American Hospital Association

Regulatory Advisory

AHA's Regulatory Advisory, a service to members, is produced whenever there is a significant development that affects the job you do in your community.

Medicare Inpatient PPS: The Final Rule for FY 2006

A Message to AHA Members:

The Centers for Medicare & Medicaid Services (CMS) published in the August 12 *Federal Register* the final rule for the fiscal year (FY) 2006 hospital inpatient prospective payment system (PPS). Responding to AHA requests, the agency changed its method for estimating the market basket and guidelines for relocating critical access hospitals (CAHs). We are disappointed, however, that CMS is expanding its post-acute transfer policy. The rule also makes changes to the diagnosis-related groups (DRGs), outlier payments, quality reporting, hospital wage index and payments for graduate medical education. The policies and payment rates become effective October 1, 2005.

The rule is available at www.access.gpo.gov/su_docs/fedreg/a050812c.html. Key provisions in the final rule include:

Payment Update: The rule includes a higher market basket update of 3.7 percent, up from 3.2 percent in the proposed rule for hospitals submitting data on 10 quality measures as part of the Hospital Quality Alliance and 3.3 percent for those that do not. CMS changed the market basket estimation methodology as requested by the AHA, which led to the 0.5 percent increase in the market basket rate.

Transfers: CMS will expand the post-acute care transfer provision from 30 DRGs to 182 DRGs by establishing a new set of criteria to determine the applicability of this policy. While CMS states that this policy will cost providers $780 million in FY 2006, our estimates suggest that the policy will decrease payments to providers by more than $1 billion. The AHA is extremely disappointed with the expansion, and will continue to work with Congress to address this misguided policy.

Critical Access Hospitals: The AHA is pleased that CMS has relaxed the restrictive guidelines proposed earlier this year for the replacement/relocation of necessary provider CAHs. The proposal would have barred CAHs from relocating more than 250 yards from their current location, unless they were under development by December 8, 2003. In response to the AHA's advocacy, CMS removed the arbitrary date restrictions and will allow existing necessary providers to relocate as long as 75 percent of their staff, services and patients remain in the new location.

Outliers: The rule reduces the outlier threshold from its current level of $25,800 to $23,600, similar to the AHA's recommendation. If the threshold had remained at the proposed $26,675, the AHA estimates $615 million of the 5.1 percent outlier pool would have been unspent.

Limited-Service Hospitals:

- **Definition of a hospital.** CMS repeated its plan to review its standards and process for enrolling new limited-service hospitals under Medicare, suspend issuing new provider numbers to such hospitals until the review is complete, and review whether existing limited-service hospitals meet the definition of a hospital. If its review indicates the need for regulatory changes in the definition or in the conditions of participation, CMS will issue a proposed rule.

- **Cardiac payment changes.** The rule replaces nine cardiac DRGs with 12 new DRGs. Specifically, CMS will differentiate payment based on the presence or absence of major cardiovascular conditions for cardiac patients undergoing certain procedures. While this likely affects the relative profitability of cardiac DRGs, this neither addresses payments to orthopedic or surgical limited-service hospitals, nor affects the overarching problem of physician self referral.

After reviewing this advisory, check off the following items from your to-do-list:

- ✓ Share this advisory with your senior management team.

- ✓ Ask your chief financial officer to examine the payment changes to the rule and the negative impact of the expanded transfer provision on your 2006 Medicare revenue.

- ✓ Share this advisory with your billing and medical records departments and clinical leadership to ensure they are aware of all policy changes impacting DRG coding as well as items eligible to receive new technology add-on payments in FY 2006.

The AHA will work with CMS to ensure a smooth transition to the FY 2006 payments and policies. In addition, we will work with Congress to address the inappropriate expansion of the post-acute care transfer policy.

Sincerely,

Rick Pollack
Executive Vice President August 26, 2005

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Background

The Centers for Medicare & Medicaid Services (CMS) published in the August 12 Federal Register the final rule for the hospital inpatient prospective payment system (PPS) for fiscal year (FY) 2006. While the final rule's changes primarily will affect inpatient operating and capital payments, they also will affect critical access hospitals (CAHs), long-term care hospitals (LTCHs), and other inpatient PPS-exempt providers. In addition to providing an inflationary payment increase for inpatient hospital services, the rule makes changes to the diagnosis-related groups (DRGs), post-acute care transfer rules, outlier payments, quality reporting, hospital wage index, occupational mix adjustment, payments for graduate medical education, and necessary provider status for CAHs.

The final rule is available at www.access.gpo.gov/su_docs/fedreg/a050812c.html, and takes effect October 1.

Inpatient PPS Rate Update

For 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provided an update to inpatient PPS rates equal to the full market basket rate – a measure of hospital inflation – for those hospitals that submit data on 10 specific clinical measures of quality care. The most current forecast of the market basket rate increase for 2006 is 3.7 percent, up from 3.2 percent in the proposed rule. CMS changed the market basket estimation methodology as requested by the AHA, which led to the significantly higher market basket rate. Those hospitals that do not submit quality data will receive a payment update of market basket minus 0.4 percentage points, or 3.3 percent. (See "Reporting of Hospital Quality Data" for more information.)

The MMA also permanently raised the standardized amount for other urban and rural hospitals to the large urban rate (or the urban and other area rates for Puerto Rico). By law, CMS must then 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 wage index). Beginning in 2005, the MMA authorizes CMS to use 62 percent as the labor-related share for all hospitals that would benefit, or those hospitals with a wage index less than 1.0. For hospitals with a wage index greater than 1.0, CMS will reduce the labor-related share from 71.1 percent to 69.7 percent. (More information on this reduction is provided in "Hospital Market Basket.")

The final operating standardized amounts for 2006 are as follows:

Area Wage Index Greater Than 1.0

Full Update (3.7%)		Reduced Update (3.3%)	
Labor-Related	Nonlabor-Related	Labor-Related	Nonlabor-Related
$3,297.84	$1,433.63	$3,285.12	$1,428.10

Area Wage Index Less Than 1.0

Full Update (3.7%)		Reduced Update (3.3%)	
Labor-Related	Nonlabor-Related	Labor-Related	Nonlabor-Related
$2,933.52	$1,797.95	$2,922.20	$1,791.02

For hospitals in Puerto Rico, the MMA mandated that the payment rate 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.

For Hospitals in Puerto Rico

	Rates if Wage Index is Greater than 1.0		Rates if Wage Index is Less than 1.0	
	Labor-Related	Nonlabor-Related	Labor-Related	Nonlabor-Related
National	$3,297.84	$1,433.63	$2,933.52	$1,797.95
Puerto Rico	$1,402.46	$859.57	$1,327.81	$934.22

The final capital standard federal payment rate for FY 2006 is $420.65, as compared to the proposed $419.90. For Puerto Rico, the rate is $201.93.

Reporting of Hospital Quality Data

As required by the MMA, hospitals that do not voluntarily submit data on the 10 quality indicators included in the Hospital Quality Alliance (HQA) starter set will receive a 0.4 percentage point reduction to their payment updates from fiscal years 2005 through 2007. According to CMS, 98 percent of eligible hospitals submitted the required data and received full updates for FY 2005.

To be eligible for a full market basket update for FY 2006 payments, a hospital must have continued submitting the required 10 measures each quarter according to the schedule found at www.qnetexchange.org. In addition, the hospital's third quarter data for calendar year 2004 must have passed validation with a minimum of 80 percent reliability, based upon the chart-audit validation process. These data were due to the clinical warehouse by February 15, 2005. Once the validation check was done, hospitals were informed of the results. If a hospital disagreed with any of the results, it had 10 days to appeal these results to its Quality Improvement Organization, which made the final determination. A hospital also may have asked that its third and fourth quarter data be reviewed together instead of just looking at third quarter 2004 data to determine if it passed validation.

The HQA plans to publish all four quarters of calendar 2004 data in September 2005. This program

has been the subject of earlier CMS notices and directions. For more information, go to www.qnetexchange.org.

Hospital Market Basket

The market basket is an input price index that measures price changes from a base period to another point in time. Price proxies, like the consumer price index, are used to estimate the price changes in a mix of goods and services purchased by hospitals. The MMA required CMS to update the inpatient PPS market basket at least once every five years. However, CMS plans to update it every four years, beginning with rebasing and revising the market basket for FY 2006. The base period of comparison will shift from 1997 to 2002. Thus, CMS will use 2002 cost reports to determine the relative portion of the total costs that are attributable to each category of hospital goods or services except the "all other" category that will be based on the 1997 Benchmark Input-Output tables from the U.S. Department of Commerce. The 1997 data will be inflated to 2002 by applying the annual price changes from the price proxies to the associated cost categories.

In addition, CMS will update all of the PPS indices (PPS operating, PPS capital, excluded hospital with capital, skilled nursing facilities, home health agencies, and Medicare Economic Index) at the same time.

Categories and Proxies. CMS maintains the same categories and proxies with one exception. The agency removed the blood and blood products category from the market basket and placed those costs in the miscellaneous products category. CMS believes that the Bureau of Labor Statistics Producer Price Index (PPI) for blood and derivatives "may not be consistent with the trends in blood costs faced by hospitals," and that "the PPI for finished goods minus food and energy moves most like the recent blood cost and price trends."

Labor-Related Share. The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index (AWI) is applied. CMS will reduce the labor-related share from 71.1 percent to 69.7 percent due to more recent data and the removal of postage from the labor-related share. The labor share for hospitals with AWIs less than 1.0 will remain at 62 percent as specified in the MMA. This change will be applied in a budget neutral manner by increasing the standardized amount for all hospitals, and will reduce payments to hospitals with an AWI greater than 1.0 by more than $80 million in FY 2006.

CMS also will update the labor-related share for Puerto Rico from 71.3 percent to 58.7 percent. Because there are no Puerto Rico-specific relative weights for professional fees and labor-intensive services, CMS will use the national weights.

Excluded Hospital Market Basket [1]

Beginning in FY 2003, the applicable annual rate-of-increase for hospitals and hospital units excluded from the inpatient PPS has been the excluded hospital operating market basket. This market basket is currently based on FY 1997 excluded hospital cost report data, but in the final rule CMS rebased it using 2002 excluded hospital cost report data. This rebased excluded hospital

[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 (IRF) was effective January 1, 2002; long-term care hospitals (LTCH) October 1, 2002; and inpatient psychiatric facilities (IPF) January 1, 2005. The remaining excluded hospitals are paid under the reasonable cost system, subject to the rate-of-increase limits.

market basket also is used to determine the annual update to the reasonable cost-based portion for inpatient psychiatric facilities (IPFs) and long-term care hospitals (LTCHs) currently transitioning from a full cost-based reimbursement system subject to rate of increase limits to full PPS.[2] For FY 2006, the excluded market basket will be 3.8 percent, up from 3.4 percent in the proposed rule.

However, as proposed by CMS, the rate-of-increase limits for cancer hospitals, religious non-medical health care institutions, and children's hospitals will be updated by the market basket percentage increase of 3.7 percent, up from 3.2 percent in the proposed rule.

Wage Index

The wage index adjusts DRG payments to reflect the differences in labor costs across geographic areas. The final rule will base the 2006 wage index on data from hospitals' FY 2002 cost reports. According to CMS, the national average hourly wage increased 6.2 percent compared to 2005. 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 at other hospitals. We recommend that you verify that wage data used for your hospital is accurate. It can be found on the CMS Web site at www.cms.hhs.gov/providers/hipps/ippswage.asp.

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 (CBSA). The new standards establish two categories of CBSAs:

- Metropolitan Statistical Areas with populations of 50,000 or more
- Micropolitan Statistical Areas with populations from 10,000 – 49,999

CMS adopted new MSA definitions based on the 2000 census data, which created 49 new MSAs and significantly reconfigured existing MSAs. Like the 2005 rule, the 2006 rule does not adopt the OMB definition of Micropolitan Statistical Areas for use in the Medicare payment system. Rather, hospitals in Micropolitan Statistical Areas will remain part of the statewide rural area for purposes of inpatient PPS payments.

By adopting these changes, a small number of hospitals that were classified as urban in FY 2004 became classified as rural in FY 2005. Since 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 – 2007). While these hospitals will continue to be paid based on their previous MSA assignments, they will be considered rural for all other purposes, including adjustments they will no longer be eligible for, such as the large urban add-on to the capital rates. Beginning in 2008, these hospitals will receive their statewide rural wage index, although they are eligible to apply for reclassification during the transition period and in subsequent years.

In FY 2005, CMS also provided a blend of wage indices to those hospitals that would experience a drop because of the adoption of the new labor market areas. During FY 2005, such hospitals are receiving 50 percent of the wage index using the new labor market index definition and 50 percent

[2] IRFs are paid at 100 percent of the IRF-PPS adjusted federal rate. Approximately 98 percent of all LTCHs are paid at the LTCH-PPS adjusted federal rate. IPFs began a three-year transition to the full IPF-PPS adjusted federal rate for cost reporting periods beginning on or after January 1, 2005.

of the wage index that the provider would have received under the old MSA standards. Beginning in FY 2006, hospitals will receive 100 percent of their AWI based on the new CBSA configurations.

Wage Index Calculation Change. The inpatient PPS proposed rule contained a change in the wage index calculation. This change was made in step four of the computation of the proposed FY 2006 unadjusted wage index on page 23373 in the *Federal Register*.

The change is in the calculation for overhead wage-related cost allocation to excluded areas. This calculation is made up of three steps:

- Determine the ratio of overhead hours to revised hours to calculate the overhead hours ratio;
- Compute overhead wage-related cost by multiplying the overhead hours ratio by the wage-related costs; and then
- Multiply the overhead wage-related costs by the excluded hours ratio.

For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01 of Worksheet S–3, Part III of the cost report). This change creates a higher ratio of overhead hours to revised hours, which results in an increase in the overhead cost allocated to excluded areas. This new calculation ultimately lowers the hospital's average hourly rate.

CMS is finalizing this change, despite the AHA's objections. We feel strongly that CMS should have discussed this significant change in the proposed rule.

Occupational Mix. The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 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. The adjustment is to control for the effect of hospitals' employment choices – such as the use of registered nurses versus licensed practical nurses or the employment of physicians – rather than geographic differences in the costs of labor.

CMS will continue to use the same methodology, which consists of determining an adjustment for each of the seven general occupational categories and applying each adjustment separately to the wage index. In addition, given the potential financial impact on hospitals, CMS again will limit the use of occupational mix adjustment at 10 percent. Thus, 10 percent of the wage index will be based on an average hourly wage adjusted for occupational mix, and 90 percent will be based on an average hourly wage unadjusted for occupational mix. CMS indicates that 27.7 percent of rural areas and 52.1 percent of urban areas will see a decrease in their wage index as a result of the adjustment. The largest negative impact for a rural area will be 0.18 percent, while the largest negative impact for an urban area will be 0.43 percent. The largest positive impact for a rural area will be 0.37 percent, while the largest increase for an urban area will be 2.2 percent.

Out-Migration Adjustment. Section 505 of the MMA provides hospitals in lower wage areas a wage index adjustment if a significant number of hospital workers commute from the lower wage area to higher wage areas nearby. This wage index 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 wage index adjustment is effective for three years. Also, under changes prescribed by the MMA, hospitals that receive this adjustment are not eligible for geographic

reclassification. Hospitals noted in Table 4J, found at www.cms.hhs.gov/providers/hipps/ippswage.asp will receive this out-migration adjustment.

Hold-Harmless for Certain Urban Hospitals Redesignated as Rural. Last year, CMS discovered an instance where the approved redesignation of an urban hospital as rural resulted in the hospital's data adversely impacting the rural wage index. To address this concern, CMS will apply the hold-harmless rule that currently applies when rural hospitals are reclassified as urban to situations when urban hospitals are reclassified as rural. Thus, the wage data of an urban hospital reclassifying to a rural area will be included in the rural area's wage index, if including the urban hospital's data increases the wage index of the rural area. Otherwise the wage data are excluded.

Section 508 Reclassifications. Section 508 of the MMA provided $900 million over three years for a one-time geographic reclassification opportunity. While the 508 reclassifications do not expire until March 31, 2007, applications for reclassification for FY 2007 are due September 1, 2005. As requested by the AHA, CMS clarifies its position on the second half of FY 2007 (April 1, 2007–September 30, 2007).

In the final rule, CMS states that individual hospitals reclassified under Section 508 will be allowed to request regular reclassification for the portion of the three-year period that the hospital is not receiving Section 508 funding, or to turn down the Section 508 reclassification for the first half of FY 2007 and reclassify under the regular process.

In order for a group to reclassify, all hospitals in the area must agree to do so. Thus, CMS will allow section 508 hospitals to turn down such reclassification for the first half of FY 2007 and join a group, or to maintain Section 508 reclassification while the rest of the group gets their home wage index for the first half of the year and then join the entire group to get regular group reclassification for the rest of the three-year period.

Multi-Campus Hospitals. Payment is determined using the wage index value for the MSA in which a campus is located even though the other campuses may be in different labor market areas. Because multi-campus hospitals submit a single cost report that does not break down the wage data by campus, an individual campus historically has been unable to reclassify. For FYs 2006 (if application already is submitted), 2007 and 2008 reclassifications, CMS will allow an individual campus to use the average hourly wage data of the entire multi-campus hospital system to seek geographic reclassification to the labor market area in which the other campus(es) is located. CMS also will continue to consider mechanisms to collect the necessary data for geographic reclassifications in the future that are not unduly burdensome for providers. The deadline for reclassification for FY 2007 is September 1, 2005, thus eligible hospitals should act quickly to take advantage of this change.

Post-Acute Care Transfers

In a disappointing move, CMS will expand the post-acute care transfer policy from 30 DRGs to 182 DRGs in FY 2006. While CMS states that this policy will cost providers $780 million in FY 2006, the AHA's estimates suggest that the policy will decrease payments to providers by more than $1 billion.

Medicare patients in certain DRGs who are discharged to a post-acute care setting – such as rehabilitation hospitals and units, long-term care hospitals, or skilled nursing facilities – or are

discharged within three days to home health services are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount, up to the full inpatient PPS rate. Thus, if a patient has a shorter than average inpatient stay, the hospital is paid less than the full DRG rate.

Currently to be included in the transfer-DRG list, a DRG must have the following for the two most recent years:

- At least 14,000 discharges to post-acute care;
- At least 10 percent of its discharges to post-acute care occurring before the geometric mean length of stay;
- A geometric mean length of stay of at least three days; and
- If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent five year period of at least 7 percent.

CMS proposed to expand the application of the post-acute care transfer policy to any DRG that meets the following criteria:

- At least 2,000 discharges to post-acute care;
- At least 20 percent of its discharges are to post-acute care;
- At least 10 percent of its discharges to post-acute care occur before the geometric mean length of stay for the DRG;
- A geometric mean length of stay of at least three days; and
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

For FY 2006, CMS will expand the DRGs subject to the policy based on the following criteria:

- The DRG must have a geometric mean length of stay of at least three days;
- The DRG must have at least 2,050 post-acute care transfer cases;
- At least 5.5 percent of the cases in the DRG must be discharged to post-acute care prior to reaching the geometric mean length of stay for that DRG; and
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs will be included if either one meets the three criteria above.

CMS chose the threshold of 2,050 post-acute care transfer cases and 5.5 percent of discharges before reaching the geometric mean length of stay because both are the 55th percentile. CMS made this change in response to comments from the AHA and others that 231 DRGs could not have a high-volume of post-acute care discharges and disproportionate use of post-acute care as specified in the statute. The AHA continues to believe that the 55th percentile is in the range of average and hardly "disproportionate."

Table 5, found at www.cms.hhs.gov/providers/hipps/ippspufs.asp on the CMS Web site, denotes which DRGs are subject to the policy and will be eligible for the special payment provision (50 percent of the DRG on the first day) under the post-acute care transfer policy.

The AHA is extremely disappointed with the expansion, and will continue to work with Congress to address this misguided policy. It is not in the best interests of patients or caregivers, and it undermines clinical decision-making. Moreover, it penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting.

Changes to DRG Classifications and Weights

The Secretary of Health and Human Services (HHS) is required to revise the DRG groups and weights annually to reflect changes in technology, medical practice and other factors. In constructing the DRG weights for FY 2006, CMS recalibrated the DRG weights based on charge data for Medicare discharges using the FY 2004 MedPAR file.

The major DRG changes are:

- DRG 559 has been created to better recognize the higher costs associated with caring for acute ischemic stroke patients treated with thrombolytic agents. Proper DRG grouping will require the accurate reporting of administration of thrombolytic agents (ICD-9-CM code 99.10), which CMS believes is being underreported because it did not affect DRG assignment prior to this change.

- Cardiac electrophysiological stimulation and recording studies (ICD-9-CM code 37.26) have been removed from the list of cardiac catheterizations for DRGs 535 and 536. This procedure has been moved to DRG 515.

- Nine cardiac DRGs were deleted and replaced with 12 new DRGs on the basis of the presence or absence of a major cardiovascular condition. New codes take effect October 1 to provide additional specificity on the number of vessels treated and the number of stents inserted. CMS will continue to consider whether the structure of these DRGs ought to reflect these differences on the basis of the additional information being provided by the new codes.

- Extracorporeal membrane oxygenation (ECMO) is being moved to a higher paying DRG. ECMO will be moved from DRG 104 and 105 to DRG 541 since the average charges for ECMO cases are closer to the average charges for tracheostomy patients in DRG 541.

- Separate DRGs have been created for revisions of hip and knee replacements. Data has shown that revisions are clinically more difficult and significantly more resource intensive procedures than the original hip and knee replacements. New codes take effect October 1 to differentiate a wide variety of hip and knee replacement procedures that vary in their clinical indications, resource intensity and clinical outcomes. Claims data using these new and more specific codes should provide improved data on these procedures for future DRG modifications.

- Repair of atrial septal defect with prosthesis, closed technique (ICD-9-CM code 35.52) is being moved from DRG 108 to DRG 518. Cases in DRG 518 more closely resemble this procedure in average length of stay, average charges and clinical coherence.

- DRG 103 has been reconfigured. This DRG will render higher payments for patients who receive both an implant and an explant of an external heart assist system during a single hospital stay. The intent is to recognize the higher costs of patients who have a longer length of stay and are discharged alive with their native heart.

- A new DRG has been created for non-cervical spinal fusions for cases with scoliosis, malignant neoplasm of the vertebra or a pathologic fracture. Data has shown that the presence of these principal diagnoses has a significant affect on resource use for spinal fusion patients.

Implementation of ICD-10

The AHA recommended that CMS act immediately to adopt coordinated implementation of ICD-10-CM and ICD-10-PCS in the United States and referenced the National Committee on Vital and Health Statistics' concerns that ICD-9-CM is "increasingly unable to address the needs for accurate data for health care billing, quality assurance, public health reporting, and health services research." We also expressed concern about CMS' ability to implement add-on payments for new services and technologies in the near future given that the ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

In the final rule, CMS agreed that it is becoming increasingly difficult to update ICD-9-CM and stated that it continues to revise ICD-9-CM and create codes that recognize new medical technology. The agency also will continue to update ICD-10-PCS on an annual basis to reflect changing technology. CMS agreed that it is important to have an accurate and precise coding system for this purpose. However, CMS also noted the observation of many commenters that the transition from one coding system to another raises many complex operational issues. The final rule said that HHS would continue to study this matter as it considers whether to adopt ICD-10.

New Technology Payments

Section 503 of the MMA provided new money for add-on payments for new medical services and technologies under the inpatient PPS. Previously, increases in payments for new technologies decreased payments for all other inpatient services. In addition, the MMA lowered the cost threshold for new technologies to qualify for new technology payments to the lesser of 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.

CMS approved two new applications and will maintain payment for one currently approved technology.

Re-evaluation of FY 2005 Approvals. CMS will discontinue the new technology add-on payment for INFUSE™ (Bone Morphogenetic Proteins (BMPs) for Spinal Fusions), Stryker's OP-1™ Putty, and InSync® Defibrillator System (Cardiac Resynchronization Therapy with Defibrillation).

However, CMS will continue add-on payments for Kinetra® Implantable Neurostimulator in FY 2006, which was approved by the Food and Drug Administration (FDA) on December 16, 2003. The Kinetra® implantable neurostimulator is designed to deliver electrical stimulation to the subthalamic nucleus (STN) or internal globus pallidus (GPi) in order to relieve symptoms caused by abnormal neurotransmitter levels that lead to abnormal cell-to-cell electrical impulses in Parkinson's Disease and essential tremor.

Cases receiving Kinetra® for Parkinson's disease or essential tremor are eligible to receive an add-on payment of up to $8,285, or half the cost of the device, which is approximately $16,570. These cases are identified by the presence of procedure codes 02.93 (Implantation or replacement of intracranial neurostimulator leads) and 86.95 (Insertion or replacement of dual array

neurostimulator pulse generator). If a claim has only the procedure code identifying the implantation of the intracranial leads, or if the claim identifies only insertion of the generator, no add-on payment is made.

Reconsideration of FY 2005 Applications. CMS denied the reconsideration applications submitted for INFUSE™ Bone Graft BMPs for Tibia Fractures, Aquadex TM System 100 Fluid Removal System (System 100). CMS does not believe these technologies meet the newness requirements.

New FY 2006 Applications. CMS denied the applications submitted for Safe-Cross® Radio Frequency Total Occlusion Crossing System, Wingspan™ Stent System with Gateway™ PTA Balloon Catheter (No FDA approval), CHARITE™ Artificial Disc, and Trident® Ceramic Acetabular System.

CMS has approved the applications for GORE TAG and Restore® for FY 2006. At the time of initial application, the FDA had not yet approved the Endovascular Graft Repair of Thoracic Aorta (GORE TAG) device, but did so on March 25. CMS stated in the proposed rule that FDA approval had occurred too late for it to conduct cost threshold and significant clinical improvement analyses. In the final rule, CMS determined that the GORE TAG satisfies all three criteria and therefore will be eligible for add-on payments beginning in FY 2006. These cases generally are in DRGs 110 and 111. Cases involving the device should code for the device using the newly created ICD-9-CM procedure code 39.73 (Endovascular implantation of graft in thoracic aorta). The cost of a single device is $12,798. Because the average patient receives 1.8 endovascular prostheses, CMS estimated the cost of the device to be $21,198 per patient. Therefore, beginning October 1 cases that include code 39.73 will be eligible to receive new technology add-on payments up to $10,599, or half the cost of the device.

CMS also approved the application for Restore Rechargeable Implantable Neurostimulator. In the final rule, based on numerous comments on the proposed rule, CMS determined that the device is substantially different from predecessor devices and represents a substantial clinical improvement. Cases involving these devices will be identified by the presence of newly created ICD-9-CM code 86.98 (Insertion or replacement of dual array rechargeable neurostimulator pulse generator). These cases are generally included in the following DRGs: 7, 8, 499, 500, 531 or 532. The maximum add-on payment for the device will be $9,320.

Blood-Clotting Factors

CMS will reimburse for blood-clotting factors administered to patients with hemophilia based on 106 percent of Average Sales Price, or $0.14 per individual unit. This will make payment for blood-clotting factors consistent across Medicare Parts A and B.

Outlier Payments

Cases will qualify for outlier payments in FY 2006 if their costs exceed the inpatient PPS rate for the DRG, including indirect medical education, disproportionate share hospital (DSH), and new technology payments, plus the fixed-loss threshold of $23,600. Had CMS set the threshold at the proposed $26,675, we estimate that CMS would not spend at least $610 million of the 5.1 percent of payments set aside for outliers for FY 2006. While this is a great improvement, the AHA remains concerned that CMS may not spend the full 5.1 percent set aside given that CMS' methodology only considers charge inflation and not actual cost growth.

Graduate Medical Education

The rule makes a number of changes to direct graduate medical education (GME) and indirect medical education (IME).

Initial Residency Period. Last year, CMS instituted a new policy for weighting the direct GME resident count for residents that pursue specialties requiring an initial year of broad-based training, such as anesthesiology or radiology. The new policy allows the initial residency period to be based on the period of board eligibility for the specialty, rather than the clinical-base year. For FY 2006, CMS will expand the policy to base the initial residency period on the period of board eligibility for the specialty when a resident matches directly to an "advanced program" even though the resident did not match for an initial clinical base-year training program at the same time. This will allow hospitals to be paid an entire full-time equivalent (FTE) for such residents until they are board eligible if the residents arrange for a clinical base-year outside of and subsequent to the matching program.

Affiliation Agreements. Previously, rural hospitals that began residency training programs on or after January 1, 2005 were able to establish affiliation agreements with hospitals that had existing residency programs. CMS believed that this was necessary for rural hospitals that may not have the patient volume to support a program on their own. To ensure that the hospitals were not establishing programs and entering into agreements with the purpose of increasing the resident cap at another hospital's existing program, CMS required the rural hospitals to provide at least one third of the FTE residents' training. In this year's final rule, CMS will allow urban hospitals that create a new residency program to establish affiliation agreements with another hospital so long as the agreement results in a positive adjustment to the hospital's cap. This will prevent hospitals from creating new residency programs and then moving most or all of its residents over to an existing program.

IME Adjustment. While not mentioned in the preamble of the rule, the impact analysis indicates that CMS is reducing the IME payment adjustment from 5.8 percent to 5.55 percent as required by section 502 of the MMA.

IME Adjustment for TEFRA Hospitals Converting to Inpatient PPS Hospitals. For the purposes of determining the number of residents that a hospital may include in its FTE count for direct GME and IME payment, a hospital's unweighted FTE count may not exceed the hospital's unweighted FTE count for its most recent cost reporting period ending on or before December 31, 1996. During the process of determining this baseline, the fiscal intermediaries did not determine IME FTE resident counts for hospitals excluded from the inpatient PPS. However, if an excluded hospital converts to the inpatient PPS and has a residency program, it is eligible for IME payments.

To address this, CMS will use the FTE count for the respective hospital used to determine the hospital's direct GME FTE cap. The new inpatient PPS hospital's IME FTE cap will be subject to the same rules and adjustments as any inpatient PPS hospital's IME FTE cap. For instance, if the GME count on which CMS is basing the IME count for that hospital included residents training in non-hospital settings, CMS will adjust the cap downwards proportionately as such residents are not to be included in the IME count.

In addition, CMS also clarifies that this policy will not apply to distinct-part units. CMS asserts that when a distinct-part unit is subsumed within an acute-care hospital, and thus is newly subject to the inpatient PPS, it is "equivalent to an expansion in the bed size of the acute-care hospital." Given that such expansions do not qualify a hospital for an increase in its IME FTE cap, CMS will not apply this policy to distinct-part units that convert.

Rural IME FTE Cap Adjustments. If a rural hospital is redesignated as urban due to changes in the labor market areas, CMS will allow the hospital to retain the 130 percent adjustment to its IME FTE resident cap for rural track training programs. However, once such a hospital becomes urban, it may no longer seek FTE cap adjustments relating to new training programs. The hospital may retain only the adjustment it received for the new programs added when it was rural.

Medicare policy allows an urban hospital to become rural under a reclassification request and receive the 130 percent adjustment to its IME FTE resident cap. However, an urban hospital treated as a rural hospital may subsequently withdraw its election and return to its urban status. In the final rule, CMS states that a teaching hospital that rescinds its rural reclassification within 10 years of such reclassification and returns to being urban would not be eligible for permanent increases in its IME cap. Rather, any adjustments the hospital received to its IME cap due to its rural status would be forfeited upon returning to urban status. Hospitals that are reclassified for 10 or more years will be able to retain the adjustment, as it is clear that the hospital did not reclassify for the purpose of increasing its cap.

Low-Volume Hospitals

Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per case of low-volume hospitals. 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 specified 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 maintains a 25 percent increase in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS will not provide an adjustment.

New Rural Referral Centers

If a hospital wants to become a Rural Referral Center (RRC), but does not meet the bed size criterion of 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 final rule updates the alternative criteria for RRC designation in FY 2006 to:

- A case-mix index that is at least equal to the lower of the median case-mix index for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median case-mix index for all hospitals nationally (1.31721); 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 (or at least 3,000 for osteopathic hospitals).

No region has a discharge value of less than 5,000. The median case-mix index values are:

Region	Median Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.2300
2. Middle Atlantic (PA, NJ, NY)	1.2469
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.3277
4. East North Central (IL, IN, MI, OH, WI)	1.2762
5. East South Central (AL, KY, MS, TN)	1.2911
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.2252
7. West South Central (AR, LA, OK, TX)	1.3532
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.3620
9. Pacific (AK, CA, HI, OR, WA)	1.3241

Provider-Based Determinations

CMS will add rural health clinics with 50 or more beds that are affiliated with hospitals to the list of specific types of facilities and organizations for which determinations of provider-based status will not be made.

Critical Access Hospitals

Necessary Provider Status. Currently, a governor may certify a hospital as a "necessary provider," which allows that hospital to become a CAH even if it fails to meet the distance requirement of being more than 35 miles (or 15 miles in mountainous areas or by secondary roads) away from a PPS hospital or another CAH. The MMA terminates a state's authority to grant necessary provider status as of January 1, 2006; however, it includes a grandfather provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation.

CMS initially proposed very restrictive guidelines for rebuilding or relocating CAHs that have necessary provider status. The proposed rule would have allowed hospitals to rebuild on the existing site within 250 yards, or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For hospitals that moved any further than that, the hospital would be relocating and would have to have shown that it**:**

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Met the *same* criteria for necessary provider status (e.g., in a health professional shortage area (HPSA) and remains in a HPSA);
- Served the same community (75 percent of same services, 75 percent of same population, 75 percent of the same staff);
- Complied with the same conditions of participation; and

- Was "under development" as of December 8, 2003 using similar criteria as specialty hospitals (architectural plans, financing, zoning, construction bids, etc).

However, CMS relaxed these restrictions in its final rule. Of note, CMS removed the arbitrary date restrictions and will not make a distinction between rebuilding and relocating. Beginning, January 1, 2006, necessary providers that wish to rebuild must:

- Serve 75 percent of the same population;
- Retain 75 percent of the same staff; and
- Provide 75 percent of the same services.

If the relocation results in the CAH no longer serving the *same* community, meaning it cannot meet the 75 percent test described, CMS will consider relocation as a cessation of business at one location and establishment of a new business at another location. CMS states that a cessation of business is a voluntary termination of the provider agreement, and thus providers are not able to appeal if they lose necessary provider status due to relocation. This means that CAHs with necessary provider status, which cannot reapply for necessary provider status as of January 1, 2006, will lose CAH status altogether and have to convert back to the inpatient PPS.

The AHA will work with CMS to ensure that the 75 percent test is clearly laid out and applied fairly.

CAHs in "Lugar Counties." One of the requirements for CAH designation is that the hospital must be located in or reclassified to a rural area. The MMA provided that hospitals located in a rural county that is adjacent to one or more urban counties are considered to be located in the urban MSA to which the greatest number of workers in the county commute, if certain conditions are met. Such rural counties are referred to as "Lugar counties" (named after Sen. Richard G. Lugar (R-IN) who authored this provision).

Certain counties that previously were not considered Lugar counties were, effective October 1, 2004, redesignated as Lugar counties as a result of the most recent labor market definitions. This caused some CAHs located in these counties to be unable to meet the rural location requirement, even though they were in full compliance at the time they were designated as critical access. CMS proposed to hold these facilities harmless until September 30, 2006, which CMS believed was sufficient time to seek reclassification as rural.

However, in the final rule, CMS changed its position to ease the burden of reclassifying for these facilities. Beginning in FY 2006, facilities in Lugar counties will be considered for purposes of CAH participation to be located in rural areas. In other words, the Lugar reclassifications will not be considered in determining whether a hospital is rural. As a result, CAHs will not need to submit an application for reclassification to remain in compliance with the conditions of participation. CMS said that it believed this change would achieve the desired result without increasing the administrative burden for CAHs or the Medicare program. CMS emphasized that this change will be effective only for purposes of CAH participation and will not otherwise affect the status of hospitals or CAHs in Lugar counties.

Rural Community Hospital Demonstration Program

Section 410 of the MMA requires CMS to conduct a demonstration program in rural areas where 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. In order to participate in this demonstration project, a rural community hospital must be located in one of the following states with the lowest population density: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah and Wyoming. CMS will implement this demonstration in a budget neutral manner by offsetting inpatient PPS payments to other hospitals by $12.7 million.

Medicare Disproportionate Share Hospitals

Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. Hospitals can choose whether to use the data based on the federal fiscal year or their own fiscal year. CMS will proceed as planned and release a MedPAR limited data set for both Supplemental Security Income, or SSI, and Medicare free of charge. However, hospitals will have to rely on their states for the Medicaid information. CMS declined to alter the state plan regulations to tighten the requirements around the quality of data furnished to providers by the states.

Long-Term Care Hospitals

The final rule implements the recalibration of the LTCH DRG relative weights for FY 2006. CMS estimates that the impact of this recalibration will be an aggregate 4.2 percent reduction in Medicare payments to LTCHs, a slightly smaller reduction than the proposed rule estimate.

The LTCH DRG recalibration in the final rule was based on 2004 claims. The AHA and others urged CMS to recalibrate the LTCH DRGs in a budget neutral manner, as it does for the general acute-care hospital DRGs. However, the final rule re-states CMS' interpretation that the statute only requires the LTCH PPS to adjust for budget neutrality in its first year of implementation (FY 2003) and following the five-year phase-in of the payment system.

In the final rule, the agency also states that the new relative weights and the resulting lower payments are appropriate since LTCH costs have substantially decreased since the LTCH PPS was introduced in 2002. CMS also notes that the 4.2 percent decrease in payments caused by recalibration is offset by the annual LTCH payment update for rate year 2006. LTCHs saw a 5.7 percent increase in July due to the annual LTCH market basket update and outlier changes implemented through the LTCH PPS rulemaking process. The recalibration of the LTCH DRGs is linked to the changes to the inpatient PPS DRGs included in this rule.

The AHA is disappointed that CMS failed to implement a dampening policy recommended to mitigate the substantial payment cuts resulting from the LTCH DRG recalibration.

Limited-Service Hospitals

In the final rule, CMS repeated its plan to carefully review its standards and process for determining whether limited-service applicants for a hospital provider number meet the Medicare definition of a hospital, including a review of current limited-service hospitals, to ensure they are primarily hospitals, not ambulatory surgical centers (ASC). That review is expected to last until December 2005, and no new hospital provider numbers will be issued to limited-service hospitals during that review. CMS' actions effectively extend by six months a congressional moratorium on physician

self-referral to new limited-service hospitals in which they have an ownership interest. The notice also states CMS' intent to publish a separate proposed rule if its review indicates the need to modify current regulations on the definition of a hospital. In a separate fact sheet released with the inpatient PPS notice, CMS said that an open door session would be held in September to solicit comments on this issue. In addition, CMS noted it is developing a new ASC payment system, for implementation by 2008 that would reduce the financial incentive for ASCs to convert to limited-service hospitals.

Finally, the rule replaces nine cardiac DRGs with 12 new DRGs. Specifically, CMS will differentiate payment based on the presence or absence of major cardiovascular conditions for cardiac patients undergoing certain procedures. While this likely affects the relative profitability of cardiac DRGs, this neither addresses payments to orthopedic or surgical limited-service hospitals, nor affects the overarching problem of physician self-referral.

Financial Impact on Hospitals

According to the impact assessment, the overall changes will provide, on average, a 3.5 percent payment increase to hospitals. Urban hospitals will receive a 3.5 percent average increase while rural hospitals will receive a 3.4 percent average increase. CMS estimates that the total impact of these changes for FY 2006 operating payments compared to FY 2005 is approximately a $3.33 billion increase. Total spending is projected to increase to $108 billion.