American Hospital Association

Regulatory Advisory

May 6, 2010

MEDICARE INPATIENT PPS: THE PROPOSED RULE FOR FISCAL YEAR 2011

The Issue:

On April 19, the Centers for Medicare & Medicaid Services (CMS) issued its hospital inpatient and long-term care hospital prospective payment system (PPS) proposed rule for federal fiscal year (FY) 2011. The proposed rule is available at http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS and was published in the May 4 *Federal Register*. Comments are due to CMS by June 18. A final rule will be released by August 1, and changes will take effect October 1.

This proposed rule affects inpatient PPS, as well as long-term care and critical access hospitals. A detailed summary including changes in operating payments; the documentation and coding adjustment; quality measure reporting; hospital-acquired conditions; and capital, disproportionate share hospital and rural hospital payments is attached. The summary was prepared for the AHA by Health Policy Alternatives, Inc.

Our Take:

The AHA is extremely disappointed with the level of payment for FY 2011 and is determining the hospital-specific impact of the behavioral offset cuts. We also are conducting a detailed and thorough analysis of CMS' proposal and methodology for determining the behavioral offset for use in our comment letter on the FY 2011 proposed rule. We are committed to helping ensure that hospitals receive an appropriate update for FY 2011.

What You Can Do:

Please share this Advisory with your senior management team and ask your chief financial officer to examine the potential impact of the proposed payment changes on your Medicare revenue.

Further Questions:

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

AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. A 67-page summary of this issue follows.

MEDICARE HOSPITAL INPATIENT OPERATING AND CAPITAL PAYMENT FISCAL YEAR 2011 PROPOSED RULE

SUMMARY

On April 19, 2010, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule for federal fiscal year (FY) 2011 changes to Medicare's acute care hospital inpatient prospective payment system (IPPS). The payment rates and policies described in the proposed rule will affect Medicare's operating and capital payments for short-term acute care hospital inpatient services paid under the IPPS as well as payments for inpatient services provided by certain "IPPS-exempt" providers, such as critical access hospitals (CAHs). The proposed rule was published in the *Federal Register* on May 4, 2010 with a 60-day comment period (from the date of public display) closing on June 18, 2010. Most of the new rates and proposed policy changes, as modified by the final rule due to be published by August 1, 2010, will be effective October 1, 2010. The proposed rule also includes changes affecting Medicare's long-term care hospital (LTCH) prospective payment system; these changes will be described in a separate summary.

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I. Impact

CMS estimates that operating payments to all hospitals under the IPPS will decrease by $142 million in FY 2011, a reduction of 0.1 percent, and that capital payments will decrease by $20 million, for a combined reduction of $162 million taking into account all changes in the proposed rule. The estimate of operating IPPS payments in FY 2011 does not include any projection of changes in hospital admissions or real case-mix intensity, which also would affect overall payments. The proposed rule also does not include changes made by the health care reform laws, the *Patient Protection and Affordable Care Act* (PPACA) and the *Health Care and Education Reconciliation Act of 2010* (HCERA) because enactment was too late to include their changes. The major changes in these laws affecting IPPS payments in FY 2011 are a market basket update reduction of 0.25 percentage points each year, FY 2010 and FY 2011; $200 million in additional payments for hospitals in counties in the lowest quartile with respect to Medicare spending per beneficiary; and extensions of expiring provisions, including Section 508 wage index reclassifications and several rural provisions.

The major changes in the proposed rule affecting IPPS operating payments are the proposed market basket increase of 2.4 percentage points applicable to operating payments and a proposal to reduce payments by 2.9 percentage points to recover a portion of payments made due to coding or classification changes that do not reflect real changes in case-mix. (This proposal is described in section III.B below.) Average operating payments per case are projected to decrease 0.1 percent despite the +2.4 percentage point market basket update and the -2.9 adjustment for documentation and coding due to an additional factor. CMS projects that actual outlier payments in FY 2010 will be about 4.7 percent compared to the 5.1 percent outlier offset. For FY 2011, CMS again will apply a 5.1 percent outlier offset and it projects that payments will equal the 5.1 percent offset. Thus, compared to FY 2010, outlier payments in FY 2011 will be 0.4 percent higher.

The proposed rule impact analysis shows that average operating payments per case will decrease 0.1 percent, with relatively small variation by type of hospital. Rural hospitals will experience an average reduction of 0.5 percent. The biggest variation in the rule's impact is by geographic area. Urban hospitals in the New England and Middle Atlantic regions show decreases of 0.9 and 0.6 percent respectively while urban hospitals in the Pacific region are projected to gain 1.5 percent. Rural hospitals in the New England, Pacific, Middle Atlantic and East North Central regions experience decreases of 1.6, 1.5, 0.8 and 0.7 respectively while rural hospitals in the West North Central gain 0.4 percent. The 19 cardiac specialty hospitals are projected to see average payments per case rise 0.8 percent.

Estimates of the impacts are displayed in Table I of the proposed rule (included in the appendix of this summary). The table below shows the impact by major hospital category.

Hospital Type	All Proposed Rule Changes
All Hospitals	-0.1%
Large Urban	-0.1%
Other Urban	-0.1%
Rural	-0.5%
Major Teaching	0.0%

Breaking down the 0.2 percentage point decrease in average FY 2011 IPPS capital payments per case overall, hospitals in urban areas will lose -0.2 percentage points while those in rural areas fall -0.7 percentage points. Major factors affecting capital IPPS payments are an update of 1.5 percent based on the capital input price index, an assumed increase in case mix of 1.0 percent, and a 0.957 adjustment to the proposed FY 2011 capital Federal rate for changes in documentation and coding (discussed in section VI below).

II. Proposed IPPS Rate Updates

The proposed rule provides a FY 2011 market basket update for operating costs of 2.4 percent, the estimated full market basket increase (as required by current law) for hospitals that report the required quality measures to CMS; hospitals which do not satisfy the reporting requirements would get a 0.4 percent update. According to the proposed rule, 104 hospitals did not receive the full market basket increase in FY 2010 due to failure to report quality measures satisfactorily. (See section V.A below for details of the FY 2011 voluntary quality reporting requirement.)

The standardized amounts in the proposed rule include the -2.9 percentage point documentation and coding adjustment but they do not include the market basket update reduction of 0.25 percentage points each year, FY 2010 and FY 2011. The combined FY 2011 impact of the two years of market basket update reductions is a reduction 0.499 percentage points. Excluding these reductions, the proposed rule projects the following rates effective October 1, 2010:

TABLE 1A.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)

Full Update (2.4 Percent)		Reduced Update (0.4 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,566.91	$1,617.55	$3,497.24	$1,585.96

TABLE 1B.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)

Full Update (2.4 Percent)		Reduced Update (0.4 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,214.37	$1,970.09	$3,151.58	$1,931.62

TABLE 1C.—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
	Labor	**Nonlabor**	**Labor**	**Nonlabor**
National	$3,566.91	$1,617.55	$3,214.37	1,970.09
Puerto Rico	$1,530.25	$933.92	$1,527.79	$936.38

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

	Rate
National	$420.99
Puerto Rico	$199.43

III. Proposed Changes to DRG Classifications and Relative Weights

A. Proposed MS-DRGs for FY 2011

In the proposed rule for FY 2011, CMS proposes to continue to use the MS-DRG classification system with very few changes from FY 2010. The system will have 747 MS-DRGs in FY 2011, one more than in FY 2010 after eliminating one MS-DRG and adding two new ones. CMS refers readers to the FY 2008 final rule (published in the Federal Register at 72 FR 47140 through 47189) for a detailed description of the process used to develop the MS-DRGs.

For the FY 2011 proposed rule, CMS based its MS-DRG analysis on data from the September 2009 update of the FY 2009 MedPAR file, which contains hospital bills received through September 30, 2009, for discharges occurring through September 30, 2009. Specific MS-DRG changes that CMS proposes for FY 2011 are described in section E below.

Many of the annual changes to the MS-DRG classifications are the result of specific issues brought to CMS' attention by interested parties. CMS encourages individuals to raise such issues no later than early December for them to be considered for the next annual proposed rule updating the IPPS. The preamble also notes that CMS will

consider requests to use non-MedPAR data in the recalibration process according to a process described in the FY 2000 IPPS final rule (64 FR 41500). Under this process, a significant sample of the non-MedPAR data should be submitted by mid-October with final data due in early December.

B. Proposed FY 2011 Documentation and Coding Adjustment

Background

FY 2008 and FY 2009. When the transition to MS-DRGs began in FY 2007, CMS projected that the average case-mix index (CMI) would increase, especially in the initial years, due to improved medical record documentation as well as more complete and accurate coding. Such CMI changes increase payments to hospitals, but CMS states they do not reflect the type of real increases in the severity of cases that require additional hospital resources. CMS actuaries estimated that maintaining budget neutrality required an adjustment of -4.8 percent to the national standardized amount. In the FY 2008 final rule, CMS phased in this -4.8 percent adjustment over 3 years, with prospective documentation and coding adjustments scheduled to be -1.2 percent in FY 2008, -1.8 percent in FY 2009, and -1.8 percent in FY 2010.

Responding to hospital concerns, on September 29, 2007 Congress enacted the *Transitional Medical Assistance, Abstinence Education, and Qualifying Individuals Programs Extension Act of 2007* (P. L. 110-90). Section 7(a) of the law reduced the documentation and coding adjustment to -0.6 percent for FY 2008 and -0.9 percent for FY 2009, but did not adjust the FY 2010 -1.8 percent adjustment. To implement these changes, CMS promulgated a final rule on November 27, 2007 (72 FR 66886).

In the final rule for FY 2009, CMS applied a documentation and coding adjustment of -0.9 percent to the national standardized amounts as required by P.L. 110-90. Because the documentation and coding adjustments established in the FY 2008 IPPS final rule were cumulative, the -0.9 percent adjustment in FY 2009 was in addition to the -0.6 percent adjustment in FY 2008, yielding a combined effect of -1.5 percent for FY 2009. The adjustments made in FYs 2008 and 2009 are carried forward and affect future standardized amounts.

FY 2010. P. L. 110–90 requires the Secretary to make adjustments in fiscal years 2010 to 2012 to the extent that case-mix changes due to improved documentation and coding differ from the level assumed in the prospective adjustments made by Congress. Two types of corrections are required. Section 7(b)(1)(A) of P. L. 110–90 requires an appropriate adjustment to the extent that the Secretary determines that actual changes in documentation and coding during FY 2008 or FY 2009 are different than the prospective adjustments that were applied. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. The adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the

prospective adjustments in FY 2008 and FY 2009 reflected the change that actually occurred in those years.

Similarly, if the Secretary determines, based on a retroactive evaluation of claims data, that changes in documentation and coding during FY 2008 or FY 2009 are different from the prospective adjustments, then section 7(b)(1)(B) of P. L. 110-90 requires the Secretary to make an additional adjustment to the standardized amounts. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the actual documentation and coding effect and the documentation and coding adjustments which were applied in the respective fiscal years.

For the FY 2010 proposed rule, CMS estimated the documentation and coding increase in FY 2008 to be 2.5 percent. The analyses were repeated for the final rule using more complete FY 2008 MedPAR data (claims processed through March 2009 versus claims processed through December 2008) and the results did not change. The proposed rule reduced the national standardized amounts by 1.9 percent to satisfy the requirement of section 7(b)(1)(A) of P. L. 110-90 to correct IPPS rates going forward, but the proposal delayed recovery of the additional FY 2008 payments made in FY 2008 due to the underestimate of the prospective adjustment. CMS stated it would wait for more complete data and make the necessary recoveries in FYs 2011 and 2012. CMS had estimated that these additional payments amounted to approximately $2.2 billion.

In last year's rulemaking, CMS noted that the additional adjustments that P. L. 110-90 requires for FYs 2011 and 2012 could be substantial. They estimated that the total adjustments required over the 3-year period FY 2010 to FY 2012 were 8.5 percent, The proposed rule would have reduced FY 2010 standardized amounts by 1.9 percent, leaving 6.6 percent to be deducted from the standardized amounts in FYs 2011 and 2012 (if the estimations proved correct).

In the FY 2010 final rule, CMS confirmed its proposed rule analysis and conclusions, but chose not to make any prospective or retrospective adjustments in FY 2010 for documentation and coding-related increases occurring in FY 2008. The final rule stated, *"we believe that it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY 2009 claims data. If the estimated documentation and coding effect determined based on a full analysis of FY 2009 claims data is more or less than our current estimates, it would change, possibly lessen, the anticipated cumulative adjustments that we currently estimate we would have to make for FY 2008 and FY 2009 combined adjustment."* CMS also indicated that it would consider applying a prospective adjustment based upon a complete analysis of FY 2008 and FY 2009 claims data over an extended time period, such as 5 years, beginning in FY 2011. During this phase-in, the agency also would address any difference between the documentation and coding-related case-mix increase in FY 2009 and the -0.9 percent

prospective documentation and coding adjustment applied in FY 2009 under section 7(a) of P. L. 110-90.

FY 2011 proposed rule

For the FY 2011 proposed rule, CMS performed the same analysis on FY 2009 claims data and used the same methodology as it did on FY 2008 claims data for the FY 2010 proposed and final rules. Based on its analysis, CMS estimates that the documentation and coding increase in FY 2009 not reflective of real changes in case-mix was 5.4 percent. Compared to the prospective adjustments of 0.6 and 0.9 percentage points made in FYs 2008 and 2009 respectively, for a cumulative prospective adjustment of 1.5 percentage points, the actual 5.4 percent increase in FY 2011 represents a gap of 3.9 percentage points. Thus, the proposed rule states that 3.9 percent of FY 2009 payments represent excess payments to be recovered – about $6.9 billion, with appropriate interest as required by law. Combined with the 1.9 percent in excess FY 2008 payments (about $2.2 billion) stemming from a documentation and coding increase of 2.5 percentage points in FY 2008 compared to a 0.6 percentage point prospective adjustment, CMS reports that the total amount of excess payments to be recovered is 5.8 percent – or about $9.1 billion plus interest.

Section 7(b)(1)(B) of Pub. L. 110-90 requires CMS to recover the excess payments by the end of FY 2012. The FY 2011 proposed rule reduces the PPS standardized amounts by 2.9 percentage points in FY 2011 to recover about one-half of the excess payments. The adjustment to the standardized amounts is temporary. CMS anticipates removing it from the rates in FY 2012, when it would also be necessary under current law to apply the remaining approximately -2.9 percent adjustment required by section 7(b)(1)(B) of Pub. L. 110-90. These two steps in FY 2012, restoring the -2.9 percent adjustment made in FY 2011, and applying the remaining adjustment of approximately -2.9 percent, would effectively cancel each other out. The result would be an aggregate adjustment of approximately 0.0 percent (subject to the need to account for accumulated interest) in FY 2012.

As noted, Section 7(b)(1)(A) of Pub. L. 110-90 requires CMS to make prospective adjustments to correct the rates going forward in order to avoid making future excess payments. Through FY 2009, the cumulative increase in documentation and coding not reflecting real CMI increase is 5.4 percentage points and the cumulative prospective adjustment made through FY 2009 is 1.5 percentage points, leaving 3.9 percentage points to be made in future prospective adjustments. In the proposed rule, CMS states that the law gives it discretion concerning when to make these prospective adjustments – and no adjustment is proposed for FY 2011. The table below (from page 96 of the display copy of the proposed rule) shows the aggregate level of adjustments required by law (9.7 percentage points) and the amount that would remain to be recovered (6.8 percentage points) in FY 2012 and future years.

	Required Prospective Adjustment for FYs 2008-2009	Required Recoupment Adjustment for FYs 2008-2009	Total Adjustment	Proposed Recoupment Adjustment for FY 2011	Adjustment
FY 2011 Proposal Amount of Adjustment	-3.9	-5.8	-9.7	-2.9	-6.8

Applying adjustments to the hospital-specific and Puerto Rico-specific rates

In the FY 2009 IPPS final rule, CMS concluded that it has the authority to apply the documentation and coding adjustment to the hospital-specific rates applicable to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs) using the special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. CMS said that it would examine FY 2008 claims data for evidence of significant increases in case mix and would consider proposing an adjustment for documentation and coding-related increases in its rulemaking for FY 2010.

Similarly, CMS concluded in the FY 2009 IPPS final rule that it could use the special exceptions authority to apply a documentation and coding adjustment to the 25 percent Puerto Rico-specific portion of the PPS payment for hospitals in Puerto Rico. (The other 75 percent of the payment for these hospitals is based on the national IPPS rate.) It said it would evaluate FY 2008 claims data and consider application of the adjustment to the Puerto Rico standardized amount in rulemaking for FY 2010. MedPAC supported application of the documentation and coding adjustment to the hospital-specific and Puerto Rico-specific rates, but many other commenters were opposed.

FY 2010. CMS' retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology as for other IPPS hospitals found that, independently for both SCHs and MDHs, the documentation and coding-related case-mix increase during FY 2008 slightly exceeded the 2.5 percent result discussed earlier for all hospitals, but did not significantly differ from that result. Therefore, the FY 2010 proposed rule would have reduced the hospital-specific rate by 2.5 percent. The hospital-specific reduction of 2.5 percent was larger than the 1.9 percent reduction applicable to other IPPS hospitals because the prospective adjustment of -0.6 percent was not applied to the hospital-specific rate. A similar analysis for Puerto Rico hospitals found that the documentation and coding-related increase during FY 2008 was approximately 1.1 percent. Based on its findings, CMS proposed to reduce the Puerto Rico-specific rate by 1.1 percent in FY 2010.

Following the pattern established by postponing the FY 2010 adjustment for IPPS hospitals generally, the FY 2010 final rule delayed implementation of the documentation and coding-related adjustment for both the hospital-specific and Puerto Rico-specific rates to allow for a more complete analysis of FY 2009 claims data. CMS said that it would consider a phase-in of the adjustment over an appropriate period, beginning in FY 2011.

FY 2011 Proposed Rule. CMS' best estimate of the documentation and coding increase (not reflective of real CMI increase) in discharges from SCHs and MDHs yields a result similar to the experience of IPPS hospitals generally. Thus, a cumulative adjustment of -5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments. Unlike the case of standardized amounts paid to IPPS hospitals, CMS has not made any previous adjustments to the hospital-specific rates paid to SCHs and MDHs so that the entire -5.4 percent adjustment remains to be implemented. In the proposed rule for FY 2011, CMS proposes to phase in the reduction by reducing the hospital-specific rate applicable to SCHs and MDHs in FY 2011 by 2.9 percent, slightly more than one-half of the total 5.4 percentage points requiring ultimate adjustment according to CMS' estimate. The 2.9 percent reduction is a prospective adjustment that would be carried forward into future years' rates.

Similarly, CMS' analysis of FY 2009 claims data found that a cumulative adjustment of -2.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. The proposed rule would remove the full 2.4 percent from Puerto Rico-specific rates in FY 2011 in a prospective adjustment that would carry forward to future years. CMS notes that its proposed -2.4 percent adjustment represents the full adjustment that is warranted for the Puerto Rico-specific rate and that it does not anticipate proposing any additional adjustments to the rate for documentation and coding effects.

C. Refinement of the MS-DRG Relative Weight Calculation

The FY 2011 proposed rule makes no significant changes in the methodology for calculating the MS-DRG relative weights. FY 2009 was the first year that the relative weights were fully cost-based, having completed the 3-year transition begun in the FY 2007 final rule from relative weights based on hospitals' billed charges to weights based on hospitals' costs. Costs are determined by calculating cost-to-charge ratios (CCRs) from hospital cost reports and using national CCRs to convert billed charges to costs. The final IPPS rules for FY 2007 and FY 2008 describe the details of the cost-based weight calculation methodology.

Charge compression and cost report changes. The FY 2011 proposed rule again discusses the issues of charge compression and cost report refinement. The proposed rule notes that a new subscripted line 55.01 for Implantable Devices Charged to Patients was created in July 2009 as part of CMS' Transmittal 20 update to the existing cost report Form CMS-2552-96. This new subscripted cost center is available for use for cost reporting periods beginning on or after May 1, 2009. Also, the new draft hospital cost report Form CMS-2552-10 was published in the Federal Register on July 2, 2009 and was subject to a 60-day review and comment period, which ended August 31, 2009. CMS received numerous comments on the draft hospital cost report Form CMS-2552-10, several suggesting the creation of new cost centers from which data could be used to potentially improve the accuracy of the

relative weights calculation. By this summer, CMS plans to issue the revised draft of the hospital cost report Form CMS-2552-10, including a standard cost center for Implantable Devices Charged to Patients and response to comments received last year, through a notice in the Federal Register, which will allow for a 30-day comment period. The FY 2011 IPPS proposed rule responds to these comments concerning the cost report.

- CMS agreed with public comments urging the agency to create standard cost centers for magnetic resonance imaging (MRI), Computed Tomography (CT), and cardiac catheterization and to require hospitals to report the costs and charges for these services under new cost centers on the revised Medicare cost report.

- CMS disagreed with public comments suggesting that new standard cost centers be created for nuclear medicine services, for drugs that require detailed coding, and for magnetoencephalography (MEG).

CMS expects the data from the proposed standard cost centers for CT, MRI, and cardiac catheterization respectively, if they are finalized, to be available for possible use in calculating the relative weights not earlier than 3 years after Form CMS-2552-10 becomes available. At that time, CMS would analyze the data from these cost centers and determine if it is appropriate to use those data to create distinct CCRs for use in calculating the relative weights for the respective payment systems.

D. Preventable Hospital-Acquired Conditions (HACs), Including Infections

Since October 1, 2008, an inpatient hospital discharge is not assigned to a higher paying MS-DRG if a selected hospital-acquired condition (HAC) was not present on admission (POA). That is, the case will be paid as though the secondary diagnosis was not present. The selected HACs are among those that CMS determines (1) are high cost, high volume or both, (2) would result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence based guidelines.

For FY 2011, CMS proposes to retain the 10 current categories of HACs. However, for the HAC category Blood Incompatibility, it proposes to replace existing ICD-9-CM code 999.6 (ABO incompatibility reaction) with a new ICD-9-CM subcategory of five codes. The table given below lists the proposed HACs for FY 2011, with the proposed coding changes for blood incompatibility shown in bold-face type. CMS invites comments on this proposed list for FY 2011.

HAC	CC/MCC (ICD-9-CM Code)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)

HAC	CC/MCC (ICD-9-CM Code)
Blood Incompatibility - **Unspecified** - **With hemolytic transfusion reaction not specified as acute or delayed** - **With acute hemolytic transfusion reaction** - **With delayed hemolytic transfusion reaction** - **Other ABO incompatibility reaction**	 **999.60 (CC)** **999.61 (CC)** **999.62 (CC)** **999.63 (CC)** **999.69 (CC)**
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
Vascular Catheter Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 (CC) 249.10-249.11 (MCC) 249.20-249.21 (MCC
Surgical Site Infection	
Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19
Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-

HAC	CC/MCC (ICD-9-CM Code)
	81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	*Principal Diagnosis* – 278.01 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures	415.11 (MCC) 415.19 (MCC) 453.40-453.42 (MCC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54

CMS also uses the proposed rule to discuss some of the findings of an ongoing evaluation of the HAC-POA policies being conducted by Research Triangle Incorporated (RTI). In the final rule, CMS intends to update its summary of these analyses with additional data that have become available.

Using MedPAR claims data from October 2008 through June 2009, RTI found a total of about 50.22 million secondary diagnoses across about 7.17 million discharges. The chart given below shows the distribution of these secondary diagnoses by POA indicator. As noted in the chart, 83.52 percent of all secondary diagnoses were reported with a POA indicator of "Y" (condition present on admission).

POA Code Distribution Across All Secondary Diagnoses

		Number	Percentage
Total Discharges in Final File		7,175,139	
Total Number of Secondary Diagnoses Across Total Discharges		50,216,195	100.00
POA	**Indicator Description**		
Y	Condition present on admission	41,938,234	83.52
W	Status cannot be clinically determined	12,547	0.02
N	Condition not present on admission	3,440,815	6.85
U	Documentation not adequate to determine if condition was present on admission	110,771	0.22
1	Exempted ICD-9-CM code	4,713,828	9.39

Source: RTI Analysis of MedPAR IPPS Claims, October 2008 through June 2009.

In the proposed rule, CMS notes that beginning on or after January 1, 2011, hospitals using the new 5010 format (that is, Version 5010 of the electronic transaction standards) will no longer need to report a POA indicator of "1" for codes exempt from POA reporting. This indicator was established as a workaround to blank reporting on the electronic 4010A1 but such a workaround will not be necessary under the new

5010 format. The POA field will instead be left blank for codes exempt from POA reporting. CMS plans to issue instructions on this reporting change.

RTI also evaluated POA indicator reporting for specific HAC-associated secondary diagnoses and the results of this analysis are shown in the following chart. CMS welcomes comments on these data, especially those "that can provide insight into the accuracy of the data, using comparative data sets or analysis such as how aspects of the coding system might influence these data."

POA Status of Current HACs:
October 2008 Through June 2009

Selected HAC	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		No.	%	No.	%	No.	%	No.	%
1. Foreign Object Retained After Surgery (CC)	378	172	45.5	0	0.0	206	54.5	0	0.0
2. Air Embolism (MCC)	29	23	79.3	0	0.0	6	20.7	0	0.0
3. Blood Incompatibility (CC)	23	8	34.8	0	0.0	15	65.2	0	0.0
4. Pressure Ulcer Stages III & IV (MCC)	80,190	944	1.2	56	0.1	79,165	98.7	25	0.0
5. Falls and Trauma (MCC & CC)	132,666	4,081	3.1	232	0.2	128,286	96.7	67	0.1
6. Catheter-Associated UTI (CC)	11,424	1,887	16.5	15	0.1	9,496	83.1	26	0.2
7. Vascular Catheter-Associated Infection (CC)	5,470	2,091	38.2	19	0.3	3,348	61.2	12	0.2
8. Poor Glycemic Control (MCC)	11,070	344	3.1	9	0.1	10,711	96.8	6	0.1
9A. Surgical Site Infection Mediastinitis CABG (CC)	29	21	72.4	0	0.0	8	27.6	0	0.0
9B. Surgical Site Infection Following Bariatric Surgery for Obesity (CC)	12	10	83.3	0	0.0	2	16.7	0	0.0
9B. Surgical	202	125	61.9	1	0.5	75	37.1	1	0.5

Selected HAC	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		No.	%	No.	%	No.	%	No.	%
Site Infection Following Certain Orthopedic Procedures (CC)									
10. Pulmonary Embolism & DVT Orthopedic (MCC)	2,706	2,029	75.0	15	0.6	647	23.9	15	0.6
Total*	244,199			347				152	

* Discharges can appear in more than one row. The total figure is not adjusted for the 47 discharges with more than one HAC that appear as secondary diagnoses (15 of these discharges resulted in MS-DRG reassignment).

CMS says that the above findings and other RTI analyses do not warrant any change in current policy under which CMS does not pay at the higher CC/MCC amount when a selected HAC diagnosis code is reported with a POA indicator of "N" (condition not present on admission) or "U" (documentation not adequate to determine if condition was present on admission).

RTI's analyses also yield the following findings:

- Of the 216,764 discharges with a HAC-associated diagnosis as a secondary diagnosis, 3,038 discharges ultimately resulted in MS-DRG reassignment (or 26.69 percent of the 11,383 HAC cases with a POA of "N" or "U").

- RTI found 47 cases in which two HACs were reported on the same discharge.

- The four main reasons why a MS-DRG assignment did not change despite the presence of a HAC-associated secondary diagnosis with a POA indicator of "N" or "U" were: (1) other MCCs/CCs prevented reassignment (6,074 cases); (2) the relevant MS-DRG is subdivided solely by the presence or absence of an MCC and the HAC does not impact MS-DRG assignment (1,446 cases); (3) the MS-DRG is not subdivided by severity levels (818 cases); and (4) the MS-DRG logic precludes reassignment, such as when the presence of a procedure code dictates MS-DRG assignment despite the presence of the HAC-associated secondary diagnosis code (7 cases).

- There was an increase in the reporting of secondary diagnoses that are currently designated as HACs from FY 2007 to FY 2008 but a decrease in such diagnoses from FY 2008 to FY 2009 (CMS draws no conclusions from this finding in the proposed rule).

- The estimated net savings of current HACs, based on MedPAR claims from the 9-month period of October 2008 through June 2009, was roughly $16.44 million ($5,456 per discharge), with most of the savings associated with the following HAC categories: Falls and Trauma ($7.58 million), Orthopedic Pulmonary Embolism/DVT ($5.61 million) and Pressure Ulcer Stages III & IV ($1.87 million). There were no savings associated with the Blood Incompatibility category.

While the HAC policy-related savings were clearly modest, CMS nevertheless believes that the sentinel effect resulting from CMS identifying HACs is "critical" and the agency intends "to continue to monitor trends associated with the frequency of these HACs and the estimated net payment impact through RTI's program evaluation and possibly beyond."

Finally, RTI found a total of 159,485 discharges with at least one of 7 previously considered candidate HACs (including clostridium difficile-associated disease and ventilator-associated pneumonia) reported as a secondary diagnosis. Of those, 47,010 discharges were reported with a POA indicator of "N" or "U" and 2,932 discharges could have resulted in MS-DRG reassignments. However, CMS says these findings do not provide additional information that would require the agency to change its previous determinations regarding previously considered candidate HACs.

In the proposed rule, CMS also acknowledges the following:

- Specific instructions on how to select the correct POA indicator for each diagnosis code are included in the *ICD-9-CM Official Guidelines for Coding and Reporting*, available on the CDC Web site at http://www.cdc.gov/nchs/data/icd9/icdguide09.pdf; and

- CMS has been collaborating with the American Hospital Association to promote the *Coding Clinic for ICD-9-CM* as the source for coding advice about the POA indicator.

More detailed information about HAC issues can be found in several tables in the proposed rule. In addition, the following, more detailed reports from RTI regarding various HAC issues, in Adobe PDF or Microsoft Excel format, can be accessed at http://www.rti.org/reports/cms:

- Evidence Based Guidelines Report;
- Detailed Analysis of Selected HACs;
- Analysis of Previously Considered Candidate HACs;
- Detailed Analysis of POA Indicators for Selected HACs;
- Detailed Analysis of POA Indicators for Previously Considered Candidate HACs;
- Coding Changes by Selected HAC (FY 2007 – FY 2009); and
- Payment Savings From MS-DRG Reassignment by Selected HACs.

CMS estimates the Medicare savings from the HAC payment provision for the next 5 fiscal years as follows:

Year	Savings In Millions
FY 2011	$23
FY 2012	$24
FY 2013	$25
FY 2014	$26
FY 2015	$26

E. Proposed Changes to Specific MS-DRG Classifications

1. Pre-Major Diagnostic Categories (MDCs)

a. Postsurgical Hypoinsulinemia (MS-DRG 008 (Simultaneous Pancreas/Kidney Transplant)

Occasionally, secondary diabetes may be surgically induced following a pancreas transplant. This condition would be identified by using ICD-9-CM diagnosis code 251.3 (Postsurgical hypoinsulinemia). Currently the list of principal diagnosis codes assigned to surgical MS-DRG 008 (Simultaneous Pancreas/Kidney Transplant) does not include diagnosis code 251.3. Therefore, when diagnosis code 251.3 is assigned to a case as a principal diagnosis, the case is not assigned to MS-DRG 008. Instead, these cases are grouped to MS-DRG 652 (Kidney Transplant) under MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). CMS believes this is an error of omission and proposes to add diagnosis code 251.3 to the list of principal or secondary diagnosis codes assigned to MS-DRG 008. As a conforming change, CMS also proposes to add diagnosis code 251.3 to the list of principal or secondary diagnosis codes assigned to MSDRG 010 (Pancreas Transplant).

b. Bone Marrow Transplants

CMS received two requests to review whether cost differences between an autologous bone marrow transplant (where the patient's own bone marrow or stem cells are used) and an allogeneic bone marrow transplant (where bone marrow or stem cells come from either a related or unrelated donor) necessitate the creation of separate MS-DRGs to more appropriately account for the clinical nature of the services being rendered as well as the costs. CMS conducts the requested analysis and concludes the cost differences warrant separate MS-DRGs for these procedures. Therefore, CMS proposes to delete MS-DRG 009 (Bone marrow transplant) and create two new MS-DRGs: MS-DRG 014 (Allogeneic Bone Marrow Transplant) and MS-DRG 015 (Autologous Bone Marrow Transplant).

2. MDC 1 (Nervous System): Administration of Tissue Plasminogen Activator (tPA) (rtPA)

During the comment period for the FY 2010 IPPS proposed rule, CMS received a request to conduct an analysis of diagnosis code V45.88 (Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility) under MDC 1 (Diseases and Disorders of the Nervous System). In the FY 2010 final rule, CMS noted that the comment was out of scope for the FY 2010 proposed rule and reiterated that the deadline for requesting data review and potential MS-DRG changes had been the previous December.

Diagnosis code V45.88 was created for use beginning October 1, 2008, to identify patients who are given tissue plasminogen activator (tPA) at one institution and then transferred and admitted to a comprehensive stroke center for further care. This situation is referred to as “drip-and-ship.” The commenter believed that the data would show that the use of this code could potentially result in a new MS-DRG or a new set of MS-DRGs in FY 2011.

For this proposed rule, CMS reviews the 2009 data for all of the cases in MS-DRGs 064, 065, and 066, compared to the subset of cases containing the V45.88 secondary diagnosis code, and concludes that the movement of cases with diagnosis code V45.88 as a secondary diagnosis from MS-DRGs 064, 065, and 066 into MS-DRGs 061, 062, and 063 is not warranted. Therefore, for FY 2011, CMS does not propose any change to MS-DRGs 061, 062, 063, 064, 065, or 066, or any change involving the assignment of diagnosis code V45.88.

3. MDC 5 (Diseases and Disorders of the Circulatory System): Intraoperative Fluorescence Vascular Angiography (IFVA) and X-Ray Coronary Angiography in Coronary Artery Bypass Graft Surgery

During the comment period for the FY 2010 IPPS proposed rule, CMS received a number of comments that recommended creating new MS-DRGs to separately identify the use of intraoperative angiography, by any method, in CABG surgery under MDC 5 (Diseases and Disorders of the Circulatory System). According to the commenters, intraoperative angiography would reduce graft failure complications and hospital readmissions while improving patient care outcomes. The commenters expressed concern that the costs related to intraoperative angiography are not fully realized in the current structure of the MS-DRGs. In the FY 2010 final rule, CMS rejected these requests as outside the scope of the issues addressed in the proposed rule and did not provide responses to the comments in the final rule.

For this proposed rule, CMS responds to the following requests from the manufacturer of the IFVA technology and other public commenters:

a. New MS-DRGs for Intraoperative Fluorescence Vascular Angiography (IFVA) with CABG

The manufacturer requested the creation of four new MS-DRGs for CABG to distinguish CABG surgeries performed with IFVA and those performed without IFVA. These four new MS-DRGs would correspond to the existing MS-DRG for CABG but would also include intraoperative angiography. CMS analyzed the FY 2009 claims data and found the data did not support moving IFVA cases (procedure code 88.59) from MS-DRGs 235 and 236 to MS-DRGs 233 and 234. Specifically, if the cases identified by procedure code 88.59 were proposed to be reassigned from MS-DRGs 235 and 236 to MS-DRGs 233 and 234, they would be significantly overpaid. In addition, because the cases in MS-DRGs 235 and 236 did not actually have a cardiac catheterization performed, a proposal to reassign cases identified by procedure code 88.59 would result in lowering the relative weights of MS-DRGs 233 and 234 where a cardiac catheterization is truly performed. Therefore, CMS does not propose to make any MS-DRG modifications for cases reporting procedure code 88.59 for FY 2011.

b. New MS-DRG for Intraoperative Angiography, by any Method, with CABG

CMS also received a request to create a single MS-DRG for any type of intraoperative angiography utilized in CABG surgery. CMS notes the only ICD-9-CM procedure code that identifies an intraoperative angiography is procedure code 88.59 (Intraoperative fluorescence vascular angiography) and that it is not possible to distinguish when other types of angiography are performed intraoperatively. Therefore, CMS is unable to evaluate any data, other than that described above and does not propose to create a new MS-DRG in FY 2011 for coronary bypass with intraoperative angiography, by any method.

c. New Procedure Codes

One requestor suggested the creation of new ICD-9-CM procedure codes to separately identify the two technologies used to perform intraoperative coronary angiography in CABG surgery: X-ray coronary angiography with cardiac catheterization and fluoroscopy versus intraoperative fluorescence coronary angiography (IFVA). In response, CMS recommends the submission of a proposal for creating a new procedure code(s). This topic will be further evaluated through the ICD-9-CM Coordination and Maintenance Committee meeting process.

d. MS-DRG Reassignment of Intraoperative Fluorescence Vascular Angiography (IFVA)

One requestor suggested reassigning procedure code 88.59 (Intraoperative Fluorescence Vascular Angiography), to the "Other Cardiovascular MS-DRGs": MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, CC, and without CC/MCC, respectively). CMS notes that, in the surgical hierarchy, MS-DRGs 228, 229, and 230 rank higher than MS-DRGs 233, 234, 235, and 236, which were evaluated as part of the first request above. Because the data do not demonstrate that IFVA utilized an equivalent (or additional) amount of resources as a cardiac catheterization to warrant a proposal to reassign IFVA cases to MS-DRGs 233 and 234 and the fact that IFVA cases with CABG performed with a procedure assigned to MS-DRGs 228, 229, and 230 would already be grouped to those same MS-DRGs, CMS does not propose to reassign cases reporting procedure code 88.59 to MS-DRGs 228, 229, and 230 for FY 2011.

4. MDC 6 (Diseases and Disorders of the Digestive System): Gastrointestinal Stenting

In the FY 2010 IPPS final rule, CMS discussed a request to create new MS-DRGs in FY 2011 to better identify patients who undergo the insertion of a gastrointestinal (GI) stent. The request was considered outside the scope of issues addressed in that rule.

In this proposed rule, CMS responds to the requestor's analysis of GI stenting cases using relevant diagnosis codes and a combination of procedure codes with revenue code 0278 in various GI MS-DRGs. CMS points out the use of revenue codes in the reclassification process would require a major structural change from the current process that has been utilized since the inception of the IPPS. CMS concludes that the data is unreliable because the commenter included procedure codes in its analysis that do not identify the insertion of a stent. In addition, CMS notes the lack of data on the two procedure codes describing the insertion of a colonic stent that were recently implemented, effective with discharges occurring on or after October 1, 2009 (procedure code 46.86 and 46.87).

Using FY 2009 MedPAR data, CMS analyzed the three procedure codes that identify and describe the insertion of a stent (procedure codes 42.81, 51.87, and 52.93) within the various GI MS-DRGs referenced above and found only 2,011 cases with average costs ranging from a low of $5,846 to a high of $17,626. CMS does not believe it is appropriate to assign cases with such disparity in costs into a single, new MS-DRG and proposes no changes for FY 2011.

5. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Pedicle-Based Dynamic Stabilization

CMS received a request from a manufacturer to reassign procedure code 84.82 (Insertion or replacement of pedicle-based dynamic stabilization device(s)), effective

October 1, 2007, from MS-DRG 490 (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) to MS-DRG 460 (Spinal Fusion Except Cervical without MCC). According to the manufacturer, the technology that is identified by this procedure code, the Dynesys® Dynamic Stabilization System, is clinically similar to lumbar spinal fusion and requires similar utilization of resources.

CMS notes the Dynesys® Dynamic Stabilization System is currently FDA approved for use only as an *adjunct* to spinal fusion, that there is uncertainty regarding the coding and reporting of procedure code 84.82, as well as off-label use, and currently, all other similar non-fusion devices are assigned to MS-DRG 490. CMS concludes the insertion of a Dynesys® Dynamic Stabilization System is clinically not a lumbar fusion and proposes not to reassign cases reporting procedure code 84.82 from MS-DRG 490 to MS-DRG 460 for FY 2011.

6. MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period)

a. Discharges/Transfers of Neonates to a Designated Cancer Center or Children's Hospital

CMS received a request to add patient discharge status code 05 (Discharged/transferred to a designated cancer center or children's hospital) to the MS-DRG GROUPER logic for MS-DRG 789 (Neonates, Died or Transferred to Another Acute Care Facility). Currently, neonate cases with the discharge status code 05 are being assigned to MS-DRG 795 (Normal Newborn). Although CMS could find no cases in the FY 2009 claims data, CMS proposes to add discharge status code 05 to the MS-DRG GROUPER logic for MS-DRG 789 because CMS believes the request has merit in identifying neonate cases appropriately.

b. Vaccinations of Newborns

CMS received a request to examine the assignment of code V64.05 (Vaccination not carried out because of caregiver refusal) to MS-DRG 794 (Neonate with Other Significant Problems). Code V64.05 is currently being reported when a physician documents that a parent/caregiver has refused immunization for a child. The reporting of this code as a principal or secondary diagnosis impacts the MS-DRG assignment for normal newborns cases being assigned to MS-DRG 794. Although CMS could find no cases in the FY 2009 claims data, CMS concludes that code V64.05 does not indicate a significant problem with the newborn. Therefore, CMS proposes to remove code V64.05 from MS-DRG 794 and add this code to the secondary diagnosis list for MS-DRG 795 (Normal newborn).

7. Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and

demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a MS-DRG. For FY 2011, CMS proposes several changes to the MCE edits.

a. Unacceptable Principal Diagnosis Edit: Addition of Code for Gastroparesis

Because code 536.3 (Gastroparesis) has a "code first underlying disease" note it should not be used as a principal diagnosis. Therefore, code 536.3 should have been included on the list of unacceptable principal diagnoses in the MCE. For FY 2011, CMS proposes to add code 536.3 to that list.

b. Open Biopsy Check Edit

The Open Biopsy Check edit in the MCE dates back to the early years of the IPPS when the surgical and medical DRGs were not as expansive as they are today. Under the current MS-DRGs, the open biopsy codes do not have as significant of an impact as they did in the early versions of the DRGs. CMS believes the Open Biopsy Check edit no longer serves a useful purpose and proposes to delete the entire Open Biopsy Check edit from the MCE, which means removing the 63 codes from the edit. These codes are listed in the proposed rule.

c. Noncovered Procedure Edit

The ICD-9-CM procedure codes 52.80 (Pancreatic transplant, not otherwise specified) and 52.82 (Homotransplant of pancreas) alone (that is, without procedure code 55.69 (Other kidney transplantation)) are considered noncovered procedures, except when either one is combined with at least one specific principal or secondary diagnosis code. To conform to the proposed change to Pre-MDC MS-DRGs 008 and 010 as discussed in the summary of section II.G.1. above (in which CMS proposes to add code 251.3 (Postsurgical hypoinsulinemia) to those MS-DRGs), CMS proposes to add procedure code 251.3 to the list of acceptable principal or secondary diagnosis codes in the MCE.

8. Surgical Hierarchies

The surgical hierarchy, an ordering of surgical classes from most resource intensive to least resource intensive, performs as a decision rule within the GROUPER under which cases are assigned to a single DRG when an inpatient stay entails multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource intensive surgical class. For FY 2011, the following changes to the surgical hierarchy are proposed:

- In Pre-MDCs, reorder proposed new MS-DRG 014 (Allogeneic Bone Marrow Transplant) above MS-DRG 007 (Lung Transplant); and proposed new MS-DRG 015 (Autologous Bone Marrow Transplant) above MS-DRG 010 (Pancreas Transplant).
- In MDC 10, reorder MS-DRG 614 (Adrenal and Pituitary Procedures With CC/MCC) and MS-DRG 615 (Adrenal and Pituitary Procedures Without CC/MCC) above MS-DRG 625 (Thyroid, Parathyroid and Thyroglossal Procedures With MCC).

9. Complications or Comorbidity (CC) Exclusions List

CMS created the CC Exclusions List in 1987 to: (1) preclude coding of CCs for closely related conditions; (2) preclude duplicative or inconsistent coding from being treated as CCs; and (3) ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In this proposed rule, CMS presents its analysis of claims data and responds as follows to comments received on the CC Exclusions List:

- Rejects requests to add the following diagnosis codes, which are classified as non-CCs, to the CC or MCC list: 278.00 Obesity NOS; 278.01 Morbid obesity; 278.02 Overweight; 731.3 Major osseous defects; V85.35 BMI 35.0- 35.9, adult; V85.36 BMI 36.0- 36.9, adult; V85.37 BMI 37.0- 37.9, adult; V85.38 BMI 38.0- 38.9, adult; and, V85.39 BMI 39.0- 39.9, adult
- Rejects a request to add the diagnosis code V85.40 (Body mass index 40 and over, adult), which is on the CC list, to the MCC list.
- Rejects a request to change the diagnosis code 331.0 Alzheimer's disease from a non-CC to a CC.
- Accepts a request to reclassify diagnosis code 584.9 (Acute renal failure, unspecified) from a MCC to a CC.

Tables 6G and 6H, Additions to and Deletions from the CC Exclusion List, respectively, which are effective for discharges occurring on or after October 1, 2010, are not published in the Addendum to this proposed rule because of the length of the two tables. Instead, CMS is making them available through the Internet on the CMS Website at: http://www.cms.hhs.gov/AcuteInpatientPPS. A complete updated MCC, CC, and Non-CC Exclusions List is also available through the Internet on the CMS Website at: http://www.cms.hhs.gov/AcuteInpatientPPS.

Tables 6A, 6C, and 6E are included in the Addendum to this proposed rule to assist readers in identifying the changes to the MCC and CC lists that occurred as a result of updates to the ICD-9-CM codes. CMS notes there were no additions to the MS-DRG MCC List for FY 2011.

10. Review of Procedure Codes in MS DRGs 981 through 983; 984 through 986; and 987 through 989

Each year, CMS reviews cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS-DRGs that CMS adopted for FY 2008, CMS DRG 468 was split three ways and became MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

For FY 2011, CMS proposes the following:

- Not to change the procedures assigned among these MS-DRGs.
- Not to move any procedures from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into one of the surgical MS-DRGs for the MDC into which the principal diagnosis is assigned.
- Not to move any procedure codes among these MS-DRGs.

11. Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM Coding System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

a. ICD-9-CM Coding System

The ICD-9-CM Coordination and Maintenance Committee presented proposals for coding changes for implementation in FY 2011 at a public meeting held on September 16-17, 2009 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 20, 2009. Those coding changes are announced in Tables 6A through 6F in the Addendum to the proposed rule. The Committee held its 2010 meeting on March 9-10, 2010. New codes for which there was a consensus of public support and for which complete tabular and indexing changes are made by May 2010 will be included in the October 1, 2010 update to ICD-9-CM. Code revisions that were discussed at the March 9-10, 2010 Committee meeting but that could not be finalized in time to include them in the Addendum to this proposed rule will be included in Tables 6A through 6F of the final rule and will be marked with an asterisk (*).

The ICD-9-CM code changes that have been approved will become effective October 1, 2010. The new ICD-9-CM codes are listed, along with their MS-DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure

Codes, respectively) in the Addendum to the proposed rule. CMS solicits comments on the proposed classification of these new codes, which are shown in Tables 6A and 6B of the Addendum to this proposed rule. There were no requests approved for an expedited April l, 2010 implementation of an ICD-9-CM code at the September 16-17, 2009 Committee meeting.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD-10) coding system applicable to hospital inpatient services will be implemented on October 1, 2013, as described in the Federal Register on January 16, 2009. The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the Official ICD-10-CM and ICM-10-PCS Guidelines for Coding and Reporting.

In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule, there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes.

At the March 11-12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting, the public was notified that there would be a discussion at the September 16-17, 2009 ICD-9-CM Coordination and Maintenance Committee meeting of whether there was a need to freeze updates to ICD-9-CM and/or ICD-10-CM and ICD-10-PCS prior to the implementation of ICD-10.

CMS and CDC have reviewed the comments received at the ICD-9-CM Coordination and Maintenance Committee meeting as well as the written comments submitted after the meeting. Most commenters proposed a limited freeze on code updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS code sets, with an exception made for adding codes for new technologies and diseases. Providing this exception would comply with section 503(a) of Pub. L. 108-173, which includes a requirement for updating ICD-9-CM codes twice a year to capture new technologies.

In this proposed rule, CMS solicits additional input on this subject, especially in light of the requirements on hospitals for meaningful use of electronic health records.

CMS proposes the following timeline:

Date	Activity
October 1, 2011	Last regular, annual update to both ICD-9-CM and ICD-10
October 1, 2012	Limited code updates to both the ICD-9-CM and ICD-10 coding systems to capture new technologies and diseases
October 1, 2013	Limited code updates to ICD-10 to capture new technologies and diagnoses. Any other issues raised would be considered for implementation in ICD-10 on October 1, 2014, a year after ICD-10 is implemented

CMS believes that this advance notice of a partial code freeze will provide the health care industry ample time to request last major code updates to ICD-9-CM and ICD-10, which could be discussed at the September 15-16, 2010 and the March 2011 ICD-9-CM Coordination and Maintenance Committee meetings. CMS welcomes public comments on whether a freeze is needed to help with adoption of health IT, given other priorities such as achievement of meaningful use and implementation of ICD-10 by FY 2013.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

CMS has received repeated requests from the hospital community to process all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Hospitals can submit up to 25 diagnoses and 25 procedures; however, CMS' current system limitations allow for the processing of only the first 9 diagnoses and 6 procedures. While CMS accepts all 25 diagnoses and 25 procedures submitted on the claims, CMS does not process all of the codes because of these system limitations.

CMS recognizes that much valuable information is lost by not processing the additional diagnosis and procedure codes that are reported by hospitals and summarizes its ongoing activities as follows:

- CMS is currently undergoing extensive system updates as part of the HIPPA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update, which includes the ability to accept ICD-10 codes. This complicated transition involves converting many internal systems prior to October 1, 2013, when ICD-10 will be implemented.
- CMS plans to complete the expansion of this internal system capability so they can process up to 25 diagnoses and 25 procedures on hospital inpatient claims when received on the 5010 format starting on January 1, 2011.

F. Recalibration of MS-DRG Weights

The Secretary is required by statute to revise the DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. In developing relative weights for the FY 2011 proposed rule, CMS used two data sources:

- FY 2009 MedPAR data for discharges occurring on October 1, 2008, through September 30, 2009, based on bills received by CMS through December 31, 2009, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2009 MedPAR file used in calculating the proposed relative weights includes data for approximately 11,004,046 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. The data also exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken; and

- FY 2008 Medicare cost report data files from HCRIS (that is, cost reports beginning on or after October 1, 2007, and before October 1, 2008), which represents the most recent full set of cost report data available. CMS used the December 31, 2009 update of the HCRIS cost report files for FY 2008 in setting the relative cost-based weights for the proposed rule.

Adhering to the process used to calculate the weights for FY 2010, charges were converted to costs using national average CCRs. The proposed rule includes a table (pages 242 through 249 of the display copy) showing the 15 cost centers that were used in the relative weight calculation along with the associated lines on the cost report and the corresponding revenue codes that were used to create the 15 national cost center CCRs. The resulting 15 national average CCRs used for the FY 2011 proposed rule are shown in the table below (for comparison, the FY 2010 final rule CCRs also are shown):

Group	CCR FY 2010 Final Rule	CCR FY 2011 Proposed Rule
Routine Days	0.553	0.553
Intensive Days	0.480	0.480
Drugs	0.200	0.200
Supplies & Equipment	0.344	0.348
Therapy Services	0.415	0.415
Laboratory	0.163	0.163
Operating Room	0.282	0.282
Cardiology	0.181	0.181
Radiology	0.161	0.161
Emergency Room	0.278	0.278
Blood and Blood Products	0.424	0.424

Group	CCR FY 2010 Final Rule	CCR FY 2011 Proposed Rule
Other Services	0.426	0.426
Labor & Delivery	0.462	0.462
Inhalation Therapy	0.201	0.201
Anesthesia	0.136	0.136

The new cost-based relative weights were normalized by an adjustment factor of 1.57461 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

G. Add-On Payments for New Services and Technologies

1. Background

The new medical service or technology add-on payment policy provides additional payments for cases with high costs involving eligible new medical services or technologies. To qualify, services must be new, more costly than existing technology and represent a substantial clinical improvement.

Current regulations provide that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). CMS does not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered “new” for purposes of new technology add-on payments if it is “substantially similar” to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In determining substantial similarity, CMS considers: (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology, CMS would conclude that the technology is not new and, therefore, not eligible for the new technology add-on payment.

Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS-DRG prospective payment rate, CMS evaluates whether the charges for cases involving the new technology exceed certain threshold amounts. CMS applies "a threshold...that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges)

or 75 percent of one standard deviation for the diagnosis-related group involved." Table 10 that was included in the final rule published in the Federal Register on August 27, 2009, contains the final thresholds that are being used to evaluate applications for new technology add-on payments for FY 2011. CMS notes that the agency plans to issue separate documents in the Federal Register addressing the provisions of health care reform in Pub. L. 111-148, as amended, that affect the proposed policies and payment rates for FY 2011 under the IPPS and the LTCH PPS. At the time CMS issues those documents, CMS plans to update Table 10 that was published in the Federal Register on August 27, 2009 and Table 10 in the Addendum to this proposed rule.

Under the third criterion, current regulations provide that a new technology is an appropriate candidate for an additional payment when it represents "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

CMS also requires that all applicants for new technology add-on payments must have FDA approval for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

For an approved new technology, if the costs of the discharge (determined by applying cost to charge ratios) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology. Add-on payments for new medical services or technologies for FY 2005 and later years are not subjected to budget neutrality.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2011, CMS published a notice in the Federal Register on November 27, 2009, and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 19, 2010. Each of the three FY 2011 applicants presented information on its technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. These three technologies are described below, following a summary of comments received

on the new technology add-on payment process in general and a summary of the technologies approved for add-on payments in FY 2010.

One commenter, a medical technology association, recommended that CMS, in its consideration as to whether a new technology meets the substantial clinical improvement criterion, judge a diagnostic device on the basis of a diagnostic outcome (improved diagnosis) rather than a therapeutic outcome, recognizing that earlier and improved detection of disease often leads to improved patient outcomes. CMS essentially dismisses this comment stating this approach would deem a device that led to the identification of new information as a substantial improvement in diagnosis even if such detection has not been "demonstrated to represent a substantial improvement in caring for Medicare beneficiaries" and was not linked to evidence-based, significant, and positive changes in the management of patients or, ultimately, to changes in clinical outcomes.

One commenter, a medical device association, recommended that CMS "deem a device to satisfy the substantial clinical improvement criteria if it was granted a humanitarian device exemption or priority review based on the fact that it represents breakthrough technologies, which offer significant advantages over existing approved alternatives, for which no alternatives exist, or the availability of which is in the best interests of the patients." CMS does not respond to this recommendation other than to note that this issue was addressed in the FY 2008 IPPS final rule. (For the record, CMS rejected the request in that final rule)

3. FY 2011 Status of Technologies Approved for FY 2010 Add-On Payments

a. Spiration® IBV® Valve System

CMS approved an application for new technology add-on payments for the Spiration® IBV® Valve System (Spiration® IBV®) for FY 2010. The Spiration® IBV® is a device that is used to place, via bronchoscopy, small, one-way valves into selected small airways in the lung in order to limit airflow into selected portions of lung tissue that have prolonged air leaks following surgery while still allowing mucus, fluids, and air to exit, thereby reducing the amount of air that enters the pleural space. CMS limits the add-on payment to cases involving prolonged air leaks following lobectomy, segmentectomy and LVRS in MS-DRGs 163, 164, and 165. The average cost of the Spiration® IBV® is reported as $2,750. Based on data from the FY 2010 application, the average amount of valves per case is 2.5. Therefore, the total maximum cost for the Spiration® IBV® was expected to be $6,875 per case ($2,750 x 2.5). New technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, CMS finalized a maximum add-on payment for a case involving the Spiration® IBV® as $3,437.50. CMS does not propose any changes for FY 2011.

b. CardioWest™ Temporary Total Artificial Heart System (CardioWest™ TAH-t)

SynCardia Systems, Inc. submitted an application for approval of the CardioWest™ temporary Total Artificial Heart system (TAH-t) in FY 2009. The TAH-t was approved by the FDA on October 15, 2004, for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. In the past, Medicare did not cover artificial heart devices, including the TAH-t. However, on May 1, 2008, CMS issued a final national coverage determination (NCD) expanding Medicare coverage of artificial hearts when they are implanted as part of a study that is approved by the FDA and is determined by CMS to meet CMS' Coverage with Evidence Development (CED) clinical research criteria. For this reason, despite the FDA approval date of the technology, CMS determined that TAH-t would still be eligible to be considered "new" for purposes of the new technology add-on payment because the TAH-t met the newness criterion on the date that Medicare coverage began, consistent with issuance of the final NCD, effective on May 1, 2008.

CMS continued to make new technology add-on payments for the TAH-t in FY 2010. The new technology add-on payment for the TAH-t for FY 2010 is triggered by the presence of ICD-9-CM procedure code 37.52 (Implantation of total heart replacement system), condition code 30, and the diagnosis code reflecting clinical trial--V70.7 (Examination of participant in clinical trial). For FY 2010, CMS finalized a maximum add-on payment of $53,000 (that is, 50 percent of the estimated operating costs of the device of $106,000) for cases that involve this technology.

For FY 2011, CMS proposes to continue new technology add-on payments for cases involving the TAH-t with a maximum add-on payment of $53,000. CMS seeks public comment regarding whether there is new evidence that demonstrates that the TAH-T continues to be effective and whether it should still be considered to be a substantial clinical improvement for FY 2011.

4. FY 2011 Applications for New Technology Add-On Payments

CMS received five applications to be considered for new technology add-on payment for FY 2011. However, two applicants withdrew their applications: Nycomed Austria GmbH, which submitted an application for new technology add-on payments for FY 2011 for TachoSil®; and Zimmer, which submitted an application for new technology add-on payments for FY 2011 for the Dynesys Dynamic Stabilization System. Nycomed Austria GmbH withdrew its application from further review in January 2010, and Zimmer withdrew its application in February 2010. Because both applications were withdrawn prior to the town hall meeting and publication of this proposed rule, CMS does not discuss these two applications in this proposed rule.

A discussion of the remaining three applications is presented below. At the time this proposed rule was developed, one of the technologies had not yet received FDA approval. Consequently, the discussion below of this application may be limited.

a. Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. CMS notes that the applicant submitted an application for new technology add-on payments for FY 2010 but withdrew its application prior to the FY 2010 IPPS/RY 2010 LTCH PPS final rule.

AutoLITT™is a minimally invasive, MRI-guided catheter tipped laser designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue.

Newness criterion

The AutoLITT™ received a 510K FDA clearance in May 2009. The technology can be identified by ICD-9-CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which were effective on October 1, 2009. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. The first sale of the product took place on March 19, 2010. Because the product was already available for use in December 2009, CMS believes the newness date would begin in December 2009. CMS expresses concern that the AutoLITT™may be substantially similar to the device that it listed as its predicate device in its application to the FDA for approval. The applicant identified Visual-ase as its predicate device (which was approved by the FDA in 2006), which is also used to treat tumors of the brain. The applicant maintains that AutoLITT™can be distinguished from the Visual-ase by its mechanism of action (that is, side-firing laser versus elliptical firing). CMS seeks comments regarding whether or not the AutoLITT™is substantially similar to the Visual-ase and if it meets the newness criteria.

Cost criterion

The applicant used 2007 Medicare data from the Healthcare Cost and Utilization Project (HCUP) to identify cases potentially eligible for the AutoLITT™. The applicant found 41,021 cases and weighted the standardized charge per case based on the number of cases found within each of the diagnosis codes listed above rather than the percentage of cases that would group to different MS-DRGs. Based on this analysis, the applicant calculated an average standardized charge per case of $57,511. While the applicant's analysis established a case-weighted average charge per case in the aggregate, it did not provide a case-weighted average standardized charge per case by MS-DRG (as required by the application).

Although the applicant submitted data related to the estimated cost of the AutoLITT™ per case, the applicant stated that the cost of the device was proprietary information.

Based on a study of charge compression data by RTI[4] and charge master data from Stanford University and University of California, San Francisco, the applicant estimates $38,886 in charges related to the AutoLITT™ (CMS notes that some of the data used a markup of 294 percent of the costs). Adding the estimated charges related to the device to the average standardized charge per case resulted in a total average standardized charge per case of $96,397 ($57,511 plus $38,886). Because the total average standardized charge per case exceeds the threshold amount for each individual MS-DRG to which the technology would map (MS-DRGs 25, 26, and 27), the applicant maintains that the AutoLITT™ would meet the cost criterion. CMS invites public comment on whether or not the AutoLITT™ meets the cost criterion.

Substantial clinical improvement criterion

With respect to the substantial clinical improvement criterion, the applicant maintains that it meets this criterion in its application. Specifically, the applicant stated that several non- AutoLITT™ clinical trials have demonstrated that nonfocused LITT (and more recently, the use of LITT plus MRI) improved survival, quality of life, and recovery in patients with advanced glioblastoma multiforme tumors and advanced metastatic brain tumors that cannot be effectively treated with surgery, radiosurgery, radiation, chemotherapy, or any currently available clinical procedure.

CMS acknowledges the future potential of this therapy, but expresses concerns that to date the AutoLITT™ has been used for the treatment of only a few patients as part of a safety evaluation with no comparative efficacy data. Therefore, there may not be sufficient objective clinical evidence to determine if the AutoLITT™ meets the substantial clinical improvement criteria. CMS requests additional clinical data to demonstrate whether the AutoLITT™ meets the substantial clinical improvement criterion and invites public comment.

b. LipiScan™ Coronary Imaging System

InfraReDx, Inc. submitted an application for new technology add-on payments for FY 2011 for the LipiScan™ Coronary Imaging System (LipiScan™). The LipiScan™ device is a diagnostic tool that uses Intravascular Near Infrared Spectroscopy (INIRS) during an invasive coronary catheterization to scan the artery wall in order to determine coronary plaque composition. CMS notes that an application was also submitted for FY 2010, but the application was denied on the grounds that it did not meet the substantial clinical improvement criterion at that time. The application for FY 2011 contains some additional clinical and charge data that was not available at the time that the FY 2010 new technology add-on payment decisions were made.

Newness criterion

The LipiScan™ received a 510K FDA clearance for a new indication on April 25, 2008, and was available on the market immediately thereafter. On June 23, 2006, InfraReDx, Inc. was granted a 510K FDA clearance for the “InfraReDx Near Infrared

(NIR) Imaging System." Both devices are under the common name of "Near Infrared Imaging System" according to the 510K summary document from the FDA. However, the InfraReDx NIR Imaging System device that was approved by the FDA in 2006 was approved "for the near infrared imaging of the coronary arteries," whereas the LipiScan™ device cleared by the FDA in 2008 is for a modified indication. CMS determined in the FY 2010 IPPS final rule that LipiScan™ would be considered to be "new" to the market as of the date of its FDA approval in April 2008. Because a technology may be considered new for a period of up to 3 years if, during the third year, the technology is new for more than 6 months of the fiscal year, the technology would still be in the newness period for FY 2011. CMS seeks comments on whether LipiScan™ meets the newness criterion.

The LipiScan™ technology is identified by ICD-9-CM procedure code 38.23 (Intravascular spectroscopy), which became effective October 1, 2008, and cases involving the use of this device generally map to the MS-DRGs for percutaneous cardiovascular procedures.

Cost criterion

The applicant used the FY 2010 final rule After Outliers Removed (AOR) file (posted on the CMS Web site) to identify cases potentially eligible for LipiScan™. The applicant believes that every case within MS-DRGs 246, 247, 248, 249, 250, and 251 is eligible for LipiScan™. The applicant calculated a case-weighted average standardized charge per case of $52,230. Although the applicant submitted data related to the estimated cost per case of LipiScan™, the applicant stated that the cost of the device is proprietary information. Based on a sampling of all 10 non-VA hospitals that are actively using the device, the applicant determined that the average charge for the device was $7,497. Adding the estimated average charge related for the device to the case-weighted standardized charge per case (based on the case distribution from the applicant's FY 2010 AOR analysis) results in a total case-weighted average standardized charge per case of $59,727 ($52,230 plus $7,497). Using the FY 2011 thresholds published in Table 10 of the FY 2010 IPPS final rule, the case-weighted threshold for MS-DRGs 246, 247, 248, 249, 250, and 251 is $56,487. Because the applicant's calculation of the total case-weighted average standardized charge per case for the applicable MS-DRGs exceeds the case-weighted threshold amount, the applicant maintains that LipiScan™ meets the cost criterion.

CMS believes the more appropriate way to determine the case-weighted average standardized charge per case and the case-weighted threshold amount for evaluating the cost criterion is to use the actual distribution of cases in the applicable MS-DRGs based on the number of cases from the AOR file because this would more accurately reflect the number and type of Medicare cases typically treated in the applicable MS-DRGs. CMS calculates a case-weighted average standardized charge per case of $46,657. Adding the estimated charges related to the device to the case-weighted average standardized charge per case (based on the case distribution from

the FY 2010 AOR final rule file) results in a total case-weighted average standardized charge per case of $54,154 ($46,657 plus $7,497). This alternative calculation of total case-weighted average standardized charge per case for the applicable MS-DRGs also exceeds the case-weighted threshold amount. CMS seeks public comment on whether or not LipiScan™ meets the cost criterion.

Substantial clinical improvement criterion

CMS determined that the FY 2010 new technology add-on payment application for LipiScan™ did not meet the substantial clinical improvement criterion because there was a lack of evidence that demonstrated that LipiScan™ affected the medical management of patients in which the device was used. The applicant maintains that the device meets this criterion based on evidence described in the proposed rule. Nonetheless, CMS continues to express concern over a lack of evidence that use of the device to make a diagnosis affects the medical management of the patient and leads to improved clinical outcomes. CMS seeks comments regarding whether or not the LipiScan™ technology represents a substantial clinical improvement in the Medicare population.

c. LipiScan™ Coronary Imaging System with Intravascular Ultrasound (IVUS)

InfraReDx, Inc. submitted an application for new technology add-on payments for FY 2011 for the LipiScan™ Coronary Imaging System with Intravascular Ultrasound (LipiScan™ IVUS). The LipiScan™ IVUS device is a diagnostic device that uses Intravascular near infrared spectroscopy (INIRS) combined with intravascular ultrasound (IVUS) during an invasive coronary angiography to determine the chemical composition of coronary plaques, which is accomplished using near infrared spectroscopy (INIRS) and to visualize stents and the structural features of coronary lesions, which is accomplished using IVUS.

Newness criterion

CMS notes that this device is not currently approved by the FDA, but the manufacturer anticipates that FDA approval will be granted in the second quarter of 2010. However, CMS also notes that IVUS has existed for over 20 years and concludes that IVUS, on its own, would not meet the newness criterion. CMS seeks public comments regarding whether LipiScan™ IVUS, as a combined technology, should be considered to be substantially similar to each individual technology separately as of the date that each separate technology received FDA approval (or the date that each technology became available on the market).

Cost criterion

In an effort to demonstrate that the technology meets the cost criterion, the applicant applied the same methodology used for LipiScan™ and estimated a case-weighted average standardized charge per case of $52,230 for LipiScan™ IVUS. The applicant

indicated that the case-weighted average standardized charge per case does not include charges related to LipiScan™ IVUS. The applicant stated that the cost of the device is proprietary information. Using Hospital Cost Report Information System ("HCRIS") data from 2008, the applicant searched for the 100 cardiac catheterization labs that had the highest volume of cases in the United States. Based on the HCRIS data from these 100 labs, the applicant determined the mean cost-to-charge ratio was 0.188 with a mark-up of 532 percent yielding a charge of $15,957 for LipiScan™ IVUS. Adding the estimated average charge related for the device to the case-weighted standardized charge per case (based on the case distribution from the applicant's FY 2010 AOR analysis) results in a total case-weighted average standardized charge per case of $68,190 ($52,230 plus $15,960) which meets the cost criterion.

CMS performs an alternative calculation of total case-weighted average standardized charge per case for the applicable MS-DRGsand and states "it appears that LipiScan™ IVUS would meet the cost criterion." CMS invites public comment on whether or not LipiScan™ IVUS meets the cost criterion.

Substantial clinical improvement criterion

The applicant asserts that LipiScan™ IVUS lends all the same benefits of LipiScan™ by itself (see discussion of LipiScan™ with respect to clinical improvement in the above application analysis) and also gives added benefits of IVUS. Specifically, the applicant maintains that LipiScan™ IVUS is superior to perfusion imaging and coronary angiography because those procedures only provide information about the lumen, but not the wall of the vessel. The applicant asserts that LipiScan™ IVUS affects the management of the patient by improving the safety and efficacy of stenting.

CMS expresses concern that, in the LipiScan™ IVUS application, the applicant has generally repeated the statements made regarding use of LipiScan™ alone and has not provided information that indicates that combined use of LipiScan™ plus IVUS offers additional clinical benefit. CMS notes that most of the studies that were presented in an effort to support that LipiScan™ by itself as a substantial clinical improvement were also included to support the LipiScan™ IVUS application. The applicant did not present any published peer-reviewed journal articles that were specifically related to the clinical merits of the combined LipiScan™ IVUS device. CMS seeks public comment on whether the LipiScan™ IVUS represents a substantial clinical improvement over existing technologies as well as public comments on what is the appropriate comparison for LipiScan™ IVUS.

IV. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Requirements of Section 106 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Pub. L. 109-432 (MIEA-TRHCA)

In the IPPS/LTCH PPS FY 2010 final rule, CMS noted it had contracted with Acumen LLC to study and report on the MedPAC's June 2007 congressionally required report to revise the area wage index. The study resulted in a two-part final report. In the first part of the report, which was posted after the publication of the IPPS/LTCH PPS FY 2010 final rule, Acumen suggested that MedPAC's recommended method for revising the wage index represented an improvement over the existing methods, and that the Bureau of Labor Statistics (BLS) data should be used so that the MedPAC approach could be implemented. In the second part of the report, Acumen found that MedPAC's recommended method of improving upon the definition of the wage areas used in the current wage index was also an improvement. However, Acumen went on to say that although MedPAC's method diminishes the size of differences between adjacent areas, the method does not guarantee an accurate representation of a hospital's labor market and would not necessarily eliminate or reduce hospitals' desire to reclassify for a higher wage index. Acumen recommended further exploration of labor market definitions using a wage area framework based on hospital-specific characteristics, such as commuting times from hospitals to population centers, to construct a more accurate hospital wage index. These reports are available at www.acumenllc.com/reports/cms).

In the proposed rule CMS says it is not proposing any additional changes in regards to reforming the wage index for the FY 2011 IPPS.

CMS also noted hospital reclassification policies adopted as part of the FY 2009 IPPS final rule. Under these policies, CMS sought to increase the minimum average hourly wage index of the area to which an urban hospital sought reclassification from 84 percent to 88 percent and for rural hospitals from 80 percent to 84 percent transitioned over a two year period from FY 2010 to FY 2011. Section 3137 as modified by Section 10317 of the PPACA (P.L. 111-148), however, effective FY 2011 restored the hourly wage comparison of 84 percent for urban hospitals and 80 percent for rural hospitals and provided that these percentages would remain in effect until one year after the Secretary submitted a required hospital wage index improvement plan. This report is due no later than December 31, 2011. CMS said that the PPACA changes would be addressed in a separate rulemaking document.

CMS acknowledged in the proposed rule that in the FY 2009 IPPS final rule, the agency adopted state level budget neutrality (rather than the national budget neutrality adjustment) for the rural and imputed floor, effective beginning with the FY 2009 wage index. This change was to have been implemented over a 3-year period (FY 2009 – FY 2011). Section 3141 of PPACA, effective FY 2011, requires that the budget neutrality adjustment for the rural and imputed floor be done on a national basis rather than a state-specific basis. CMS said that these PPACA changes also would be addressed in a separate rulemaking document.

The proposed rule includes a listing of changes to the principal cities and in some cases name changes to the Core-Based Statistical Areas (CBSAs). These changes were announced by the Office of Management and Budget (OMB) on December 1, 2009 and can be found at the OMB web site at http://www.whitehouse.gov/OMB - go to "Agency Information" and click on "Bulletins".

B. Occupational Mix Adjustment

For the FY 2010 hospital wage index, CMS used occupational mix data collected on a revised 2007-2008 Medicare Wage Index Occupational Mix Survey (under which hospital-specific wages and hours data were collected for the period of July 1, 2007 through June 30, 2008). CMS stated, that "again, for the proposed FY 2011 hospital wage index, we used data from the 2007-2008 survey . . . . to compute the proposed FY 2011 adjustment." CMS went on to say that it would use the 2007-2008 survey for the FY 2012 wage index but would, per requirement, develop a new measurement of occupational mix for FY 2013. The new measurement survey using FY 2010 data was published in the *Federal Register* on January 15, 2010 (75 FR 2548).

For purposes of calculating the proposed occupational mix adjustment for FY 2011, CMS is following the same methodology it used for FY 2010. The resulting FY 2011 proposed occupational mix adjusted national average hourly wage is $34.9124 (the FY 2011 proposed occupational mix adjusted Puerto Rico-specific average hourly wage is $14.7567). For FY 2011, the occupational mix adjustment is being applied to 100 percent of the FY 2011 proposed wage index.

CMS compared the proposed FY 2011 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. It found that the proposed FY 2011 wage index values for 203 (51.9 percent) urban areas and 32 (68.1 percent) rural areas would increase, while the values for 168 (48.1 percent urban areas and 15 (31.9 percent) rural areas would decrease. No urban or rural areas would be unaffected.

To gain a better understanding of why some hospitals are not submitting the occupational mix data, CMS said that beginning with the new 2010 occupational mix survey, the agency will require hospitals that do not submit occupational mix data to provide an explanation for not complying with the submission requirements.

C. Other Wage Index Issues

CMS notes that 311 hospitals were approved for wage index reclassifications for FY 2011 by the Medicare Geographic Classification Review Board (MGCRB), and because such reclassifications are effective for 3 years a total of 832 hospitals are in a reclassification status for FY 2011 (including those initially approved by the MGCRB for FY 2009 and FY 2010). Applications for FY 2012 reclassifications are due to the MGCRB by September 1, 2010. This is also the deadline for canceling a previous wage index reclassification withdrawal or termination.

The proposed rule lists rural ("Lugar") counties and states. Hospitals located in these counties qualify under section 1886(d)(8)(B) of the Social Security Act to receive the wage index of a specified urban area.

Section 508 of P.L. 108-173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although the benefits for the qualifying hospitals expired September 30, 2009, CMS noted that Section 10317 of the PPACA extended the benefit again through September 30, 2010. CMS went on to say that it intended to "imminently issue instructions regarding implementation" of the section.

Table 4J in the Addendum to the proposed rule lists the proposed out-migration wage index adjustments for FY 2011. The out-migration adjustment is based on commuting patterns of hospital employees and provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. Such adjustments to the wage index are effective for 3 years, unless a hospital requests to waive the application of the adjustment. Hospitals that are not otherwise reclassified or redesignated will automatically receive the listed adjustment, and redesignated/reclassified hospitals will be deemed to have waived the out-migration adjustment unless CMS was otherwise notified within the necessary timeframe.

CMS said that, "we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2010." This is the same labor-related share as was used in FY 2010.

Finally, CMS reviews in detail its established processes for verifying wage data, computing hospital wage index values, and requesting wage index data corrections. It also discusses the criteria it uses for (rarely) making midyear corrections to the wage index for an area.

V. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

A. Reporting of Hospital Quality Data for Annual Hospital Payment Update

1. Overview

Under the Reporting of Hospital Quality Data for Annual Payment Update (RHQDAPU) program, hospitals that do not meet requirements for reporting specific quality information for a payment year receive a 2 percentage point reduction in that year's inpatient hospital payment update factor. Items 2 through 4 of this section discuss CMS' proposed quality measures. Items 5 and 6 discuss proposed quality data reporting procedures. Items 7 and 8 discuss proposed data validation and acknowledgements. Items 9, 10 and 11 address proposed public display

requirements, reconsideration and appeals procedures, and program withdrawal deadlines, respectively. Item 12 discusses electronic health records (EHRs). Finally, item 13 proposes qualifications for registries for RHQDAPU data submission.

2. Retirement of RHQDAPU Program Measure/Quality Measures for FY 2011

The quality measures to be used for the FY 2011 payment determination under the RHQDAPU were finalized in the FY 2009 IPPS final rule, totaling 46 measures. CMS now proposes to retire one of those measures, the AHRQ composite measure on Mortality for Selected Surgical Procedures, leaving the 45 measures listed in the following table that will be used for FY 2011 payment determinations. CMS indicates that following NQF evaluation of the AHRQ composite surgical mortality measure in June 2009, the AHRQ issued guidance indicating that the measure is not recommended for comparative reporting due to significant evidence gaps. CMS thus proposes to retire this measure, meaning that it will not be calculated for the FY 2011 payment determination or displayed on the Hospital Compare website (http://www.hospitalcompare.hhs.gov). The remaining measures for the RHQDAPU FY 2011 payment determinations are shown in the following table.

RHQDAPU Program Quality Measures for the FY 2011 Payment Determination	
Acute Myocardial Infarction (AMI)	
	• AMI-1 Aspirin at arrival
	• AMI-2 Aspirin prescribed at discharge
	• AMI-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic
	• AMI-4 Adult smoking cessation advice/counseling
	• AMI-5 Beta blocker prescribed at discharge
	• AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes
	• AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
Heart Failure (HF)	
	• HF-1 Discharge instructions
	• HF-2 Left ventricular function assessment
	• HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic
	• HF-4 Adult smoking cessation advice/counseling
Pneumonia (PN)	
	• PN-2 Pneumococcal vaccination status
	• PN-3b Blood culture performed before first antibiotic received in hospital
	• PN-4 Adult smoking cessation advice/counseling
	• PN-5c Timing of receipt of initial antibiotic following hospital arrival
	• PN-6 Appropriate initial antibiotic selection
	• PN-7 Influenza vaccination status
Surgical Care Improvement Project (SCIP)	

RHQDAPU Program Quality Measures for the FY 2011 Payment Determination	
	• SCIP-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	• SCIP-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time
	• SCIP-VTE-1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients
	• SCIP-VTE-2: VTE prophylaxis within 24 hours pre/post surgery
	• SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients
	• SCIP-Infection-4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
	• SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal
	• SCIP–Infection-9: Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2*
	• SCIP-Infection-10: Perioperative Temperature Management*
	• SCIP-Cardiovascular-2: Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period
Mortality Measures (Medicare Patients)	
	• MORT-30-AMI: Acute Myocardial Infarction 30-day mortality – Medicare patients
	• MORT-30-HF: Heart Failure 30-day mortality Medicare patients
	• MORT-30-PN: Pneumonia 30-day mortality -Medicare patients
Patients' Experience of Care	
	• HCAHPS survey
Readmission Measure (Medicare Patients)	
	• READ-30-HF: Heart Failure 30-Day Risk Standardized Readmission Measure (Medicare patients)
	• READ-30-AMI: Acute Myocardial Infarction 30-Day Risk Standardized Readmission Measure (Medicare patients)
	• READ-30-PN: Pneumonia 30-Day Risk Standardized Readmission Measure (Medicare patients)
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	• PSI 06: Iatrogenic pneumothorax, adult
	• PSI 14: Postoperative wound dehiscence
	• PSI 15: Accidental puncture or laceration
	• IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)
	• IQI 19: Hip fracture mortality rate
	• Complication/patient safety for selected indicators (composite)
	• Mortality for selected medical conditions (composite)
AHRQ PSI and Nursing Sensitive Care	
	• Death among surgical inpatients with serious, treatable complications

RHQDAPU Program Quality Measures for the FY 2011 Payment Determination	
Cardiac Surgery	
	• Participation in a Systematic Database for Cardiac Surgery
Stroke Care	
	• Participation in a Systematic Clinical Database Registry for Stroke Care
Nursing Sensitive Care	
	• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care

3. Proposed Expansion Plan for Quality Measures for the FY 2012, FY 2013 and FY 2014 Payment Determinations

In this proposed rule, CMS departs from its past practice of identifying quality measures for a single payment year, and instead proposes a three-year plan for expanding quality measures required under RHQDAPU. The nature of RHQDAPU necessitates identifying the quality measures on an advanced basis, but CMS has only ever done so for a single year. For example, during the rulemaking cycle for FY 2010, CMS proposed and finalized the RHQDAPU measures that hospitals would report for FY 2011 payment determinations. Now, CMS proposes quality measures for FY 2012, FY 2013 and FY 2014 payment determinations. In taking this multi-year approach, CMS believes hospitals will have greater certainty in planning to meet future reporting requirements, and CMS will have more time to prepare the infrastructure to collect data on the measures and make payment determinations.

General Discussion of Adding Measures. With respect to adding measures generally, CMS cites its continued interest in expanding and updating quality measures while minimizing reporting burden, using of registries as an alternative to direct hospital submission of data for RHQDAPU, and possibly using of electronic health records (EHRs) and all-payer data in the RHQDAPU program.

CMS specifically solicits comments on changing its priorities to include measures that assess performance on healthcare associated infections (HAIs), and on measures that could be added to RHQDAPU and publicly reported that promote improvement in healthcare associated infection rates.

A total of 10 new data elements are proposed for the FY 2012 payment determination, 3 for the FY 2013 payment determination, and another 4 for the FY 2014 payment determination. In addition, beginning with the FY 2013 payment determination, hospitals will be required to report registry-based measures on a choice of one of four topics, which will add between 1 and 15 more measures. **If all these measures are adopted, absent the future retirement of any measures, the RHQDAPU measure set for FY 2014 would total between 63 and 78 data elements, depending on the hospital's chosen registry topic.** Additionally,

beginning with the FY 2012 payment determination, hospitals will be required to submit all-patient volume data for selected MS-DRGs.

Measures for FY 2012 Payment Determinations.

CMS proposes to retain the 45 measures used for FY 2011 payment determinations and proposes adding 10 new claims-based data elements: 2 AHRQ Patient Safety Indicators and 8 Hospital Acquired Conditions. In addition, CMS proposes that hospitals begin submitting all-patient data on 55 MS-DRGs that relate to RHQDAPU program measures.

Retaining FY 2011 Measures; Possible Retirements. With respect to proposing continuing use of the FY 2011 measures for FY 2012 payment determinations, CMS indicates concern about hospital reporting burden in light of the proposed addition of new measures, and invites comments on whether some FY 2011 measures should be retired. In particular, CMS identifies 11 measures that were recommended for retirement by commenters during last year's rulemaking process and seeks comments on whether to retire these particular measures. Moreover, CMS indicates that it is considering an approach under which the addition of a broad measure that encompasses data reported on a narrower measure would prompt retirement of the narrower measure. The example offered is that if proposed measures of influenza and pneumoccocal vaccination for all patients were finalized, the existing measures that apply only to pneumonia admissions (PN-2 and PN-7) would be retired.

New Claims-Based Data Elements. The 10 proposed claims-based data elements are listed below. Two are AHRQ Patient Safety Indicators addressing post-operative complications, which CMS states is an area under-represented in the current RHQDAPU measure set. These measures are both endorsed by the National Quality Forum (NQF), and are identified by AHRQ as having the strongest (Tier 1) evidence base. The remaining 8 data elements are among the 10 conditions identified as hospital acquired conditions for Medicare payment purposes. The HAC measures would be based on Medicare-only claims with a present-on-admission (POA) coding of "N" or "U". (For discussion of HACs and POA indicators see section II.F. above.)

AHRQ Patient Safety Indicators (PSIs):
PSI 11: Post Operative Respiratory Failure
PSI 12: Post Operative PE or DVT

Hospital Acquired Conditions:
Foreign Object Retained After Surgery
Air Embolism
Blood Incompatibility
Pressure Ulcer Stages III & IV
Falls and Trauma (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)
Vascular Catheter-Associated Infection
Catheter-Associated Urinary Tract Infection (UTI)

Manifestations of Poor Glycemic Control

All-Patient Volume Reporting by MS-DRG. CMS proposes that beginning with January 1, 2011 discharges, hospitals would once a year submit all-patient volume data for the 55 MS-DRGs that relate to the RHQDAPU measures. These volume data would be reported on the Hospital Compare website instead of the Medicare-only volume data that is currently displayed. CMS believes all-patient data would provide better context for users of Hospital Compare. Hospitals would not be required to group the all-patient claims data by MS-DRG. They would submit claims data including all the information needed to group the claims by MS-DRG and CMS would do the grouping. CMS invites comments on an alternative under which hospitals would submit all-patient volume data based on ICD-9-CM codes related to the proposed MS-DRGs. The 55 MS-DRGs are: 038; 039; 190; 191; 193; 219; 220; 221; 224; 226; 235; 236; 237; 243; 247; 280; 281; 282; 291; 292; 293; 328; 329; 330; 331; 353; 354; 417; 418; 459; 461; 462; 466; 467; 468; 469; 470; 471; 472; 477; 478; 490; 507; 515; 656; 657; 658; 659; 668; 673; 674; 675; 713; 743; and 748.

Measures for FY 2013 Payment Determinations.

In addition to continuing the 55 measures proposed for FY 2012, CMS proposes the addition of 3 measures for the FY 2013 payment determinations, and proposes that in addition hospitals choose one of four topic areas (implantable cardioverter defibillator (ICD) complications, cardiac surgery, stroke, or nursing-sensitive care) for which measures would be reported through a qualified registry. Depending on the topic chosen, hospitals would report from 1 to 15 additional measures via a registry for FY 2013 payment determination.

- *AMI Statin at discharge*. This proposed measure is a chart-abstracted heart attack measure. CMS provides a clinical rationale for statin use by patients hospitalized for AMI and indicates this measure for heart attack patients is similar to an NQF-endorsed measure (NQF#0439) for stroke patients “Ischemic stroke patients with LDL>=100mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization and are discharged on a statin medication.” CMS indicates that an ad-hoc NQF review of the proposed new AMI measure is underway and is expected to be completed prior to publication of the final rule. CMS’ final decision on whether to adopt this measure in the final rule will be based on whether it achieves NQF endorsement and public comments.

- *HAI measures.* Two proposed new measures are healthcare associated infection measures that are collected by the Centers for Disease Control and Prevention (CDC) through the National Healthcare Safety Network (NHSN). One measures central line associated blood stream infection and the other surgical site infections; both have been endorsed by NQF. Specifically, the first measures the rate of laboratory-confirmed cases of bloodstream infection or sepsis among ICU patients. The second measures the number of NHSN-defined operative procedures with a surgical site infection within 30 days, or 1 year if an implant is in

place. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant time frame.

Collection of these HAI measures would begin with January 1, 2011 discharges. According to CMS, 21 states require hospitals to report HAIs using the NHSN, and 2,000 hospitals are using NHSN. (CMS' proposed process for reporting measures is discussed in item 5 below.)

- *Registry-Based Topics.* CMS proposes that hospitals be required to choose one of the four topic areas described below and report the identified measures to a qualified registry. Hospitals would direct the registry to calculate the measure results and release the results and other required information to CMS for the RHQDAPU program. Data reporting for all of these measures would begin with January 1, 2011 discharges and CMS would provide a list of qualified registries prior to that date. (The process CMS proposes to use in identifying qualified registries is summarized under item 13 at the end of this section on RHQDAPU.)

    - ICD Complications. CMS proposes the addition of this topic, which involves reporting on one measure, pending NQF endorsement. The final NQF endorsement decision is expected this fall, after publication of the final rule, so a final decision regarding inclusion of this topic and measure for the FY 2013 payment determination will be made as part of the final outpatient rule for CY 2011. The proposed measure (identified as NQF #OTI-007-09) is a risk-adjusted complication and mortality rate following implantation of ICDs in Medicare fee-for-service patients at least 65 years of age, with complication specific outcome time frames. It was developed using data submitted to the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) ICD registry, linked with CMS claims data used to identify procedural complications. Under this measure, for each ICD index admission, one or more complications or mortality are indicated within 30 or 90 days (depending on the complication) following ICD implantation. Complications are counted only if they occur during the hospital stay. Those counted for 30 days include pneumothorax or hemothorax plus a chest tube; hematoma plus a blood transfusion or evacuation; cardiac tamponade or pericardiocentesis; and death. Complications counted for 90 days include mechanical complications requiring system revision, device-related infection, and additional ICD implantation.

      CMS notes that under the National Coverage Determination for ICDs for primary prevention, hospitals are currently submitting patient information to the ACC-NCDR ICD registry to determine whether the procedure was reasonable and necessary. The proposed ICD complication measure would require reporting data for all ICD patients, not just primary prevention patients.

With respect to registries, CMS proposes to qualify only one registry for this topic because all the data must be collected in a single repository to calculate the measure. CMS notes that the ACC-NCDR ICD registry is already qualified to receive the data for the National Coverage Determination, but states that this does not preclude another registry from self-nominating to become a qualified registry for this proposed RHQDAPU topic.

- Stroke. For the stroke topic option, eight registry-based stroke measures are proposed (and shown in the following table); they are NQF endorsed. CMS indicates that commenters on the FY 2010 proposed rule expressed support for these measures.

Proposed Measures for Stroke Registry-Based Topic	
STK-1: Venous Thromboembolism (VTE) Prophylaxis for patients with ischemic or hemorrhagic stroke (NQF #0434)	Patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two.
STK-2: Ischemic stroke patients discharged on antithrombotic therapy. (NQF #0435)	Patients with an ischemic stroke prescribed antithrombotic therapy at discharge.
STK-3: Anticoagulation therapy for atrial fibrillation/flutter. (NQF #0436)	Patients with an ischemic stroke with atrial fibrillation discharged on anticoagulation therapy.
STK-4: Thrombolytic Therapy for Acute ischemic stroke patients. (NQF #0437)	Acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.
STK-5: Antithrombotic therapy by the end of hospital day two. (NQF #0438)	Patients with ischemic stroke who receive antithrombotic therapy by the end of hospital day two.
STK-6: Discharged on statin medication. (NQF #0439)	Ischemic stroke patients with LDL >/= 100 mg/dL, or LDL not measured, or, who were on cholesterol reducing therapy prior to hospitalization are discharged on a statin medication.
STK-8: Stroke education. (NQF #0440)	Patients with ischemic or hemorrhagic stroke or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of

	emergency
STK-10: Assessed for rehabilitation services. (NQF #0441)	Patients with an ischemic stroke or hemorrhagic stroke who were assessed for rehabilitation services.

- Nursing Sensitive Care. Eight registry-based nursing sensitive care measures (listed below) are proposed for this topic option; all are NQF-endorsed. Hospitals would report these measures to a qualified nursing-sensitive care registry. The existing nursing sensitive care measures would continue to be reported to the RHQDAPU program, as they have been, through the QIO Clinical Warehouse.

Proposed Measures for Nursing Sensitive Care Registry-Based Topic
Patient Falls: All documented falls with or without injury, experienced by patients on an eligible unit in a calendar month. (NQF #0141)
Falls with Injury: All documented patient falls with an injury level of minor or greater. (NQF #0202)
Pressure Ulcer Prevalence (NQF #0201)
Restraint Prevalence (vest and limb) (NQF #0203)
Skill Mix: Percentage of hours worked by: RN, LPN/LVN, UAP, Contract/Agency (NQF #0204)
Hours per patient day worked by RN, LPN, and UAP (NQF #0205)
Practice Environment Scale-Nursing Work Index (NQF #0206)
Voluntary turnover for RN, APN, LPN, UAP (NQF #0207)

- Cardiac Surgery. CMS proposes 15 measures for reporting under this registry-based topic option; all have been endorsed by NQF. CMS states that nearly 90% of hospitals performing these procedures already report these data to clinical registries. The existing RHQDAPU cardiac surgery structural measure (Participation in a Systematic Database for Cardiac Surgery) would continue to be reported by hospitals, as it has been, to the QIO Clinical Warehouse.

  Because 5 of these measures require risk adjustment for calculation, CMS anticipates qualifying only one registry to collect all of the data for this topic. (These measures are shown first in the list below.) Although the other 10 measures do not require risk adjustment, CMS believes it may be burdensome for hospitals to submit data on this topic to more than one registry. CMS specifically invites comment on this.

Proposed Measures for Proposed Cardiac Surgery Registry-Based Topic
Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft CABG (NQF# 0119)
Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR) (NQF# 0120)
Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR) (NQF# 0121)

Risk-Adjusted Operative Mortality MVR+CABG Surgery (NQF# 0122)
Risk-Adjusted Operative Mortality for AVR+CABG (NQF# 0123)
Post-operative Renal Failure (NQF# 0114)
Surgical Re-exploration (NQF# 0115)
Anti-Platelet Medication at Discharge (NQF# 0116)
Beta Blockade at Discharge (NQF# 0117)
Anti-Lipid Treatment Discharge (NQF# 0118)
Pre-Operative Beta Blockade (NQF# 0127)
Duration of Prophylaxis for Cardiac Surgery Patients (NQF# 0128)
Prolonged Intubation (ventilation) (NQF# 0129)
Deep Sternal Wound Infection Rate (NQF# 0130)
Stroke/Cerebrovascular Accident (NQF# 0131)

Measures for FY 2014 Payment Determinations.

In addition to the measures proposed for FY 2013, CMS proposes to add 4 chart-abstracted measures to the RHQDAPU measure set for the FY 2014 payment determination. Two measures relate to emergency department throughput, and two are all patient immunization measures. CMS states that all the measures are NQF endorsed, and the technical specifications for the global immunization measures will be available for preview in the April 2010 specifications manual. CMS discusses the importance of these measures and states that although this proposal would add to hospitals' reporting burden, this could be mitigated. Specifically, the addition of the new immunization measures could permit the retirement of two existing immunization measures that apply only to pneumonia patients, as discussed earlier. (CMS does not propose this retirement, but invites comments.) In addition, the emergency department measures have been specified for EHR-based collection, which CMS views as possibly reducing reporting burden in the future.

ED Throughput – Admit Decision Time to ED Departure Time for Admitted Patients (NQF #0497)
ED Throughput - Median time from emergency department arrival to ED departure for admitted patients (NQF #0495)
Global Flu Immunization
Global Pneumonia Immunization

4. Possible New Quality Measures for Future Years

CMS also includes a table (displayed here) of additional measures that it reports to be considering for future years, and invites comments in support of additional measures and topics that are not included on the list.

Possible RHQDAPU Program Future Measures and Topics	
Possible Future Measures/ Topics	**Measurement Topic Measure Title/ Description/Concept**
Surgical Safety	Surgical checklist use for surgical procedures

Complications	Lower Extremity Bypass Complications
PCI Readmission	30-day risk-standardized readmission rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older.
PCI Mortality	30-day risk-standardized mortality rate following PCI for STEMI/shock patients.
PCI Mortality	30-day risk-standardized mortality rate following PCI for non-STEMI/non-shock patients.
VTE	VTE-1: Venous Thromboembolism Prophylaxis
VTE	VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis
VTE	VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy
VTE	VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol
VTE	VTE-5: Venous Thromboembolism Discharge Instructions
VTE	VTE-6: Incidence of Potentially-Preventable Venous Thromboembolism.
Care Transitions for AMI	30-Day Post-Hospital AMI Discharge ED Visit Measure
Care Transitions for AMI	30-Day Post-Hospital AMI Discharge Evaluation and Management Service Measure Care Transitions for AMI
Care Transitions for AMI	30-Day Post-Hospital AMI Discharge Care Transition Composite Measure
Care Transitions for Heart Failure	30-Day Post-Hospital HF Discharge ED Visit Rate
Care Transitions for Heart Failure	30-Day Post-Hospital HF Discharge Evaluation and Management Service Measure
Care Transitions for Heart Failure	30-Day Post-Hospital HF Discharge Care Transition Composite Measure
Care Transitions for Pneumonia	30-Day Post-Hospital Pneumonia Discharge ED Visit Rate
Care Transitions for Pneumonia	30-Day Post-Hospital Pneumonia Discharge Evaluation and Management Service Measure
Care Transitions for Pneumonia	30-Day Post-Hospital Pneumonia Discharge Care Transition Composite Measure
Healthcare Associated Infections	Ventilator Associated Pneumonia
Healthcare Associated Infections	Multidrug-resistant organism (MDRO) infection
Healthcare Associated Infections	Clostridium Difficile Associated Diseases (CDAD)
Health Care Personnel Immunization	Influenza Vaccination for Healthcare Personnel
Cardiac Rehabilitation Referral	Cardiac Rehabilitation Referral for AMI, HF, Cardiac Surgery
End of Life Care	Appropriate Pain Management
Serious Reportable Events	NQF approved Serious Reportable Events

5. Form, Manner, and Timing of Quality Data Submission

Beginning with the FY 2013 payment determination, CMS proposes to synchronize the timing of reporting for various measures so that all measures will be required to be reported for the four calendar quarters of calendar year 2011. Currently, different reporting periods apply to different measures. Along with this, CMS proposes that data validation will be required for 4 consecutive calendar quarters beginning with the 4th quarter of the calendar year that occurs 2 years before the payment determination. So, for the FY 2013 payment determination, validation will be required for the data reported for the 4th calendar quarter of calendar year 2010 through the third quarter of calendar year 2011. CMS believes this is appropriate given the time required for the validation abstraction and appeal process.

By September 15th each year CMS will post a table on the QualityNet website showing the discharge quarters that will be used to make each fiscal year payment determination. Among several reasons provided for proposing this change, CMS indicates that it will assist the agency in implementing the Value Based Purchasing provision required under the Patient Protection and Affordable Care Act.

The following table summarizes the proposed time periods described in the proposed rule with respect to different data elements.

Data on Which Payment Determinations Will Be Based

Measure	Payment Determination Year		
	FY 2012	**FY 2013**	**FY 2014**
HCAHPS	April 1, 2010 – December 31, 2010	January 1, 2011-December 31, 2011	January 1, 2012-December 31, 2012
Chart Abstracted Data Submitted Directly to CMS via QualityNet	4Q CY 2009 - 4Q CY 2010 (5 quarters)	1Q CY 2011-4Q CY 2011	1Q CY 2012-4Q CY 2012
Population and sampling data for chart abstraction measures	2Q CY 2010 - 4Q CY 2010 (3 quarters)	1QCY 2011-4Q CY 2011	1Q CY 2012-4Q CY 2012
Claims based data (time period for data CMS would use to calculate measures)	Up to 3 yrs of discharges prior to Jan 1, 2011	Up to 3 yrs of discharges prior to Jan 1, 2012	Up to 3 yrs of discharges prior to Jan 1, 2013
Structural Measures (registry participation)	Submit once between July 1, 2011 and Aug 15, 2011 for time period July 1, 2010 through 12/31/2010	None proposed	None proposed
All-patient volume data for selected MS-DRGs	Quarterly submission via QualityNet beginning 1/1/2011 discharges	Continued quarterly submission via QualityNet	Continued quarterly submission via QualityNet
HAI measures reported	N/A	1QCY 2011-4Q CY	1Q CY 2012-4Q CY

via NHSN*		2011	2012
Registry-based measures	N/A	Specified by registry	Specified by registry

For the new chart-abstracted measures proposed to begin in FY 2013, data collection would begin with the 1st calendar quarter 2011 discharges, for which the data submission deadline would be August 15, 2011. That is, CMS proposes to retain the requirement that patient level data for the chart abstracted measures be submitted by 4 ½ months following the last discharge date of the quarter.

With respect to the HAI measures to be reported via the CDC's NHSN, hospitals will be required once a quarter to use an automated function that will be provided to generate a quarterly report with information needed to calculate the two proposed measures. CMS specifically invites comments on the proposed mechanism for submitting data for these two measures.

With respect to the requirement that hospitals report on 1 of 4 registry-based topics beginning with FY 2013 payment determinations, CMS anticipates posting the list of qualified registries by December 31, 2010. Hospitals would make arrangements with the qualified registry with respect to data reporting to the registry, in compliance with HIPPAA. CMS proposes that hospitals choosing to report on the ICD measures also must allow the qualified registry to report to CMS the patient level data needed to calculate the measure. For the other 3 registry-based topics, hospitals would agree to allow the registry to send to CMS calculations of the measures, numerator, denominator and exclusion counts.

Finally, with respect to the requirement that hospitals submit quarterly counts of Medicare and non-Medicare discharges for the topic areas for which chart abstracted measures apply (currently heart attack, heart failure, pneumonia and surgical infection), CMS proposes a clarification that hospitals must submit a number for each category. That is, even if the hospital has not treated any patients in the category in the quarter, the hospitals must submit a zero for that topic.

6. RHQDAPU Program Disaster Extensions and Waivers

CMS proposes and invites comment on a process under which hospitals facing extraordinary circumstances could request and be granted a waiver from reporting required data for RHQDAPU. (CMS solicited comments on this issue during last year's rulemaking, but no policy was proposed or finalized.)

Specifically, a hospital facing extraordinary circumstances beyond its control, may submit to the QIO in the state a request form signed by the hospital's CEO that includes the reason for the extension request or waiver, evidence of the impact of the circumstances, such as photographs and news articles, and a date when the hospital will begin again to report, along with a justification for the date. The form must be submitted within 45 days of the event prompting the request. The QIO will forward the

request to CMS, which will provide written acknowledgement of receipt of the request and a formal response with a decision.

CMS states that its proposal does not preclude it from granting an extension or waiver to a hospitals that have not requested them if an extraordinary circumstance, such as an act of nature, affects an area. In such a case, CMS would announce the decision through normal means of communicating with hospitals, vendors and QIOs, including email and the Qualitynet website.

7. Proposed Chart Validation Requirements for Chart-Abstracted Measures

For the FY 2012 RHQDAPU payment determination, CMS proposes no changes to the chart validation requirements that were adopted for the FY 2011 payment determination. These requirements involve validating records for an annual sample of 800 hospitals among those that submitted chart-abstracted data for at least 100 discharges combined for all topics. The requirements for FY 2012 will be posted on the Qualitynet website after the FY 2011 final rule is issued.

Beginning with FY 2013, CMS proposes to continue the same validation process with four changes. First, a targeting criterion will be added. All hospitals that fail the validation process in a year will be selected for validation again in the next year. Based on past experience, CMS estimates this will add about 20 to 40 hospitals to the sample for FY 2013 payment determinations.

Second, CMS proposes to eliminate the 100 discharges minimum beginning with the validation sample for the FY 2013 payment determination which will be selected in January 2011. The sample will be chosen from among all hospitals that successfully submitted at least one RHQDAPU case for the third calendar quarter two years prior to the validation year. For example, any hospital submitting at least one case in the third quarter of calendar year 2010 will be eligible for selection in the sample for FY 2013. CMS believes that this change will improve the robustness of the validation sampling by adding smaller hospitals to the sampling pool.

Third, for hospitals chosen to be part of the validation sample, CMS proposes to modify the methodology for sampling discharges in cases where hospitals have fewer than 3 cases in a topic area in a quarter. When this occurs, more cases will be chosen from other topic areas to ensure that 12 cases are reviewed per quarter. CMS expects this to be a rare occurrence.

Finally, CMS proposes to adjust the timing of data validation to be consistent with the proposed synchronization of RHQDAPU data discussed earlier (item 5). The data proposed to be validated for the FY 2013 payment determination are data from the 4th quarter of calendar year 2010 through the 3rd quarter of calendar year 2011.

CMS identifies additional changes in the data validation requirements that it is considering for later years. Beginning with the FY 2014 payment determination, CMS

is considering the addition of 2 samples of 3 cases per quarter, one to validate cases for the two HAI measures it is proposing to add to RHQDAPU beginning in FY 2013 and the other for the ED throughput and immunization measures proposed to begin with the FY 2014 determination. This would increase the total number of cases reviewed per quarter from 12 to 18. In addition, CMS is considering requiring hospitals to sign a written form explicitly granting CMS access to the data submitted to the NHSN on the HAI measures.

Beginning with the FY 2015 payment determination, CMS is considering adding hospitals to the data validation sample that were operating in FY 2012 but not selected as part of the data validation sample in the previous three years. In this way, all hospitals would be subject to data validation at least once every 4 years.

8. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2011 Payment Determination and Subsequent Years

Consistent with the approach finalized in last year's rule, CMS proposes that hospitals electronically acknowledge the accuracy and completeness of their data once between July 1, 2010 and August 15, 2010 for the FY 2012 RHQDAPU payment determination.

9. Proposed Public Display Requirements for the FY 2012 Payment Determination and Subsequent Years

CMS proposes no changes related to procedures for display of information on the Hospital Compare website.

10. Proposed Reconsideration and Appeal Procedures for the FY 2011 Payment Determination

The deadline for submitting a request for reconsideration of the FY 2011 payment determination is November 1, 2010. CMS proposes to continue the process used for FY 2010 requests for reconsideration, but again seeks comments on whether the procedures are less costly for hospitals and will reduce appeals.

11. Proposed RHQDAPU Program Withdrawal Deadlines

CMS proposes to accept RHQDAPU withdrawal forms for FY 2012 payment determination until August 15, 2011. Hospitals that withdraw from participation will receive a 2 percentage point reduction in their update factor.

12. Electronic Health Records

CMS discusses its efforts to encourage hospitals to adopt EHRs that will allow reporting of quality data directly, and anticipates that as early as the summer of 2011 it will move forward with testing of accepting data from EHRs on the ED, stroke, and

VTE measures. These measures have not been adopted for use in RHQDAPU, and CMS indicates that the testing of measures for EHR purposes does not signal it will be adopted in RHQDAPU. In addition, CMS discusses overlap between RHQDAPU and the HITECH Act and notes that nothing in the proposed rule implements or implicates HITECH Act, which is the subject of separate rulemaking.

13. Qualification of Registries for RHQDAPU Data Submission

As described earlier (item 3) CMS proposes that beginning with quality reporting for the FY 2013 payment determination, hospitals will choose one of four topics for registry-based quality reporting. This section of the proposed rule sets forth the process and requirements CMS proposes to use in determining qualified registries to collect and submit these quality data.

CMS notes that although a registry will have to meet certain requirements to be qualified, it would not be a CMS contractor and hospitals will be responsible for making sure the registry successfully processes and transmits to CMS the data the hospital reports to the registry.

CMS proposes a self-nomination process for registries seeking to submit data on behalf of hospitals for a particular topic. To self-nominate, a registry will have to meet all the requirements listed below. Registries are instructed to submit a self-nomination letter by October 15, 2010.

- The registry has been collecting the data elements needed to calculate the proposed measures for the topic at least 3 years prior to January 1, 2010.
- As of January 1, 2010, the registry has been collecting data from at least 750 hospitals.
- The registry has the capability to collect from hospitals all the data elements needed for the measure specifications and calculate results for the specified measures.
- The registry agrees to report specified data to CMS via Qualitynet. The data will include the volume of eligible cases, the volume of numerator events for the quality measure, the number of cases excluded from the measure, and the measure results.
- The registry must agree to submit the data in CMS-specified format, which CMS expects will be available in late 2010.
- The registry must be able to perform data validation checks to determine the accuracy of the data received by hospitals and agree to submit an acceptable data validation strategy by December 15, 2011. An acceptable strategy may involve random sampling or require hospitals to adhere to a required sampling method.
- The registry must maintain an appropriate HIPAA-compliant Business Associate agreement with its participating hospitals.

- The registry must maintain signed documentation showing that each participating hospital has authorized the registry to calculate and submit the CMS-specified quality measure data to CMS.
- The registry must agree to allow CMS, upon request, to review the data submitted by hospitals for purposes of the RHQDAPU program.
- The registry must agree to indicate to CMS upon request whether a particular hospital has satisfied the registry's participation requirements.
- The registry must agree to provide CMS with a signed, written statement attesting that the quality measure data that the registry has submitted to CMS on behalf of its participating hospitals is accurate and complete.
- The registry must agree to provide at least 1 feedback report per year to participating hospitals.
- The registry must agree to provide on-going technical assistance to its participating hospitals with respect to submission of RHQDAPU data.
- The registry must agree to participate in periodic RHQDAPU program support calls hosted by CMS.

B. Payment for Transfer of Cases to Nonparticipating Hospitals and CAHs

CMS proposes to extend application of payment adjustments under the transfer policy to include a transfer of a case from an IPPS hospital to 1) a nonparticipating acute care hospital that would otherwise be eligible for payment under the IPPS, and 2) to a critical access hospital.

CMS notes that hospitals will be required to use the following codes on IPPS claims for transfer cases to these facilities:

- For transfers to CAHs, patient discharge status code "66" (Discharged/Transferred to a Critical Access Hospital).
- For transfers to nonparticipating acute care hospitals, patient status code "02" (Discharged/Transferred to a Short-Term General Hospital for Inpatient Care).

C. Technical Change to Regulation

The proposed rule corrects a technical error under paragraph (b) of section 485.610 to clarify that critical access hospitals may also be treated, for purposes of condition of participation, as being located in a rural area under paragraph (b)(4) of that section, relating to a transition period (ending September 30, 2011) during which a CAH that is located in a county reclassified as urban by reason of an OMB reclassification of 3 Micropolitan Statistical Areas may seek rural redesignation.

D. Medicare-Dependent, Small Rural Hospital (MDHs)

Under the IPPS, separate special payment protections are provided to a Medicare-Dependent, Small Rural Hospital (MDH). An MDH is a hospital that is located in a rural area, has not more than 100 beds, is not a sole community hospital (SCH), and,

for a specified base year, has at least 60 percent of its inpatient days or discharges that are attributable to individuals receiving Medicare Part A benefits.

CMS is proposing to revise the Medicare-dependency criterion to replace the term "receiving" with the phrase "entitled to." This would expand the count of Medicare inpatient days or discharges attributable to individuals entitled to the Medicare Part A insurance benefit, including individuals who have exhausted their Medicare Part A inpatient hospital coverage benefit. Currently CMS does not count inpatient days or discharges attributable to those beneficiaries who have exhausted their Medicare Part A inpatient hospital coverage benefit. CMS estimates that this proposal could allow 48 more inpatient PPS hospitals to qualify as MDHs, which would increase Medicare payments by $3.6 million in FY 2011.

E. Rural Referral Centers (RRCs)

CMS proposes revised criteria for purposes of determining rural referral center (RRC) status, including updated minimum national and regional CMI values and updated minimum national and regional numbers of discharges. These factors are among those used to determine whether a given hospital qualifies for RRC status.

More specifically, to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2010, CMS is proposing that a rural hospital not having 275 or more beds available for use must, among other things:

- Have a CMI value for FY 2009 that is at least 1.5127 or the (newly updated) median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) calculated by CMS for the census region in which the hospital is located. These proposed median regional CMIs are listed in the proposed rule.
- Have as the number of discharges for its cost reporting period that began during FY 2008 a figure that is at least 5,000 (3,000 for an osteopathic hospital) or the (newly updated) median number of discharges for urban hospitals in the census region in which the hospital is located. However, since the proposed median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, CMS notes that 5,000 discharges is the minimum criterion for all hospitals (3,000 for osteopathic hospitals).

F. Indirect Medicare Education (IME) Adjustment

The proposed rule would continue the IME adjustment factor at 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

See section H (Payments for DGME) below for clarification of rules identifying approved medical residency training programs that apply for purposes of IME and DGME.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs): Supplemental Security Income (SSI) Fraction

Background: In response to the decision in *Baystate Medical Center v. Leavitt*, CMS proposes to revise its data matching process for the SSI fraction of the Medicare DSH adjustment formula. The District Court concluded 1) that the SSI eligibility data used failed to include stale and forced pay SSI records; 2) that CMS' use of only a single Title II number and one Health Insurance Claims Account Number (HICAN) was faulty; and 3) that the match process used did not appropriately account for retroactive SSI eligibility determinations and lifting of payment suspensions.

Proposed Process for Matching Medicare and SSI Eligibility Data:

a. Inclusion of Stale Records and Forced Pay Records in the SSI Eligibility Data Files

All SSI payment records are now, and will continue to be, included in the data files provided by Social Security Administration (SSA). This includes payments that were automated or manual or were for an individual whose record was active or stale.

b. Use of SSNs in the Revised Match Process

Databases Used:

SSI eligibility data file contains a unique SSN for every SSI record and will include up to 10 different Title II numbers for the records related to one individual.

The Medicare Enrollment Database (EDB) contains a SSN for virtually every record in the EDB and can hold up to 10 historical HICANs for a specific Medicare enrollee.

The MedPAR file contains Medicare hospital inpatient claims provided to Medicare beneficiaries and includes one HICAN number for each and every record of services provided to a Medicare beneficiary admitted to a Medicare-certified hospital or skilled nursing facility. It does not contain SSNs.

Revised Match: 4-Step Process:

1. CMS' proposed revised match process would use the EDB which includes SSNs as well as all of an HICANs.
    a. The individual's SSN, contained in the SSI eligibility data file, would be compared to the SSNs in the Medicare EDB.
    b. Each matched SSN would then be cross-walked within the EDB to find any and all HICANs associated with the individual's SSN.
    c. The resulting HICANs would then be matched against those HICANs contained in the MedPAR claims data files.

    CMS believes this process should identify all relevant SSI records in which a SSN is associated with an individual who is simultaneously enrolled in Part A and in the SSI program.

2. CMS proposes to compare the complete list of Title II numbers from the SSI eligibility data file (up to 10 Title II numbers for any one individual) to the list of HICANs generated through Step 1. Any Title II numbers not already identified in Step 1 will be compared to any and all HICANs in MedPAR.

3. CMS will further ensure consistency among the HICANs in the EDB, the Title II numbers, and the HICANs in the MedPAR file by converting the Beneficiary Identification Code (BIC) identifiers to the identifiers indicated on inpatient claims in the MedPAR file. CMS also proposes to attempt to match beneficiaries' HICANs in the MedPAR file for those SSI-eligible beneficiaries receiving Medicare benefits based on their own account but whose records have not already been matched. CMS would add an “A” to all the SSNs in the SSI eligibility data file in those cases where individuals were not identified in the first two steps but the MedPAR file indicates that the provision of Medicare services.

4. CMS would calculate the SSI fraction in the same manner as it has done in the past.

c. Timing of the Match

CMS notes that section 6404 of PPACA requires the submission of hospital inpatient claims no later than 1 year after the date of service or by September 30, 2012 for claims with a September 30, 2011 service date.

For FY 2011 and subsequent years, CMS proposes to use SSI eligibility data files compiled by SSA and MedPAR claims information that are updated 15 months after the close of each Federal fiscal year versus the 6 months under current practice. CMS believes use of claims data that are updated 15 months after the close of the Federal fiscal year would provide it the best available data. CMS expects to publish the FY 2011 SSI fractions around March 2013 which would be used to settle cost reports for reporting periods beginning during FY 2011. CMS would also continue using each hospital's latest available SSI fraction to determine IPPS interim payments.

CMS provides an example of a timeline to calculate FY 2011 SSI fractions under the proposed rule on page 515 as follows:

Cost Reports That Use the FY 2011 SSI Ratios	Deadline for Timely Filing of Claims	MedPAR File Used	SSI Eligibility File Used	Cost Reports Normally Accepted	Cost report Final Settlement	SSI Fraction Available
Cost reports beginning October 1, 2010 through September 30, 2011	December 2012	December 2012 update of FY 2011 MedPAR	December 2012 update of FY 2011 SSI eligibility	Generally between March 2012 and February 2013	Generally between March 2013 and February 2014	Spring 2013

CMS Rulings:

CMS prepared a Ruling addressing CMS' process for matching Medicare and SSI eligibility data and calculating hospitals' SSI fractions requiring the Medicare administrative appeals tribunal to remand each qualifying appeal to the appropriate Medicare contractor.

On remand, for a provider with a cost report that is not a final settled report, CMS and the contractor will recalculate the provider's DSH payment adjustment, and make any payment owing, by applying the provisions of the Ruling, on the data matching process issue (and two other DSH issues, as applicable). Specifically, for qualifying appeals of the data matching issue and for cost reports not yet final settled by an initial NPR, CMS will apply any new data matching process that is adopted in the FY 2011 IPPS final rule for each appeal that is subject to the Ruling.

The data matching process provisions of the Ruling would apply to properly pending appeals and open cost reports for cost reporting periods beginning prior to October 1, 2010.

The Ruling further states that, if a new data matching process is not adopted in the FY 2011 IPPS final rule, CMS would apply to claims subject to the Ruling the same data matching process described above as it was the process used to implement the *Baystate* decision.

Clarification of Language on Inclusion of Medicare Advantage Days in the SSI Fraction of the Medicare DSH Calculation:

CMS is concerned that there is some confusion about its policy to reflect inclusion of days associated with MA beneficiaries, specifically regarding whether it implied that MA beneficiaries are not actually entitled to receive benefits under Part A by using the word "or" in §412.106(b)(2)(i)(B) and §412.106 (b)(2)(iii)(B) with respect to MA days. CMS proposes to replace the word "or" with the word "including" in those sections.

H. Payments for Direct Graduate Medical Education (GME) Costs

Identifying Approved Medical Residency Programs: CMS reports confusion among some teaching hospitals on the question of whether trainees are residents for purposes of direct GME and IME FTE counts, arising most often with respect to subspecialty training and “fellows."

CMS notes generally that an approved program is one that 1) is accredited by one of several listed national organizations (such as the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA); or 2) leads to board certification by the American Board of Medical Specialties (ABMS). CMS further observes that the term “approved” connotes formality, including a formal application, acceptance, and enrollment process as well as the expectation of an employment contract with the hospital. For training to be considered an approved program, it must prepare the individual for certification in the particular specialty or subspecialty.

The tests CMS applies in determining whether an individual is a resident (for purposes of DGME and IME payment) in a training program versus a physician (for the purposes of billing under the Part B Physician Fee Schedule) are whether the individual 1) needs the training in order to meet board certification requirements in that specialty; and 2) is formally participating in an organized, standardized, structured course of study. Individuals enhancing their expertise in training or programs that do not lead to full certification requirements will be counted and reimbursed under Medicare as physicians.

CMS proposes to revise the definition of resident to mean “an intern, resident or fellow who is formally accepted, enrolled, and participating in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.“ The definition of primary care resident would be revised in a similar manner. The change in the definition would be effective for DGME and IME payment for cost reporting periods beginning on or after October 1, 2010.

CMS provides examples of the type of training activities that will not count toward DGME and IME purposes:

- Individuals participating in specialized training courses created by senior physicians (not under the auspices of a national accrediting body) for which there is no explicit existing board certification.
- Individuals who have completed a residency program and met board eligibility requirements in a specialty, and who participate in additional training that does not provide additional skills applicable for board certification in a subspecialty.

Electronic Submission of Affiliation Agreements: CMS proposes to permit the electronic submission of Medicare GME affiliation agreements that are required to be

submitted to the CMS Central Office, using either an e-mail mailbox or a specified Internet website. CMS would require a scanned copy or PDF version of the hard copy agreement and would not accept formats subject to manipulation. The proposed deadline for electronic submission is 11:59 p.m. on July 1 of each academic year.

A fiscal intermediary or MAC may continue to specify agreement submission requirements for hospitals in its servicing area.

I. Certified Registered Nurse Anesthetist (CRNA) Services Furnished in Rural Hospitals and CAHs.

Medicare provides reimbursement to hospitals on a reasonable cost basis for the costs that a rural hospital or a rural CAH incurs in connection with the services of a certified registered nurse anesthetists (CRNA). CMS points out that under existing regulations, neither CAHs/hospitals that have reclassified from urban to rural nor CAHs/hospitals located in "Lugar" counties (requires hospitals located in a rural county adjacent to one or more urban areas to be treated as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute) are eligible to receive pass-through payments for anesthesia services and related care furnished by non-physician anesthetists.

CMS is proposing to revise existing regulations to state that effective for FY 2011, that the above rural CAHs and rural hospitals that have reclassified from urban to rural would be eligible to be paid based on reasonable cost of anesthesia services and related care furnish by a non-physician anesthetist. CMS is not proposing to extend this proposal for hospitals located in "Lugar" counties.

J. Rural Community Hospital Demonstration Program

CMS reports that it was unable to calculate the costs of the demonstration corresponding to FY 2007 and as a result is unable to propose the specific numeric adjustment that would be applied to the national IPPS rates in order to ensure budget neutrality. CMS said, however, that it expected cost reports beginning in FY 2007 for hospitals that participated in the demonstration during FY 2007 to be settled before the FY 2011 IPPS final rule is published.

CMS also acknowledges that Section 3123 of the PPACA made a number of changes to the rural community demonstration program. These changes included a 5-year extension of the demonstration (on top of the original 5-year time-line). CMS said it would address these changes in a separate rulemaking document.

VI. Proposed Changes to the IPPS for Capital-Related Costs

For FYs 2008 and 2009, CMS applied prospective documentation and coding adjustments to the payment rates applicable to capital-related costs. The national

Federal capital rate was reduced by 0.6 and 0.9 percentage points in FYs 2008 and 2009 respectively – the same adjustments that were made to the national operating standardized amounts in those years. No adjustments were made to the Puerto Rico-specific capital rate.

For FY 2010, CMS had proposed to make documentation and coding adjustments to the national Federal capital rate and the Puerto Rico-specific capital rate to eliminate the full effect of the FY 2008 documentation and coding changes resulting from adoption of the MS-DRGs. CMS proposed a -1.9 percent adjustment to the national Federal capital rate and a -1.1 percent adjustment to the Puerto Rico-specific capital rate, the first time a documentation and coding adjustment would have applied to the Puerto Rico-specific capital rate. However, as in the case of operating IPPS standardized amounts, CMS postponed the adoption of any documentation and coding adjustments to the capital rates in FY 2010 until a full analysis of FY 2009 case-mix changes was completed.

For FY 2011, CMS proposes prospective documentation and coding adjustments to the national Federal capital rate and the Puerto Rico-specific capital rate to address the effect of the FY 2008 and FY 2009 documentation and coding changes resulting from adoption of the MS-DRGs. As discussed in section III.B, CMS analyses determined that the cumulative documentation and coding change unrelated to real CMI increases is 5.4 percent nationally through FY 2009. Previous reductions in the national Federal capital rate total 1.5 percent cumulatively, leaving 3.9 to be removed to eliminate the full extent of documentation and coding-related change in future years. For FY 2011, CMS proposes to reduce the national Federal capital rate by 2.9 percent, leaving 1.0 percent for a future adjustment. This adjustment is prospective and intended to prevent future excess payments; as such, it would apply to FY 2011 and future years. CMS lacks authority to recover excess payments for capital-related costs made in prior years.

Similarly, CMS analyses found that the cumulative change in documentation and coding not reflective of real CMI change is 2.4 percent for Puerto Rico-specific experience. The proposed rule would remove the full 2.4 percent from the Puerto Rico-specific capital rate in FY 2011. This is a prospective adjustment to the base rate to avoid future excess payments and as such would affect all future years.

The proposed annual update to the payment rates for capital-related costs for FY 2011 is 1.5 percent; the capital payment rates, including the annual updates, are established by regulation using the Secretary's authority in section 1886(g), unlike the updates to the operating standardized amounts which are established by statute.

VII. Proposed Changes for Hospitals Presently Excluded from the IPPS

A. Separate Market Basket for Certain Hospitals Presently Excluded from IPPS

In the FY 2006 IPPS final rule (70 FR 47396), CMS adopted the use of the FY 2002-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and religious nonmedical health care institutions (RNHCIs), which are still reimbursed under the reasonable cost-based system subject to the rate-of-increase limits. The proposed rule for FY 2011 would continue to use the IPPS market basket – with the proposed rebasing and revision – to update the rate-of-increase limits for these hospitals. CMS estimates the FY 2011 update to be 2.4 percent.

CMS notes the estimate may be revised in the final rule if more recent data become available. CMS also notes that the transition periods to prospective payment systems for inpatient rehabilitation facilities, inpatient psychiatric facilities, and long-term care hospitals have ended.

B. CAHs

Impact of Health Care Reform Laws: CMS notes that the proposed rule does not reflect changes made by public laws 111-148 (PPACA) and 111-152 (HCERA). CMS will address those changes that affect CAHs in the *Federal Register* or by further instructions.

Method II/Optional Method for Payment of Outpatient Services: Effective for cost reporting periods beginning on or after October 1, 2010, CMS proposes to eliminate the requirement for CAHs to annually elect the optional method of payment (a payment made to the CAH for the reasonable cost of facility services plus 115 percent of the amount otherwise payable for the professional services). Under the proposal, the election of optional method would remain in effect until terminated. This would apply to CAHs which have made such an election for the most recent cost reporting period beginning before October 1, 2010, as well as for those that make that election for an upcoming cost reporting period.

Elections for the optional method, as well as requests to terminate those elections, must be made no later than 30 days before the beginning of the cost reporting period involved. CAHs with cost reporting periods beginning in October or November 2010 would have until December 1, 2010, to terminate the election, and the termination would apply for the entirety of the FY 2011 cost reporting period.

CMS notes that the optional payment method should not apply to those physicians and practitioners who have not reassigned their billing rights to the CAH for the services involved. CMS also notes that a CAH is responsible for notifying its fiscal intermediary or MAC when changes in reassignment of billing rights occur.

Costs of Provider Taxes as Allowable Costs:

Currently under regulations, certain taxes assessed against a provider may be allowable costs 1) if they are related to cost of care of Medicare beneficiaries; and 2) to the extent they are actually incurred (the net tax expense). Medicare contractors will determine whether costs are allowable on a case-by-case basis.

The Provider Reimbursement Manual states the policy with respect to taxes and allowable costs and also lists taxes that are not allowable (see sections 2122.1 and 2122.2). Responding to confusion in the interpretation of these sections, CMS proposes to clarify that the list of taxes is not exclusive. The absence of a specific type of tax from the list does not necessarily mean that the tax is an allowable cost. Further CMS is concerned that even if a tax on a provider is allowable, the provider may not actually incur the entire amount of the assessed tax—subsequent reimbursement may offset some or all of the assessed tax.

This policy may affect providers paid on the basis of their reasonable costs; it may also affect providers paid on a prospective payment basis to the extent they are paid on a cost-basis prospective payment system that is rebased using more current reported reasonable cost data.

VIII. Determination of Effective Date of Provider Agreements and Supplier Approvals

Providers and suppliers wishing to do business with Medicare must submit an enrollment application and undergo a survey to determine their compliance with applicable health and safety standards. Enrollment applications are processed by Medicare contractors and surveys are conducted by State survey agencies and national accreditation organizations approved by CMS (and, on occasion, by others). Generally, a survey is conducted only after a prospective provider or supplier has demonstrated that it meets the Medicare enrollment requirements (although a Medicare contractor often continues to perform enrollment verification tasks, such as onsite visits, even after it has signaled that the survey and certification process can be initiated).

CMS proposes a number of regulatory changes to make it clearer when a provider has satisfied the requirements for participation in the Medicare program. These changes are being made as a result of a September 28, 2009 decision by the Appellate Division of the Departmental Appeals Board (in the case of *Renal CarePartners of Delray Beach, LLC v. Centers for Medicare and Medicaid Services*), DAB Decision No. 2271, with which CMS disagrees. Under that decision, the DAB concluded that there was no basis in regulation or policy issuances for CMS' position that CMS contractor approval is a requirement a supplier must satisfy "before it may furnish services for which it will be reimbursed under Medicare once it is enrolled and obtains billing privileges." In this case, a State survey agency had completed an initial certification survey of the renal dialysis facility but the relevant CMS contractor had not yet recommended approval of the facility's Medicare enrollment application.

As a result of the outcome of this appeal and other considerations, CMS proposes regulatory changes to accomplish the following:

- Make it clearer that it is only CMS that determines whether health care facilities have satisfied the requirements for participation in the Medicare program, not State survey agencies or national accreditation organizations;

- Clarify that surveys of nonaccredited facilities may be conducted not only by State survey agencies, but also by CMS staff or contractors, as appropriate (in recognition of the fact that CMS contractors now conduct certain types of surveys, such as life safety code, transplant program and psychiatric hospital special conditions surveys, and CMS employees have traditionally surveyed Indian Health Service facilities and religious nonmedical health care institutions);

- Make explicit that the effective date of a provider agreement or supplier approval may not be earlier than the latest of the dates on which each applicable Federal requirement (explicitly including enrollment requirements) is determined to be met;

- Include language concerning accredited facilities to assure that accredited and nonaccredited facilities are treated in the same manner; and

- Remove permissive language under which CMS could have (but apparently never did) grant accredited facilities a provider agreement/supplier approval effective date retroactive up to 1 year prior to what otherwise would be their effective date.

With respect to the last change, CMS argues that the discretionary provision had caused confusion and led some accredited providers and suppliers to believe they were entitled to a retroactive effective date. CMS adds that preferential treatment of accredited facilities "would also seriously undermine [its] policy concerning change of ownership without assumption of the seller's provider agreement or supplier approval."

CMS estimates that the provider agreement policy changes would have a negligible impact.

IX. Proposed Changes to Medicare Conditions of Participation Affecting Hospital Rehabilitation Services and Respiratory Care Services

CMS proposes to revise the Medicare hospital conditions of participation relating to the ordering of rehabilitation and respiratory care services. In doing so, the agency says it is responding to questions raised about apparent inconsistencies in its policies and between the conditions of participation and many State laws.

First, CMS proposes to "clarify" that only qualified, licensed practitioners who are responsible for the care of the patient and who are acting within the scope of practice under State law may order rehabilitation services. Such individuals would also need to be authorized to order rehabilitation services by the hospital's medical staff, in accordance with both hospital policies and procedures and State laws. This change is clearly intended to allow nurse practitioners (NPs) and/or physician assistants (PAs) to order rehabilitation services (provided all applicable requirements are met). On the other hand, CMS notes that it feared that the current regulatory language could have allowed a hospital's medical staff to grant ordering privileges for rehabilitation services to personnel who are responsible for providing such services (such as physical therapists, occupational therapists, audiologists, and speech-language pathologists), something the agency labels "a conflict of interest."

Second, CMS proposes to revise the existing conditions of participation to allow qualified, licensed practitioners (including NPs and PAs) to order respiratory care services as long as such privileges are authorized by the medical staff and are in accordance with both hospital policies and procedures and State laws, and provided that the ordering practitioner is responsible for the care of the patient. While prior policy allowed doctors of medicine and osteopathy to delegate the ordering of respiratory care services to NPs and PAs, it required such physicians to countersign the NP/PA orders, something CMS considers "burdensome."

CMS believes that the revised conditions of participation would impose "minimal burden" on hospitals (mainly the one-time cost related to the revision of a hospital's medical staff bylaws and its policies and procedures relating to the ordering of rehabilitation and respiratory care services) and that the proposed regulatory flexibility "would greatly benefit hospitals overall."

X. Proposed Changes to the Accreditation Requirements for Medicaid Providers of Inpatient Psychiatric Services for Individuals under Age 21

Inpatient psychiatric services provided to individuals under the age of 21 were authorized as part of the Medicaid program by the Social Security Amendments of 1972. At the time, these services were only permitted to be provided by psychiatric hospitals accredited by the Joint Commission on Accreditation of Hospitals (later renamed the Joint Commission on Accreditation of Healthcare Organizations and now named the Joint Commission). In 1984, Congress eliminated the requirement that such hospitals be accredited exclusively by the Joint Commission.

Inpatient psychiatric services provided to individuals under the age of 21 were also authorized to be provided in inpatient psychiatric programs within hospitals and in psychiatric hospitals other than hospitals, called psychiatric treatment facilities (PRTFs). While PRTFs were given the flexibility to seek accreditation from other organizations than the Joint Commission, the Joint Commission has remained a requirement for psychiatric hospitals and inpatient psychiatric programs within hospitals.

In response to concerns expressed by several providers as well as the Joint Commission itself, CMS is proposing to remove the requirement that psychiatric hospitals and hospitals with inpatient psychiatric programs must obtain accreditation from the Joint Commission in order to provide these services under the Medicaid program. Rather these providers would be given a choice of accreditation options.

XI. Appendices

A. Regulatory Impact Analysis

TABLE I: IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2011

	No. of Hospitals	Proposed FY 2011 Weights & MS-DRG Changes (1)	Appli-cation of Recali-bration Budget Neutrality (2)	Proposed FY 2011 Wage Data (3)	Applica-tion of Wage Budget Neutrality (4)	Proposed FY 2011 DRG, Rel. Wts., Wage Index Changes, with Wage and Recal-ibration Budget Neutrality (5)	FY 2011 MGCRB Reclass-ifica-tions (6)	Proposed Rural Floor Budget Neutrality and Within State Rural Floor Budget Neutrality (7)	Pro-posed FY 2011 Out-Migra-tion Adjust-ment (8)	All Pro-posed FY 2011 Changes Prior to the CMI Adjust-ment (9)	All Pro-posed FY 2011 Changes w/CMI Adjust-ment (10)
All Hospitals	3,472	0.3	0	0	0	0	0	0	0	2.8	-0.1
By Geographic Location:											
Urban hospitals	2,502	0.3	0	0	0	0	-0.2	0	0	2.8	-0.1
Large urban areas	1,365	0.2	-0.1	0	0.1	0	-0.3	-0.1	0	2.8	-0.1
Other urban areas	1,137	0.4	0.1	-0.1	-0.1	0	0	0.1	0	2.9	-0.1
Rural hospitals	970	0.3	0	0	0	0	1.6	-0.1	0.1	2.4	-0.5
Bed Size (Urban):											
0-99 beds	635	0.6	0.2	0	0	0.3	-0.5	0	0	2.9	0
100-199 beds	791	0.2	-0.1	0	0	0	0	0.1	0	2.7	-0.2
200-299 beds	461	0.3	0	0	0	0	-0.1	0	0	2.7	-0.2
300-499 beds	425	0.3	0	0	0	0	-0.2	0	0	2.8	-0.1
500 or more beds	190	0.3	0	-0.1	-0.1	0	-0.2	-0.1	0	3	0.1
Bed Size (Rural):											
0-49 beds	337	0.6	0.3	0.1	0.1	0.3	0.6	0	0.2	2.9	0
50-99 beds	366	0.3	0	0	0	0	0.6	0	0.1	2.1	-0.8
100-149 beds	164	0.3	0	0	0	0	2.1	-0.1	0.1	2.5	-0.4
150-199 beds	61	0.3	0	0	0	0.1	2.4	-0.1	0	2.6	-0.3
200 or more beds	42	0.2	-0.1	0	0.1	-0.1	2.3	0	0	2.1	-0.8
Urban by Region:											
New England	121	0.1	-0.2	-0.4	-0.4	-0.6	0.9	0	0	2	-0.9
Middle Atlantic	330	0.3	0	-0.3	-0.3	-0.3	0.2	0	0	2.3	-0.6

	No. of Hospitals	Proposed FY 2011 Weights & MS-DRG Changes (1)	Appli-cation of Recali-bration Budget Neutrality (2)	Proposed FY 2011 Wage Data (3)	Applica-tion of Wage Budget Neutrality (4)	Proposed FY 2011 DRG, Rel. Wts., Wage Index Changes, with Wage and Recal-ibration Budget Neutrality (5)	FY 2011 MGCRB Reclass-ifica-tions (6)	Proposed Rural Floor Budget Neutrality and Within State Rural Floor Budget Neutrality (7)	Pro-posed FY 2011 Out-Migra-tion Adjust-ment (8)	All Pro-posed FY 2011 Changes Prior to the CMI Adjust-ment (9)	All Pro-posed FY 2011 Changes w/CMI Adjust-ment (10)
South Atlantic	383	0.1	-0.2	0	0	-0.2	-0.3	0	0	2.8	-0.1
East North Central	403	0.1	-0.1	0.2	0.2	0.1	-0.2	0	0	3	0.1
East South Central	155	0.4	0.2	-0.5	-0.6	-0.4	-0.2	0	0	2.5	-0.4
West North Central	166	0.5	0.2	-0.1	-0.1	0.1	-0.7	0	0	3	0.1
West South Central	342	0.5	0.2	0.2	0.2	0.4	-0.6	0	0	3.2	0.3
Mountain	162	0.3	0	0	0	0	-0.3	0	0	3	0
Pacific	390	0.6	0.2	0.4	0.4	0.5	-0.3	0	0	3.4	0.5
Puerto Rico	50	0.9	0.7	-0.3	-0.3	0.4	-0.8	0	0	3.1	0.3
Rural by Region:											
New England	24	0.2	-0.2	0	0	-0.2	0.5	0	0	1.2	-1.6
Middle Atlantic	70	-0.1	-0.4	0.4	0.4	0	1.4	-0.1	0	2.1	-0.8
South Atlantic	165	-0.2	-0.5	-0.3	-0.4	-0.9	2	0	0.1	1.8	-1
East North Central	120	0.3	0	-0.1	-0.1	-0.2	1.3	0	0	2.2	-0.7
East South Central	175	0.6	0.3	0.2	0.2	0.5	2.4	-0.1	0.2	2.7	-0.2
West North Central	100	0.7	0.4	0	0	0.4	0.5	0	0	2.8	-0.1
West South Central	214	0.7	0.5	0.3	0.4	0.8	1.9	0	0.1	3.4	0.4
Mountain	71	0.7	0.4	0	0	0.4	0.1	0	0	2.8	-0.1
Pacific	31	0	-0.4	0.3	0.3	-0.1	0.9	-0.3	0	1.4	-1.5
By Payment Classification:											
Urban hospitals	2,555	0.3	0	0	0	0	-0.2	0	0	2.8	-0.1
Large urban areas	1,403	0.2	0	0	0.1	0	-0.3	-0.1	0	2.8	-0.1
Other urban areas	1,152	0.4	0.1	-0.1	-0.1	0	0	0.1	0	2.9	-0.1

	No. of Hospitals	Proposed FY 2011 Weights & MS-DRG Changes (1)	Appli-cation of Recali-bration Budget Neutrality (2)	Proposed FY 2011 Wage Data (3)	Applica-tion of Wage Budget Neutrality (4)	Proposed FY 2011 DRG, Rel. Wts., Wage Index Changes, with Wage and Recal-ibration Budget Neutrality (5)	FY 2011 MGCRB Reclass-ifica-tions (6)	Proposed Rural Floor Budget Neutrality and Within State Rural Floor Budget Neutrality (7)	Pro-posed FY 2011 Out-Migra-tion Adjust-ment (8)	All Pro-posed FY 2011 Changes Prior to the CMI Adjust-ment (9)	All Pro-posed FY 2011 Changes w/CMI Adjust-ment (10)
Rural areas	917	0.3	0	0	0	0	1.4	0	0.1	2.3	-0.5
Teaching Status:											
Nonteaching	2,434	0.4	0	0.1	0.1	0.1	0.2	0	0	2.8	-0.1
Fewer than 100 residents	798	0.3	0	-0.1	-0.1	-0.1	-0.2	0	0	2.7	-0.2
100 or more residents	240	0.3	0	-0.1	-0.1	-0.1	-0.2	-0.1	0	2.9	0
Urban DSH:											
Non-DSH	834	0.5	0.1	0	0	0	0.1	0	0	2.9	0
100 or more beds	1,510	0.3	0	0	0	0	-0.2	0	0	2.8	-0.1
Less than 100 beds	340	0.2	-0.1	0	0	0	-0.3	-0.1	0	2.4	-0.5
Rural DSH:											
SCH	407	0.3	0	0	0	0	0.2	0	0.1	2.3	-0.6
RRC	209	0.2	-0.1	0.1	0.1	0	2.3	-0.1	0	2.3	-0.6
100 or more beds	30	0.1	-0.2	-0.3	-0.3	-0.5	1.2	0	0.3	2.3	-0.6
Less than 100 beds	142	0.4	0.2	0	0.1	0.2	0.9	-0.1	0.5	2.2	-0.7
Urban teaching and DSH:											
Both teaching and DSH	806	0.3	0	-0.1	-0.1	-0.1	-0.3	0	0	2.8	-0.1
Teaching and no DSH	169	0.3	-0.1	-0.2	-0.2	-0.2	0.4	0	0	2.7	-0.2
No teaching and DSH	1,044	0.3	0	0.2	0.2	0.2	0	0.1	0	2.8	-0.1
No teaching and no DSH	536	0.6	0.2	0	0	0.2	-0.2	0	0	3.1	0.2
Special Hospital Types:											
RRC	183	0.4	0.1	0	0	0.2	2.9	-0.1	0	2.5	-0.4
SCH	340	0.3	0	0	0	0	0	0	0	2.3	-0.5

	No. of Hospitals	Proposed FY 2011 Weights & MS-DRG Changes (1)	Appli-cation of Recali-bration Budget Neutrality (2)	Proposed FY 2011 Wage Data (3)	Applica-tion of Wage Budget Neutrality (4)	Proposed FY 2011 DRG, Rel. Wts., Wage Index Changes, with Wage and Recal-ibration Budget Neutrality (5)	FY 2011 MGCRB Reclass-ifica-tions (6)	Proposed Rural Floor Budget Neutrality and Within State Rural Floor Budget Neutrality (7)	Pro-posed FY 2011 Out-Migra-tion Adjust-ment (8)	All Pro-posed FY 2011 Changes Prior to the CMI Adjust-ment (9)	All Pro-posed FY 2011 Changes w/CMI Adjust-ment (10)
MDH	187	0.2	-0.1	0	0	-0.1	0.4	-0.1	0.2	2.3	-0.6
SCH and RRC	108	0.2	-0.2	-0.1	-0.1	-0.2	0.7	0	0	2.1	-0.8
MDH and RRC	13	0.4	0	0.2	0.2	0.2	0.2	0	0.1	2.2	-0.6
Type of Ownership:											
Voluntary	1978	0.3	0	0	0	0	0	0	0	2.7	-0.2
Proprietary	837	0.4	0.1	0.2	0.2	0.3	-0.1	0	0	3	0.1
Government	577	0.3	0	-0.1	-0.1	0	0.1	0.1	0	2.9	-0.1
Medicare Utilization as a Percent of Inpatient Days:											
0-25	353	0.2	-0.1	0	0	0	-0.4	-0.1	0	2.8	-0.1
25-50	1,593	0.3	0	0	0	0	-0.3	0	0	2.9	-0.1
50-65	1,202	0.3	0	0	-0.1	-0.1	0.6	0	0	2.6	-0.3
Over 65	237	0.4	0.2	-0.1	-0.2	0	0.6	0.1	0	2.7	-0.2
FY 2011 Reclassifications by the Medicare Geographic Classification Review Board:											
All Reclassified Hospitals	810	0.3	0	0.1	0.1	0	1.8	-0.1	0	2.8	-0.1
Non-Reclassified Hospitals	2,662	0.3	0	0	0	0	-0.6	0	0	2.8	-0.1
Urban Hospitals Reclassified	488	0.3	0	0.1	0.1	0	1.6	-0.2	0	2.9	-0.1
Urban Nonreclassified Hospitals, FY 2011:	1,985	0.3	0	0	0	0	-0.7	0.1	0	2.8	-0.1
All Rural Hospitals Reclassified FY 2011:	322	0.3	0	0.1	0.1	0.1	2.7	-0.1	0	2.6	-0.3
Rural Nonreclassified	585	0.4	0	0	0	0.1	-0.3	0	0.2	2.2	-0.7

	No. of Hospitals	Proposed FY 2011 Weights & MS-DRG Changes (1)	Appli-cation of Recali-bration Budget Neutrality (2)	Proposed FY 2011 Wage Data (3)	Applica-tion of Wage Budget Neutrality (4)	Proposed FY 2011 DRG, Rel. Wts., Wage Index Changes, with Wage and Recal-ibration Budget Neutrality (5)	FY 2011 MGCRB Reclass-ifica-tions (6)	Proposed Rural Floor Budget Neutrality and Within State Rural Floor Budget Neutrality (7)	Pro-posed FY 2011 Out-Migra-tion Adjust-ment (8)	All Pro-posed FY 2011 Changes Prior to the CMI Adjust-ment (9)	All Pro-posed FY 2011 Changes w/CMI Adjust-ment (10)
Hospitals FY 2011:											
All Section 401 Reclassified Hospitals:	37	-0.1	-0.4	-0.1	-0.1	-0.5	-0.3	0	0	1.8	-1.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	63	-0.2	-0.5	-0.2	-0.2	-0.6	2.9	-0.1	0	1.7	-1.2
Specialty Hospitals											
Cardiac specialty Hospitals	19	1.1	0.8	0.3	0.3	1.1	-0.8	0	0	3.7	0.8

1 Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2009, and hospital cost report data are from reporting periods beginning in FY 2008 and FY 2007.
2 This column displays the payment impact of the proposed changes to the Version 28 GROUPER and the recalibration of the MS-DRG weights based on FY 2009 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act.
3 This column displays the application of the recalibration budget neutrality factor of 0.996856, in accordance with section 1886(d)(4)(C)(iii) of the Act.
4. This column displays the proposed payment impact of the update to wage index data using FY 2007 cost report data.
5This column displays the payment impact of the application of the wage budget neutrality factor in accordance with section 1886(d)(3)(E)(i) of the Act. This factor is calculated separately from the recalibration budget neutrality factor. The wage budget neutrality factor is 1.000107.
6 This column displays the combined payment impact of the proposed changes in Columns 2 through 5 and the proposed cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The cumulative wage and recalibration budget neutrality factor of 0.996963is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.
7 Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2011 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2011.

Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991756.

8 This column displays the effects of the rural floor and the imputed floor, including the transition to the rural floor budget neutrality adjustment at the State level. Under the transition, hospitals will receive a blended wage index that is 100 percent of a wage index with the State level rural and imputed floor budget neutrality adjustment.

9 This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

10 This column shows the proposed changes in payments from FY 2010 to FY 2011. It reflects the impact of the proposed FY 2011 market basket update, and the proposed reductions to the FY 2011 standardized amount due to the documentation and coding effect. The proposed FY 2011 documentation and coding adjustment is -2.9 percent to the IPPS standardized amounts, -2.9 percent to the hospital-specific rates, and -2.4 percent to the Puerto Rico-specific amount. It also reflects changes in hospitals' reclassification status in FY 2011 compared to FY 2010. It incorporates all of the proposed changes displayed in Columns 5, 6, 7, and 8 (the changes displayed in Columns 2, 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.