rule, CMS adopted as final all the policies included in both of those rules, except for two, which CMS adopted with modification.

First, CMS is further modifying the deadline for the submission of emergency Medicare GME affiliation agreements. For such agreements required to be submitted on or after October 1, home and host hospitals must submit the agreements by 180 days after the end of the academic year in which the emergency event occurred, and for the next academic year following the emergency event. For the remaining three academic years in which home and host hospitals are permitted to execute emergency Medicare GME affiliation agreements, hospitals are required to submit agreements on or before July 1 of the relevant academic year.

Second, for home and host hospitals with valid emergency Medicare GME affiliation agreements, CMS provides an exemption from the intern/resident-to-bed (IRB) ratio cap. Specifically, IME payments for home and host hospitals with valid agreements are calculated based on the current year's IRB ratio (subject to the three year rolling average full-time equivalent resident provision and the hospital's Medicare IME cap).

Outlier Payments

Tentatively, cases would qualify for outlier payments in FY 2009 if their costs exceed the inpatient PPS rate for the DRG, including IME, disproportionate share hospital and new technology payments, plus a the fixed-loss threshold of $20,185 (pending new budget neutrality changes for extension of Section 508 area wage index reclassification). This is down from $22,185 in FY 2008. For FY 2008, CMS estimates that it only will pay out 4.7 percent of the 5.1 percent of payments withheld for outlier cases. The decrease in the outlier threshold should make it easier for hospitals to qualify for outlier payments and help ensure that the total funds withheld for outlier cases in FY 2009 are returned to hospitals in outlier payments.

New Technology Payments

The inpatient PPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies. New technology add-on payments are not subject to budget neutrality and, therefore, do not reduce payments for all other inpatient services. To gain approval for such payments, a technology must be considered new, be inadequately paid otherwise and represent a substantial clinical improvement over previously available technologies. The cost threshold for new technologies to qualify for add-on payments is the lesser of either 75 percent of the standardized amount (increased to reflect the difference between costs and charges) or 75 percent of one standard deviation above mean charges for the DRG involved.

CMS received four applications for new technology add-on payments for FY 2009. The agency approved add-on payments of up to $53,000 for the CardioWestTM Temporary Total Artificial Heart System, which is used as a bridge to heart transplant patients with end-stage biventricular failure. CMS did not approve add-on payments for the three other applications it received (Emphasys Medical Zephyr® Endobronchial Valve, Oxiplex® and TherOx Downstream® System), as Food and Drug Administration (FDA) approval was still pending for these applicants; therefore, they do not meet the newness criterion. CMS encouraged these applicants to reapply for consideration during the FY 2010 inpatient PPS rulemaking process if FDA approval is received in time.

CMS also finalized its proposal to make July 1 of each year the deadline by which new technology add-on payment applications must receive FDA approval.

Applications that have not received FDA approval by July 1 will not be considered in the final rule, even if they were summarized in the corresponding inpatient PPS proposed rule.

Rural Referral Centers

If a hospital wants to become a rural referral center (RRC), but does not have 275 or more beds, it must meet two mandatory criteria – a minimum case-mix index and a minimum number of discharges – and one of three additional criteria relating to specialty composition of medical staff, source of inpatients or referral volume. The final rule updates the alternative criteria for RRC designation in FY 2009 to include:

- A case-mix index that is at least equal to either the median case-mix index for urban hospitals in its census region (excluding hospitals with approved teaching programs) or the national median case-mix index (1.4270), whichever is lower; or
- At least 5,000 discharges per year (at least 3,000 for osteopathic hospitals) or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located.

The median case-mix index values and number of discharges are listed in the chart below.

Region	Median Case-mix Index Value	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	1.2532	8,158
2. Middle Atlantic (PA, NJ, NY)	1.2661	10,659
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3588	10,982
4. East North Central (IL, IN, MI, OH, WI)	1.3579	9,290
5. East South Central (AL, KY, MS, TN)	1.3051	7,927
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.3571	8,206
7. West South Central (AR, LA, OK, TX)	1.4208	6,589
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.4669	9,738
9. Pacific (AK, CA, HI, OR, WA)	1.3945	8,620

Rural Community Hospital Demonstration Program

Section 410 of the MMA required CMS to conduct a demonstration program in rural areas under which up to 15 qualifying hospitals with fewer than 51 beds receive cost-based reimbursement rather than PPS payment for inpatient acute-

care and swing-bed services for a five-year period. Critical Access Hospitals (CAHs) are not eligible for this program. To participate, a rural community hospital must be located in one of the following states: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah or Wyoming. Nine rural community hospitals located within these states are participating in the demonstration program. In February 2008, CMS announced a solicitation for up to six additional hospitals to participate in the demonstration program; four additional hospitals were selected. CMS continues to implement this program in a budget-neutral manner, as required by law, by offsetting inpatient PPS payments to all hospitals by $22.8 million to account for the additional spending by the participating hospitals.

Volume Decrease Adjustment for SCHs and MDHs: Updated Data Sources

An SCH or MDH may apply for special payments if it experiences a decrease of 5 percent or more in the total number of inpatient discharges from one cost-reporting period to another that was out of its control. If the hospital qualifies, it must demonstrate that it took measures to scale back its nursing force commensurately. The adjustment is intended to cover the fixed costs that the hospital is unable to reduce in the year following the volume decrease. CMS believes that only "core staff and services" should be covered by these special payments.

In the FY 2009 final inpatient PPS rule, CMS further refined and finalized its methodology and published the data sources that can be used to determine the core staffing factors used for calculating the volume adjustment. The following summarizes the data and in which years they can be applied for these volume decrease calculations.

The FY 2006 Occupational Mix Survey may be used for the volume decrease adjustment calculations for decreases in discharges occurring in cost reporting periods beginning in FYs 2006, 2007 and 2008 (Table 1). If the provider believes it would benefit from a recalculation of its volume decrease adjustment using the 2006 Occupational Mix Survey data, rather than the HAS Monitrend data, it may submit a request for such a recalculation. These data are updated every three years. The FY 2009 Occupational Mix Survey data will be used for adjustments in FYs 2009, 2010 and 2011 and will be posted to CMS's Web site when they become available.

Table 1: 2006 Occupational Mix Survey
Paid Nursing Hours per Patient Day

	Census Region								
Number of Beds	New England (1)	Mid Atlantic (2)	South Atlantic (3)	East North Central (4)	East South Central (5)	West North Central (6)	West South Central (7)	Mountain (8)	Pacific (9)
0-49	25.47	20.60	20.61	24.42	20.30	25.96	22.22	24.01	20.99
50-99	21.17	18.60	20.61	23.16	18.58	22.40	20.58	21.89	19.14
100-199	18.28	16.25	17.24	19.04	17.08	19.77	16.90	18.22	16.50
200-399	16.91	13.87	16.02	17.89	15.55	18.94	14.88	17.06	16.57
400+	17.52	14.51	16.70	18.31	14.84	16.67	16.05	15.50	18.09

Source: CMS FY 2009 Final IPPS rule, July 31, 2008 Page 752 of the display copy.

In 2006, the AHA amended its survey to more closely mirror the occupational mix survey so that data could be made available on an annual basis. Consequently, there are no data available prior to 2006 that can be used in these calculations. The 2006 AHA Survey data can be used for FY 2006 (Table 2). The 2007 Annual Survey is expected to be released this fall. The AHA will provide updated data to CMS for posting to its Web site.

Table 2: 2006 AHA Annual Survey
Paid Nursing Hours per Patient Day

	Census Region								
Number of Beds	New England (1)	Mid Atlantic (2)	South Atlantic (3)	East North Central (4)	East South Central (5)	West North Central (6)	West South Central (7)	Mountain (8)	Pacific (9)
0-49	26.59	24.17	22.32	28.08	19.29	29.29	25.24	27.10	25.52
50-99	22.13	20.35	22.31	24.40	22.68	24.00	21.17	19.37	20.36
100-199	19.30	17.09	18.34	19.77	19.05	20.32	19.55	18.99	18.71
200-399	18.84	15.04	15.67	17.10	15.62	20.35	16.17	18.96	18.43
400+	18.98	16.58	17.65	21.46	16.73	18.23	16.06	17.76	21.82

Source: CMS FY 2009 Final IPPS rule, July 31, 2008 Page 755 of the display copy.

For open adjustments – those that have not been resolved by the fiscal intermediary – in FY 2007, an SCH or MDH is allowed the option of using any of the three data sources: 1) the 2006 Occupational Mix Survey Results; 2) the 2006 AHA Survey data; and 3) the HAS Monitrend data. However, the FY 2006 Occupational Mix Survey data and the 2006 AHA Annual Survey data cannot be used for open volume adjustment requests prior to FY 2006.

Hospitals with open adjustments prior to FY 2006 must use the HAS Monitrend data. If you would like a copy of these data, please let us know by emailing IPPSQuestions@aha.org.

Rebasing of SCHs

The *Medicare Improvements for Patients and Providers Act of 2008* provided that, for cost reporting periods beginning on or after January 1, 2009, SCHs will be paid based on a FY 2006 hospital-specific rate, if it results in the greatest payment to the SCH. Thus, SCHs will be paid based on the rate that results in the greatest aggregate payment, using either the federal rate or their hospital-specific rate based on their 1982, 1987, 1996 or 2006 costs per discharge. In this final rule, CMS incorporated this provision into its regulations.

Hospitals and Hospital Units Excluded from the Inpatient PPS

Only cancer hospitals, children's hospitals and religious, non-medical health care institutions remain subject to the historical TEFRA limits, with payments based on reasonable costs subject to rate-of-increase limits. The final rule establishes a 3.6 percent increase in the rate-of-increase limits for FY 2009, which is based on the inpatient PPS operating market basket. These hospitals do not need to report on any quality measures to receive the full increase in the rate-of-increase limits.

Long-term Care Hospital Provisions

Budget-neutral Update. As proposed, the final rule updates the payment categories for long-term care hospitals (LTCH) – the MS-LTC-DRGs – in a budget-neutral manner. To accomplish this, CMS applied a normalization factor of 1.03887 and a budget neutrality factor of 1.04186 to the FY 2009 relative weights. While aggregate Medicare payments to LTCHs will not increase or decrease as a result of this update, payments for certain MS-LTC-DRGs have changed.

State-owned, Co-located LTCHs. The final rule changes a Medicare criterion for state-owned hospital-within-hospital LTCHs that are co-located on the campus of a state-owned hospital to allow these providers to keep their Medicare certification, even if state law does not allow the LTCH to maintain a separate governing board, as otherwise required by Medicare.

"No volume" MS-LTC-DRGs. CMS finalized a new method for basing weights for "no volume" MS-LTC-DRGs on the weights of MS-LTC-DRGs with similar clinical and cost characteristics. LTCHs had no discharges for 203 of the 746 MS-LTC-DRGs. The final rule notes that CMS determined the relative costliness of a "no-volume" MS-LTC-DRG by asking medical officers with significant DRG experience to assess the resource use, clinical cohesiveness, and the comparability of services provided for the "no-volume" MS-LTC-DRGs in order to crosswalk them to other DRGs.

Return to Fiscal Year Calendar Cycle. The final rule also references the 2009 LTCH PPS final rule that transitioned Medicare's budget cycle for LTCHs from a rate year to the federal fiscal year. As a result, the LTCH PPS rulemaking will once again coincide with the inpatient PPS rulemaking.

Physician Self-referral Provisions

"Stand in the Shoes" Provisions. CMS finalized only one of its proposed revisions to the physician "stand in the shoes" provisions, but chose not to finalize the "stand in the shoes" provisions related to the designated health services entity side of the financial arrangement (e.g., collapsing a hospital and its medical foundation for purposes of analyzing the financial arrangements under the self-referral law). Noting that CMS suggested that it was likely to provide additional guidance about "indirect compensation arrangements" that would necessarily directly affect the "stand in the shoes" policy and provisions and, in fact, lessen the need for CMS to use a complex regulatory construct for its "stand in the shoes" provisions, the AHA had urged CMS to take a more holistic view of the issues involved in order to develop a simplified approach to "stand in the shoes."

The final rule does adopt a simpler approach to the physician "stand in the shoes" regulation, whereby only physicians who have an ownership or investment interest in a physician organization will "stand in the shoes" of that physician organization for purposes of analyzing the financial arrangement under the physician self-referral law. Characterizing it as a "narrow exception" for titular owners, CMS states that physicians without the ability or right to receive any financial benefits of ownership or investment, such as distribution of profits, dividends, sale proceeds or similar returns on investment, are not required to "stand in the shoes" of their physician organizations.

Consistent with its long-standing view that parties are entitled to use any available exception of which they can satisfy all of its applicable requirements for complying with the self-referral law, CMS will *permit* physicians who are not owners or investors in the physician organization (e.g., employed or contractors physicians) to "stand in the shoes" of the physician organization. And if parties to a financial arrangement elect to treat them as such, they would be required to satisfy the requirements of one of the direct compensation arrangement exceptions under the self-referral law. It is unclear just how useful this option will be because these exceptions generally contain additional and/or stricter requirements for compliance, such as a minimum one-year term and compensation that is "set in advance."

CMS also clarified that the physician "stand in the shoes" provisions do not apply to an arrangement that satisfies the exception in the physician self-referral law for academic medical centers. CMS also revises the definitions of "physician" and "physician organization to clarify that:

- A physician and his or her solely owned professional corporation (PC) are always treated the same in applying the physician "stand in the shoes" rules; and
- A physician who stands in the shoes of his or her wholly-owned PC also stands in the shoes of his or her physician organization.

The revisions to the "stand in the shoes" provisions will be effective October 1.

Obstetrical Malpractice Insurance Subsidies. Responding to expressed concerns of the AHA and others that the existing physician self-referral exception for obstetrical malpractice insurance subsidies was unnecessarily restrictive and unlikely to expand access to needed obstetrical services, **CMS expanded the circumstances permitting certain entities, including hospitals, to provide obstetrical malpractice insurance subsidies to physicians.** The expansion allows only hospitals, federally qualified health centers (FQHCs) and rural health clinics to provide a subsidy to a physician who regularly provides obstetrical services as a routine part of his or her medical practice if the medical practice is located in a rural area or area with a demonstrated need for obstetrical services, as determined by the Secretary in an advisory opinion. CMS also retained the current exception, permitting subsidies if the physician's practice is located in a primary care health provider shortage area (HPSA), or has patients at least 75 percent of whom live in a medically underserved area (MUA) or are part of a medically underserved population (MUP).

CMS was unwilling to extend the exception beyond hospitals, FQHCs and rural health clinics because the agency was not persuaded that there would be no risk of program or patient abuse as required under the physician self-referral law. In addition, CMS maintains that limiting the provisions of the subsidy to physicians who provide obstetrical services in an underserved area or to an underserved population is necessary to ensure that "this valuable benefit is provided only to maintain or improve patient access to needed services, not to induce referrals to the hospitals providing the subsidy."

CMS cautions that this revision is an exception specific to the self-referral law and does not change the insurance subsidy safe harbor under the anti-kickback statute.

Space and Equipment Leases. The final rule made two changes to the requirements for space and equipment leases.

- **The rule prohibits rental payments based on per-use or "per-click" to the extent that such charges reflect services provided to patients who are referred by the lessor to the lessee.** This includes situations in which a physician is the lessor and the patients served were referred by that physician to the lessee (e.g., a physician leases test equipment to a hospital and then refers patients to the hospital for diagnostic testing). It also includes situations in which a physician is the lessee (e.g., of equipment owned by a hospital) and the per-use payments are for services provided to a patient referred by the lessor (e.g., hospital) for those services. CMS' concern is that payments on a per-use basis could result in payment to a physician-lessor or -lessee related to referrals that

involve the use of that space or equipment. The effective date of this change is delayed until October 1, 2009 (FY 2010) to allow needed time for those who must restructure arrangements.

- **The use of percentage-based-compensation is prohibited in the determination of rental charges for the lease of office space or equipment.** CMS' concern is that if the rental charges are determined as a percentage of revenues raised in the office or by the equipment, there is an incentive for the lessor to increase referrals to the lessee and increase the rental payment. In the proposed rule CMS would have permitted percentage-based compensation only as payment for services personally performed by a physician, which the AHA argued against because it could have prohibited payment arrangements based on achieving quality measures, patient satisfaction and efficiencies. The final rule affects only lease arrangements. This provision is relevant for determining whether compensation is "set-in-advance," a requirement for meeting several of the compensation exceptions.

Services Furnished "Under Arrangements*."* **The final rule brings physician-owned entities under contract with hospitals to provide services for hospital patients under the self-referral rules.** CMS' concern is the risk of overutilization with respect to services provided "under arrangements" to hospitals, in particular hospital outpatient services for which Medicare pays on a per-service basis. Under the final rule, physician-owned entities that perform designated health services would be subject to the self-referral law even if they do not bill Medicare for the services (and another entity, e.g., the hospital does the billing). As a result, referrals to these physician-owned facilities will have to satisfy an ownership exception. The effective date for this change is delayed until October 1, 2009 to allow needed time for those who must restructure arrangements.

Alternative Method of Complying with Signature Requirements in Certain Self-Referral Exceptions*.* **CMS finalized a provision intended to address certain failures to satisfy procedural or "form" requirements of exceptions to the physician self-referral law or regulations.** As part of the CY 2008 physician fee schedule proposed rule, CMS offered eight criteria that, if met, would allow a financial arrangement that did not satisfy all of the existing prescribed criteria of an exception to nevertheless meet the exception. As stated in the FY 2009 inpatient PPS final rule, a financial relationship that fully satisfies all applicable requirements, except for the signature requirement, of an exception will nevertheless comply with the exception if the missing signature is obtained:

- *Within 90 days* of initiating the financial relationship (without regard to whether any referrals have occurred or any compensation has been paid during that 90-day period) *when the failure to comply was inadvertent*; or

- *Within 30 days* of initiating the financial relationship (without regard to whether any referrals have occurred or any compensation has been paid during that 30-day period) *when the failure to comply was **not** inadvertent*.

CMS makes clear that the financial relationship in question must satisfy all requirements of the applicable exception – except the signature requirement – at the commencement of the financial relationship. This alternative method of compliance can be used by an entity only once every three years with respect to the same referring physician.

At this time, CMS will not extend this relief to failures to meet other prescribed procedural or "form" criteria in any exception, because it is not requiring self-disclosure of failures to meet the exception's criteria and has not imposed a requirement that CMS make a determination that the alternative criteria have been met. CMS also notes that commenters did not identify other procedural or "form" criteria to which the alternative method of compliance should apply. CMS suggests that it will evaluate the experience with this new provision and, at a later date, may propose modifications that are either more or less restrictive.

Period of Disallowance. **CMS also finalized, without substantive modification, its proposed provisions for determining the "period of disallowance" when a financial relationship between a designated health services entity and a referring physician fails to satisfy all of an exception's requirements.** CMS dismissed the AHA's expressed concerns that the proposal, by relying heavily on a "pay back" concept or the specific facts and circumstances analysis in determining the period of disallowance, reached beyond the duration of the noncompliant relationship and would seem to inhibit self-reporting and self-correction of compliance problems.

The "period of disallowance" is the period of time for which a physician could not refer patients for designated health services to an entity and for which the entity could not bill Medicare. The period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception. Asserting that the provision adopted in the final rule provides increased certainty about when referrals made and claims submitted will no longer violate the self-referral provisions, CMS establishes that:

- Where the reason for noncompliance does not relate to compensation (e.g., a signature is missing or an agreement is not in writing), the period of disallowance would end **no later than** the date the arrangement satisfies all requirements of an applicable self-referral exception; and
- Where the reason for noncompliance relates to payment of either too little or too much compensation, the period of disallowance would end **no later than** the date all of the shortfall is made up or all of the excess compensation is returned by the party who owes the shortfall or has received the excess compensation, provided that the arrangement

otherwise satisfies all requirements of an applicable self-referral exception.

Nothing in the rule, according to CMS, prevents the parties from arguing that the period of disallowance ended earlier.

CMS recognizes that parties to a noncompliant financial relationship may be unable to bring the arrangement into compliance (e.g., the relationship already has expired under the terms of the underlying agreement or has ended earlier or later than the expiration date in the underlying agreement). A party owing a shortfall or receiving excess compensation also may never make up the shortfall or repay the excess compensation. The determination of the period of disallowance in such circumstances, CMS indicates, depends on the specific facts and circumstances involved.

In the final rule's preamble, CMS is clear that the rule is not meant to establish when a specific financial relationship begins or ends. The beginning and ending dates, according to CMS, do not necessarily correspond to the beginning and end dates of a written agreement. As an example, CMS suggests that an arrangement where excess compensation is paid to a physician may raise a question about whether the excess was intended as a reward for referrals that took place prior to the beginning date of any written agreement and/or as an inducement for referrals subsequent to the ending date of the agreement. Accordingly, the financial relationship begins and ends based on the conduct of the parties and the specific facts involved.

Disclosure of Financial Relationships Report (DFRR)

CMS intends to go forward with its proposed collection of information on hospital financial relationships with physicians, to include no more than 500 hospitals. It will be a one-time collection effort; CMS does not adopt a regular reporting or disclosure process at this time. CMS adjusted its estimate of burden upwards for the second time based on comments from the AHA and others, from 33 hours to 100 hours for each hospital. CMS must obtain clearance from the Office of Management and Budget before the DFRR can be sent to hospitals; that process includes a public notice and comment period. CMS indicates that the number of hospitals receiving the DFRR may be reduced depending on public comments received during the clearance process. The AHA will, again, file comments urging that CMS not be permitted to move forward because it has not demonstrated a sufficient need to justify the burden for community hospitals.

Disclosure Regarding Physician Ownership and Coverage

In the FY 2008 inpatient PPS final rule, CMS revised the Medicare provider agreement regulations to require a physician-owned hospital to disclose to all patients that it is physician-owned and, if requested, the names of its physician owners. The FY 2009 inpatient PPS final rule clarifies that this disclosure requirement applies to hospitals in which an immediate family member of a

physician holds an ownership or investment interest, even if the referring physician does not. CMS made this change to create consistency between the disclosure requirements and the physician self-referral statute and regulations. A potential conflict of interest occurs not only in instances where a physician has a financial relationship, but also where the referring physician's immediate family member has a similar interest.

CMS also finalized its proposal to exempt physician-owned hospitals from making the ownership/investment disclosure if the hospital has:

- No physician owners who refer patients to the hospital; and
- No referring physicians who have an immediate family member with an ownership or investment interest in the hospital.

In this circumstance, the hospital must attest in writing that it meets these conditions and maintain the attestation in its files for governmental oversight.

Additionally, CMS finalized the proposed requirement that the physician-owned hospital must provide a list of owners at the time the patient, or someone on behalf of the patient, makes the request.

CMS also added a new ownership disclosure requirement that a hospital require all members of its medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing any ownership or investment interest in the hospital held by the physician or the physician's immediate family member to all patients who they refer to the hospital. The disclosure must be made at the time of the referral. This is similar to a requirement CMS proposed, but did not adopt, in the FY 2008 inpatient PPS rules.

The final rule permits CMS to enforce these disclosure requirements by terminating the hospital's provider agreement.

Finally, CMS previously adopted a requirement that hospitals and CAHs furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a physician is not present in the hospital 24 hours per day, seven days per week, and describe how the emergency medical needs of any patient will be handled when no physician is present. CMS will enforce this requirement through hospital provider agreements, including terminating Medicare participation for any hospital that fails to comply. CMS again rejected the call to apply this requirement only to physician-owned hospitals or at least exempt rural hospitals and CAHs. The final rule clarifies that this disclosure must be made by any hospital or CAH that does not have 24/7 physician coverage. In response to comments by the AHA, CMS said it would consider in future rulemaking the potential limitation of this disclosure to inpatient admissions and certain outpatient visits, excluding emergency department services.

Emergency Medical Treatment and Labor Act (EMTALA)

CMS did not finalize its proposal to apply EMTALA to the transfer of an inpatient. Specifically, the agency stated that, "if an individual with an unstable emergency medical condition is admitted, the EMTALA obligation has ended for the admitting hospital and even if the individual's emergency medical condition remains unstabilized and the individual requires special services only available at another hospital, the hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual."

Under the proposed rule, EMTALA would have been extended to cover the transfer of an inpatient admitted through the emergency department for stabilizing treatment. The AHA urged CMS not to finalize its proposal, arguing that it contradicted current policy, was unnecessary because inpatients already have the protection of the Conditions of Participation and state law, and that the change would worsen the strains already faced by emergency departments and especially trauma centers.

CMS did finalize its proposal to allow hospitals to meet their on-call list obligation through participation in a "community-call plan." These plans must be formal among the participating hospitals, include specified elements and each participating hospital must have written policies and procedures in place to respond to situations in which the on-call physician is unable to respond due to situations beyond his or her control. Pre-approval by CMS is not required before hospitals implement such plans. At a minimum, plans must include the following elements:

- Clear delineation of on-call coverage responsibilities (i.e., when each hospital participating in the plan is responsible for on-call coverage);
- Description of the specific geographic area to which the plan applies;
- A signature by an appropriate representative of each hospital participating in the plan;
- Assurances that any local and regional emergency medical system protocol formally includes information on community on-call arrangements;
- A statement specifying that even if an individual arrives at a hospital that is not designated as the on-call hospital, that hospital still has an EMTALA obligation to provide a medical screening examination and stabilizing treatment within its capability, and hospitals participating in community call must abide by the EMTALA regulations governing appropriate transfers; and
- An annual assessment of the community call plan by the participating hospitals. (As urged by the AHA, CMS eliminated a requirement for an additional assessment specific to specialty on-call needs.)

In addition, the obligation of a hospital to maintain an on-call list was relocated from the EMTALA section of the regulations to the hospital provider agreement section (to be consistent with the language in the EMTALA statute). Technical

corrections were made regarding the non-applicability of EMTALA provisions in an emergency area during an emergency period (to include language that had been inadvertently omitted).

NEXT STEPS

Given the major changes included in this year's final rule, the AHA encourages hospital leaders to estimate the impact of the provisions on their facilities. Tentative wage data are posted on the CMS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp, and the tentative impact file can be found at http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp.

CMS is still implementing Section 508 reclassification extensions contained in the *Medicare Improvements for Patients and Providers Act of 2008*. Therefore, final wage index data are not available. CMS will publish final data in a separate notice prior to October 1. The AHA will notify hospitals when CMS publishes these data. For hospitals in labor markets affected by the section 508 extension, CMS stated that it will assign the hospital a wage index that it believes results in the highest FY 2009 wage index for which the hospital is eligible. **A hospital will have 15 days from the date of publication of the separate notice to inform CMS if it wishes to revise the decision CMS made on its behalf.**

Appendix A: List of Current and Newly Finalized Reporting Measures

Condition	Measure
Acute Myocardial Infarction (AMI)/Heart attack	Aspirin at arrival
	Aspirin at discharge
	Beta-blocker at arrival
	Beta-blocker at discharge
	Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for left ventricular systolic dysfunction (LVSD)
	Smoking cessation advice/counseling
	Thrombolytic medication received within 30 minutes of arrival
	Percutaneous Coronary Intervention (PCI) received within 90 minutes of arrival
	30 day mortality rate
Heart Failure	Left ventricular systolic function evaluation
	ACE inhibitor or ARB for LVSD
	Discharge instructions received
	Smoking cessation advice/counseling
	30 day mortality rate
Pneumonia	Initial antibiotic(s) received within 6 hours of arrival
	Oxygenation assessment
	Pneumococcal vaccination
	Blood culture performed prior to administration of first antibiotic(s)
	Smoking cessation advice/counseling
	Received most appropriate antibiotic
	Influenza vaccination
	30-day mortality rate
Surgical Care Improvement	Prophylactic antibiotic(s) one hour before incision
	Prophylactic antibiotic(s) stopped within 24 hours after surgery
	Selection of antibiotic given to surgical patients
	Prophylaxis to prevent venous thromboenbolism ordered
	Prophylaxis to prevent venous thromboenbolism received
	Appropriate hair removal
	Cardiac surgery patients with controlled 6 a.m. postoperative serum glucose
	Surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period *
Patient Experience of Care	HCAHPS survey results on patient interaction with doctors, nurses, and hospital staff; cleanliness of the organization; pain control; communication about medicines; and discharge information

* Indicates measure finalized in the FY 2009 IPPS final rule.

Readmission	Heart failure 30-day risk standardized readmission measure *
AHRQ Patient Safety Indicators	Death among surgical patients with treatable serious complications *
	Iatrogenic pneumothorax, adult *
	Postoperative wound dehiscence *
	Accidental puncture or laceration *
AHRQ Inpatient Quality Indicators (IQI)	Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) *
	Hip fracture mortality rate *
AHRQ IQI Composite Measures	Mortality for selected surgical procedures (composite) *
	Complication/patient safety for selected indicators (composite) *
	Mortality for selected medical conditions (composite) *
Nursing Sensitive Measures	Failure to rescue *
Cardiac Surgery Measures	Participation in a systematic database for cardiac surgery *

* Indicates measure finalized in the FY 2009 IPPS final rule.