American Hospital Association

Regulatory Advisory

August 14, 2007

MEDICARE INPATIENT PPS: THE FINAL RULE FOR FISCAL YEAR 2008

AT A GLANCE

The Issue:

On August 1, the Centers for Medicare & Medicaid Services (CMS) released its final rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS). The rule, available at http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1533-FC.pdf, will be published in the August 22 *Federal Register* and will take effect October 1. The rule affects inpatient PPS, long-term care, psychiatric and critical access hospitals. Major changes in the rule include:

- A 3.3 percent market-basket update for eligible hospitals that submit data on 27 quality measures and 1.3 percent update for those hospitals that do not.

- The creation of 745 new Medicare-severity diagnosis-related groups (MS-DRGs) to replace the current 538 DRGs, implemented over two years.

- A prospective 1.2 percent cut to both operating and capital payments in FY 2008 and a 1.8 percent cut in both FYs 2009 and 2010 **totaling more than $20 billion in cuts over five years**. The cut is to eliminate what CMS claims will be the effect of coding or classification changes (the so-called "behavioral offset") it says do not reflect real changes in case-mix. A Special Bulletin outlining the impact of this cut on your hospital was sent to you last week.

  CMS went well beyond its charge in finalizing this arbitrary and unnecessary cut against the will of Congress. This backdoor budget cut will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging. We will continue to send a clear message that this cut threatens care for the elderly covered by Medicare as well as care for other patients, and work with Congress to reverse it.

- The elimination of the 3 percent add-on to capital payments for large urban hospitals and a phase-out – discussed in the CMS proposed rule but never actually proposed – of the indirect medical education (IME) adjustment to capital payments in FYs 2009 and 2010. In addition, CMS will not freeze capital payments as proposed, but will instead increase payments for all hospitals by 0.9 percent.

These changes will result in a cut to hospitals of nearly $2 billion over five years, including $1.3 billion resulting from the IME cut. These capital payments help hospitals invest in the latest medical technology and make critical updates to their facilities and information systems to enhance patient quality and reduce health care costs. These payments also help hospitals invest in the next generation of doctors through medical residency programs. Hospitals that have made long-term investments to improve care counting, in part, on Medicare paying its share of these costs have now had the rug pulled out from under them. We will continue to oppose this cut.

What You Can Do:

- ✓ Watch for more information on what you can do to help prevent these cuts, which we will pursue when Congress returns in September.

- ✓ 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 2008-2010. The final wage data are posted on the CMS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp; the final 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.

- ✓ In order to receive a full payment update, **hospitals also should submit by August 15 a "Notice of Participation"** indicating that they will continue to submit quality measure data. The form is available at http://www.qualitynet.org under "Forms" in the "RHQDAPU" section of the Web site.

Further Questions:

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

American Hospital Association

Regulatory Advisory

August 14, 2007

MEDICARE INPATIENT PPS: THE FINAL RULE FOR FISCAL YEAR 2008

TABLE OF CONTENTS

BACKGROUND

On August 1, the Centers for Medicare & Medicaid Services (CMS) released its final rule for the fiscal year (FY) 2008 hospital inpatient prospective payment system (PPS). The rule, available at http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1533-FC.pdf, will be published in the August 22 *Federal Register* and will take effect October 1.

While the rule provides a 3.3 percent market-basket update, total average payments will increase by only 2.1 percent. This is because of a so-called "behavioral offset" – a payment cut – of 1.2 percent CMS justifies by claiming that all hospitals will alter their coding as a result of the newly created diagnosis-related groups (DRGs). With this 1.2 percent reduction in payments, average payments to urban hospitals would increase by only 2.6 percent, while rural hospitals would experience no increase in payment.

A summary of the proposed rule is provided below.

AT ISSUE

Operating PPS Payment Rates

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 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 2008 operating PPS payments is projected to be 3.3 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 and cancer hospitals and religious non-medical health care institutions.

As required by law, hospitals that do not report the 27 quality measures established in regulation will receive an update of the market basket minus 2.0 percentage points, or 1.3 percent for FY 2008. (See "Reporting of Hospital Quality Data" for more information.)

The *Medicare Modernization Act of 2003* (MMA) also permanently raised the standardized amount for other urban and rural hospitals to equal the large urban rate (or, for Puerto Rico, the urban and other area rates). 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 2008, CMS will maintain a labor-related share 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 will leave the labor-related share for Puerto Rico at 58.7 percent.

The final operating standardized amounts for 2008 are as follows:

Area Wage Index Greater Than 1.0

Full Update (3.3%)		Reduced Update (1.3%)	
Labor-related	Non-labor-related	Labor-related	Non-labor-related
$3,459.66	$1,503.98	$3,392.68	$1,474.86

Area Wage Index Less Than 1.0

Full Update (3.3%)		Reduced Update (1.3%)	
Labor-related	Non-labor-related	Labor-related	Non-labor-related
$3,077.46	$1,886.18	$3,017.87	$1,849.67

For Puerto Rico hospitals, the 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 final operating standardized amounts for Puerto Rico for 2008 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	$3,459.66	$1,503.98	$3,077.46	$1,886.18
Puerto Rico	$1,454.91	$891.72	$1,377.47	$969.16

Capital PPS Payment Rates

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 inpatient capital PPS that adjusts payments by the same DRG for each case, as is done under the operating PPS. Capital PPS payments include indirect medical education (IME) and disproportionate share hospital (DSH) adjustments similar to those made under the operating PPS. In addition, hospitals may receive outlier payments under the capital PPS for cases with unusually high costs.

For FY 2008, CMS did not adopt its proposal to provide a differential update for Medicare capital payments to urban and rural hospitals. Instead it will provide all hospitals with a 0.9 percent increase in capital payments. However, CMS is proceeding with its plan to eliminate the current 3 percent add-on to capital payments for hospitals in large urban areas – a $600 million cut over the next five years. In addition, CMS finalized a new provision to phase out the IME adjustment to capital payments by reducing payments by 50 percent in FY 2009 and then providing no IME payments in

FY 2010 and thereafter. CMS also clarified in this rule that capital payments are not eligible for the new technology add-on adjustment.

Eliminating the IME adjustment from the capital PPS will reduce payments to teaching hospitals by $1.3 billion over five years. While the phase out of the IME adjustment is final, it does not take effect until FY 2009, and CMS is allowing for a 90-day comment period. CMS will review and respond to the comments in the FY 2009 inpatient PPS final rule. The AHA will submit comments to CMS on this change this summer, urging CMS to reverse this unnecessary cut, and will work with Congress to address the issue. AHA members will receive a model comment letter from the association and are urged to submit comments of their own.

The final capital standard federal payment rate for FY 2008 is $423.34, down from $424.42 in FY 2007. This decrease in rates, despite a positive update, is due to the so-called "behavioral offset" applied to both operating and capital payments as a result of the implementation of the Medicare-severity DRGs (MS-DRGs). (See "Behavioral Offset" for more information.)

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 final FY 2008 special capital rate for Puerto Rico is $199.80, down from $202.98 in FY 2007.

The elimination of the large urban hospital 3 percent add-on and IME adjustment to capital payments will cost hospitals nearly $2 billion over the next five years. The AHA opposed these unnecessary cuts, which ignore how vital these capital payments are to invest 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.

Excluded Hospital Market Basket [1]

The excluded hospital market basket previously applied to rehabilitation, psychiatric, long-term care, cancer and children's hospitals, as well as religious non-medical health care institutions. However, CMS created separate prospective payment systems for three of these provider types in recent years and, as a result, developed the rehabilitation, psychiatric and long-term care hospital – or "RPL" – market basket index. This index, now used to update the PPS-based portion of payments for these three provider types, is updated through other rulemaking. At the same time, CMS decided to use the inpatient PPS hospital market basket to update the rate-of-increase limits for cancer hospitals, religious non-medical health care institutions and children's hospitals. Thus, CMS will update payments for these providers by 3.3 percent for FY 2008, as previously noted.

[1] Excluded hospitals and units include inpatient rehabilitation and psychiatric hospitals and units, long-term care hospitals, children's hospitals, cancer hospitals and religious non-medical health care institutions. The PPS for inpatient rehabilitation facilities was effective January 1, 2002; the long-term care hospitals PPS went into effect October 1, 2002; and inpatient psychiatric facilities PPS was effective January 1, 2005. The remaining excluded hospitals are paid under the reasonable cost system, subject to the rate-of-increase limits.

However, CMS must continue to maintain the excluded market basket, as it is used to determine the annual update to the reasonable cost-based portion for inpatient psychiatric facilities (IPFs) currently transitioning from a cost-based reimbursement system (subject to rate-of-increase limits) to a PPS. Once that transition concludes, the excluded-hospital market basket will no longer be necessary. For FY 2008, CMS will update the reasonable cost-based portion of IPF payments by an excluded-hospital market basket of 3.3 percent.

Cost-based DRG Weights

CMS will continue the three-year transition from charge-based DRG weights to cost-based weights, as planned, with two-thirds of each weight based on an estimation of costs and one-third based on charges in FY 2008.

However, CMS is expanding the cost centers used in calculating the DRG weights. CMS currently groups charges into 13 cost centers and then converts the charges to costs using cost-to-charge ratios (CCRs). While CMS considered expanding the cost center groupings to 19 in order to separate services that have substantially different CCRs from the other services currently in the same cost center, it will instead expand the cost center groupings to 15. Specifically, CMS is breaking out emergency room and blood and blood products from "other services." These changes can be made using existing cost report data, while the other cost centers considered would require either changes to the structure of the cost report or the application of a regression-based adjustment.

In the final rule, CMS also discussed its support for a cost-reporting initiative the AHA is undertaking with the Association of American Medical Colleges (AAMC), Federation of American Hospitals (FAH) and Healthcare Financial Management Association (HFMA) regarding improved cost-based weighting. Two sources of data currently are used in establishing the DRG weights: the Medicare Provider and Review (MedPAR) files (an accumulation of Medicare patient claims filed by each hospital) and the Medicare cost report. For FY 2008, charges are taken from the MedPAR files, grouped into 15 categories and reduced to CCRs calculated from the Medicare cost reports for these same 15 categories.

An examination of the cost-based weights developed for FY 2007 revealed that problems occur when using these two different data sources together. First, the method used by CMS to group hospital charges for the MedPAR files differs from that used by hospitals to group Medicare charges, total charges and overall costs on the cost report. Second, hospitals group their Medicare charges, total charges and overall costs in different departments on their cost reports for various reasons. Third, hospitals across the country complete their cost reports in different ways, as allowed by CMS. Fourth, CMS' new approach for categorizing all charges and costs into 15 specific categories may not yield the most appropriate CCR for each cost category.

This mismatch between MedPAR charges and cost report CCRs can distort the resulting DRG weights. It is important to note that the cost report was not designed to support the estimation of costs at the DRG level.

The AHA, AAMC and FAH convened a workgroup to make recommendations for short-term changes to cost reporting that better support cost-based weights and do not require changes to the cost report itself or its instructions. The full set of recommendations can be found on the AHA Web site at http://www.aha.org/aha/content/2007/pdf/070426-ippsrecommendations.pdf. The group's primary recommendation is as follows:

> ***In order to achieve more accurate DRG cost-based weights, the cost report workgroup recommends that all hospitals prepare their Medicare cost reports so that Medicare charges, total charges and overall costs are aligned with each other and with the categories currently utilized in the MedPAR file.*** *This allows for a consistent grouping of departments within the 15 categories that will be identified in the August 22, 2007 final inpatient PPS rule that are used to create the cost-based weights. The workgroup recommends that the primary area of focus for these efforts should be the medical supplies category.*

In the final rule, CMS states that it supports this initiative and will be communicating with its fiscal intermediaries (FIs) and Medicare administrative contractors (MACs) to assure that the contractors work with hospitals to achieve consistency within the cost report and with MedPAR. We are in the process of educating hospitals about these recommendations through newsletter and magazine articles, webinars and presentations at regional meetings. Watch for more information in the near future.

Severity-adjusted DRGs

Last year, CMS proposed moving to an entirely new DRG system that adjusts for patient severity based on 3M's All-Patient Refined DRGs (APR-DRGs), also known as consolidated severity-adjusted DRGs. However, CMS did not adopt this proposal and, through its contractor, the Rand Corporation, conducted a study comparing this system to other severity-adjusted DRG systems. While the findings of the report are not yet available to the public, CMS proposed and finalized major revisions to the current DRGs to create a set of new Medicare-severity DRGs (MS-DRGs) for FY 2008. CMS also states in the rule that it expects the move to MS-DRGs to be permanent. This more modest approach to refining the DRGs creates 745 new MS-DRGs to replace the current 538 and will be implemented over two years. In FY 2008, the final payment relative weights are comprised of a 50/50 blend of the new MS-DRGs and the old CMS DRGs. Since more than one CMS DRG may map to a single MS-DRG, CMS calculated half of the relative weights using a weighted average of the old DRGs that mapped to each MS-DRG. These relative weights were then blended with MS-DRG relative weights. **The final relative weight tables in the rule reflect this 50/50 blend. Hospitals will need to code only for the MS-DRGs, not both systems.**

The MS-DRGs are rooted in the current system but regroup diagnoses into up to three tiers of payment per base DRG based on the presence or absence of complications and/or comorbidities (CCs). For example, under the current system adult pneumonia patients can be grouped into either:

- DRG 089 (Simple Pneumonia and Pleurisy, Age Greater than 17 with CC); or
- DRG 090, (Simple Pneumonia and Pleurisy, Age Greater than 17 without CC).

Instead, CMS will divide diagnosis codes into three different levels of CC severity – cases with a major CC (MCC) will be paid the most, while non-CC cases will be paid the least. Not all DRGs will have a three-way split – some DRGs will have combined tiers of MCC/CC or CC/non-CC, while others will have only one regardless of complications and comorbidities (mostly low-volume DRGs). Under the new system, adult pneumonia patients would be grouped as follows:

- MS-DRG 193 (Simple Pneumonia and Pleurisy with MCC);
- MS-DRG 194 (Simple Pneumonia and Pleurisy with CC); or
- MS-DRG 195 (Simple Pneumonia and Pleurisy without CC/MCC).

When reviewing the CC list, CMS first designated as an MCC any diagnosis that was a CC in the revised CC list *and* was an All-Patient-DRG (AP-DRG) major CC *and* an APR-DRG default severity level 3 (major) or 4 (extensive). CMS designated as a non-CC any diagnosis that was a non-CC in the revised CC list *and* an AP-DRG non-CC *and* an APR-DRG default severity level of 1 (minor). Any diagnoses that did not meet either of the above criteria were designated as CCs. The only exception to this approach was for the newborns, maternity and congenital anomalies codes. CMS instead used APR-DRGs to categorize these diagnoses. Any secondary diagnoses used to assign a specific base MS-DRG were excluded from the determination of the CC category for patients assigned to that base MS-DRG.

Next, CMS used the following criteria to determine whether an MCC and/or CC subgroup was appropriate within this system:

- A reduction in variance of charges of at least 3 percent;
- At least 5 percent of the patients in the MS-DRGs fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- At least a 20 percent difference in the average charges between subgroups; and
- A $4,000 difference in average charges between subgroups.

The MS-DRGs, while further differentiating payment based on patient severity, maintain the progress CMS has made over the years in considering resource use and complexity of patients. For instance, DRGs that use major devices will continue to be split out and paid differently from DRGs for the same diagnoses that do not use sophisticated devices.

These changes, though budget neutral, would significantly redistribute money across hospitals. In general, larger urban and teaching hospitals, which tend to treat more complex cases, tend to gain, while smaller and rural hospitals tend to lose because of lower patient severity. Because of the significant redistribution in payments, CMS

states that it will phase in the MS-DRGs over two years beginning in FY 2008. The view of the hospital field is that it should be phased in over four years, with one year to allow hospitals and CMS to prepare for the change.

Behavioral Offset

The final rule also includes a cut of 1.2 percent to both operating and capital payments in FY 2008 and a 1.8 percent cut in both FYs 2009 and 2010. This offset is intended to eliminate what CMS claims will be the effect of coding or classification changes it says do not reflect real changes in case-mix. **The AHA opposes this so-called "behavioral offset," which will cut payments to hospitals by more than $20 billion over five years. CMS went well beyond its charge in finalizing this arbitrary and unnecessary change against the will of Congress (recently, the U.S. House of Representatives voted, 412-12, to prevent CMS from imposing the behavioral offset.)** This backdoor budget cut will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging. We will continue to send a clear message that this cut is unwarranted and irresponsible, and we will work to prevent its implementation.

Comprehensive Review of the Complications or Comorbidities List

As part of their effort to better recognize severity of illness, CMS conducted the most comprehensive review of the CC list since the creation of the DRG classification system. Currently, 115 DRGs are split based on the presence or absence of a CC. For these DRGs, the presence of a CC assigns the discharge to a higher-weighted DRG. CMS reviewed each of the 13,549 secondary diagnosis codes using a combination of mathematical data from Medicare claims data and the judgment of their medical officers. The codes for external cause of injury and poisoning (E800-E999), newborns, maternity and congenital abnormality were not reviewed in creating the revised CC list because of the low occurrence of these diagnoses in the Medicare population.

CMS has modified the current CC list from 3,326 diagnosis codes to a revised list of 1,584 codes on MCC list, and 3,343 codes on the CC list. Under the current DRG system and CC list, 77.66 percent of cases qualify for higher payment. The proposed rule would have reduced this to 41.24 percent, but the final rule brings the total percent of cases qualifying for higher payment based on an MCC or CC up to 59 percent. The following table provides more details on the distribution of cases.

DRG system	Severity Tier	% of Cases
CMS DRGs	CC	78%
CMS DRGs	non-CC	22%
MS-DRGs	MCC	22%
MS-DRGs	CC	37%
MS-DRGs	non-CC	41%

A condition was included in the revised CC list if it would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). Compared with

the existing CC list, the revised list requires a secondary diagnosis to have a consistently greater impact on hospital resources. The revised list is essentially comprised of significant acute disease, acute exacerbation of significant chronic diseases, advanced or end-stage chronic diseases and chronic diseases associated with extensive debility. The new CC list is contained in Table 6J, available on the CMS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/.

Changes to DRG Classifications and Coding

Intestinal Transplantation. In 2006, CMS evaluated intestinal and liver transplant cases and found that intestinal-only transplants and combination liver-intestine transplants had higher average charges than other cases in CMS DRG 480 (Liver Transplant and/or Intestinal Transplant). CMS did not believe these cases warranted creation of a separate DRG since they are extremely rare. For FY 2008, CMS reassigned all intestinal transplant cases to MS-DRG 005. CMS also redefined MS-DRG 005 as "Liver Transplant with MCC or Intestinal Transplant" and MS-DRG 006 as "Liver Transplant without CC."

Implantable Neurostimulators. Effective October 1, 2006, new ICD-9-CM codes were created for central and chronic pain syndrome and chronic pain (codes 338.0, 338.21, through 338.29 and 338.4). For FY 2008, CMS added diagnosis codes 338.0, 338.21, 338.22, 338.28, 338.29 and 338.4, when assigned as a principal diagnosis to MDC 1. The acute pain codes (codes 338.11 and 38.19) remained in MDC 23.

Intracranial Stents. For FY 2008, CMS has assigned ICD-9-CM procedure code 00.62 (Percutaneous angioplasty or atherectomy of intracranial vessel(s)) to MS-DRGs 23-27. Claims containing code 00.62 must be accompanied by code 00.65 (Percutaneous insertion of intracranial vascular stent(s)) to qualify as a covered procedure.

Under the MS-DRGs, procedure codes 39.72 (Endovascular repair or occlusion of head and neck vessels), 39.74 (Endovascular removal of obstruction from head and neck vessel(s)) and 39.79 (Other endovascular repair (of aneurysm) of other vessels) are assigned to MS-DRGs 23-27. Although there are concerns about assigning additional endovascular procedures to an open surgical DRG, CMS agreed that there is clinical consistency between procedure code 00.62 and codes 39.72, 39.74 and 39.79.

CMS states that there are not enough cases to warrant creation of a separate base DRG for endovascular intracranial procedures. However, this issue will be revisited when additional data become available to analyze these cases.

Cochlear Implants. Cochlear implants were assigned to CMS DRG 49 (Major Head and Neck Procedures) in MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat). CMS has moved the cochlear implant cases to the higher DRG severity level within CMS DRG 49 (Major Head and Neck Procedures). Although these cases will continue to have higher charges than other cases in their assigned DRG, there are not enough inpatient cochlear implant cases to warrant the creation of a separate DRG.

For FY 2008, cochlear implants are assigned to MS-DRG 129. MS-DRG 129 has been redefined as "Major Head and Neck Procedures with CC or MCC or Major Device."

Hip and Knee Replacements. In the FY 2006 inpatient PPS final rule, CMS deleted DRG 209 (Major Joint and Limb Reattachment Procedures of Lower Extremity) and created two new DRGs: 544 (Major Joint Replacement or Reattachment of Lower Extremity) and 545 (Revision of Hip or Knee Replacement). Effective October 1, 2005, new codes were implemented to differentiate new and revised hip and knee replacements, and to identify the joint components replaced.

CMS believes that the MS-DRGs greatly improve their ability to identify joint procedures with higher resource costs. The MS-DRGs include two new severity of illness levels to the base DRG for "Major Joint Replacement or Reattachment of Lower Extremity," as well as three new severity of illness levels to the base DRG for "Revision of Hip or Knee Replacement." The new MS-DRGs are as follows:

- MS-DRG 466 (Revision of Hip or Knee Replacement with MCC);
- MS-DRG 467 (Revision of Hip or Knee Replacement with CC);
- MS-DRG 468 (Revision of Hip or Knee Replacement without CC/MCC);
- MS-DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC); and
- MS-DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC).

Spinal Fusion. As part of the analysis of the DRG system, CMS performed a comprehensive review of the entire group of spine DRGs to determine whether additional refinements beyond the MS-DRGs were necessary. This group included DRG 496 (Combined Anterior/Posterior Spinal Fusion), DRGs 497 and 498 (Spinal Fusion Except Cervical with and without CC, respectively), DRGs 499 and 500 (Back and Neck Procedures Except Spinal Fusion with and without CC, respectively), DRGs 519 and 520 (Cervical Spinal Fusion with and without CC, respectively) and DRG 546 (Spinal Fusion Except Cervical with Curvature of the Spine or Malignancy).

For FY 2008, CMS implemented a two- or three-way split for each of these spine DRGs to further recognize severity of illness, complexity of service and resource utilization. In addition, it examined the codes for multiple fusion or refusion of the vertebrae and determined that further refinement was necessary when nine or more vertebrae were fused.

Further analysis demonstrated that spinal fusion cases with a principal diagnosis of tuberculosis or osteomyelitis have higher average charges than other cases in CMS DRG 497 (MS-DRGs 549 and 460) and are more similar to cases in CMS DRG 546 (MS-DRGs 456 through 458). Tuberculosis of the vertebral column and osteomyelitis of other specified sites have been added to the list of principal diagnoses for MS-DRGs 456 through 458. The titles for MS-DRGs 456-458 have been revised as follows:

- MS-DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or 9+ Fusions with MCC);
- MS-DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or 9+ Fusions with CC); and
- MS-DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or 9+ Fusions without CC/MCC).

Spinal Disc Devices. For FY 2008, CMS collapsed CMS DRGs 499 and 500 (Back and Neck Procedures except Spinal Fusion with and without CC, respectively). Under the MS-DRGs, these CMS DRGs were split into two severity levels: MS-DRG 490 (Back and Neck Procedures except Spinal Fusion with CC or MCC) and MS-DRG 491 (Back and Neck Procedures except Spinal Fusion without CC or MCC).

CMS also analyzed data for other spinal disc devices, including the X STOP® Interspinous Decompression Device (code 84.58) and Coflex, Dynesys, M-Brace (code 84.59). The data demonstrate that the average charges for CHARITE™ (code 84.65, Insertion of total spinal disc prosthesis, lumbosacral) and the other devices are higher than other cases in MS-DRGs 490 and 491 but lower than MS-DRGs 453 through 455 and 459 and 460. CMS did not assign any of these devices to the spinal fusion MS-DRGs since the average charges for cases using these devices are more similar to the higher severity level in MS-DRG 490.

For FY 2008, CMS moved cases with procedure codes 84.58, 84.59 and 84.65 into MS-DRG 490 and revised the title to reflect disc devices. The modified MS-DRG title is: MS-DRG 490 (Back and Neck Procedures except Spinal Fusion with CC or MCC or Disc Devices).

For FY 2008, CMS moved cases identified with procedure code 84.62 (Insertion of total spinal disc prosthesis, cervical) from MS-DRG 491 to MS-DRG 490. CMS agreed that these cases appear to require greater utilization of resources than other cases in MS-DRG 491 and are clinically similar to other spine disc prostheses assigned to MS-DRG 490.

Other Spinal DRGs. CMS did not identify any data to support moving cases in or out of CMS DRGs 496 (Combined Anterior/Posterior Spinal Fusion), 519 (Cervical Spinal Fusion with CC) or 520 (Cervical Spinal Fusion without CC).

For FY 2008, CMS DRG 496 has been split into three severity levels:

- MS-DRG 453 (Combined Anterior/Posterior Spinal Fusion with MCC);
- MS-DRG 454 (Combined Anterior/Posterior Spinal Fusion with CC); and
- MS-DRG 455 (Combined Anterior/Posterior Spinal Fusion without CC).

CMS DRG 519 has also been split into three severity levels:

- MS-DRG 471 (Cervical Fusion with MCC);

- MS-DRG 472 (Cervical Fusion with CC); and
- MS-DRG 473 (Cervical Fusion without CC).

Endoscopic Procedures. ICD-9-CM procedure codes 33.71 (Endoscopic insertion or replacement of bronchial valve(s)), 33.78 (Endoscopic removal of bronchial device(s) or substances) and 33.79 (Endoscopic insertion of other bronchial device or substances) took effect October 1, 2006. Since these codes have been in use for only a few months, CMS assigned them based on the advice of its medical officers to a clinically similar DRG. Because of the lack of supporting data, these codes will remain assigned to MS-DRGs 843, 844 and 845 (Other Myeloproliferative Disease or Poorly Differentiated Neoplasm Diagnosis w/MCC, w/CC or w/o MCC respectively) until data are available to suggest a different DRG assignment is warranted.

Medicare Code Editor (MCE) Changes. For FY 2008, CMS made the following changes to the MCE edits:

- Non-Covered Procedure Edit – CMS made a conforming change and added the following language to this edit: "Procedure code 00.62 (Percutaneous angioplasty or atherectomy of intracranial vessel(s)) is identified as a noncovered procedure except when it is accompanied by procedure code 00.65 (Intracranial stent)."
- Non-Specific Principal Diagnosis Edit 7 and Non-Specific Operating Room Procedures Edit 10 – These edits were created at the beginning of the inpatient PPS with the intent of encouraging hospitals to code as specifically as possible. CMS has found these two edits to be misunderstood and claims erroneously denied, rejected or returned as a result. In November 2006, the agency instructed all FIs to deactivate these edits. For FY 2008, CMS made a conforming change to the MCE to remove codes from edit 7 and 10.
- Limited Coverage Edit 17– CMS made conforming Medicare Part A payment edits to the MCE, consistent with the requirements of the organ transplant regulation (CMS-3835-F), to ensure that Medicare covers only those organ transplants performed in Medicare-approved facilities.
- Revision to Part 1, Pancreas Transplant Edit A – Effective for services performed on or after April 26, 2006, CMS published a National Coverage Determination (NCD) for Pancreas Transplants stating that pancreas alone transplants are reasonable and necessary for Medicare beneficiaries in facilities that are Medicare-approved for kidney transplantations. In addition, patients must have a diagnosis of Type 1 diabetes mellitus. CMS is removing Edit A in its entirety from the MCE.

Surgical Hierarchies. For FY 2008, CMS did not make any revisions to the surgical hierarchy for any Major Diagnostic Categories (MDC). In general, the MS-DRGs follow the same hierarchical order as the CMS DRGs, except for DRGs that were deleted and consolidated.

Complication/Comorbidities Exclusions List. For FY 2008, CMS made 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. CMS made these changes in accordance with the principles established when the CC exclusions list was created in 1987.

Review of Procedure Codes in CMS DRGs 468, 476 and 477. For FY 2008, CMS did not make any changes to the procedures assigned among these CMS DRGs.

Reporting of Hospital Quality Data

The Deficit Reduction Act of 2005 (DRA) gave the Secretary of Health and Human Services (HHS) the authority to annually expand the number of quality indicators that hospitals must report in order to receive their full annual payment update. The DRA also increased the penalty for not reporting quality data from a 0.4 percentage point reduction in the annual payment rate update to a 2.0 percentage point reduction.

Last fall, CMS adopted six additional quality measures that hospitals must report to be eligible for a full market-basket update for the inpatient PPS in FY 2008, bringing the total number of quality measures that hospitals must report to 27. The measures must be identified approximately a year in advance of the fiscal year for which they are required so that the data warehouse can build the capacity to receive and validate the data, hospitals and their data vendors can build the capacity to collect and report the data to the warehouse, and the data collection can begin. The measures added for FY 2008 are:

- HCAHPS;
- Heart attack mortality;
- Heart failure mortality;
- Venous thromboembolism (VTE) prophylaxis ordered for surgery patients;
- VTE prophylaxis given within 24 hours pre/post surgery; and
- Optimal prophylactic antibiotic selected for surgical patients.

Hospitals must continuously submit quarterly information on the quality measures and pass the validation process to be considered a reporting hospital.

In this year's proposed rule, CMS suggested five additional measures for inclusion in FY 2009; however, the final rule adds only one of these measures: pneumonia mortality. CMS did not finalize the other proposed measures because they have not yet received National Quality Forum (NQF) endorsement. However, CMS expects the following three measures to be endorsed by NQF this fall and, if so, will adopt them in the final outpatient PPS rule for implementation in FY 2009:

- Cardiac surgery patient with controlled 6 AM postoperative serum glucose;
- Surgery patients with appropriate hair removal; and
- Surgery patients on a beta-blocker prior to arrival who received a beta-blocker during the perioperative period.

The other proposed measure, colorectal patients with immediate postoperative normothermia, is not expected to be endorsed in time for implementation in FY 2009.

The AHA is pleased that CMS finalized only the measure that is both NQF-endorsed and Hospital Quality Alliance-adopted for implementation in FY 2009. However, we disagree with CMS' decision to finalize other measures for FY 2009 in the 2008 outpatient PPS final rule, should they receive NQF endorsement by that time. We do not believe that timeframe provides hospitals and their data vendors sufficient notice to implement plans for data collection.

For FY 2009, the validation process will be the same as in previous years, except that CMS will use four quarters of data (fourth quarter CY 2006 through third quarter 2007), instead of three quarters to validate hospitals' reporting.

Hospital-acquired Conditions

The DRA requires CMS to identify by October 1 at least two preventable complications of care that could cause patients to be assigned to a higher-paying DRG, one designated for patients with additional co-morbidities that are likely to make care more difficult and expensive to provide. The law requires CMS to identify conditions that are high cost or high volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable by the hospital through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, the presence of one or more of these preventable complications will not lead to the patient being assigned to a higher-paying DRG. That is, the case will be paid as though the secondary diagnosis is not present. Recognizing that some of these complications could have occurred prior to admission, the DRA requires hospitals to submit the secondary diagnoses that are present on admission (POA) when reporting payment information for discharges on or after October 1. If the complication is POA, it could be used to assign the patient to the higher-paying DRG. Due to complications implementing this change, CMS has delayed the POA coding requirement until January 1, 2008.

In the proposed rule, CMS listed 13 conditions it was considering for implementation and proposed six for implementation in FY 2009. The AHA agreed that three of the six conditions – object left in during surgery, air embolism and blood incompatibility – were appropriate for this policy. However, the final rule adopts eight conditions for which CMS will not provide higher payments if the selected event occurs while a patient is under the care of the hospital. The change will take effect with Medicare patients discharged on or after October 1, 2008 and will include:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility;
- Catheter-associated urinary tract infections;
- Pressure ulcers;

- Vascular catheter-associated infections;
- Mediastinitis after coronary artery bypass graft; and
- Hospital-acquired injuries (including fractures, dislocations, intracranial injury, crushing injury and burns).

The AHA is very concerned about the expansion of this list and disagrees with CMS' decision to include additional conditions beyond what was recommended in the proposed rule. We believe that it is not always possible to know whether a condition is POA, and we have concerns about the ability of hospitals to implement POA coding for some of these conditions, such as pressure ulcers and catheter-associated urinary tract infections. Several of the selected conditions are not always reasonably preventable. In addition, we are concerned that CMS altered its focus from injuries sustained from falls in the proposed rule to a broader category of injuries in the final rule. The agency did not receive the benefit of public comment and review on these conditions because they were not specifically listed in the proposed rule. We do not believe that burns, intracranial injuries or some of the other injuries listed by CMS are always related to falls in the hospital, and we do not believe they meet the statutory requirements of this provision, as we are not aware of any evidence-based guidelines for the prevention of these injuries.

Outlier Payments

According to the final rule, cases would qualify for outlier payments in FY 2008 if their costs exceed the inpatient PPS rate for the MS-DRG, including IME, DSH and new technology payments, in addition to the fixed-loss threshold of $22,635 (note that there was a typo in the preamble of the rule). This is down from $24,485 in FY 2007 due to the implementation of the MS-DRGs and the new threshold calculation CMS implemented in FY 2007. The agency estimates that it will spend 4.6 percent of total payments on outliers in FY 2007 and 4.65 percent in FY 2006, even though 5.1 percent was set aside. This suggests that the full amount set aside is unlikely to be spent again in FY 2008, especially given the complicating factor of the MS-DRG implementation.

Wage Index

The area wage index adjusts payments to reflect the differences in labor costs across geographic areas. The FY 2008 wage index is based on data from hospitals' FY 2004 cost reports. According to CMS, the national average hourly wage increased 4.3 percent compared to the FY 2007 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 the CMS Web site at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp or in the Addendum to the proposed rule.

New Hospital Labor Markets. In June 2004, the Office of Management and Budget (OMB) released revised standards defining Metropolitan Statistical Areas (MSAs) based on the 2000 Census data, including its new definitions of Core-Based Statistical Areas. CMS, therefore, adopted changes to its labor market definitions in the FY 2005 rule. As

a result, a small number of hospitals that were classified as urban in FY 2004 were reclassified as rural in FY 2005. Because moving from an MSA to the rural statewide average would have resulted in a significant decline in these hospitals' wage indices, CMS implemented a three-year transition period (FYs 2005 through 2007). Beginning in 2008, these hospitals will receive their statewide rural wage index.

Occupational Mix. The MMA requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices – such as greater use of registered nurses versus licensed practical nurses or certified nurse aides – rather than geographic differences in the costs of labor.

In the rule, CMS uses six-month's worth of data collected from January 1 through June 30, 2006 to fully adjust the wage index for occupational mix. While CMS sought comments on whether it should impose penalties on those hospitals that did not turn in the occupational mix data or turned in unreliable data for future wage indices, it is not implementing a penalty. Instead, CMS uses the average occupational mix adjustment for a labor market area for hospitals that did not turn in data in either quarter or turned in unreliable data. For areas where no hospitals turned in data, CMS uses the national average occupational mix adjustment, or 1.0. For hospitals that turned in one quarter's worth of data, the adjustment is based on those data. However, CMS warned that it will reconsider a penalty after the next data collection period.

CMS also noted that while the next occupational mix survey has not been released in final form, it plans to do so imminently and will essentially finalize what was proposed earlier this year. Specifically, the data collection period will be July 1, 2007 through June 30, 2008, the cost center list will be expanded, surgical technicians and paramedics will be included, the instructions will be clarified and there will be no distinction between nursing management and staff nurses under the registered nurse category. More information on the proposed survey and these changes can be found on the AHA Web site at http://www.aha.org/aha_app/issues/Medicare/IPPS/advocacy-ipps.jsp.

Contract Labor. CMS expanded its collection of contract labor with cost reporting periods beginning on or after October 1, 2003 to include: administrative and general (A&G); contract management that is not part of A&G and are not top management contracts (i.e., CEO, CFO, COO, etc); housekeeping; and dietary. After an audit by the FIs, CMS believes that the data are reasonable and accurate. Thus CMS will integrate these data into the wage index calculation for FY 2008. However, CMS has corrected a calculation error pointed out by the AHA that alters the expected impact of the policy change. While the vast majority of hospitals will not be affected (85 percent), 327 hospitals will experience a decrease in their wage index and 209 will experience an increase in their wage index.

Budget Neutrality. CMS will apply the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008. This new methodology will ensure that the reduction does not compound over time.

Out-migration Adjustment. Section 505 of the MMA provided hospitals in lower wage areas with a wage index adjustment if a significant number of hospital workers commute from a lower-wage area to higher-wage areas nearby. This adjustment is a complicated equation based on the percentage of out-migration of hospital employees and the differences in wage indices between or among the areas. By law, the provision is **not** budget neutral so it does not affect payments for other hospitals. The adjustment is effective for three years (FYs 2005 through 2007), thus CMS is re-calculating the adjustment for FYs 2008 through 2010. In addition, CMS is altering the adjustment calculation by using the post-reclassification wage index rather than the pre-reclassification wage index.

Under changes prescribed by the MMA, hospitals that receive this adjustment are not eligible for geographic reclassification. Thus, hospitals that did not follow the proper procedures to terminate their reclassification or redesignation will not receive the out-migration adjustment. Table 4J, found in the Addendum to the final rule or at http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp, lists the eligible hospitals and the out-migration adjustments they will receive.

Rural Hospitals

Low-volume Hospitals. Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for low-volume hospitals' higher costs per case. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges during the year – including Medicare and non-Medicare patients. The law further states that the payment adjustment may not be greater than 25 percent based on a formula developed by CMS that takes into account the standardized cost per case, the number of hospital discharges and the incremental costs for these discharges.

The rule will maintain a 25 percent increase in payments to hospitals with fewer than 200 discharges. For those hospitals with 200 to 800 discharges, CMS will not provide an adjustment. CMS noted that only two hospitals in the country will qualify under these criteria for FY 2008.

Rural Referral Centers (RRCs). If a hospital wants to become an RRC but does not have 275 or more beds, it must meet two mandatory alternative criteria and one of three additional criteria (relating to specialty composition of medical staff, source of inpatients or referral volume). The rule updates the alternative criteria for RRC designation in FY 2008 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 (1.4049), whichever is lower; or

- At least 5,000 discharges per year or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located (at least 3,000 for osteopathic hospitals).

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)	1.2348	7,758
2. Middle Atlantic (PA, NJ, NY)	1.2665	10,603
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3515	10,627
4. East North Central (IL, IN, MI, OH, WI)	1.3393	9,325
5. East South Central (AL, KY, MS, TN)	1.2904	7,966
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.2869	7,986
7. West South Central (AR, LA, OK, TX)	1.4010	7,225
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.4260	9,082
9. Pacific (AK, CA, HI, OR, WA)	1.3772	8,439

RRCs and Sole Community Hospitals. CMS proposed that a hospital with a special rural designation under the inpatient PPS, such as an RRC or an SCH, that chooses to cancel its rural redesignation would remain rural for at least one 12-month cost-reporting period and until the beginning of the next federal fiscal year following both the request for cancellation and the conclusion of the 12-month cost-reporting period. This would prevent a facility from electing rural status to become an RRC in order to take advantage of the less stringent reclassification rules and then quickly returning to urban status. In addition, the deadline for seeking a cancellation would be not less than 120 days before the end of the federal fiscal year. While CMS is finalizing this provision for RRCs, it will not apply this policy to other rural providers. For other providers, such as critical access hospitals (CAHs) and SCHs, the cancellation will take effect with the hospital's next cost-reporting period.

Rural Community Hospital Demonstration Program. Section 410 of the MMA requires CMS to conduct a rural demonstration program under which qualifying hospitals with fewer than 51 beds will receive cost-based reimbursement rather than PPS payment for inpatient acute care and swing-bed services for a five-year period. 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. CMS will implement this program in a budget-neutral manner by offsetting inpatient PPS payments to all hospitals by $9.7 million to account for the additional spending by the participating hospitals.

Long-term Care Hospitals (LTCHs)

The move to MS-DRGs also will apply to LTCH DRGs. However, in an appropriate change from the proposed rule, the so-called "behavioral offset" will not apply to

LTCHs. CMS based this change on analysis by The Lewin Group that demonstrates that 62 percent of LTCH discharges would qualify for the highest comorbidity tier under the new MS-DRG system and 34 percent of LTCH cases are short-stay outliers paid on a cost rather than DRG basis. Therefore, any change in coding in response to the new payment system would not alter LTCH payments. The final rule also updated the CCR ceiling for LTCHs to 1.284 and established statewide average CCRs for urban and rural providers in Table 8c of the final rule Addendum.

Emergency Medical Treatment and Active Labor Act (EMTALA)

CMS amended the EMTALA regulations as they relate to actions taken in an emergency area during either a national emergency declared by the president or a national public health emergency declared by the Secretary of HHS. Currently, the regulations specify that EMTALA sanctions for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area. To implement the changes made by the *Pandemic and All Hazards Preparedness Act*, CMS made two changes. First, it specified that the EMTALA sanctions that do not apply are those for either the inappropriate transfer of an individual who has not been stabilized or those for the direction or relocation of an individual to receive medical screening at an alternate location. Second, it revised the regulations to clarify that a waiver of EMTALA sanctions is limited to a 72-hour period beginning with the implementation of a hospital disaster protocol. However, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will remain in effect until the termination of the applicable declaration of a public health emergency.

Physician Ownership in Hospitals

CMS adopted a new requirement that physician-owned hospitals disclose to patients that they are physician-owned and make available a list of physician investors. The disclosure would be required at the beginning of a hospital stay or outpatient visit, both of which begin with registration and/or pre-admission testing. CMS defines a physician-owned hospital as any Medicare-certified hospital in which a physician or physicians have any ownership or investment interest, except physician investments in publicly-traded stock or mutual funds. Failure to comply with this disclosure requirement could result in decertification of the physician-owned hospital.

Patient Safety – Emergency Services

CMS considered a number of changes to the provider agreement and/or conditions of participation to further ensure patient safety with respect to the provision of emergency services – some dealt with the capacity to deliver emergency services and others dealt with disclosure of how hospitals handle emergencies when no physician is on the premises. In the end, the agency deferred taking action on standards for the delivery of emergency care, opting only for a patient disclosure requirement.

CMS will require all hospitals – including inpatient acute (whether PPS or exempt), critical access, long-term care, psychiatric, rehabilitation, children's and cancer hospitals – that do not have physicians available on the premises 24 hours per day, 7 days per

week (24/7) to inform patients of that limitation prior to their receiving an inpatient or outpatient service. CMS does not plan to prescribe specific language for the notice, but its discussion of the requirement indicates that the notice must specifically state that the hospital does not have physicians on the premises 24/7. The notice also must describe how the hospital will meet any emergency service needs when a doctor is not on the premises. The disclosure would be required at the point of registration and/or pre-admission testing. This policy takes effect October 1.

CMS does not intend to provide standard language for the new disclosure notice, but the notice still requires Office of Management and Budget (OMB) review and clearance under the *Paperwork Reduction Act*. Hospitals subject to the requirement (those who do not have 24/7 physician coverage on site) will need to create a disclosure notice and a plan for distributing it at all inpatient admissions and outpatient encounters. Available information suggests that hospitals simply need to provide the notice to each patient, without obtaining patient signatures documenting individual receipt. Hospital policies and procedures must be documented. However, the AHA cautions against finalizing the notice and procedures until CMS receives OMB clearance and issues provider manual instructions. CMS already has completed the first part of the clearance process by soliciting public comment on the proposed disclosure requirement. The AHA submitted comments urging significant changes. CMS has yet to publish another notice with a 30-day comment period directly to OMB. It is expected that instructions will not be circulated to hospitals until they receive OMB clearance, which is not likely to occur until shortly before the October 1 effective date.

New Technology Payments

New technology add-on payments are not subject to budget neutrality and, therefore, do not reduce payments for 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 either 75 percent of the standardized amount (increased to reflect the difference between costs and charges) or 75 percent of one standard deviation for the DRG involved, whichever is less.

CMS will discontinue add-on payment for all three of the currently approved technologies and did not approve the only 2008 application under consideration. CMS no longer considers GORE TAG®, which is used for endovascular graft repair of the descending thoracic aorta, and Restore®, which is rechargeable implantable neurostimulator, as meeting the newness criteria. While X STOP®, an interspinous process decompression system, is still considered new, CMS no longer believes it satisfies the cost threshold based on the new MS-DRGs. Thus, CMS also will discontinue add-on payments for X STOP®. While CMS sought additional comments on Wingspan®, a stent system, CMS rejected the applications as it is unsure that the technology meets the substantial clinical improvement criteria.

Payment for Replaced Devices

In the FY 2007 inpatient PPS final rule, CMS indicated it was considering whether it would be appropriate to reduce Medicare payment when an implanted device is replaced at reduced or no cost to the hospital, or with partial or full credit for the removed device. In the CY 2007 outpatient PPS final rule, CMS adopted a policy that requires a reduced payment to a hospital or ambulatory surgical center when a device is provided to them at no cost. CMS believes that payment of the full inpatient PPS DRG in cases in which the device was replaced under warranty, or in which there was a full or partial credit for the price of the recalled or failed device, effectively results in Medicare payment for a non-covered item.

Unlike the current outpatient PPS policy (which applies only when a device is provided at no cost), CMS proposed to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital or with full credit for the removed device. However, CMS also proposed to apply the policy only to those DRGs under the inpatient PPS where the implantation of the device determines the base DRG assignment and situations where the hospital receives a credit equal to 20 percent or more of the cost of the device.

CMS finalized the reduction of the DRG payment by the cost of the replaced device. However, it only applies the policy to the implantation of devices that determine the base DRG assignment and it raises the threshold from 20 percent to 50 percent or more of the cost of the device. CMS does not specify what documentation must be submitted to determine if the threshold is exceeded. Invoices or other documentation would be at the discretion of the FI or MAC.

CMS also provides the option for hospitals to either submit claims immediately without Condition Code 49 and a claim adjustment with Condition Code 49 at a later date once a credit determination is made, or to hold the claim until a determination is made on the level of the credit. Under the first option, hospitals are still subject to the customary claims adjustment rules found at http://www.cms.hhs.gov/manuals/downloads/clm104c01.pdf.

Hospitals must use new condition codes to identify which claims are subject to reduced payment. They are defined below:

- Condition Code 49 – Product Replacement within Product Lifecycle. Replacement of a product earlier than the anticipated lifecycle due to an indication that the product is not functioning properly.
- Condition Code 50 – Product Replacement for Known Recall of a Product. The manufacturer or the Food and Drug Administration has identified the product for recall and replacement.

CMS agrees with commenters' concerns that the nomenclature for Condition Code 49 only describes device malfunctions while the policy may apply to other situations. Thus,

CMS will bring these concerns to the National Uniform Billing Committee for further consideration.

CMS will apply the policies to the MS-DRGs listed in the chart below. Note that the final list is more extensive than the one included in the proposed rule.

MS-DRG	Narrative Description of DRG
1 & 2	Heart Transplant or Implant of Heart Assist System with and without MCC, respectively (former CMS-DRG 103, Heart Transplant or Implant of Heart Assist System)
25 & 26	Craniotomy and Endovascular Intracranial Procedure with MCC or with CC, respectively (former CMS-DRG 1, Craniotomy Age > 17 With CC)
26 & 27	Craniotomy and Endovascular Intracranial Procedure with CC or without CC/MCC, respectively (former CMS-DRGs 2, Craniotomy Age > 17 Without CC)
40 & 41	Peripheral & Cranial Nerve & Other Nervous System Procedure with MCC; or with CC or Peripheral Neurostimulator, respectively (former CMS-DRG, 7 Peripheral & Cranial Nerve & Other Nervous System Procedures With CC)
42	Peripheral & Cranial Nerve & Other Nervous System Procedure without CC/MCC (former CMS-DRG 8, Peripheral & Cranial Nerve & Other Nervous System Procedures without CC)
23 & 24	Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant; and without MCC [or Chemotherapy Implant], respectively (former CMS-DRG 543, Craniotomy With Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis)
129 & 130	Major Head & Neck Procedures with CC/MCC or Major Device; or without CC/MCC, respectively (former CMS-DRG 49, Major Head & Neck Procedures)
216, 217, & 218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization With MCC; or with CC; or without CC/MCC, respectively (former CMS-DRG 104, Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization)
219, 220, & 221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC; or with CC, or without CC/MCC, respectively (former CMS-DRG 105, Cardiac Valve & Other Major Cardiothoracic Procedures Without Cardiac Catheterization)
237	Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair (former CMS-DRG 110, Major Cardiovascular Procedures With CC)
238	Major Cardiovascular Procedures without MCC (former CMS-DRG 111, Major Cardiovascular Procedures without CC)
260,	Cardiac Pacemaker Revision Except Device Replacement with MCC, or with

MS-DRG	Narrative Description of DRG
261, & 262	CC, or without CC/MCC, respectively (former CMS-DRGs117, Cardiac Pacemaker Revision Except Device Replacement)
258 & 259	Cardiac Pacemaker Device Replacement With MCC, and Without MCC, respectively (former CMS-DRG 118, Cardiac Pacemaker Device Replacement)
226 & 227	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC and without MCC, respectively (former CMS-DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization)
215	Other Heart Assist System Implant (former CMS-DRG 525, Other Heart Assist System Implant)
222 & 223	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRGs 535, Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock)
224 & 225	Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRG 536, Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock)
242, 243, & 244	Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (MS-DRG 551, Permanent Cardiac Pacemaker Implant with Major Cardiovascular Diagnosis or AICD Lead or Generator
242, 243, & 244	Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (former CMS-DRG 552, Other Permanent Cardiac Pacemaker Implant without Major Cardiovascular Diagnosis)
461 & 462	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC, or without MCC, respectively (former CMS-DRG 471, Bilateral or Multiple Major Joint Procedures of Lower Extremity)
469 & 470	Major Joint Replacement or Reattachment of Lower Extremity with MCC or without MCC, respectively (former CMS-DRG 544, Major Joint Replacement or Reattachment of Lower Extremity)
466, 467, & 468	Revision of Hip or Knee Replacement with MCC, with CC, or without CC/MCC, respectively (former CMS-DRG 545, Revision of Hip or Knee Replacement)

Graduate Medical Education

IME Adjustment. As required by section 502 of the MMA, CMS raised the IME payment adjustment multiplier from 1.32 to 1.35. This will increase the adjustment to a 5.55 percent increase in payments for every 10 percent increase in a hospital's resident-to-bed ratio.

Time Spent by Residents on Vacation or Sick Leave and Orientation. Since CMS' exclusion of residents' time spent in non-patient care activities from the resident count

for purposes of IME and direct graduate medical education (DGME) payment, it has received questions about the treatment of vacation or sick leave and orientations. CMS proposed to *exclude* both sick and vacation leave from the full-time equivalent (FTE) count altogether, but proposed to *include* time spent in orientations. It believes that vacation and sick leave are neither patient care nor non-patient care time, but rather a third category of time that should not be classified as either. Orientation time, as CMS explains it, may not be patient care, but it prepares residents for providing patient care. CMS did not finalize its proposal to remove sick and vacation time from the FTE counts due to the administrative burden it would impose on hospitals. However, CMS will consider how to implement such a policy in the future. CMS will continue to count orientation time in the FTE counts for hospital settings and will allow hospitals to begin counting this time for non-hospital settings with cost reporting periods beginning on or after October 1.

Disproportionate Share Hospitals (DSH)

The final rule makes a technical correction related to the inclusion of Medicare Advantage (MA) days in the Medicare fraction of the DSH calculation. When initially adopted in the FY 2005 inpatient PPS final rule, CMS did not make the appropriate changes to the related regulations. The rule officially makes these changes. CMS also released a "MLN Matters" article explaining the implementation requirements of this change, available at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5647.pdf. This article is based on Change Request (CR) 5647, which states that, as of January 7, 2008, hospitals (including acute care hospitals paid under the inpatient PPS, LTCHs and inpatient rehabilitation facilities (IRFs)) must begin to submit "no pay" bills to their Medicare contractor for stays by MA beneficiaries. This will allow for the days of those stays to be eventually captured in the DSH (or low-income patient for IRFs) calculations.

NEXT STEPS

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

In order to receive a full payment update, hospitals also should submit by August 15 a "Notice of Participation" indicating that they will continue to submit quality measure data. The form is available at http://www.qualitynet.org under "Forms" in the "RHQDAPU" section of the Web site.

Hospitals should prepare to implement the emergency services disclosure notice if they do not have 24/7 physician coverage on site. That means developing a disclosure notice and written policies and procedures for dissemination of the notice, but the notice and procedures should not be implemented until CMS obtains OMB approval and issues provider instructions.