

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

SUMMARY

On July 30, 2010, the Centers for Medicare and Medicaid Services (CMS) released its final 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 final 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 “IPPS-Exempt” providers. The final rule also implements relevant provisions of the Affordable Care Act (ACA) and other legislation, including the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111-192), which was enacted on June 25, 2010 and revises Medicare’s payment policy for outpatient services provided during the “3-day payment window”. The 3-day payment window policy is promulgated as an interim final rule with comment period ending on September 29.

The final rule is scheduled for publication in the *Federal Register* on August 16, 2010. The new rates and policy changes are effective October 1, 2010 except for the new policies pertaining to the 3-day payment window, which are effective June 25, 2010 as required by law. The final rule also includes changes affecting Medicare’s long-term care hospital (LTCH) prospective payment system; these changes are described in a separate summary.

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I. IPPS Rate Updates and Impact of the Final Rule

CMS estimates that payments under the final rule to general acute care hospitals for operating expenses in FY 2011 will decline by 0.4 percent, or \$440 million, compared with FY 2010, taking into account all factors that would affect spending. The estimate does not include any projection of changes in hospital admissions or real case-mix intensity, which also would affect overall payments.

The major changes in the final rule affecting IPPS operating payments are a market basket update of 2.35 percentage points and a reduction of 2.9 percentage points to recover a portion of excess payments made due to coding or classification changes that according to CMS do not reflect real changes in case-mix. The 2.35 market basket update is the result of a market basket increase of 2.6 percentage points and the market basket update reduction of 0.25 percentage points required by the ACA. The final rule also implements an ACA provision providing \$200 million in additional payments for hospitals in counties in the lowest quartile with respect to Medicare spending per beneficiary.

Average operating payments per case are projected to decrease only 0.4 percent despite the -2.9 percentage point adjustment for documentation and coding exceeding the 2.35 percentage point market basket update because CMS projects that actual outlier payments in FY 2010 will be about 4.7 percent compared to the 5.1 percent outlier offset – an underpayment of 0.4 percent in FY 2010. 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 final rule impact analysis shows that average operating payments per case will decrease 0.4 percent, with relatively small variation by type of hospital, including rural hospitals. 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 -0.7 and -0.9 percent respectively while urban hospitals in the Pacific region are projected to gain 1.45 percent. Rural hospitals in the Pacific, Middle Atlantic, South Atlantic and East North Central regions experience decreases of -1.6, -1.2, -1.2 and -0.9 percent respectively while rural hospitals in the West North Central gain 0.8 percent. The 19 cardiac specialty hospitals are projected to see average payments per case rise 0.3 percent. Estimates of the impact on operating payments are in Table I of the final rule (included in the appendix of this summary). The table below shows the impact by major hospital category from Tables I and III (which includes capital payments).

Hospital Type	Change in Operating Payments	Total Change in Payments (including Capital)
All Hospitals	-0.4%	-0.5%
Large Urban	-0.4%	-0.5%
Other Urban	-0.4%	-0.5%
Rural	-0.4%	-0.7%
Major Teaching	-0.5%	-0.3%

Final IPPS Rate Updates

The final rule provides a FY 2011 market basket update for operating costs of 2.35 percent for hospitals that report the required quality measures to CMS; hospitals which do not satisfy the reporting requirements would get a 0.35 percent update. According to the final 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 final rule include the -2.9 percentage point documentation and coding adjustment. The final rule establishes the following rates effective October 1, 2010:

TABLE 1A.— 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 (2.35 Percent)		Reduced Update (0.35 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
\$3,552.91	\$1,611.20	\$3,483.49	\$1,579.72

TABLE 1B.— 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 (2.35 Percent)		Reduced Update (0.35 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
\$3,201.75	\$1,962.36	\$3,139.19	\$1,924.02

TABLE 1C.— 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	\$3,552.91	\$1,611.20	\$3,201.75	\$1,962.36
Puerto Rico	\$1,518.14	\$926.53	\$1,515.70	\$928.97

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

	Rate
National	\$420.01
Puerto Rico	\$197.66

II. Changes to DRG Classifications and Relative Weights

A. MS-DRGs for FY 2011

The final rule for FY 2011 continues 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. Specific MS-DRG changes for FY 2011 are described in section E below. 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 final rule, CMS based its MS-DRG analysis on data from the March 2010 update of the FY 2009 Medicare Provider Analysis and Review (MedPAR) file, which contains hospital bills received through March 31, 2010 for discharges occurring through September 30, 2009.

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. FY 2011 Documentation and Coding Adjustment

The final rule maintains the 2.9 percent documentation and coding adjustment set forth in the proposed rule despite numerous comments and analyses raising issues about the magnitude of the adjustment, as described below.

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. CMI changes of this nature increase payments to hospitals, but 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 address the FY 2010 adjustment of -1.8 percent. 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, using the authority of Section 1886(d)(3)(A)(vi) of the Act to adjust the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These 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 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 estimated that these additional payments amounted to approximately \$2.2 billion.

In the FY 2010 final rule, CMS 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.

In the FY 2010 rulemaking, CMS noted that the additional adjustments that P. L. 110-90 requires for fiscal years 2011 and 2012 could be substantial. It estimated that the total adjustments that could be required over the 3-year period FY 2010 to FY 2012 was a reduction of 8.5 percent.

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 estimated 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 stated 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 in that year, CMS reported 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 reduced 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 reflective of 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 grants discretion concerning when to make these prospective adjustments – and no adjustment were proposed for FY 2011.

FY 2011 Final Rule

In comments on the proposed rule, MedPAC reported corroborating analyses and supported both CMS' analysis and conclusions concerning the effect of documentation and coding changes. The American Hospital Association (AHA) and other hospital groups, however, strongly disagreed with the CMS analysis on grounds that it considered only one year of data and thus failed to account for what is a long-term trend in case-mix increase pre-dating implementation of MS-DRGs. They submitted an analysis of multiple years of Medicare claims to show that a significant portion of the change which CMS found actually is the continuation of historical trends, rather than the effect of documentation and coding changes due to implementation of MS-DRGs. Their analysis found a documentation and coding effect of 0.9 percent for FYs 2008 and 2009. The AHA comments also included corroborating trend analyses of the percentage of Medicare discharges involving the ICU, of data from the Medical Expenditure Panel Survey (MEPS), and a of data from the Healthcare Cost and Utilization Project (HCUP). Each of these indicated an historical pattern of case-mix increase.

CMS rejected the hospitals' comments on two grounds. It said that its direct analytical approach is more reliable than the trend analysis – and it noted that the law does not require the agency to use a specific methodology. Second, it said that trend analysis is sensitive to the time period selected for the analysis and of the cohort of

hospitals which are included – in this case, whether all critical access hospitals were excluded from the analysis. It presented data from a MedPAC analysis showing case-mix change from 1998 to 2009 in which the annual change from 1998-2001 was negative each year. The first year in the AHA analysis was 2001 and CMS speculated that the AHA case-mix trend line would be lower if the earlier years were included. The final rule adopts the proposal to reduce the FY 2011 standardized amount by -2.9 percent, representing approximately one-half of the aggregate recoupment adjustment required under section 7(b)(1)(B) of Pub. L. 110-90.

The table below (from page 121 of the display copy of the final rule) shows the aggregate level of adjustments that are 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.

FY 2011 MS-DRG Documentation and Coding Adjustment

	Required Prospective Adjustment for FYs 2008-2009	Required Recoupment Adjustment for FYs 2008-2009	Total Adjustment	Proposed Recoupment Adjustment for FY 2011	Remaining Adjustment
Level of Adjustments	-3.9	-5.8	-9.7	-2.9	-6.8

Noting the absence of any prospective adjustment to the rates, MedPAC’s comments expressed concern about the “progressive accumulation in overpayments, which cannot be recovered based upon current statutory authority.” MedPAC recommended completing the retrospective adjustment in FY 2012, with accumulated interest, to fulfill the requirements of section 7(b)(1)(B) of Pub. L. 110-90 and then making additional prospective adjustments in that year of -2.0 percent. CMS states simply that it has not yet made a formal proposal for FY 2012 but notes that the two steps contemplated for FY 2012, restoring the FY 2011 -2.9 percent adjustment and then 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).

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

In the FY 2009 IPPS final rule, CMS concluded that it has 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)(l)(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, some citing a lack of legal authority.

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 and Final Rules. 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 and final rules for FY 2011, CMS decided to phase in the adjustment 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 point reduction that is required. The 2.9 percent reduction is a prospective adjustment that will be carried forward into future years' rates.

Similarly, CMS' analysis of FY 2009 claims data for the final rule found that a cumulative adjustment of -2.6 percent is required to eliminate the full effect of the

documentation and coding changes on future payments from the Puerto Rico-specific rate. Data available for the proposed rule analysis had showed that a cumulative adjustment of -2.4 percent was needed. The final rule removes the full 2.6 percent from Puerto Rico-specific rates in FY 2011 in a prospective adjustment that will carry forward to future years. CMS notes that the -2.6 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.

C. Refinement of the MS-DRG Relative Weight Calculation

The FY 2011 proposed and final rule make 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 FY 2007 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. To address potential bias in the MS-DRG weights due to "charge compression," which is the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services, CMS created new cost centers in 2009. The change established one cost center for "Medical Supplies Charged to Patients" and one cost center for "Implantable Devices Charged to Patients," essentially splitting the then current CCR for "Medical Supplies and Equipment" into one CCR for low-cost medical supplies and another CCR for high-cost implantable devices in order to mitigate some of the effects of charge compression. (See Transmittal 20 of the Provider Reimbursement Manual, Part II (PRM-II), Chapter 36, Form CMS-2552-96, which was issued in July 2009. The cost center changes were available for use for cost reporting periods beginning on or after May 1, 2009.)

Because there is approximately a 3-year lag in the availability of cost report data for ratesetting purposes, CMS expects it will be able to use data from the revised cost report form for the FY 2013 IPPS regulation.

The proposed and final rules also note that a new draft hospital cost report Form CMS-2552-10 was published in the Federal Register on July 2, 2009, with a comment period which ended on August 31, 2009. The proposed changes included creating new standard cost centers for Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and Cardiac Catheterization in Form CMS-2552-10. If these standard cost centers are finalized, when the data become available CMS will analyze the cost and charge data to determine if it is appropriate to use them to create distinct CCRs for use in determining the MS-DRG weights. A revised draft of hospital cost report Form CMS-2552-10 went on public display on April 23, 2010, and appeared in the *Federal Register* on April 30, 2010 (75 FR 22810) with a 30-day public comment

period that ended on June 1, 2010. The preamble indicates that the final cost report form will be issued later this summer.

Separate cost centers for advanced imaging and cardiac catheterization. CMS agrees with several 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, but the agency also received numerous comments raising concerns about creating them. Commenters who objected thought it was premature to establish standard cost centers for CT scanning and MRI scans without understanding the payment implications of the changes on both IPPS relative weights and OPSS payments. They suggested that some hospitals consider CT and MRI equipment costs to be capital costs, which are spread across various cost centers based on square footage or another allocation methodology, resulting in an under-allocation of capital costs to the radiology department and CT and MRI nonstandard cost centers and inappropriately low CCRs for these services. They believed that some hospitals report CT and MRI equipment costs as part of hospital fixtures and not as moveable equipment, allocating their direct capital costs across the whole hospital, rather than to the radiology cost center. Commenters were concerned that adoption of the cost centers would result in very low CCRs for these services, as already observed in the nonstandard cost centers and estimated by RTI in its July 2008 report. They believed that if the proposal were finalized, a chest CT scan could be paid at the same level as a routine chest X-ray under the OPSS. Finally, commenters were concerned that the change would adversely impact payment for the technical component of imaging services paid under the Medicare Physician Fee Schedule (MPFS), which is capped at the level paid under the OPSS fee schedule.

CMS states that it is clear that CT and MRI equipment are “major moveable equipment” and are neither a building cost nor a building equipment cost, and it gives several policy citations. It says that with its current data it cannot assess whether inappropriate payments would result and believes that it should collect standard cost center cost and charge data for these areas and analyze the impact. Therefore, the agency is establishing standard cost centers for CT scanning and MRI services in hospital cost reports for cost report periods beginning on or after May 1, 2010. CMS reassures concerned commenters that the cost report data that could be used for the calculation of the relative weights will not be available for at least 3 years and that the agency will thoroughly analyze and run impacts on the data and provide the public with the opportunity to comment before distinct CCRs for MRI and CT scans are finalized for use in the calculation of the relative weights.

CMS disagrees 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).

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 finalizes its proposal to retain the 10 current categories of HACs. For the HAC category Blood Incompatibility, CMS also finalizes its proposal 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 final HACs for FY 2011 with the adopted coding changes for blood incompatibility shown in bold-face type.

HAC	CC/MCC (ICD-9-CM Code)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	
- Unspecified	999.60 (CC)
- With hemolytic transfusion reaction not specified as acute or delayed	999.61 (CC)
- With acute hemolytic transfusion reaction	999.62 (CC)
- With delayed hemolytic transfusion reaction	999.63 (CC)
- Other ABO incompatibility reaction	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)

HAC	CC/MCC (ICD-9-CM Code)
	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: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	<i>Principal Diagnosis –</i> 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 final rule to update findings of an ongoing evaluation of the HAC-POA policies being conducted by Research Triangle Incorporated (RTI). The updated information is based on a full 12 months of MedPAR claims data (October 2008 through September 2009), rather than only the 9 months of data reported in the proposed rule.

For the full 12 months of FY 2009, RTI found a total of about 65.22 million secondary diagnoses across about 9.3 million discharges. The chart given below shows the distribution of these secondary diagnoses by POA indicator. As noted in the chart, 83.69 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		9,298,503	
Total Number of Secondary Diagnoses Across Total Discharges		65,224,895	100.00
POA	Indicator Description		
Y	Condition present on admission	54,588,241	83.69
W	Status cannot be clinically determined	15,639	0.02
N	Condition not present on admission	4,379,972	6.72
U	Documentation not adequate to determine if condition was present on admission	138,825	0.21
1	Exempted ICD-9-CM code	6,102,218	9.36

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

The final rule also provides updated information regarding POA indicator reporting for specific HAC-associated secondary diagnoses, as shown below.

**POA Status of Current HACs:
October 2008 Through September 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)	441	189	42.9	0	0.0	252	57.1	0	0.0
2. Air Embolism (MCC)	33	24	72.7	0	0.0	9	20.3	0	0.0
3. Blood Incompatibility (CC)	28	8	28.6	0	0.0	20	71.4	0	0.0
4. Pressure Ulcer Stages III & IV (MCC)	105,092	1,311	1.2	56	0.1	79,165	98.7	25	0.0
5. Falls and Trauma (MCC & CC)	153,284	5,684	3.7	270	0.2	147,257	96.1	73	0.0
6. Catheter-Associated UTI (CC)	14,089	2,323	16.5	19	0.3	11,717	83.2	30	0.2
7. Vascular Catheter-	6,933	2,555	36.9	22	0.3	4,342	62.6	14	0.2

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.	%
Associated Infection (CC)									
8. Poor Glycemic Control (MCC)	14,303	435	3.0	10	0.1	13,851	96.8	7	0.0
9A. Surgical Site Infection Mediastinitis CABG (CC)	35	26	74.3	0	0.0	8	25.7	0	0.0
9B. Surgical Site Infection Following Orthopedic Procedures (CC)	260	157	60.4	1	0.4	101	38.8	1	0.4
9C. Surgical Site Infection Following Bariatric Surgery (CC)	17	15	88.2	0	0.0	2	11.8	0	0.0
10. Pulmonary Embolism & DVT Orthopedic (MCC)	3,377	2,505	74.2	17	0.5	832	24.6	23	0.7
Total*	297,892	15,232	5.1	404	0.1	257,556	86.5	178	0.1

* Discharges can appear in more than one row. The total figure is not adjusted for the 60 discharges with more than one HAC that appear as secondary diagnoses (15 of these discharges resulted in MS-DRG reassignment).

In presenting the above data, CMS says it is “important to note that the number of secondary diagnosis codes classified as POA is likely overstated due to coding practices, and, therefore, the number of HACs not POA are expected to be greater than indicated in the above chart.” Examples would be conditions acquired at the hospital in an outpatient setting or through a prior admission.

In the final rule, CMS repeats what it said in the proposed rule: RTI’s findings 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). The agency also agrees with one commenter who stated that intracranial injury cases that have a loss of consciousness after admission should be assigned a POA indicator of “Y” rather than “N.”

RTI’s updated analyses (based on 12 months of claims data) also yield the following findings:

- Of the 264, 810 discharges with a HAC-associated diagnosis as a secondary diagnosis, 3,416 discharges ultimately resulted in MS-DRG reassignment (or 22.72 percent of the 14,681 HAC cases with a POA of “N” or “U”).
- RTI found 60 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 (8,208 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 (1,793 cases); (3) the MS-DRG is not subdivided by severity levels (1,255 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 (9 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 (as was the case in the proposed rule, CMS draws no conclusions from this finding).
- The estimated net savings of current HACs was roughly \$18.78 million (compared to \$16.44 million using only 9 months of claims data), or \$5,522 per discharge. Most of the savings was associated with the following HAC categories: Falls and Trauma (\$8.09 million), Orthopedic Pulmonary Embolism/DVT (\$6.92 million) and Pressure Ulcer Stages III & IV (\$2.16 million). There were no savings associated with the Blood Incompatibility category.

CMS refers readers to the RTI detailed report available at the following Web site: <http://www.rti.org/reports/cms>. In the final rule, CMS repeats what it said in the proposed rule: that the sentinel effect resulting from CMS identifying HACs is “critical” and that 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.”

The final rule also notes that RTI found a total of 203,844 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 (based on 12 months of FY 2009 claims data). Of those, 57,902 discharges were reported with a POA indicator of “N” or “U” and 3,527 discharges could have resulted in MS-DRG reassignments. However, CMS again says these findings do not provide additional information that would require the agency to change its previous determinations regarding previously considered candidate 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	\$20
FY 2012	\$22
FY 2013	\$23
FY 2014	\$25
FY 2015	\$27

This 5-year total of \$117 million is 5.6 percent lower than the \$124 million estimate provided in the proposed rule.

E. 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 was an error of omission and in the FY 2011 proposed rule, proposed 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 proposed to add diagnosis code 251.3 to the list of principal or secondary diagnosis codes assigned to MS-DRG 010 (Pancreas Transplant).

Commenters supported the proposals and CMS adopts them as final without modification.

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 conducted the requested analysis and concluded the cost differences warrant separate MS-DRGs for these procedures. Therefore, CMS proposed 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).

Commenters generally supported the proposal. In the final rule, CMS rejects a request to for a three-way split for each proposed MS-DRG (with MCC, with CC, and without MCC or CC). CMS finalizes the proposed changes without modification.

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 the FY 2011 proposed rule, CMS reviewed 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 concluded 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 was not warranted. Therefore, for FY 2011, CMS did not propose any change involving the assignment of diagnosis code V45.88.

In the final rule, CMS responds to a request for further analysis of the data and concludes the differences in the average lengths of stay and the average costs are too small to warrant an assignment to higher weighted MS-DRGs, and the differences in the length of stay and costs are not substantial enough to justify the creation of additional MS-DRGs. Therefore, for FY 2011, CMS makes no changes to MS-DRGs 061, 062, 063, 064, 065, 066, 067, and 068 and no changes to the MS-DRG assignment of diagnosis code V45.88. CMS will continue to monitor these MS-DRGs and diagnosis code V45.88 in upcoming annual reviews of the IPPS.

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 (CABG)

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 the FY 2011 proposed rule, CMS responded to the requests from the manufacturer of the IFVA technology and other public commenters. The final CMS decision for each request for FY 2011 follows the summaries of the specific requests.

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-DRGs for CABG but would also include intraoperative angiography. For the FY 2011 proposed rule, 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 did not propose to make any MS-DRG modifications for cases reporting procedure code 88.59 for FY 2011.

In the final rule, CMS responds to the comments and analysis submitted by the manufacturer. CMS concludes that the analysis conducted by the manufacturer was not appropriate since it only provided data from those facilities that are using the technology. The CMS analysis examined cases reporting procedure code 88.59 against all cases in the specified MS-DRGs. CMS concludes that new MS-DRGs are not warranted and finalizes the proposal to not reassign cases involving 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 noted 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 was unable to evaluate any data, other than that described above and did not propose to create a new MS-DRG in FY 2011 for coronary bypass with intraoperative angiography, by any method.

In the final rule, CMS finalizes its proposal to not create a new MS-DRG. In response to a comment from the manufacturer that the creation of a new ICD-9-CM procedure code to identify intraoperative angiography by conventional X-ray angiography would allow CMS to obtain accurate data on intraoperative or completion angiography by either method, CMS explains that proposals for creating a new procedure code must be submitted to the ICD-9-CM Coordination and Maintenance Committee for consideration.

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 recommended the submission of a proposal for creating a new procedure code(s).

In the final rule, CMS summarizes the outcome of the March 2010 ICD-9-CM Coordination and Maintenance Committee. A proposal was submitted by the manufacturer and presented. Effective October 1, 2010 (FY 2011), procedure code 88.59 has been revised to uniquely identify intraoperative coronary fluorescence vascular angiography and new code 17.71 has been created to identify noncoronary intraoperative fluorescence vascular angiography. CMS concludes additional data are needed to fully evaluate the volume of cases and resources involved to perform intraoperative completion angiography using X-ray technology versus IFVA. Therefore, for FY 2011, the proposal not to make any changes to MS-DRGs 233, 234, 235 or 236 for cases reporting the use of procedure code 88.59 is finalized.

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 noted in the proposed rule 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 did not propose to reassign cases reporting procedure code 88.59 to MS-DRGs 228, 229, and 230 for FY 2011.

Commenters supported this proposal and it is finalized 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 the FY 2011 proposed rule, CMS responded 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 noted that 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 concluded that the data are unreliable because the commenter included procedure codes in its analysis that do not identify the insertion of a stent. In addition, CMS noted 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 codes 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 concluded it was inappropriate to assign cases with such disparity in costs into a single, new MS-DRG and proposed no changes for FY 2011.

In the final rule, CMS agrees with the commenters that the CMS data and claims analysis supported the proposal to not make any MS-DRG modifications for cases involving the use of gastrointestinal stents for FY 2011. Therefore, CMS finalizes the proposal to not make any MS-DRG modifications for cases involving the use of gastrointestinal stents 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.

In the FY 2011 proposed rule, CMS noted 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 concluded the insertion of a Dynesys® Dynamic Stabilization System was clinically not a lumbar fusion and proposed not to reassign cases reporting procedure code 84.82 from MS-DRG 490 to MS-DRG 460 for FY 2011.

In the FY 2011 final rule, CMS reviews an analysis by the manufacturer but concludes that the reassignment of procedure code 84.82 to the spinal fusion MS-DRG would be inappropriate at this time. For FY 2011, CMS finalizes the proposal not to reassign cases with procedure code 84.82 from MS-DRG 490 to MS-DRG 460.

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 proposed to add discharge status code 05 to the MS-DRG GROUPER logic for MS-DRG 789 because CMS believed the request had merit in identifying neonate cases appropriately.

Commenters supported the proposal. For FY 2011, all newborn cases assigned to MS-DRGs 790 through 795 and identified with discharge status 05 will be reassigned to MS-DRG 789 for transferred neonates.

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 concluded that code V64.05 does not indicate a significant problem with the newborn. Therefore, CMS proposed to remove code V64.05 from MS-DRG 794 and add this code to the secondary diagnosis list for MS-DRG 795 (Normal newborn).

Commenters supported the proposal. FY 2011, CMS finalizes the proposal to remove code V64.05 from MS-DRG 794 and add it to the secondary diagnosis list for MS-DRG 795.

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 proposed 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 proposed to add code 536.3 to that list.

In the final rule, CMS agrees with the commenters that diagnosis code 536.3 should not be included in the MCE’s Unacceptable Principal Diagnosis Edit, and therefore withdraws the proposal. Diagnosis code 536.3 will not be added to the MCE in FY 2011. The issue of the “code first” note will be addressed by the ICD-9-CM Coordination & Maintenance Committee in September 2010.

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 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 in the FY 2011 proposed rule,

proposed to delete the entire Open Biopsy Check edit from the MCE, which means removing the 63 codes from the edit.

CMS did not receive any public comments regarding the proposal to delete the Open Biopsy Check edit from the MCE and it is finalized for FY 2011.

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 proposed to add code 251.3 (Postsurgical hypoinsulinemia) to those MS-DRGs), CMS proposed to add procedure code 251.3 to the list of acceptable principal or secondary diagnosis codes in the MCE.

CMS did not receive any public comments regarding the proposal to add procedure code 251.3 to the list of acceptable principal or secondary diagnosis codes in the MCE and it is finalized for FY 2011.

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 were 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).

Commenters generally supported the proposals and CMS finalizes them for FY 2011.

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 the proposed rule, CMS presented its analysis of claims data and responded as follows to comments received on the CC Exclusions List:

- Rejected 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.
- Rejected 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.
- Rejected a request to change the diagnosis code 331.0 Alzheimer's disease from a non-CC to a CC.

Commenters generally supported these CMS proposals. In the final rule, CMS again presents a detailed analysis of the claims for these conditions. The analysis supports the proposals and they are finalized for FY 2011.

In the proposed rule, CMS proposed to reclassify diagnosis code 584.9 (Acute renal failure, unspecified) from a MCC to a CC. Most commenters opposed this proposal. In the final rule, CMS presents its analysis of the data and responds to these comments. CMS acknowledges that code 584.9 has been used to describe a wide range of severity levels. However, the claims data show that the code is being used predominately to describe those patients who are not at the highest severity level. CMS concludes that the current classification of these patients at the highest severity level greatly distorts the national data, giving the impression that a large number of patients have an MCC severity level when they may in fact have only minor renal symptoms. CMS notes the data support that patients with diagnosis code 584.9 are more appropriately classified at the CC severity level and this change is made final for FY 2011.

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 the final rule because of the length of the two tables. Instead, CMS is making them available through the Internet on the CMS Web site at: <http://www.cms.hhs.gov/AcuteInpatientPPS>. Each of these principal diagnoses for which there is a CC exclusion is shown in Tables 6G and 6H in the Addendum to the final rule with an asterisk, and the conditions that will not count as a CC, are provided in an indented column immediately following the affected principal diagnosis. The complete updated MCC, CC, and Non-CC Exclusions List is also available through the Internet on the CMS Web site at: <http://www.cms.hhs.gov/AcuteInpatientPPS>.

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 proposed 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.

CMS received no comments on these proposals and they are adopted as final for FY 2011.

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 final 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 were 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 the

FY 2011 IPPS/LTCH PPS proposed rule are included in Tables 6A through 6F of the Addendum to this final rule and are 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 FY 2011 final rule.

In the FY 2011 proposed rule, CMS solicited comments on the proposed classification of the new codes. The CMS decisions in response to comments received on the proposed classification are summarized below:

- CMS accepts a recommendation that the new codes 488.01 (Influenza due to identified avian influenza virus with pneumonia) and 488.11 (Influenza due to identified novel H1N1 influenza virus with pneumonia) be assigned to the pneumonia MS-DRGs to be consistent with the MS-DRG definitions and classification of diagnosis code 487.0 (Influenza with pneumonia).
- CMS accepts a recommendation to reclassify from non-CC to CC the codes 780.33 (Post traumatic seizures) and 278.03 (Obesity hypoventilation syndrome).
- CMS rejects a request to assign new procedure code 35.97 (Percutaneous mitral valve repair with implant) to the same MS-DRG as open surgery so that higher payment would result. CMS notes that the MitraClip® device is not yet FDA approved and that there are no claims data on which to evaluate such a MS-DRG assignment. CMS goes on to note that “the most important concept for denying these requests is that the MitraClip® device is delivered percutaneously. To assign this percutaneous procedure to MS-DRGs utilizing an open approach would not conform to the structure of the MS-DRGs, and disregards the concept of clinical coherence.” For FY 2011, CMS assigns new procedure code 35.97 to the MS-DRGs assignment where the current percutaneous valve procedures are now assigned (246, 247, 248, 249, 250, and 251).
- CMS rejects requests to assign new procedure code 37.37 (Excision or destruction of other lesion or tissue of heart, thoracoscopic approach) to MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedure with MCC, with CC, and without CC/MCC, respectively) because CMS practice has been to assign new ICD-9-CM codes to the same MS-DRG(s) as their predecessor codes. For this reason, procedure code 37.37 is assigned to MS-DRGs 228, 229, and 230 for FY 2011.

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

CMS proposed 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

In the proposed rule, CMS stated its belief that this advance notice of a partial code freeze would 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 welcomed 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.

Most commenters supported a limited freeze but some opposition was expressed. In the final rule, CMS announces that the final decision on whether or not there will be a partial code freeze will be announced at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting. CMS invites additional comments that will be considered before the final decision will be announced at the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee. CMS restates its proposals as follows:

- Codes discussed at the September 15-16, 2010 and the March 2011 ICD-9-CM Coordination and Maintenance Committee meeting would be considered for the final major code updates on October 1, 2011.
- Any code issues raised after that time would be addressed at the ICD-9-CM Coordination and Maintenance Committee meetings in September 2011 through March 2013 to determine if they represented new technologies or new diseases.
- Any new technologies and diseases would be added during the regular annual updates.
- Other code requests would be held for implementation on October 1, 2014.

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 in the FY 2011 proposed rule summarized its ongoing activities as follows:

- CMS is currently undergoing extensive system updates as part of the HIPAA 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.

Commenters expressed support for the plan and CMS indicates in the final rule that it will continue to proceed as described above.

d. ICD-10 MS-DRGs

CMS received comments on the creation of the ICD-10 version of the MS-DRGs, which will be implemented on October 1, 2013 (FY 2014) when the reporting of ICD-10 codes is implemented. While CMS has not proposed an ICD-10 version of the MS-DRGs, CMS has been actively involved in converting the current MS-DRGs from ICD-9-CM codes to ICD-10 codes and sharing this information through the ICD-9-CM Coordination and Maintenance Committee. CMS undertook this early conversion project to assist other payers and providers in understanding how to go about their own conversion projects. CMS posted ICD-10 MS-DRGs based on V26.0 (FY 2009) of the MS-DRGs. CMS will continue to keep the public updated on the maintenance efforts for ICD-10-CM and ICD-10-PCS coding systems as well as the General Equivalence Mappings that assist in conversion through the ICD-9-CM Coordination and Maintenance Committee. CMS will continue to work with the public to explain the conversion of MS-DRGs to ICD-10 and will post drafts of updates as they are developed for public review. The final version of the ICD-10 MS-DRGs to be implemented in FY 2014 will be subject to notice and comment rulemaking.

12. Other Issues Not Addressed in the Proposed Rule

CMS received a number of public comments on issues that were not discussed in the FY 2011 proposed rule. CMS does not address these issues other than to provide a brief summary of the requests. Commenters are encouraged to resubmit their comments no later than December 2010 so they can be considered for possible inclusion in the FY 2012 proposed rule. The issues raised in the public comments that will not be addressed for FY 2011 are:

- a. Rechargeable Dual Array Deep Brain Stimulation System;
- b. IntraOperative Electron RadioTherapy (IOERT);
- c. Brachytherapy; and
- d. Excisional Debridement.

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 final 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 March 31, 2010, 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 final relative weights includes data for approximately 10,898,371 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 March 31, 2010 update of the HCRIS cost report files for FY 2008 in setting the relative cost-based weights for the final rule.

Following the process used to calculate the weights for FY 2010, charges were converted to costs using national average CCRs. The final rule includes a table (pages 335 through 341 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 CMS used to create the 15 national cost center CCRs. The resulting 15 national average CCRs used for the FY 2011 final 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	0.539
Intensive Days	0.480	0.473
Drugs	0.200	0.202
Supplies & Equipment	0.344	0.345
Therapy Services	0.415	0.403
Laboratory	0.163	0.155
Operating Room	0.282	0.272
Cardiology	0.181	0.169
Radiology	0.161	0.152
Emergency Room	0.278	0.263
Blood and Blood Products	0.424	0.415
Other Services	0.426	0.416
Labor & Delivery	0.462	0.470
Inhalation Therapy	0.201	0.200
Anesthesia	0.136	0.128

The new cost-based relative weights were normalized by an adjustment factor of 1.57489 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 were used to evaluate applications for new technology add-on payments for FY 2011.

CMS issued a supplemental proposed rule in the Federal Register on June 2, 2010 that addressed the provisions of the ACA that affected the proposed policies and payment rates for FY 2011 under the IPPS and the LTCH PPS. In addition, CMS issued a Federal Register notice on June 2, 2010 and further instructions that addressed the provisions of the ACA that affected the policies and payment rates for FY 2010 under the IPPS and the LTCH PPS. In those documents, CMS updated Table 10 that was published in the Federal Register on August 27, 2009 and Table 10 in the Addendum to the FY 2011 IPPS PPS proposed rule to reflect the changes made by the ACA.

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 indirect medical education (IME) and disproportionate share hospital (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

The process for evaluating new medical service and technology applications requires CMS to:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

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 the technologies approved for add-on payments in FY 2010.

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 number 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 did not propose any changes for FY 2011.

The manufacturer submitted a comment explaining that there are instances when a hospital performs the initial surgery and then determines that treatment of the patient with the IBV[®] valve is appropriate but the hospital has not been approved to perform the IBV[®] valve insertion procedure under the Humanitarian Device Exemption (HDE) regulations. Therefore, the hospital must transfer the patient to an approved facility for treatment with the IBV[®] valve. In the final rule, CMS agrees with the manufacturer that it is appropriate that all cases in which the Spiration[®] IBV[®] Valve is inserted consistent with its HDE approval be eligible for the approved new technology add-on payment. For this reason, CMS expands the new technology add-on payment for the Spiration[®] IBV[®] Valve to cases that map to MS-DRGs 199, 200, and 201 with an assigned principal diagnosis code of 512.1.

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 transplant device 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 continues 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 proposed to continue new technology add-on payments for cases involving the TAH-t with a maximum add-on payment of \$53,000. However, CMS

also sought 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.

In response to the CMS request for comments, the manufacturer provided updated statistics on the number of cases and the clinical status of patients with this device. The manufacturer also requested an increase in the add-on payment to cover the cost of a newer version of the system that contains a smaller, portable driver, known as the "Freedom Driver" as part of the TAH-t system. This device is not yet approved by the FDA.

In the final rule, CMS decides to continue new technology add-on payments for cases involving the TAH-t in FY 2011 with a maximum add-on payment of \$53,000. If the modified TAH-t device using the Freedom Driver receives FDA approval, CMS would require that a new technology application be formally submitted for review. Therefore, as proposed, CMS will continue new technology add-on payments for cases involving the TAH-t in 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 did not discuss these two applications in the FY 2011 proposed rule.

A discussion of the remaining three applications is presented below. At the time the FY 2011 proposed rule was developed, one of the technologies had not yet received FDA approval.

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™. 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.

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/RV 2010 LTCH PPS final rule.

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 stated in the FY 2011 proposed rule that the newness date would begin in December 2009. CMS expressed 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 maintained that AutoLITT™ can be distinguished from the Visual-ase by its mechanism of action (that is, side-firing laser versus elliptical firing). In the proposed rule, CMS sought comments regarding whether or not the AutoLITT™ is substantially similar to the Visual-ase and if it meets the newness criteria.

In the final rule, CMS summarizes the comments received and concludes that the AutoLITT™ is not substantially similar to the Visual-ase. Because the AutoLITT™ was available on the market beginning with December 2009 (and is not substantially similar to its predicate device), the technology is still within the 2 to 3 year newness period.

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).

The applicant submitted data related to the estimated cost of the AutoLITT™ per case, stating that the cost of the device was proprietary information. Based on a study of charge compression data by RTI and charge master data from Stanford University and the University of California, San Francisco, the applicant estimated \$38,886 in charges related to the AutoLITT™ (CMS noted 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 maintained that the AutoLITT™ would meet the cost criterion. In the FY 2011 proposed rule, CMS invited public comment on whether or not the AutoLITT™ meets the cost criterion.

The manufacturer submitted updated and revised data in support of its application. After reviewing all of the data summarized above, CMS determines that the applicant has provided a sufficient explanation for the additional charges associated with the AutoLITT™, even with a reduced recovery time and a reduced rate of complications. Additionally, a CMS analysis of the FY 2009 MedPAR data demonstrates that the average standardized charge per case (for cases eligible for the AutoLITT™) exceeds the case-weighted cost threshold. Finally, the applicant provided charge data from two centers verifying the expected high charges associated with the cases of the AutoLITT™. Therefore, CMS concludes that the AutoLITT™ meets the cost criterion.

Substantial clinical improvement criterion

With respect to the substantial clinical improvement criterion, the applicant maintained in its application that it met this criterion. 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.

In the FY 2011 proposed rule, CMS acknowledged the future potential of this therapy, but expressed 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 requested additional clinical data to demonstrate whether the AutoLITT™ meets the substantial clinical improvement criterion and invited public comment.

Commenters provided additional clinical data to demonstrate that the AutoLITT™ meets the substantial clinical improvement criteria. In the final rule, CMS summarizes these data with a focus on the peer-reviewed medical literature and the results of the clinical studies. CMS remains concerned that no prospective comparative data exist to help understand the benefit of the technology compared to other modalities. However, CMS agrees that the AutoLITT™ can improve clinical outcomes by providing an alternative treatment for brain tumors that potentially has a lower risk of adverse events and is less invasive compared to craniotomy. Also, CMS notes that the AutoLITT™ provides a new treatment option in cases where no existing treatment is available due to the risk of complications. After reviewing the totality of the

evidence, CMS determines that the AutoLITT™ meets the substantial clinical improvement criterion.

Accordingly, CMS approves the AutoLITT™ for new technology add-on payments in FY 2011. The add-on payment is intended only for use of the device in cases of glioblastoma multiforme. Therefore, CMS will limit the new technology add-on payment to cases involving the AutoLITT™ in MS-DRGs 25, 26, and 27. Cases will be identified with a procedure code of 17.61 in combination with a primary diagnosis codes that begins with a prefix of 191. The average cost of the AutoLITT™ is reported as \$10,600 per case. As a result, the maximum add-on payment for a case involving the AutoLITT™ is \$5,300.

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 noted in the FY 2011 proposed rule 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 contained 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.

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.

In the FY 2011 proposed rule, CMS sought comments on whether LipiScan™ meets the newness criterion.

In the FY 2011 final rule, CMS decides that the LipiScan™ is new as of the date of its supplemental FDA approval, April 25, 2008, because the manufacturer provided information to show that the device was not marketed until after the supplemental FDA approval. Accordingly, Lipiscan™ meets the newness criterion.

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 maintained that LipiScan™ meets the cost criterion.

In the FY 2011 proposed rule, CMS maintained that 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 calculated 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 exceeded the case-weighted threshold amount. CMS sought public comment on whether or not LipiScan™ met the cost criterion.

CMS did not receive any public comments on whether or not LipiScan™ meets the cost criterion. Therefore, for FY 2011, CMS determines that 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 maintained that the device met this criterion based on evidence described in the proposed rule. Nonetheless, CMS continued 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 sought comments regarding whether or not the LipiScan™ technology represented a substantial clinical improvement in the Medicare population.

In the final rule, CMS summarizes the many comments received on this issue. Most of the commenters who supported this technology generally made anecdotal assertions in which the information provided by LipiScan™ was useful to them in managing their patients. A review of the literature by CMS yielded no additional evidence base to support the applicant's claim regarding the effect of this technology on patient management. CMS continues to believe that the prognostic implications of detecting lipid-rich plaque are not yet sufficiently well understood and documented in the peer-reviewed evidence base to conclude that its identification will lead to widespread and evidence-based changes in the management of CAD. CMS concludes that the evidence and information available at this time does not permit a determination that LipiScan™ meets the substantial clinical improvement criterion. Accordingly, CMS does not approve LipiScan™ for new technology add-on payments for FY 2011.

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

In the FY 2011 proposed rule, CMS noted that this device was not currently approved by the FDA, but the manufacturer anticipated that FDA approval would be granted in

the second quarter of 2010. However, CMS also noted that IVUS has existed for over 20 years and concluded that IVUS, on its own, would not meet the newness criterion. CMS sought 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).

In the final rule, CMS notes that the LipiScan™ IVUS received 510(k) approval from the FDA on June 30, 2010, prior to the July 1 deadline that applicants for new technology must meet in order to be evaluated under the newness criterion. However, the FDA approval letter did not provide information that would distinguish the LipiScan™ IVUS from its predicate devices. In addition, the manufacturer did not provide enough information for CMS to distinguish the LipiScan™ IVUS from the LipiScan™, which is what CMS specifically questioned in the proposed rule. CMS concludes there is insufficient information to make an affirmative decision regarding whether the LipiScan™ IVUS is substantially similar to the LipiScan™. Accordingly, CMS does not make a determination regarding whether the LipiScan™ IVUS is substantially similar to its predicate device or the LipiScan™ in this final rule.

However, CMS notes that whether or not LipiScan™ IVUS was substantially similar to LipiScan™, the LipiScan™ IVUS is still within its newness period for FY 2011 (because the LipiScan™ was new as of April 2008 and is still within its “newness” window for FY 2011). Accordingly, CMS believes that LipiScan™ IVUS meets the newness criterion for FY 2011, but there is insufficient information to determine whether the start of the newness period began in April 2008 or June 2010. Therefore, CMS does not make a determination in the FY 2011 final rule regarding the start of the newness period.

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 did 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 to 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.

For the FY 2011 proposed rule, CMS performed an alternative calculation of total case-weighted average standardized charge per case for the applicable MS-DRGs and stated “it appears that LipiScan™ IVUS would meet the cost criterion.” CMS invited public comment on whether or not LipiScan™ IVUS meets the cost criterion.

CMS received no public comments on this issue and concludes that for FY 2011 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.

In the FY 2011 proposed rule, CMS expressed concern that, in the LipiScan™ IVUS application, the applicant generally repeated the statements made regarding use of LipiScan™ alone and did not provide information that indicated that combined use of LipiScan™ plus IVUS offered additional clinical benefit. CMS noted 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 sought public comment on whether the LipiScan™ IVUS represented a substantial clinical improvement over existing technologies as well as public comments on what is the appropriate comparison for LipiScan™ IVUS.

In the FY 2011 final rule, CMS summarizes the comments received. According to the applicant, there have only been seven cases in which the LipiScan™ IVUS has been used, none of them in the United States. CMS concludes there is insufficient clinical evidence relating to this technology to demonstrate that the technology is a substantial clinical improvement over other existing diagnostic technologies. That is, the evidence available at this time does not support that the LipiScan™ IVUS affects the medical management of the patient which, in turn, leads to improved clinical outcomes. CMS acknowledges that the technology may ultimately lead to better clinical outcomes for patients undergoing coronary stenting, but concludes no data is available at this time to support that potential. Accordingly, CMS does not approve the LipiScan™ IVUS device for new technology add-on payments for FY 2011.

III. 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 FY 2010 IPPS/LTCH PPS final rule, CMS noted that it had contracted with Acumen LLC to study and report on the Medicare Payment Assessment Commission's (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 FY 2010 IPPS/LTCH PPS 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.

As an apparent consequence, in this rule CMS finalizes the agency's proposal to not make additional changes in regards to reforming the wage index in the final rule for the FY 2011 IPPS/LTCH.

In closing, CMS says that the ACA requires the Secretary to submit to Congress, not later than December 31, 2011, a report that included a plan to reform the Medicare wage index. CMS states that "we will consider the MedPAC's and Acumen's reports and findings, along with all of the public comments and suggestions we have received, as we evaluate ways for improving the wage index."

B. Wage Index Changes in Response to Sections 3137(c) and 3141 of the Affordable Care Act

Reclassification Average Hourly Wage Comparison Criteria (ACA, section 3137(c)).

Under the policies finalized in the FY 2009 IPPS final rule, 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 ACA, however, restores, effective for FY 2011, the hourly wage comparison of 84 percent for urban hospitals and 80 percent for rural hospitals and provides that these percentages will remain in effect until one year after the Secretary submits a required hospital wage index

improvement plan (see above). Section 3137(c) also requires the revised average hourly wage standards to be applied in a budget neutral manner.

As discussed in the June 2, 2010 FY 2010 IPPS supplemental proposed rule (75 FR 30919-30920), CMS requested assistance of the Medicare Geographic Classification Review Board (MGCRB) in determining, for applications received by September 1, 2009, whether additional hospitals would qualify for reclassification for FY 2011 based on the revised average hourly wage standards. CMS determined that a total of 23 hospitals fit this category; ultimately reclassification requests were granted to 22 of the 23 hospitals as one hospital withdrew its application.

National Budget Neutrality Adjustment for the Rural and Imputed Floors (ACA, section 3141). 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). However, the ACA, effective with 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 finalizes the proposed implementation of this requirement.

Floor for Area Wage Index for Hospitals in Frontier States. The ACA establishes an adjustment to create a wage index floor of 1.00 for all hospitals located in states determined to be “frontier states,” beginning in FY 2011. Hospitals in Alaska and Hawaii were excluded from this determination because they receive a Medicare payment nonlabor-related share adjustment. The ACA defines a “frontier state” as a one in which at least 50 percent of the counties are determined to be “frontier counties.” A “frontier county” is defined as a county in which the population per square mile is less than 6 persons. The frontier state adjustment is not subject to budget neutrality calculations; CMS projects it will increase Medicare spending by about \$50 million. In this final rule, CMS implements the frontier states provision, which, according to CMS, captures 51 hospitals in Montana, Wyoming, North Dakota, Nevada, and South Dakota.

Plan for Reforming the Wage Index under Section 3137(b) of the ACA. CMS reviews some of the requirements of the ACA related to the wage index and notes that a few commenters urged CMS to involve the industry in the policy development process. One commenter “in particular suggested that CMS should adopt an advisory commission approach in addressing future changes in the wage index.” CMS indicates that it will consider these and other suggestions in the development of the plan for meeting the ACA requirements.

Core-Based Statistical Areas for the Hospital Wage Index. The final 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".

C. Occupational Mix Adjustment for the FY 2011 wage Index.

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 states that "...again, for the final FY 2011 hospital wage index, we used data from the 2007-2008 survey . . . to compute the final FY 2011 adjustment." CMS goes on to say that it will use the 2007-2008 survey for the FY 2012 wage index but will, as required, 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). At that time, CMS changed the reporting period from July 1 through June 30 to a calendar year, reflecting the suggestions of commenters, and extended the reporting period from 3-months to 6-months.

For purposes of calculating the occupational mix adjustment for FY 2011, CMS is following the same methodology it used for FY 2010. The resulting FY 2011 occupational mix-adjusted national average hourly wage is \$34.9664 (the FY 2011 occupational mix-adjusted Puerto Rico-specific average hourly wage is \$14.7620). For FY 2011, the occupational mix adjustment is being applied to 100 percent of the FY 2011 wage index.

The final FY 2011 national average hourly wages for each occupational mix nursing subcategory are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	\$36.073
National LPN and Surgical Technician	\$20.866
National Nurse Aide, Orderly, and Attendant	\$14.619
National Medical Assistant	\$16.479
<i>National Nurse Category</i>	\$30.474

CMS compared the FY 2011 occupational mix adjusted wage indices for each CBSA to the final unadjusted wage indices for each CBSA. The analysis found that the final FY 2011 wage index values for 206 urban areas (52.7 percent) and 32 rural areas (68.1 percent) would increase, while the values for 185 urban areas (47.3 percent) and 15 rural areas (31.9 percent) would decrease. No urban or rural areas would be unaffected. The final wage index values for FY 2011 are included in Tables 4A, 4B, 4C, and 4F of the Addendum to the final rule.

Hospitals not submitting occupational mix data will be required, beginning with the new 2010 occupational mix survey, to provide an explanation for not complying with the submission requirements. CMS states that the purpose of this requirement is to gain a better understanding of why some hospitals are not submitting the occupational mix data.

D. Other Wage Index Issues

Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications. CMS notes that 285 hospitals were approved for wage index reclassifications for FY 2011 by the MGCRB, and because such reclassifications are effective for 3 years a total of 823 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.

“Lugar” Counties. The law requires CMS to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the CBSA if certain criteria are met. For instance, a “Lugar” hospital must be no more than 35 miles from the area to which it seeks reclassification and the hospital must show that its average hourly wage is at least 106 percent of the average hourly wage of all other hospitals in the area in which the hospital is located. The final rule lists rural (“Lugar”) counties. 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 Hospitals. Section 508 of P.L. 108-173 allows 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 notes that the ACA extended the benefit again through September 30, 2010. Because the latest extension expires on September 30, 2010, the extension will not be applicable to FY 2011. Thus, CMS is not making any changes related to these provisions in this final rule.

FY 2011 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees. Table 4J in the Addendum to the final rule lists the 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.

Labor-Related Share for the FY 2011 Wage Index. CMS is continuing 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. Tables 1A and 1B in the Addendum to this final rule reflect this labor-related share.

IV. 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

CMS finalizes its proposals regarding the Reporting of Hospital Quality Data for Annual Hospital Payment Update (RHQDAPU) program, with several important exceptions. The exceptions are the requirements for all-payer volume reporting (proposed to begin for the 2012 payment determination) and for registry-based reporting (proposed to begin for the 2013 payment determination.) In addition, the reporting on the National Healthcare Safety Network (NHSN) measure regarding surgical site infection, proposed to begin for the 2013 payment determination, is instead finalized to begin for the 2014 payment determination. In this rule CMS finalizes the retirement of the two pneumonia immunization measures effective for the 2014 payment determination, coincident with the start of required reporting on global immunization measures.

All measures finalized in the rule for FY 2011 through FY 2014 RHQDAPU payment determinations are displayed in a table at the end of this section of the summary.

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

Noting overwhelming support from commenters, CMS finalizes its proposal to retire one of the measures finalized in the FY 2009 IPPS final rule for use in the FY 2011 payment determination under the RHQDAPU. Retirement of the Agency for Healthcare Research and Quality (AHRQ) composite measure on “Mortality for Selected Surgical Procedures” leaves 45 measures for use in making FY 2011 payment determinations.

In responding to general comments on retirement of measures, CMS indicates that some commenters expressed concern about the potential for declining quality performance if topped-out measures are retired and offered suggestions for continued monitoring. CMS states that it will consider commenters’ suggestions for periodically monitoring performance of measures that may be subsequently retired.

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

CMS proceeds with its proposal to finalize a three-year plan for expanding quality measures required under RHQDAPU. Measures are finalized for the FY 2012, FY 2013 and FY 2014 payment determinations. This multi-year approach is intended to provide hospitals with greater certainty in planning to meet future reporting requirements, and offer CMS more time to prepare the infrastructure to collect data on the measures and make payment determinations. However, CMS makes clear that it may add or remove measures for these years in future rulemaking cycles should it need to respond to agency priorities and statutory changes. These changes could, CMS says, be based on the national quality strategy that the Secretary is required to develop under the ACA.

General Discussion of Adding Measures

In both the proposed and final rules, CMS cites its continued interest in expanding and updating quality measures while minimizing reporting burden, use of registries as an alternative to direct hospital submission of data for RHQDAPU, and the possible use of electronic health records (EHRs) and all-payer claims data in the RHQDAPU program.

In response to comments, CMS discusses the relationship between quality measures in the RHQDAPU program and the electronic quality measure reporting requirements that are part of the meaningful use criteria under the HITECH EHR incentive program rule. CMS indicates it intends in the future to develop and specify electronic quality measures that will be aligned and meet the requirements of both programs. However, CMS believes alignment with the HITECH EHR program must be consistent with the data needs of the RHQDAPU program. CMS notes that RHQDAPU, unlike the HITECH EHR program, requires public reporting, and that RHQDAPU measures will form the basis of the new Hospital Value-Based Purchasing Program. CMS discusses the time needed for developing quality reporting through EHRs, and does not believe that it should wait for the complete transition to EHR-based measure collection in order to expand RHQDAPU program measures. Additionally, CMS indicates that HCAHPS cannot be reported via EHRs and that claims-based reporting may still be needed to identify prior events and diagnoses for measures that involve look-back periods or matching data for a patient across multiple settings. These issues are discussed further under item 12 “Electronic Health Records.” CMS does indicate its intention to propose in the future the addition of certain HITECH EHR measures to the RHQDAPU program, as discussed below under item 4 “Possible New Quality Measures for Future Years.”

With respect to the proposed requirement for registry-based reporting, CMS indicates that it did not intend to require hospitals to participate in a proprietary registry, and expected that most hospitals could select a registry to which it was already reporting in order to meet the requirement, with no new reporting involved. CMS acknowledges

commenter's concern about the cost and burden of participation in certain registries, and indicates that as it considers registry-based data submission in the future, it will consider whether it should be one means but not an exclusive means of reporting RHQDAPU quality measures. CMS also agrees with comments regarding the importance of standardizing data collection and submission processes by registries.

CMS summarizes its view of the statutory requirements that RHQDAPU measures reflect consensus among affected parties when adding RHQDAPU measures. It has been the long-standing position of CMS that while National Quality Forum (NQF)-endorsed measures are preferred, the statutory requirement can be met by other means such as consensus achieved during the measure development process and consensus through public comment. Under the ACA, CMS notes, beginning with FY 2013, each measure specified by the Secretary must be endorsed by a consensus entity, except in certain circumstances. CMS indicates that it appreciates the efforts and support of the Hospital Quality Alliance and considers measures adopted by it as well as other input from the public.

Measures for FY 2012 Payment Determinations

CMS finalizes its proposal to retain the 45 measures used for FY 2011 payment determinations and add 10 new claims-based measures: 2 AHRQ Patient Safety Indicators and 8 Hospital Acquired Condition (HAC) measures. However, in response to comments indicating reporting burden, it does not finalize its proposal that hospitals begin submitting all-patient data on 55 MS-DRGs that relate to RHQDAPU program measures. The measures will be calculated using up to 3 years of Medicare claims for discharges prior to January 1, 2011. (All the finalized measures for the FY 2012 payment determination are displayed in the table at the end of this section.)

With respect to the two finalized AHRQ patient safety measures, CMS responds to comments opposing their addition because they have time-limited NQF endorsement, by stating that the measures should be treated as endorsed. CMS states that only one of the measures (PSI-12 Post-Operative Pulmonary Embolism) has a 2-year NQF endorsement period rather than the standard 3-year period. CMS believes the measures address adverse surgical outcomes, a high HHS priority and one not otherwise represented in the RHQDAPU measure set.

CMS reports receiving many comments opposing the addition of the HACs as RHQDAPU measures, but finalizes their addition, stating that measures specifications will be published, and that "appropriate risk adjustment" will be applied to those HACs that are not considered Never Events, such as infection-related HACs. CMS believes the HACs reflect consensus among affected parties because they were refined during two public listening sessions and underwent public comment through rulemaking, but will consider the suggestion that it pursue NQF endorsement for the HAC measures. With respect to overlap between the HAC measures and others, CMS indicates a "close relationship" with the Hospital Acquired Infection measures to be collected through the National Health Safety Network, but states the

measures they are not identical. As proposed, the HAC measures will 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.)

Although the proposal for annual hospital reporting of all-patient volume data for the 55 MS-DRGs that relate to the RHQDAPU measures is not finalized, CMS indicates that it plans to refine the all-payer volume data submission requirements based on diagnosis codes and reintroduce the proposal in subsequent rulemaking. CMS agrees with commenters that the reporting requirement would be burdensome because hospitals would have to group the cases into one of the relevant MS-DRGs before submitting the data.

Measures for FY 2013 Payment Determinations

In addition to continuing the 55 measures finalized for FY 2012, CMS finalizes the addition of 2 of 3 measures proposed for the FY 2013 payment determinations, with reporting to begin with January 1, 2011 discharges. These are “AMI—Statin Prescribed at Discharge,” which CMS reports was supported by the majority of commenters, and “Central Line Associated Blood Stream Infection,” (CLASBI) a healthcare associated infection (HAI) measure collected by the CDC National Healthcare Safety Network. The other proposed HAI measure, “Surgical Site Infection,” is finalized, but for the FY 2014 payment determination rather than FY 2013 as proposed. (The table at the end of this section lists the finalized measure set for the FY 2013 payment determination.)

The proposal that hospitals choose one of four topic areas (implantable cardioverter defibrillator (ICD) complications, cardiac surgery, stroke, or nursing-sensitive care) for which measures would be reported through a qualified registry is not finalized. (CMS’ rationale for this decision is discussed above under “general discussion of adding measures.”)

CMS received comments on the HAI measures with respect to the burdensome NHSN data input process and concern about the capacity of the CDC/NHSN to handle expanded hospital participation. CMS reports that it has been in discussions with the CDC regarding improved user support and training materials as well as streamlined specifications for the HAI measures, and that the data elements required for RHQDPU will be limited to the subset needed to calculate the specific NQF-endorsed measures. In addition, CMS will examine the need for validation of the NHSN measures, and is considering adding them to the validation process. CMS indicates the HAI measures will be publicly reported as other RHQDPU program measures. It notes that currently the NQF specification stratifies the measure by type of unit within a hospital, and that NQF-endorsed measure specifications are subject to revisions, which CMS reflects in what it requires hospitals to submit to the RHQDAPU program.

CMS is finalizing the CLASBI measure for the FY 2013 payment determination and delaying for one year addition of the surgical site infection measure because more hospitals are already submitting the CLASBI measure under state reporting requirements. In addition, CMS indicates that this will allow more time to address measurement issues raised by commenters with respect to the surgical site infection measure. Reporting will begin for the CLASBI measure with January 1, 2011 discharges and for the surgical site infection measure, January 1, 2012 discharges. CMS states its expectation that both the HAI measures will be risk-adjusted.

CMS will require reporting of those data elements, populations and procedures needed to calculate the NQF-endorsed measures. The procedures that apply to the NQF CLASBI measure are: coronary artery bypass graft and other cardiac surgery, hip or knee arthroplasty, colon surgery, hysterectomy (abdominal and vaginal) and vascular surgery. The populations are both adult and pediatric populations. CMS states that the procedures correspond to those used in SCIP, so process and outcome data will be captured for the same patient populations.

Measures for FY 2014 Payment Determinations

CMS finalizes addition of the 4 proposed chart-abstracted measures to the RHQDAPU measure set for the FY 2014 payment determination. Two measures relate to emergency department (ED) throughput and two are all-patient immunization measures. In addition, CMS finalizes the retirement of two existing pneumonia-specific immunization measures (PN-2 and PN-7) in light of the addition of the global immunization measures. All other measures finalized for the FY 2013 payment determination will be continued as part of the measures set for the FY 2014 payment determination. In addition, as noted earlier, CMS finalizes the addition of the HAI measure on surgical site infections for the FY 2014 payment determination. A total of 60 measures are therefore included in the RHQDAPU program measure set for the FY 2014 payment determination. Reporting on the new measures will begin with January 1, 2012 discharges and at that point reporting on the retired measures will no longer be required under the RHQDAPU program. (The table at the end of this section displays the finalized measure set for the FY 2014 payment determination.)

In response to comments on the collection burden associated with the global immunization measures, CMS states that by finalizing these measures now for the 2014 payment determination, hospitals will have adequate time to develop efficient collection plans. In addition, with respect to the ED throughput measures, CMS suggests that hospitals begin to submit data voluntarily, which will be possible beginning in October 2010, in order to gain experience with these measures before the required reporting begins in January 2012.

4. Possible New Quality Measures for Future Years

The proposed rule invited comment on quality measures and topics that CMS is considering for the future, which were displayed in a table in the proposed rule. In this

final rule, CMS reports on comments received on a number of specific measures and suggested measure topic areas which it will consider for inclusion in the future.

CMS indicates its intention to add certain stroke and venous thromboembolism (VTE) measures to the RHQDAPU program in future rulemaking. The stroke measures are those that were proposed only for registry-based reporting but not finalized in this rule. CMS indicates that these measures are currently specified for chart abstraction and electronically specified for EHR submission and included in the HITECH HER incentive program for 2011 and 2012. The VTE measures that CMS intends to propose for addition are those that are included in the HITECH EHR incentive program.

CMS responds to comments that the RHQDAPU measures should be consistent with the national strategy for improving health care quality that the Secretary is required to issue by January 2011 under the ACA. CMS states that the measures included in the final rule are consistent with established HHS priorities, and include some priorities selected by the NQF National Priorities Partners process, such as patient safety, population health, and care coordination. CMS believes it is important to include a broad array of measures reflecting the range of services provided in IPPS hospitals and to provide consumers with comparative information on many topics.

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

CMS finalizes its proposal to synchronize to a calendar year basis the timing of reporting for the various RHQDAPU measures, which have differed, beginning with the FY 2013 payment determination. In addition the timeframe for 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. (For example, 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.) By September 15th each year CMS will post a table on the QualityNet.org website showing the discharge quarters that will be used to make each fiscal year payment determination.

CMS reports receiving no comments on the proposed additional procedural requirements for RHQDAPU data submission and finalizes them as proposed. (The requirements related to all-patient volume data submission and registry reporting are not finalized as this proposed new reporting requirement was not finalized in the rule.)

The final rule includes additional information that was not included in the proposed rule related to the submission of data for the new NHSN measure. For the CLASBI measure, which is finalized for inclusion in the RHQDAPU measure set for the FY 2013 payment determination, data collection will begin with January 1, 2011

discharges, and the final rule includes a table showing details of the RHQDAPU data submission time frame as it relates to the CDC-NHSN data collection time frame.¹

6. RHQDAPU Program Disaster Extensions and Waivers

CMS finalizes its proposed process under which hospitals facing extraordinary circumstances may request and be granted a waiver from reporting required data for RHQDAPU. Specifically, a hospital facing extraordinary circumstances beyond its control, may submit to the Quality Improvement Organization (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. This process does not preclude CMS 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.org website.

7. Proposed Chart Validation Requirements for Chart-Abstracted Measures

CMS finalizes its proposal to continue the chart validation requirements that were adopted for the FY 2011 payment determination for the FY 2012 RHQDAPU payment determination, and its proposed changes to that process to begin in FY 2013. 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 data validation requirements for FY 2012 will be posted on the Qualitynet.org website.

The four changes to chart validation requirements finalized to begin in FY 2013 are 1) addition of a targeting criterion under which all hospitals that fail the validation process in a year will be selected for validation again in the next year, 2) elimination of the 100 discharges minimum for validation selection, 3) modification of the methodology for sampling discharges in cases where hospitals have fewer than 3 cases in a topic area in a quarter, and 4) adjustment of the timing of data validation to be consistent with the proposed synchronization of RHQDAPU data discussed earlier (item 5 above).

As noted above, in response to comments regarding the need for validation of data submitted through the CDC/NHSN, CMS indicates that it is considering validating self-reported CDC/NHSN data by proposing two additional quarterly samples. One

¹ The table appears on pages 641-642 of the CMS display copy of the final rule (CMS 1498-F), available at <http://www.cms.gov/AcuteInpatientPPS/IPPS2011/>.

additional quarterly sample would validate NHSN measure data. CMS will solicit comments when proposed changes to the validation approach are made in future rulemaking. CMS indicates its intention to propose that beginning with the FY 2015 payment determination, the validation sample selection criteria be changed to ensure that all hospitals are selected for validation at least once every 4 years. In addition, CMS will consider comments it received on the possibility of stratifying the program validation sample in future years.

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

CMS modifies its proposal to require that for the FY 2012 payment determination, hospitals electronically acknowledge the accuracy and completeness of their data once from July 1, 2010 through August 15, 2010 by changing the dates to instead require acknowledgement once from July 1, 2011 through August 15, 2011. This was done in response to comments that much of the data reporting for the FY 2012 payment determination would occur after the proposed dates. CMS intends to propose the same July 1 through August 15 time frame for future years.

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

CMS proposed no changes related to procedures for display of information on the Hospital Compare website and reports that no comments were received on this topic.

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

CMS adopts the proposed November 1, 2010 deadline for submitting a request for reconsideration of the FY 2011 payment determination. In response to comments that CMS solicited on the extent to which the proposed procedures will be less costly for hospitals and lead to fewer PRRB appeals, CMS indicates that it is reviewing and standardizing the reconsideration process in an effort to reduce wait time, and hopes to reduce the expected 90-day wait for a determination.

11. Proposed RHQDAPU Program Withdrawal Deadlines

The final rule establishes, as proposed, August 15, 2011 as the deadline for RHQDAPU withdrawal forms for the FY 2012 payment determination. Hospitals that withdraw from participation will receive a 2 percentage point reduction in their update factor.

12. Electronic Health Records

In this section of the final rule CMS discusses its efforts to encourage hospitals to adopt EHRs that will allow reporting of quality data directly, and elaborates on its

earlier discussion of the overlap between RHQDAPU and the HITECH Act. CMS notes that by the summer of 2011, it will be testing the acceptance from EHRs on certain ED, stroke, and VTE measures. (These measures have not been adopted for use in RHQDAPU, and CMS repeats that the testing of measures for EHR purposes does not signal it will be adopted in RHQDAPU.)

In response to comments, CMS reiterates that when data collection and transmission of RHQDAPU measures can be achieved through EHR technology, it may be able to rely upon EHRs for data submission. For the two emergency department measures that the final rule adds to the RHQDAPU measure set for the FY 2014 payment determination that are also HITECH EHR measures, CMS anticipates providing hospitals with an option for electronic submission of these measures which would otherwise be chart-abstracted measures. CMS expects that over time, EHRs will be the primary source of quality measures data. Whether chart abstraction remains a data collection option for a measure that can be submitted via EHR technology will depend on the prevalence of EHR adoption by RHQDAPU-participating hospitals.

CMS responds to the suggestion by some commenters that a hospital reporting to the RHQDAPU program via a certified EHR should be deemed to satisfy the meaningful use criteria with respect to reporting clinical quality measures. CMS states that the authorizing statutes are separate and do not provide for such a recognition, and that the HITECH Act specifically requires the Secretary to avoid duplicate and redundant reporting for HITECH with respect to RHQDAPU. Moreover, CMS states that because there is little overlap in measures as finalized in this rule, it would not be appropriate to deem participation in the RHQDAPU program as meeting the requirements for successful reporting in the EHR incentive program. However, where feasible CMS intends to align the data submission requirements for measures included in each program.

13. Qualification of Registries for RHQDAPU Data Submission

Because CMS is not finalizing the proposed requirement for registry-based reporting of quality measures, it is also not finalizing its proposed requirements for qualifications of registries for RHQDAPU data submission. CMS reports that commenters offered numerous suggestions for improving on the proposed registry qualification criteria and timeline that CMS will take into consideration if it proposed to qualify registries for RHQDAPU data collection in the future.

14. RHQDAPU and Hospital Value Based Purchasing Program

CMS reports that it received many comments about the hospital value-based purchasing (HVBP) program established under the ACA, which is not addressed in this final rule. CMS indicates that it plans to convene at least one listening session or Open Door Forum to obtain public feedback on the HVBP program.

RHQDAPU Program Quality Measures Adopted for the FY 2011-FY2014 Payment Determinations				
	2011	2012	2013	2014
Acute Myocardial Infarction (AMI)				
• AMI-1 Aspirin at arrival	X	X	X	X
• AMI-2 Aspirin prescribed at discharge	X	X	X	X
• AMI-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic	X	X	X	X
• AMI-4 Adult smoking cessation advice/counseling	X	X	X	X
• AMI-5 Beta blocker prescribed at discharge	X	X	X	X
• AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes	X	X	X	X
• AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)	X	X	X	X
• AMI-Statin at Discharge			X	X
Heart Failure (HF)				
• HF-1 Discharge instructions	X	X	X	X
• HF-2 Left ventricular function assessment	X	X	X	X
• HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic	X	X	X	X
• HF-4 Adult smoking cessation advice/counseling	X	X	X	X
Pneumonia (PN)				
• PN-2 Pneumococcal vaccination status	X	X	X	(Retired)
• PN-3b Blood culture performed before first antibiotic received in hospital	X	X	X	X
• PN-4 Adult smoking cessation advice/counseling	X	X	X	X
• PN-5c Timing of receipt of initial antibiotic following hospital arrival	X	X	X	X
• PN-6 Appropriate initial antibiotic selection	X	X	X	X
• PN-7 Influenza vaccination status	X	X	X	(Retired)
Surgical Care Improvement Project (SCIP)				
• SCIP-1 Prophylactic antibiotic received within 1 hour prior to surgical incision	X	X	X	X
• SCIP-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time	X	X	X	X
• SCIP-VTE-1: Venous thromboembolism (VTE) prophylaxis ordered for surgery patients	X	X	X	X
• SCIP-VTE-2: VTE prophylaxis within 24 hours pre/post surgery	X	X	X	X
• SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients	X	X	X	X
• SCIP-Infection-4: Cardiac Surgery Patients	X	X	X	X

with Controlled 6AM Postoperative Serum Glucose				
• SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal	X	X	X	X
• SCIP–Infection-9: Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2*	X	X	X	X
• SCIP-Infection-10: Perioperative Temperature Management*	X	X	X	X
• SCIP-Cardiovascular-2: Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period	X	X	X	X
Mortality Measures (Medicare Patients)				
• MORT-30-AMI: Acute Myocardial Infarction 30-day mortality – Medicare patients	X	X	X	X
• MORT-30-HF: Heart Failure 30-day mortality Medicare patients	X	X	X	X
• MORT-30-PN: Pneumonia 30-day mortality - Medicare patients	X	X	X	X
Patients' Experience of Care				
• HCAHPS survey	X	X	X	X
Readmission Measure (Medicare Patients)				
• READ-30-HF: Heart Failure 30-Day Risk Standardized Readmission Measure (Medicare patients)	X	X	X	X
• READ-30-AMI: Acute Myocardial Infarction 30-Day Risk Standardized Readmission Measure (Medicare patients)	X	X	X	X
• READ-30-PN: Pneumonia 30-Day Risk Standardized Readmission Measure (Medicare patients)	X	X	X	X
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures				
• PSI 06: Iatrogenic pneumothorax, adult	X	X	X	X
• PSI 11: Post Operative Respiratory Failure		X	X	X
• PSI 12: Post Operative PE or DVT		X	X	X
• PSI 14: Postoperative wound dehiscence	X	X	X	X
• PSI 15: Accidental puncture or laceration	X	X	X	X
• IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)	X	X	X	X
• IQI 19: Hip fracture mortality rate	X	X	X	X
• Complication/patient safety for selected indicators (composite)	X	X	X	X
• Mortality for selected medical conditions (composite)	X	X	X	X
AHRQ PSI and Nursing Sensitive Care				
• Death among surgical inpatients with serious, treatable complications	X	X	X	X

Cardiac Surgery				
• Participation in a Systematic Database for Cardiac Surgery	X	X	X	X
Stroke Care				
• Participation in a Systematic Clinical Database Registry for Stroke Care	X	X	X	X
Nursing Sensitive Care				
• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	X	X	X	X
Healthcare Associated Infections				
• Central Line Associated Bloodstream Infection			X	X
• Surgical Site Infection				X
Hospital Acquired Condition Measures				
• Foreign Object Retained After Surgery		X	X	X
• Air Embolism		X	X	X
• Blood Incompatibility		X	X	X
• Pressure Ulcer Stages III & IV		X	X	X
• Falls and Trauma (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)		X	X	X
• Vascular Catheter-Associated Infection		X	X	X
• Catheter-Associated Urinary Tract Infection (UTI)		X	X	X
• Manifestations of Poor Glycemic Control		X	X	X
Emergency Department Throughput				
• ED Throughput – Admit Decision Time to ED Departure Time for Admitted Patients				X
• ED Throughput - Median time from emergency department arrival to ED departure for admitted patients				X
Global Immunization Measures				
• Global Flu Immunization				X
• Global Pneumonia Immunization				X

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

CMS finalizes its proposal 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 (i.e. an acute care hospital without a Medicare participation agreement) that would otherwise be eligible for payment under the IPPS, and 2) to a critical access hospital (CAH).

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).

CMS indicates that hospitals should check the National Uniform Billing Committee patient status codes because they are periodically updated.

CMS also notes in response to a comment that the statute governing post-acute care transfers does not provide for an exemption for unrelated discharges to skilled nursing facilities (SNFs); thus the post-acute transfer policy will apply without regard to whether the SNF services were related to the services furnished in the acute care hospital.

While stating that the impacts of the expansion of the transfer policy are impossible to measure, CMS believes the change in payments to hospitals will be negligible and estimates that it will not have a material impact on Medicare payments to acute care hospitals.

C. Rural Referral Centers (RRCs)

CMS finalizes revised criteria for purposes of determining rural referral center (RRC) status, including updated minimum national and regional case mix index (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.

Being classified as an RRC has a number of advantages. For one, the 12-percent cap on disproportionate share hospital (DSH) payments to rural hospitals does not apply to RRCs. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital’s average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market where the hospital is located.

To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2010, 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 1.5136 (the FY 2009 median CMI for all urban hospitals nationally) or the median CMI value for urban hospitals (excluding hospitals with approved teaching programs) calculated by CMS for the census region in which the hospital is located. These median regional CMIs are listed in the final rule (see below).

Region	Case-Mix Index Value
New England (CT, ME, MA, NH, RI, VT)	1.2993
Middle Atlantic (PA, NJ, NY)	1.3582

South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4567
East North Central (IL, IN, MI, OH, WI)	1.4251
East South Central (AL, KY, MS, TN)	1.3771
West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4407
West South Central (AR, LA, OK, TX)	1.5240
Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6204
Pacific (AK, CA, HI, OR, WA)	1.4861

- 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) discharges or the median number of discharges for urban hospitals in the census region in which the hospital is located. However, since the final 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).

D. Payment Adjustment for Low-Volume Hospitals

As discussed in the June 2, 2010 supplemental proposed FY 2011 IPPS rule the ACA amends the definition of a low-volume hospital and revised the methodology for calculating the payment adjustment for low-volume hospitals, limited to FY 2011 and FY 2012 only. Beginning FY 2013, the preexisting low-volume hospital payment adjustment and qualifying criteria, as implemented in FY 2005, will resume.

Accordingly, CMS is implementing the ACA requirements that for FY 2011 and FY 2012, to qualify for a low volume adjustment, a hospital must be more than 15 road miles (rather than 25 road miles) from the nearest hospital and discharges must total less than 1,600 discharges (rather than less than 800 discharges) of individuals entitled to, or enrolled for, benefits under Part A. Prior to the ACA amendment, discharges were defined to mean “. . . an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A.”

CMS also finalizes its proposal to use an applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment (upper limit set by law) for hospitals with 200 or fewer Medicare discharges to 0 percent for hospitals with 1,600 or more Medicare discharges. The table below is taken from the final rule.

Medicare Discharge Range	Payment Adjustment (Percent Add-On)
1 – 200	25.0000
201 – 300	23.3333
301 – 400	21.6667
401 – 500	20.0000

501 – 600	18.3333
601 – 700	16.6667
701 - 800	15.0000
801 – 900	13.3333
901 – 1,000	11.6667
1,001 – 1,100	10.0000
1,101 – 1,200	8.3333
1,201 – 1,300	6.6667
1,301 – 1,400	5.0000
1,401 – 1,500	3.3333
1,501 – 1,599	1.6667
1,600 or more	0.0000

The final rule lists hospitals with fewer than 1,600 Medicare discharges based on the March 2010 update of the FY 2009 MedPAR files. The list contains 1,444 hospitals. This list, CMS notes, does not reflect whether or not the hospital meets the mileage criterion. CMS' actuaries estimate that about 40 percent of these hospitals will meet the mileage requirement – if this is correct, then according to CMS estimates, this provision will increase Medicare payments about \$380 million in FY 2011, about \$450 million in FY 2012 and about \$50 million in FY 2013.

In order to receive the applicable low-volume percentage add-on payment, a hospital must notify and provide documentation to its fiscal intermediary or Medicare Administrative Contractor (MAC) that it meets the mileage criterion.

E. Indirect Medical Education (IME) Adjustment

The final rule continues 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, and providing for electronic submission of Medicare GME affiliation agreements.

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

CMS finalizes its proposed revision of the data matching process for the SSI fraction of the Medicare DSH payment adjustment formula.

Background. In *Baystate Medical Center v. Leavitt*, the District Court concluded that the CMS matching process did not use best available data in calculating the SSI fraction for purposes of the DSH payment formula. Specifically, the court found 1) that the SSI eligibility data used failed to include state 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 which were available to CMS at the time of the hospital's cost report settlement.

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 that were for an individual whose record was active or stale.

b. Use of SSNs in the Revised Match Process

Databases Used

- The SSI eligibility data file contains a unique Social Security number (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 (though CMS notes that greatest number of historical HICANs attributable to any beneficiary appears to be seven).
- 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' revised match process uses the Medicare EDB which includes SSNs as well as all of an individual's 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 then compares 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 are compared to any and all HICANs in MedPAR.

3. CMS ensures 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 attempts 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 adds 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 the provision of Medicare services.
4. CMS calculates the SSI fraction as it has done in the past.

In the final rule, CMS indicates that it will also ensure, as part of the process described above, that every HICAN on the MedPAR file matches a HICAN in the EDB, and will test MedPAR data accordingly. If it determines a HICAN is invalid, CMS will exclude the record from the data matching process and from the calculation of both the numerator and denominator of the SSI fraction.

In response to comments requesting more detail on its testing and validation procedures, CMS indicates it will, as part of its internal validation processes, track summary statistics including the number of SSI records received from SSA and at least all of the following information for each SSI record matched to Medicare inpatient hospital claims: the number of SSI records matched under the new process; the number of records indicating the individual is deceased; and the number of records where at least one SSI monthly indicator shows forced pay or forced due status. CMS will also produce summary statistics for SSI records that do not match Medicare inpatient claims, including the number of unmatched SSI records with none, one, or more than one Title II number; and the number of records in the EDB with a HICAN but no SSN. These statistics will not be available to the public.

In response to a comment that hospitals should be able to calculate their own SSI fractions, CMS is open, subject to restrictions under the Privacy Act and the HIPAA Privacy Rule, to affording hospitals that ability without compromising protected personally identifiable information and other protected information. CMS welcomes suggestions how this can be done and how hospital calculations could be verified without significant additional administrative burden. CMS notes that it is not authorized to share SSA data and is only permitted to use it to conduct the data match and calculate the SSI fractions.

In response to a commenter requesting that CMS publish both the Federal fiscal year SSI fractions and each hospital's cost reporting period fractions, CMS indicates it will revise, upon request, a hospital's SSI fraction based on its cost report if the period differs from the Federal fiscal year. In such a case, CMS will use data from the two

Federal fiscal years that span that cost reporting period. CMS will not track and calculate SSI fractions for every hospital's cost reporting period.

Also, CMS will not seek to add an SSN to an EDB record that lacks one choosing to rely instead on step two of its data matching process which will generate up to ten Title II numbers to identify individuals entitled to SSI benefits.

CMS disagrees with a commenter's proposed interpretation of the term "entitled" with respect to SSI to mean "paid". CMS refers to the wording of the statute for its interpretation, which only indicates a right to receive payment but does not necessarily equate to actual payment under all circumstances. CMS also believes the SSI status codes appropriately identify entitlement to SSI payment.

c. Timing of the Match

CMS notes that section 6404 of the ACA 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 will conduct the data matching process approximately, but no sooner than, 15 months after the close of each Federal fiscal year. CMS will use SSI eligibility data files compiled by SSA and MedPAR claims information that are updated to that point versus the 6 months under prior 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 in the spring of 2013 which would be used to settle cost reports for reporting periods beginning during FY 2011. CMS will also continue using each hospital's latest available SSI fraction to determine IPPS interim payments.

The table below shows the CMS example of its timeline to calculate FY 2011 SSI fractions under the rule.

Cost Reports That Use the FY 2011 SSI Ratios	Deadline for Timely Filing of Claims	MedPAR File Used	SSI Entitlement File Used	Cost Reports Normally Accepted	Cost Report Final Settlement	SSI Fraction Available
Cost reports beginning October 1, 2010 through September 30, 2011	September 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

In response to commenters' concerns, CMS indicates that cost reports under the new timing will be final settled with the appropriate SSI fraction (rather than an SSI fraction that applied to the preceding cost reporting period). For cases where cost reports are settled before the publication of SSI fractions, CMS indicates it will ensure the appropriate SSI fraction will apply to the cost report involved by instructing

contractors either to reopen cost reports or to wait until the appropriate SSI fraction is published.

CMS Ruling 1498-R.

On April 28, 2010, CMS issued a Ruling, CMS-1498-R, addressing, among other issues, CMS' process for matching Medicare and SSI eligibility data and calculating hospitals' SSI fractions. The ruling requires 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 final settled, CMS and the contractor will recalculate the provider's DSH payment adjustment, and make any payment owed, 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 notice of program reimbursement, CMS will apply the new data matching process adopted in the final rule (including the policy to exclude records for a HICAN in a MedPAR file not found in the EDB added in the 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.

CMS notes that Administrative Rulings are not subject to public comment and declines to summarize or respond to comments submitted with respect to the Ruling.

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

CMS was concerned in the proposed rule by confusion over its policy to reflect inclusion of days associated with MA beneficiaries, specifically regarding whether it implies 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) of the regulations with respect to MA days. CMS finalizes its proposal to replace the word "or" with the word "including" in those sections. CMS, in response to comments, declines to modify its longstanding policy of including MA days or exhausted benefit days.

CMS is unable to determine whether Medicare DSH adjustment payments to hospitals will generally increase or decrease under the revised data matching process, due to the various factors impacting the calculation of SSI fractions, including use of more updated data files (MedPAR claims and SSI eligibility), and other features of the revised data matching process. Better MedPAR claims data will increase the number of claims captured in the denominator, while the updated SSI eligibility file, which captures both the granting and denial of SSI claims, will affect the numerator with differing impacts on hospitals. And while the use of SSNs and a greater number of Title II numbers and HICANs may result in the identification of

additional eligible individuals and corresponding increases in SSI fractions, CMS cannot determine the extent of DSH payment increase.

G. Medicare-Dependent, Small Rural Hospitals (MDHs)

Under the IPPS, special payment protections are provided to a Medicare-dependent, small rural hospital (MDH). An MDH is defined as a rural hospital, has not more than 100 beds, is not a sole community hospital and has a high percentage of Medicare inpatient days or discharges (not less than 60 percent).

In this rule, CMS makes two changes to the policies impacting MDHs. One change involves the way that Medicare inpatients are counted. Currently, Medicare counts inpatients as those who are “receiving” Medicare Part A benefits. CMS changes the wording from “receiving” to those individuals who are “entitled” to Medicare Part A benefits. This change allows Medicare to include Part A beneficiaries who have exhausted their benefits as well as beneficiaries who are enrolled in Medicare Advantage plans, health maintenance organizations, and competitive medical plans. CMS estimates that this change will allow at least another 48 hospitals to qualify for MDH status at a cost of about \$3.6 million in FY 2011. The second policy change, required by the ACA, extends the MDH program from the end of FY 2011 to the end of FY 2012. CMS estimated this one year extension will cost about \$110 million.

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 clarifies that an approved program is one that 1) is accredited by one of several listed national organizations; or 2) leads to board certification by the American Board of Medical Specialties through an explicit board examination for the specialty involved.

CMS states that the term “approved” connotes formality: a planned structured course of study with a curriculum based on national standards with a standardized outcome based on standardized evaluations. This includes a formal application, acceptance, 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.

CMS makes a technical correction to the regulation text relating to the Accreditation Council for Graduate Medical Education (ACGME) to remove “of the American Medical Association” as ACGME is now a separate entity.

Resident or Physician. In determining whether an individual is a resident (for purposes of DGME and IME) in a training program versus a physician, CMS looks at whether the individual 1) actually needs the training in order to meet the standard

board certification requirements in that specialty; and 2) is formally participating in an organized, standardized, structured course of study.

Effective for cost reporting periods beginning on or after October 1, 2010, CMS revises the definition of resident to specify that the intern, resident or fellow, as the case may be, must be formally accepted, enrolled, and participating in an approved medical residency program (including osteopathy, dentistry and podiatry) as required in order to become certified by the appropriate specialty board. The definition of primary care resident is revised in a similar manner. CMS believes that “as required” means nationally applicable standards—not requirements determined on a case-by-case basis—and thus training only intended to enhance skills beyond the minimum required level is not part of an approved medical residency program. While CMS notes that in some cases completion of minimum training requirements may not guarantee admittance to a board examination, it relies on the national standards that boards set forth under which in most cases the minimum training requirements are sufficient.

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 clarifies that junior faculty who are not in approved residency programs or any training program will not be categorized as residents, nor will fellows in formal but nonapproved programs or those engaged in research outside the scope of any approved residency training programs.

CMS provides additional examples of the type of training activities that will not count for 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 examination.
- Individuals who have successfully completed at least one residency program and met board eligibility requirements in a specialty (regardless of whether the individuals passed board examinations for that specialty), and who participate in additional training that does not provide additional skills applicable for board certification in another subspecialty.

CMS changes its policy with respect to chief residents for cost reporting periods beginning on or after October 1, 2010. Chief residents will not be considered residents for DGME and IME purposes for periods after they have completed the accredited program and have satisfied the minimum requirements for board certification. Because chief residents in internal medicine and pediatrics do not need the training to meet board certification requirements, CMS does not consider them residents for DGME and IME purposes.

CMS also changes its policy with respect to programs operated beyond the accredited length for cost reporting periods beginning on or after October 1, 2010. CMS will not count time training in a program that extends beyond the actual

accredited length because the ACGME does not include that training as part of the accredited program. CMS previously had permitted this time to be counted if the hospital could demonstrate that the majority of participants were training for the same length of time. However, CMS notes its former position was inconsistent with that of the ACGME and changes it in this final rule.

On the issue of grandfathering subspecialty training by certain certifying boards, CMS declines to count for DGME and IME purposes individuals in training programs for which, at the time of the training, there was no ACGME accreditation or specific board certificate in the subspecialty.

With the exception of the two changes indicated above, CMS believes its policies on this issue in the final rule are the same as applied before the final rule.

CMS notes that it contemplates revising regulations at §415.202 (providing for payment under Part B of up to 80 percent of reasonable costs of services furnished by residents not in approved programs) in future rulemaking to disallow the Part B reasonable cost payment for services of any individual who has already completed one residency program, regardless of licensure status. CMS also notes it may consider in future rulemaking a recommendation to require in its regulation text that an approved program be at least one year in length.

Electronic Submission of Affiliation Agreements. CMS finalizes its proposal 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 of 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 deadline for electronic submission is 11:59 p.m. on July 1 of each academic year. However, a fiscal intermediary (FI) or MAC may continue to specify agreement submission requirements for hospitals in its servicing area.

CMS notes in response to a commenter that it intends to include a mechanism to acknowledge receipt of agreements submitted electronically. CMS will also consider commenters' suggestions to require FIs and MACs to accept electronic submission of affiliation agreements; to simplify the submission process; to ease affiliation agreement criteria; and to allow agreements to become effective on date of filing with the CMS Central Office.

CMS notes it is currently developing the electronic submission system, and, if ready in time for the July 2011-2012 academic year, CMS will notify hospitals by May 2011. CMS will continue to accept hard copies of affiliation agreement which should be sent to: Director, Division of Acute Care; Centers for Medicare and Medicaid Services; Attn: Tzvi Hefter; Mailstop C4-08-06; 7500 Security Boulevard; Baltimore, MD 21244.

Technical Correction Relating to Costs of Approved Nursing and Allied Health Education Activities. CMS corrects technical errors in regulations (§413.85(c)(2) and

§413.85(d)(1)(i)(C)), as well as in the January 12, 2001 Nursing and Allied Health Education final rule (66 FR 3371) to clarify that both inpatient and outpatient training costs for approved nursing and allied health education activities are allowable for pass-through payment. CMS notes that costs of training activities in other areas of a hospital or in nonprovider settings continue not to be allowed for pass-through payment.

Impact. CMS finds that its policy clarifications have no financial impact, and that its policy changes might have limited financial impact if hospitals previously included, but will no longer be able to include, trainees who were not formally enrolled in an approved program in FTE counts for IME and DGME purposes. CMS believes it would be rare for hospitals to have sufficient room under FTE resident caps to include any informally enrolled residents in addition to the typically enrolled residents. CMS finds the financial impact of the change in the regulatory definition of “resident” to be insignificant.

With respect to allowing the electronic submission of affiliation agreements to the CMS Central Office, CMS finds it will be helpful in tracking groups of hospitals that affiliate, as well as the numbers of FTE cap slots that are being transferred within those groups. CMS also believes electronic submission will minimize the paperwork burden for hospitals.

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 critical access hospital (CAH) incurs in connection with the services of a certified registered nurse anesthetist (CRNA). CMS points out that under existing regulations, neither CAHs or hospitals that have reclassified from urban to rural nor CAHs located in “Lugar” counties are eligible to receive pass-through payments for anesthesia services and related care furnished by non-physician anesthetists.

CMS finalizes a policy to revise existing regulations to state 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 the reasonable cost of anesthesia services and related care furnished by a non-physician anesthetist. CMS is not extending this change to hospitals located in “Lugar” counties.

J. Additional Payments for Hospitals with Lowest Per Enrollee Medicare Spending

The ACA provides additional payments totaling \$400 million for FY 2011 and FY 2012 for a qualifying hospital that is located in a county that ranks in the lowest quartile of adjusted Medicare spending per enrollee. Spending is for benefits under Parts A and B and is adjusted for age, sex and race using an approach similar to the

risk adjustment model developed for Medicare Advantage (MA) rate setting. To account for year-to-year fluctuations in expenditures, CMS actuaries used the 5-year average of each county's actual spending (from 2002 to 2006) to calculate an average geographic adjuster (AGA), which reflects the county's expenditure relative to the national expenditure. CMS then applied the AGA to the 2009 United States Per Capita Cost (USPCC) estimate, which is the national average cost per Medicare beneficiary, to determine 2009 Medicare Part A and Part B spending for each county and determine the ranking. CMS chose to use spending in 2009 because the law references allocating the \$400 million based on FY 2009 spending.

The ACA defines a qualifying hospital as a "subsection (d) hospital that is "located in" an eligible county (i.e., one which ranks in the lowest quartile of U. S. counties). Sole community and Medicare-dependent small rural hospitals (SCHs and MDHs) and Indian Health Service hospitals enrolled as Medicare providers are subsection (d) hospitals but hospitals located in Puerto Rico or the territories are not – and critical access hospitals (CAHs) also are not eligible. Hospitals and hospital units excluded from the IPPS, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals, also are not subsection (d) hospitals and therefore are excluded. The rule also states that "the hospital, as identified by the Medicare provider number or CCN, must: (1) have existed as a subsection (d) hospital as of April 1, 2010; (2) be geographically located in an eligible county; and (3) have received IPPS operating payments (in accordance with section 1886(d)) of the Act) under its Medicare provider number or CNN in FY 2009."

As required by the statute, a hospital receives the proportion of the \$400 million based on its FY 2009 IPPS operating payments made under section 1886(d) of the Act relative to the FY 2009 IPPS operating payments made to all the qualifying hospitals under section 1886(d) of the Act. CMS defined IPPS operating payments to include add-on payments for operating DSH, operating IME, operating outliers and new technology, but excluded capital PPS payments. The agency also included IME Medicare Advantage payments made to IPPS hospitals because these payments are made under section 1886(d) of the Act. CMS also included associated beneficiary liabilities (coinsurance, copayments, and deductibles) because these payments are made under section 1886(d).

Table 1 in the final rule lists 786 counties that rank in the lowest quartile of counties with respect to adjusted Medicare Part A and Part B spending per beneficiary. Of these there are only 276 counties with qualifying hospitals. Table 2 in the final rule identifies 416 qualifying IPPS hospitals. (These tables are found on pages 902-931 of the display copy of the final rule.) CMS also is publishing the final unadjusted county rates, the age-sex-race adjustments applied to the county rates, and the county rates adjusted for age-sex-race for the eligible counties that are included in the final rule on the CMS Web site at:

<http://www.cms.gov/AcuteInpatientPPS/IPPS2011/list.asp#TopOfPage>.

Based on comments received on the list of counties and hospitals, CMS has replaced two counties on the list of eligible counties. Therefore, it is soliciting public input until August 30, 2010, solely on the issue of whether there are any IPPS hospitals located in Crooks County, OR and Bottineu County, ND. CMS notes that the list of eligible counties and qualifying hospitals is otherwise finalized in this final rule. The public may submit input via email to Nisha Bhat at Nisha.Bhat@cms.hhs.gov. If CMS adds qualifying hospitals in these counties as a result of accurate notification from the public, it will publish a revised list of qualifying hospitals and their payment weighting factors on the CMS Web site identified above.

Although the law provides \$400 million for supplemental payments for FYs 2011 and 2012, CMS will distribute \$150 million for FY 2011 and \$250 million for FY 2012, as proposed. It chose to distribute a smaller amount of money for the first year, \$150 million for FY 2011, in order to give the public an opportunity to review its policy and identify possible revisions to the list of qualifying hospitals and permit adjusted payments for FY 2012. This would ensure that the agency correctly identifies qualifying hospitals and their proper payment amounts without exceeding the program's funding. The rule also stipulates that CMS will make only one determination of eligible counties and qualifying hospitals for FY 2011 and FY 2012. CMS will distribute payments through the individual hospital's Medicare contractor in an annual one-time payment during each of FY 2011 and FY 2012.

K. Rural Community Hospital Demonstration Program

The Medicare Prescription and Modernization Act of 2003 (MMA) required the establishment of a 5-year, budget neutral demonstration program to test the feasibility and advisability of establishing "rural community hospitals" to furnish covered inpatient hospital services to Medicare beneficiaries. The MMA limited the selection of participating hospitals to no more than 15 rural community hospitals in 10 states that were identified as having low population densities. Originally, 13 hospitals began participation effective October 1, 2004 (4 of these hospitals subsequently withdrew to become CAHs). CMS added 4 more hospitals effective July 1, 2008. Another 3 hospitals withdrew during CY 2009.

Rather than apply the budget neutrality adjustment to those hospitals in the demonstration program, CMS elected to apply the adjustment across aggregate IPPS payments. This was because of the very small number of rural hospitals participating in the program.

The ACA 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). In addition, those hospitals that were participating in the demonstration program on the last day of the first 5-year period would automatically continue to participate in the program unless the respective hospital elected to withdraw. The number of states was increased to 20 and the number of hospitals was increased to 30 rural community hospitals.

In order to ensure that the demonstration is budget neutral, CMS will adjust the national IPPS rates in the FY 2011 IPPS final rule to account for any added costs attributable to the demonstration. CMS estimates that the amount of the adjustment to the national IPPS rates during FY 2011 is about \$70.5 million.

L. Technical Change to Regulations

CMS finalizes correction of a technical error under paragraph (b) of section 485.610 to clarify that critical access hospitals may also be treated, for purposes of conditions 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.

M. Bundling of Payments in 3-day Payment Window

Section 102 of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111-192), enacted on June 25, 2010, revises Medicare's policy for payment of outpatient services provided during the "3-day payment window." The payment window refers to outpatient services provided on either the day of or during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) prior to a Medicare beneficiary's inpatient admission. Prior to Pub. L. 111-192, hospitals were required to include on their inpatient claims all diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary) furnished by the hospital (or by an entity that is wholly owned or wholly operated by the hospital) to the patient during the 3 days prior to the date of the patient's admission to the hospital (or 1-day prior for excluded hospitals). CMS defined "services related to the admission" as those nondiagnostic services that are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient. CMS also had clarified in April 2006 that the 3-day (or 1-day) payment window policy applies to outpatient services provided on the date of a beneficiary's admission.

Pub. L. 111-192 redefines the term "other services related to the admission" to include "all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title [Title XVIII]... (A) on the date of the patient's inpatient admission; or (B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission."

The law makes no change in the requirement to include all "diagnostic services" furnished during the payment window on the bill for the inpatient stay. Pursuant to the amendment, however, beginning June 25, 2010 all nondiagnostic services, other

than ambulance and maintenance renal dialysis services, provided on the date of a beneficiary's inpatient admission are deemed related to the admission and must be billed with the inpatient stay. In addition, outpatient nondiagnostic services, other than ambulance and maintenance renal dialysis services, provided on the first, second, and third calendar days (first calendar day for nonsubsection (d) hospitals) preceding the date of a beneficiary's admission also are deemed related to the admission and must be billed with the inpatient stay unless the hospital attests to certain nondiagnostic services as unrelated to the hospital claim. Such preadmission services, which must be clinically distinct or independent from the reason for the beneficiary's admission, should be separately billed to Medicare Part B if they are covered by Medicare Part B. CMS will establish a process (such as a condition code or modifier) for hospitals to attest to nondiagnostic services as being unrelated to the hospital claim when a hospital submits an outpatient claim. Hospitals will be required to maintain documentation in the beneficiary's medical record to support their claim that the outpatient nondiagnostic services are unrelated to the beneficiary's inpatient admission.

Pub. L. 111-192 also prohibits Medicare from reopening a claim, adjusting a claim, or making payments pursuant to any request for payment under Title XVIII that is submitted for purposes of treating as unrelated to a patient's inpatient admission, services provided during the applicable 3-day or 1-day payment window. Services affected by this prohibition are other services related to the admission which were previously included on a claim or request for payment submitted under Part A of Title XVIII for which a reopening, adjustment, or request for payment under Part B of Title XVIII, was not submitted prior to June 25, 2010 for purposes of treating, as unrelated to a patient's inpatient admission.

The amendments are effective for services furnished on or after the date of enactment, June 25, 2010. CMS waived the requirement for proposed rulemaking and has issued an interim final rule effective retroactive to June 25, 2010. Comments on the interim final rule must be filed by September 29, 2010.

CMS notes that a final rule published on February 11, 1998 defined "other services" as being "related to the admission" only when there was an exact match (for all 5 digits, if applicable) between the principal (or primary) ICD-9-CM diagnosis codes assigned for both the preadmission services and the inpatient stay. The agency observes that if hospitals, prior to the June 25, 2010 effective date of section 102 of Pub. L. 111-192, were applying the definition of "related" as adopted in that final rule, it estimates that the impact for FY 2011 would be a savings of about \$2.6 billion to Medicare Part B, and the impact on Medicare Part A would be negligible. In addition, it estimates that the impact on beneficiaries would be a savings of about \$0.5 billion for FY 2011. On the other hand, CMS says that the impact would be negligible if the policy established in 1998 was generally unknown to hospitals, as many have maintained, and the new policy under section 102(a) is more consistent with hospitals' longstanding billing practices.

N. Changes in the Inpatient Hospital Market Basket Update

The ACA reduced the FY 2010 hospital market basket update by 0.25 percentage points effective for discharges occurring on or after April 1, 2010 and also reduced the FY 2011 update by 0.25 percentage points. On May 21, 2010, CMS posted two documents for public inspection: a notice for the final FY 2010 IPPS and RY 2010 LTCH PPS rates (including the ACA market basket reduction), wage index tables and impacts; and a supplemental proposed rule to implement changes required by the ACA that affect FY 2011 IPPS and LTCH PPS payments, including the market basket reduction. Both the FY 2010 notice and the FY 2011 supplemental proposed rule were published in the *Federal Register* on June 2, 2010.

The final rule for FY 2011 adopts the policies proposed in the supplemental proposed rule without change:

- For the second half of FY 2010 (i.e., April 1 to September 30), the applicable market basket percentage update for hospitals satisfying the quality reporting requirements is the 2.1 percent market basket minus the ACA reduction of 0.25 percentage point for an update of 1.85 percent. For hospitals not satisfying the quality reporting requirements, the update is 2.0 percentage points less, or -0.15 percent. The ACA specifies that the applicable percentage increase may be less than zero.
- For FY 2011, the applicable market basket percentage update for hospitals satisfying the quality reporting requirements is the 2.6 percent market basket minus the ACA reduction of 0.25 percentage point for an update of 2.35 percent. For hospitals not satisfying the quality reporting requirements, the update is 2.0 percentage points less, or 0.35 percent. (Note that when the supplemental proposed rule was issued, the projected market basket update percentage was 2.4 percent rather than the 2.6 percent final rule percentage.)
- Because the law sets the update factor for sole community hospitals (SCHs) and Medicare-dependent small rural hospitals (MDHs) equal to the update factor for all other IPPS hospitals, the hospital specific rates for SCHs and MDHs also are subject to the ACA 0.25 percentage point reduction and the update percentages described above for FY 2010 and FY 2010 also apply to them.
- Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Since FY 2004, CMS has set the update to the Puerto Rico-specific operating standardized amount equal to the update to the national operating standardized amount for all IPPS hospitals. For FY 2011, the 0.25 percentage point reduction will apply and the update factor for the Puerto Rico-specific standardized amount is 2.6 percent minus 0.25 percentage point, or 2.35 percent.

- For FY 2010, however, CMS concluded that it lacked authority to set the FY 2010 update factor for the Puerto Rico-specific operating standardized amount for the second half of FY 2010 equal to the update factor applicable to the national standardized amount or the hospital-specific rates (that is the market basket minus 0.25 percentage point). Thus, the FY 2010 update to the Puerto Rico-specific operating standardized amount is 2.1 percent for all of FY 2010.

V. Changes to the IPPS for Capital-Related Costs

Capital Standard Rate for FY 2011. The annual update to the payment rates for capital-related costs for FY 2011 is 1.5 percent. CMS, however, is making a -2.9 percent reduction in the national capital Federal rate to partially account for documentation and coding changes that do not reflect real changes in case mix in light of the adoption of MS-DRGs (see below). This, plus the impact of other adjustments, results in an overall payment rate reduction of -2.22 percent. Thus, CMS finalized the national capital Federal rate for FY 2011 at \$420.01. The FY 2010 final capital payment rate is \$429.56.

CMS projects that in FY 2011, capital payments per case will decline about -0.5 percent across all hospitals. For urban hospitals capital payments per case are estimated to decrease -0.5 percent while capital payments per case will decline about -0.7 for rural hospitals.

Changes for FY 2011: MS-DRG Documentation and Coding Adjustment. For FY 2008 and FY 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. However, as in the case of operating IPPS standardized amounts for that year, 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 the FY 2011 IPPS/LTCH proposed rule, CMS performed a thorough retrospective evaluation of the most recent available (FY 2009) claims data, and the results of this evaluation were used by CMS actuaries to determine any necessary payment adjustments beyond the cumulative -1.5 percent previously applied. Based on this evaluation, the CMS actuaries determined that the implementation of the MS-DRG

system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. In the final rule for FY 2011, CMS adopts, as proposed, a -2.9 percent reduction in the national capital Federal rate to adjust for changes in documentation and coding. CMS notes that the -2.9 percent represents a portion of the remaining prospective adjustment of 3.9 percent that is required (5.4 percent documentation and coding effect minus the 1.5 percent adjustment already applied) and that the remaining -1.0 percent reduction will be considered during future rulemaking cycles.

Similarly, CMS analyses found that the cumulative change in documentation and coding not reflective of real CMI change is 2.6 percent for Puerto Rico hospitals. The final rule removes the full 2.6 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.

Exception Payments. The regulations provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control. The IPPS for capital-related costs was first implemented in the FY 1992 with a 10-year transition period. CMS notes that while the exception payments were first instituted during this 10-year transition period (October 1, 1991 through September 30, 2001), for eligible hospitals these exception payments are available within the subsequent 10 years following the end of the transition period.

New Hospitals. Medicare defines a "new hospital" as a hospital that has operated for less than 2 years. CMS notes that a new hospital beginning on or after October 1, 2002 would be paid 85% of its Medicare allowable capital-related through the first 2 years of operation unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate.

VI. Changes for Hospitals Excluded from the IPPS

A. Excluded Hospitals

Historically, hospitals and hospital units excluded from the IPPS receive payment on the basis of reasonable costs, subject to a rate-of-increase ceiling. Currently, payment to children's hospitals, cancer hospitals and religious non-medical health care institutions (RNHCIs) continue to be subject to the rate-of-increase ceiling based on the hospitals own historical cost experience. (Inpatient psychiatric facilities, inpatient rehabilitation facilities, and long-term care hospitals are paid under their own PPS.) Medicare will continue to use the IPPS operating market basket to update the target amounts for these providers. Based on the most current analysis, CMS will update the FY 2011 target amounts for cancer and children's hospitals and RNHCIs by 2.6 percent.

B. Critical Access Hospitals

CAH Optional Method Election for Payment of Outpatient Services. Effective for cost reporting periods beginning on or after October 1, 2010, once a CAH elects the optional outpatient payment method² (payment made to the CAH for the reasonable cost of facility services plus 115 percent of the amount otherwise payable for the professional services), including an election made for its most recent cost reporting period beginning prior to October 1, 2010, its election will remain in place until it is terminated.

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 would 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.

Changes in Payments to CAHs Made by the ACA. The ACA increases payment for outpatient facility services under the optional method and payment for ambulance services furnished by a CAH or an entity owned and operated by a CAH, from “reasonable costs” to “101 percent” of reasonable costs. Such a change was applicable to payments for services furnished during cost reporting periods beginning on or after January 1, 2004.

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 the cost of care for 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 clarifies 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

² The other CAH outpatient payment method would still pay the CAH 101 percent of its reasonable cost but would not include the physician/non-physician payment component. The physician or other practitioner would receive payment under the Medicare Physician Fee Schedule.

actually incur the entire amount of the assessed tax—subsequent reimbursement may offset some or all of the assessed tax.

CMS, in the FY 2011 IPPS final rule, affirms the policy that the Medicare contractor will continue to make a determination of whether a provider tax is allowable on a case-by-case basis.

VII. Changes to the Long-Term Care Hospital Prospective Payment System for FY 2011

Changes to the long-term care hospital prospective payment system for FY 2011 are described in a separate summary.

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 had proposed a number of regulatory changes to make it clearer when a provider has satisfied the requirements for participation in the Medicare program. These changes were proposed 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.

CMS adopts as final its proposed regulatory changes to accomplish the following (making only minor modifications in response to comments):

- 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 “surveyors” (either CMS staff or CMS contractors), as appropriate;
- 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 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.

CMS also notes, in response to comments, that:

- No changes are being made with respect to compliance reviews performed by the Office for Civil Rights (OCR) and thus there is no risk of a delay in the effective date of a provider agreement until OCR completes its review.
- New owners of existing providers or suppliers who do not accept the seller’s existing Medicare provider agreement or supplier approval and who intend to continue Medicare participation are treated as new applicants to the Medicare program and must submit to the same process as any new provider or supplier.
- In referring to the effective date of an accreditation decision by a national accrediting body, CMS is referring to the date an accreditation organization indicates its accreditation was effective (generally the date that all accreditation program requirements were met), rather than the date upon which the decision itself was issued (which may be much later).

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

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

In the proposed rule, CMS had proposed to revise the Medicare hospital conditions of participation relating to the ordering of rehabilitation and respiratory care services. First, CMS had proposed 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 hospital 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. Second, CMS had proposed 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.”

The change relating to rehabilitation services was clearly intended to allow nurse practitioners (NPs) and/or physician assistants (PAs) to order these services (provided all applicable requirements are met). However, CMS had also noted in the proposed rule 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 labeled “a conflict of interest.” In response to comments expressing concern that CMS was excluding nonphysician practitioners other than NPs and PAs (e.g., clinical nurse specialists, physical therapists, speech-language pathologists, advanced practice registered nurses, certified nurse anesthetists, and certified nurse midwives), CMS emphasizes that the regulatory language being adopted does not specifically mention any “type” of practitioner but merely requires that services be provided only under the orders of a qualified licensed practitioner, responsible for the care of the patient, acting within his or her scope of practice, and authorized by the medical staff to order the services in accordance with hospital policies and procedures and all State laws. The agency goes on to say that nothing in this requirement “would preclude a hospital rehabilitation professional from acting within the scope of practice under State law.” And while acknowledging that commenters had also expressed concern about CMS’ mention of a “conflict of interest” when discussing the ordering of rehabilitation services by rehabilitation professionals, the agency does not directly respond to these comments.

In adopting as final its two proposed changes to the hospital conditions of participation, CMS says these policies “would give hospitals and their medical staffs as much flexibility in determining which types of practitioners could order these [rehabilitation and respiratory care] services as they would choose to exercise within the constraints of their own State laws and regulations.”

Finally, CMS rejects comments asking that similar policies be adopted with respect to other hospital conditions of participation (such as nuclear medicine, dietary services, and the administration of propofol, an anesthetic induction agent) and their interpretative guidelines. The agency also rejects a comment proposing changes to require that drug administration errors, adverse drug reactions, and incompatibilities be immediately reported to the ordering practitioner. In rejecting all these comments,

CMS says that the additional, requested changes are outside the scope of the final rule or outside the purview of the rulemaking process.

In the accompanying regulatory impact analysis, CMS argues that the two changes in the hospital conditions of participation being adopted in the final rule will impose “minimal additional costs on hospitals” and that these costs “will be offset by the benefits derived from the overall intent of these changes to allow qualified, licensed practitioners, who are authorized by the medical staff, to order these [rehabilitation and respiratory care] services as long as they are responsible for the care of the patient for whom they are ordering the services and as long as such privileges are in accordance with hospital policies and applicable State laws and regulations.”

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

CMS finalizes its proposal 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 will be given a choice of approved accreditation options. A proposal to modify the regulatory language with respect to accreditation of psychiatric residential treatment facilities (PRTFs) was not finalized, but CMS says this is because the proposed change is unnecessary. CMS has decided that the existing regulatory language already permits PRTFs to seek accreditation from a variety of accrediting bodies.

XI. Appendices

A. Regulatory Impact Analysis –Table

TABLE I.--IMPACT ANALYSIS OF FINAL CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2011

	No. of Hospitals ¹	FY 2011 Weights & MSDRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
All Hospitals	3472	0.3	0	0	0	0	0	0	0	0	2.5	-0.4
By Geographic Location:												
Urban hospitals	2494	0.3	0	0	0	0	-0.2	0	0	0	2.4	-0.4
Large urban areas	1362	0.3	0	0	0	0	-0.3	0	0	0	2.4	-0.4
Other urban areas	1132	0.4	0	-0.1	-0.1	0	0	0.1	0.1	0	2.5	-0.4
Rural hospitals	978	0.4	0.1	0	0	0.1	1.7	-0.1	0	0.1	2.5	-0.4
Bed Size (Urban):												
0-99 beds	622	0.6	0.2	0.1	0.1	0.2	-0.5	0	0.1	0	2.6	-0.3
100-199 beds	785	0.2	-0.1	0	0	0	-0.1	0.2	0.1	0	2.4	-0.5
200-299 beds	460	0.3	0	0	0	0	0	0	0.1	0	2.4	-0.4
300-499 beds	430	0.3	0	0.1	0.1	0.1	-0.2	0	0.1	0	2.5	-0.4
500 or more beds	197	0.3	0	-0.1	-0.1	-0.1	-0.3	-0.1	0	0	2.5	-0.4
Bed Size (Rural):												
0-49 beds	348	0.8	0.4	0	0	0.5	0.6	-0.1	0.1	0.2	2.8	-0.1
50-99 beds	368	0.3	0	0	0	0	0.7	-0.1	0	0.1	2.2	-0.7
100-149 beds	156	0.4	0.1	0	0	0	2.3	-0.1	0	0	2.6	-0.3
150-199 beds	60	0.4	0.1	0	0	0.1	2.3	-0.1	0.1	0	2.6	-0.2
200 or more beds	46	0.1	-0.2	0.1	0.1	-0.1	2.6	-0.1	0	0	2.7	-0.2
Urban by Region:												
New England	121	0.1	-0.2	-0.5	-0.5	-0.7	0.8	0.8	0	0.2	2.2	-0.7

	No. of Hospitals ¹	FY 2011 Weights & MSDRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
Middle Atlantic	330	0.3	0.1	-0.3	-0.3	-0.2	0.3	0.2	0	0	1.9	-0.9
South Atlantic	382	0.1	-0.2	0	0	-0.2	-0.4	-0.1	0	0	2.3	-0.6
East North Central	403	0.2	-0.1	0.2	0.2	0.1	-0.3	-0.2	0	0	2.2	-0.6
East South Central	155	0.4	0.1	-0.3	-0.3	-0.1	-0.2	0	0	0	2.4	-0.5
West North Central	167	0.5	0.1	-0.1	-0.1	0	-0.7	-0.2	0.5	0	2.9	0
West South Central	336	0.5	0.2	0.2	0.2	0.3	-0.6	-0.2	0	0	2.7	-0.1
Mountain	161	0.3	-0.1	0	-0.1	-0.1	-0.4	0	0.3	0	2.6	-0.2
Pacific	389	0.6	0.2	0.5	0.5	0.6	-0.3	0.1	0	0	3.3	0.4
Puerto Rico	50	1	0.8	-0.4	-0.4	0.4	-0.8	0	0	0	2.7	-0.1
Rural by Region:												
New England	24	0.3	-0.1	0.5	0.5	0.4	2.5	-0.1	0	0	3.3	0.4
Middle Atlantic	70	0	-0.3	0.4	0.4	0.1	1.3	-0.1	0	0	1.7	-1.2
South Atlantic	165	-0.1	-0.4	-0.4	-0.5	-0.9	2	-0.1	0	0.1	1.6	-1.2
East North Central	121	0.3	0	-0.1	-0.1	-0.1	1.1	-0.1	0	0.1	1.9	-0.9
East South Central	176	0.7	0.4	0.2	0.2	0.5	2.6	-0.2	0	0.1	3.4	0.5
West North Central	100	0.8	0.4	-0.1	-0.1	0.4	0.5	0	0.1	0	2.7	-0.2
West South Central	219	0.8	0.5	0.3	0.3	0.8	2.2	-0.1	0	0.1	3.7	0.8
Mountain	72	0.8	0.4	0	0	0.4	0.4	0	0.5	0	3.2	0.3

	No. of Hospitals ¹	FY 2011 Weights & MSDRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
Pacific	31	0	-0.4	-0.1	-0.1	-0.5	1.2	-0.1	0	0	1.3	-1.6
By Payment Classification:												
Urban hospitals	2551	0.3	0	0	0	0	-0.2	0	0	0	2.4	-0.4
Large urban areas	1404	0.3	0	0	0	0	-0.3	0	0	0	2.4	-0.4
Other urban areas	1147	0.4	0	-0.1	-0.1	0	0	0.1	0.1	0	2.5	-0.4
Rural areas	921	0.4	0	0	0	0.1	1.5	-0.1	0	0.1	2.5	-0.4
Teaching Status:												
Nonteaching	2429	0.4	0.1	0.1	0.1	0.1	0.2	0	0	0	2.6	-0.3
Fewer than 100 residents	805	0.3	-0.1	0	0	-0.1	-0.1	0	0.1	0	2.4	-0.5
100 or more residents	238	0.3	0	-0.1	-0.1	-0.1	-0.2	0	0	0	2.4	-0.5
Urban DSH												
Non-DSH	779	0.5	0.1	-0.1	-0.1	0	0	0.1	0	0.1	2.5	-0.4
100 or more beds	1531	0.3	0	0	0	0	-0.2	0	0	0	2.4	-0.4
Less than 100 beds	356	0.3	0	0.1	0.1	0.1	-0.1	0	0.1	0	2.4	-0.5
Rural DSH												
SCH	423	0.4	0	0	0.1	0	2.4	-0.1	0	0	2.2	-0.7
RRC	212	0.3	-0.1	-0.3	-0.3	-0.4	1	-0.2	0	0.3	2.7	-0.2
100 or more beds	30	0.2	0.3	0	0	0.2	1.2	-0.2	0	0.4	1.7	-1.2

	No. of Hospitals ¹	FY 2011 Weights & MSDRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
Less than 100 beds	141	0.6	0	0	0	-0.1	-0.3	0	0.1	0	1.8	-1
Urban teaching and DSH:												
Both teaching and DSH	818	0.3	-0.1	-0.3	-0.3	-0.4	0.2	0.1	0	0.1	2.4	-0.5
Teaching and no DSH	161	0.3	0	0.2	0.1	0.2	0	0	0	0	2.1	-0.8
No teaching and DSH	1069	0.3	0.2	0.1	0	0.2	-0.3	0	0.1	0	2.5	-0.4
No teaching and no DSH	503	0.6	0.1	-0.1	-0.1	0.1	3.2	-0.1	0.1	0	2.8	-0.1
Special Hospital Types												
RRC	180	0.4	0	0	0	0.1	0.1	0	0.1	0	2.5	-0.4
SCH	332	0.4	0	0	0	0	0.4	-0.1	0	0.2	2.3	-0.6
MDH	194	0.3	-0.2	0	0	-0.2	0.8	0	0	0	2.1	-0.8
SCH and RRC	117	0.2	0.3	0.1	0.1	0.3	0.4	0	0	0	3	0.1
MDH and RRC	13	0.6	0	0	0	-0.1	0	0	0.1	0	2.5	-0.3
Type of Ownership												
Voluntary	1990	0.3	0.1	0.1	0.1	0.2	0	-0.1	0	0	2.4	-0.5
Proprietary	859	0.4	0	0	0	0.1	0	0	0	0	2.8	-0.1
Government	586	0.3	0	0	0	0	-0.4	-0.1	0	0	2.6	-0.3
Medicare Utilization as a Percent of Inpatient Days:												
0-25	353	0.3	0	0	0	0	-0.3	0	0.1	0	2.5	-0.3
25-50	1593	0.3	0	0	-0.1	-0.1	0.6	0	0	0	2.5	-0.4
50-65	1201	0.3	0.2	-0.2	-0.2	0.1	0.5	0.1	0	0	2.3	-0.6
Over 65	233	0.5	0	0	0	0	2	-0.1	0	0	2.5	-0.4

	No. of Hospitals ¹	FY 2011 Weights & MS DRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
FY 2011 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	773	0.3	0	0	0	0	-0.7	0	0.1	0	2.4	-0.4
Non-Reclassified Hospitals	2699	0.3	0	0	0	0	1.8	-0.1	0	0	2.5	-0.4
Urban Hospitals Reclassified	442	0.3	0	0	0	0	-0.7	0	0.1	0	2.3	-0.5
Urban Nonreclassified Hospitals, FY 2011:	2022	0.3	0	0	0	0.1	2.7	-0.1	0	0	2.5	-0.4
All Rural Hospitals Reclassified FY 2011:	331	0.3	0.1	0	0	0.2	-0.2	-0.1	0	0.2	2.8	-0.1
Rural Nonreclassified Hospitals FY 2011:	585	0.5	-0.4	-0.1	-0.1	-0.5	-0.3	0.1	0	0	2.1	-0.7
All Section 401 Reclassified Hospitals:	37	0	-0.4	-0.1	-0.1	-0.5	3.2	-0.1	0	0.1	1.8	-1

	No. of Hospitals ¹	FY 2011 Weights & MSDRG Changes ² (1)	Application of Recalibration Budget Neutrality ³ (2)	FY 2011 Wage Data ⁴ (3)	Application of Wage Budget Neutrality ⁵ (4)	Final FY 2011 MS-DRG, Relative Weights & Wage Index Changes, with Wage & Recalibration Budget Neutrality ⁶ (5)	FY 2011 MGCRB Reclassifications ⁷ (6)	Rural Floor Budget Neutrality and National Rural Floor Budget Neutrality ⁸ (7)	Application of the Frontier Wage Index ⁹ (8)	FY 2011 Out-Migration Adjustment ¹⁰ (9)	All FY 2011 Changes Prior to the CMI Adjustment (10)	All FY 2011 Changes w/CMI Adjustment (11)
Other Reclassified Hospitals (Section 1886(d)(8)(B))	63	-0.1	-0.2	-0.4	-0.4	-0.6	0.8	0.3	0.3	0	1.9	-1
Specialty Hospitals												
Cardiac specialty Hospitals	19	-0.3	0.6	0.2	0.2	0.8	-0.8	-0.2	0.2	0	3.2	0.3

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 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 0.996731, in accordance with section 1886(d)(4)(C)(iii) of the Act.

⁴ This column displays the payment impact of the update to wage index data using FY 2007 cost report data.

⁵ This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and will be calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000013.

⁶ This column displays the combined payment impact of the changes in Columns 1 through 4 and the 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 0.996744 is 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 0.991264.

⁸ This column displays the effects of the rural floor and the imputed floor, including the ACA requirement that the floor budget neutrality is at a 100 percent national level adjustment. The rural and imputed floor budget neutrality factor is 0.996641.

⁹ This column shows the impact of the new policy required under section 10324 of the ACA that hospitals located in Frontier states have a wage index no less than 1.0 beginning in FY 2011.

¹⁰ 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.

¹¹ This column shows the changes in payments from FY 2010 to FY 2011. It reflects the impact of the FY 2011 market basket update, and the reductions to the FY 2011 standardized amount due to the documentation and coding effect. The FY 2011 documentation and coding adjustment is -2.9 percent to the IPPS standardized amounts, -2.9 percent to the hospital-specific rates, and -2.6 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 changes displayed in Columns 5, 6, 7, and 8 (the changes displayed in Columns 2 and 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.