MEDICARE HOSPITAL INPATIENT OPERATING AND CAPITAL PAYMENT FISCAL YEAR 2013 FINAL RULE

SUMMARY

On August 2, 2012, the Centers for Medicare & Medicaid Services (CMS) released its final rule for federal fiscal year (FY) 2013 changes to Medicare's acute care hospital inpatient prospective payment system (IPPS) and long-term care hospital (LTCH) prospective payment system. The payment rates and policies in the final rule affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in long-term care hospitals paid under their respective prospective payment systems as well as payments for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions. The rule is scheduled for publication in the *Federal Register* on August 31, 2012 and generally is effective for hospital discharges occurring on or after October 1, 2012.

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I. PPS Rate Updates and Impact of the Final Rule

In the final rule's impact analysis representing 3,423 acute care hospitals paid under the IPPS, CMS projects that Medicare operating payments will increase about $2.45 billion in FY 2013 (or 2.3 percent) taking into account the policies and rates in the rule and all other policies affecting payment, such as the expiration of certain statutory provisions which had provided special temporary increases in payments to hospitals. FY 2013 capital payments are projected to increase an estimated $154 million (or 1.8 percent). Medicare payments to the approximately 440 LTCHs paid under the LTCH prospective payment system are projected to increase by about $92 million in FY 2013 (or 1.7 percent).

Inpatient Hospital Operating Update for FY 2013

Under the final rule, the market basket update to the standardized amounts is 1.8 percent for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR). The 1.8 percentage point increase is the net result of a hospital market basket increase equal to 2.6 percentage points, an annual multi-factor productivity (MFP) adjustment equal to -0.7 percentage points and a statutory update reduction of 0.1 percentage points. Both the annual productivity adjustment and the 0.1 percentage point reduction are required by the Affordable Care Act (ACA). The IPPS rate update applies also to the national and Puerto Rico operating standardized amounts and to the hospital-specific rates used in payment for sole community hospitals and Medicare-dependent hospitals. Hospitals that do not successfully participate in the IQR Program will receive a rate adjustment of -0.2 percent (i.e., a 2.0 percentage point reduction).

The Bureau of Labor Statistics publishes the official measure of private nonfarm business MFP; historical data on this series are available at http://www.bls.gov/mfp. Projections of the market basket increase and of MFP used for the IPPS payment updates are developed by IHS Global Insight, Inc., an economic forecasting firm, using a methodology described in the rule. More technical information on the MFP is available from BLS: http://www.bls.gov/mfp/mprtech.pdf.

The final rule increases the standardized amounts by an additional 1.0 percentage points reflecting the net documentation and coding adjustment discussed in section II.B below.

The FY 2013 update to the national standardized amounts is summarized in the table below:

FY 2013 inflation (market basket) update	2.6%
Multifactor productivity adjustment	-0.7%
Additional -0.1 percentage point update adjustment required by the ACA	-0.1%
Subtotal – payment rate inflation update	*1.8%*
Net adjustment for documentation and coding	+1.0%
Net increase in payment rates	2.8%

As discussed in discussed in section II.B below, the net documentation and coding adjustment applicable to the update of the hospital-specific rates of sole community hospitals (SCHs) is -0.5 percentage points rather than the +1.0 net percentage points adjustment applicable to the IPPS

standardized amounts. Therefore, the final rule update factor for these hospital-specific rates is 1.3 percent (which equals the 1.8 percentage point subtotal in the table above minus 0.5 percentage points for documentation and coding).

Additional Factors Affecting Payment Impact Analysis

While the FY 2013 standardized amounts increase 2.8 percent compared to FY 2012, the payment impact analysis shows aggregate payments increasing 2.3 percent. The additional factors affecting the aggregate payment impact of the final rule are summarized in the table below:

Contributing Factor	**Aggregate National Impact**
Implementation of readmissions reduction provision (described in section IV.A. below)	-0.3%
Lower SCH hospital-specific rate update (1.3% compared to 1.8% for the national standardized amounts)	-0.1%
Higher projected outlier payments in FY 2013	+0.1%
Expiration of Medicare-dependent hospital (MDH) provision	-0.2%
Implementation of frontier hospital wage index floor	+0.1%
Expiration of section 508 reclassification provision	-0.1%
Total	-0.5%

The final rule projects that actual outlier payments in FY 2012 will be about 5.0 percent compared to the 5.1 percent outlier offset. For FY 2013, CMS again applies a 5.1 percent outlier offset and it projects that payments will equal the 5.1 percent offset. Thus, compared to FY 2012, outlier payments in FY 2013 are projected to be 0.1 percentage points higher.

The final rule impact analysis shows little variation in the overall payment change by major hospital categories, as shown in the table below. Detailed impact estimates are displayed in Table I of the final rule (reproduced in the appendix to this summary).

Hospital Type	**All Final Rule Changes**
All Hospitals	2.3%
Large Urban	2.4%
Other Urban	2.6%
Rural	2.3%
Major Teaching	2.3%

Payments are shown to increase for nearly all types of hospitals, with exceptions due primarily to the expiring MDH payments. Aggregate payments decline slightly (less than a half of a percentage point) for 668 rural hospitals with fewer than 100 beds due to expiration of this provision, which alone causes about three percentage points of the loss for these small rural hospitals. Expiring MDH status also leads to aggregate reductions for 258 sole community hospitals (-0.4 percent), 296 rural disproportionate share (DSH) hospitals with fewer than 100 beds (-0.9 percent), and for the 195 former MDH hospitals (-5.1 percent). CMS also shows regional variation in the rule's

impact caused variously by the updated wage index, geographic reclassification and the rural floor. These factors contribute to an aggregate payment increase of 7.9 percent for 120 urban New England hospitals but an aggregate payment increase of only 0.9 percent and 1.2 percent for hospitals in East South Central (151 hospitals) and West South Central regions (372 hospitals) respectively.

IPPS Standardized Amounts

The final rule sets the following rates effective October 1, 2012, reflecting all adjustments to the standardized amounts including the adjustment for documentation and coding. For hospitals that fail to submit quality inpatient reporting data, the 1.8 percent market basket update is reduced by 2.0 percentage points to total -0.2 percent.

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 (1.8 Percent)		Reduced Update (-0.2 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,679.95	$1,668.81	$3,607.65	$1,636.02

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 (1.8 Percent)		Reduced Update (0.2 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,316.23	$2,032.53	$3,251.08	$1,992.59

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	$3,679.95	$1,668.81	$3,316.23	$2,032.53
Puerto Rico	$1,564.17	$954.62	$1,561.65	$957.14

TABLE 1D.— CAPITAL STANDARD FEDERAL PAYMENT RATE

	Rate
National	$425.49
Puerto Rico	$207.25

Outlier Payments and Threshold

To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS-DRG, any IME and DSH payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). The sum of these components is referred to as the outlier "fixed-loss cost threshold." To determine whether the cost of a discharge exceeds the fixed-loss cost threshold, a hospital's cost-to-charge ratio (CCR) is applied to the total covered charges billed for the case to convert the charges to estimated costs. Payments for cases with costs exceeding the fixed-loss cost threshold are then made based on a marginal cost factor, which is 80 percent of the estimated costs above the threshold.

For FY 2013, CMS continues to set the target for total outlier payments at 5.1 percent of total operating MS-DRG payments (including outlier payments). The proposed rule used the same methodology employed since FY 2009 (73 FR 48763 through 48766) to calculate a fixed-loss cost threshold consistent with the 5.1 percent target. CMS proposed an outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the MS-DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $27,425, which would be a $5,040 (or 22.5 percent) increase from the final FY 2012 outlier fixed-loss cost threshold of $22,385. Subsequently, on June 11, CMS published a correction notice because the proposed rule had calculated the proposed rule fixed-loss cost threshold using incorrect CCR adjustment factors. The correction of the error resulted in a proposed FY 2013 outlier fixed-loss cost threshold of $26,337.

Since FY 2009, the outlier fixed-loss cost threshold has varied between $20,185 and $23,140. A significant contributing factor to the large increase for the FY 2013 cost threshold was the proposed rule's 2-year charge inflation factor of 14.06 percent which CMS applied to charges in the FY 2011 MedPAR claims to compute the threshold; in comparison, the 2-year charge inflation factor applied to the FY 2010 MedPAR claims used to compute the FY 2012 final outlier fixed-loss cost threshold was 7.94 percent. The proposed rule noted concern about the large increases in both the charge inflation factor and the outlier fixed-loss cost threshold and invited public comments. It also noted that swings in the actual outlier payout – from 4.7 percent of actual total MS-DRG payments in FY 2011 to a projected (at the time of the proposed rule) 6.0 percent of actual total DRG payments in FY 2012 – suggest a potential for improving the estimation methodology to meet the 5.1 percent target. CMS welcomed public comment on ways to enhance the accuracy of the methodology.

In the final rule, CMS agrees with commenters that it had incorrectly used outdated CCRs for the proposed rule. Correcting this error, CMS determined that the proposed rule outlier fixed-loss cost threshold for FY 2013 would have been $23,630. Commenters noted that CMS had underpaid outliers in every year since FY 2003 and submitted several suggestions for improving the methodology used to set the fixed-loss cost threshold. CMS acknowledges the suggestions and indicates that it will study them for possible changes in the FY 2014 proposed rule. The final rule rejects a commenter's recommendation that CMS consider recoveries made through outlier reconciliation process in its determination of the outlier fixed-loss cost threshold; the commenter had estimated that more than $82 million had been recovered through that process.

The FY 2013 final rule uses the same methodology that CMS has used since FY 2009 to adjust the CCRs for determining the outlier fixed-loss cost threshold and calculates a final outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the MS-DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $21,821. The final rule threshold is $1,089 less than the revised corrected proposed threshold amount ($23,630) due to a reduction in the charge inflation factor from 14.06 percent in the proposed rule to 8.94 percent in the final rule, recalculated for the final rule using the most recent data available.

As proposed, the final rule does not include the hospital VBP payment adjustment and the readmissions payment adjustment in the outlier threshold calculation or the outlier offset to the standardized amount consistent with CMS' definition of the base operating DRG payment amount for these programs. Outlier payments will be calculated based on the unadjusted base DRG payment amount (as opposed to using the operating base DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment). Note, however, that CMS includes both of these adjustments in total operating DRG payments for the purpose of determining budget neutrality of the IPPS.

II. Changes to MS-DRG Classifications and Relative Weights

A. MS-DRGs for FY 2013

For FY 2013, CMS continues to use the Medicare severity diagnosis-related group (MS-DRG) classification system. Changes in specific MS-DRGs are described in section II.E. below. For a detailed description of the process used to develop the MS-DRGs, CMS refers readers to the FY 2010 final rule (published in the *Federal Register* at 74 FR 43764 through 43766), the FY 2011 final rule (75 FR 50053 through 50055), and the FY 2012 final rule (76 FR 51485 through 51487).

B. FY 2013 Documentation and Coding Adjustment

The FY 2013 final rule continues the process of documentation and coding adjustments begun in FY 2007 when the transition to MS-DRGs began. Under this process, CMS makes adjustments in the standardized amounts to the extent it estimates that increases in the average case-mix index (CMI) are due to improved medical record documentation and more complete and accurate coding that do not reflect real increases in the severity of cases requiring additional hospital resources. Past adjustments have been made both to eliminate the effects of documentation and coding changes on future payments and to recoup overpayments made in FY 2008 and FY 2009 as a result of documentation and coding improvements.

FY 2012 final rule adjustments to the standardized amounts. In the FY 2012 final rule, CMS applied a prospective adjustment of -2.0 percent, a reduction of 1.15 percentage points compared to the proposed rule level -3.15 percent which it had included in the proposed rule. Applying a prospective adjustment of -2.0 percent in FY 2012 left a remaining prospective of adjustment of -1.9 percent to be applied in the future. The table below summarizes the FY 2012 adjustments for documentation and coding.

Final Rule, FY 2012 MS-DRG Documentation and Coding Adjustment (Operating Standardized Amounts)

Required Prospective Adjustment for FYs 2008-2009	Remaining Required Recoupment Adjustment for FYs 2008-2009	Total Remaining Adjustment	Prospective Adjustment for FY 2012	Recoupment Adjustment to FY 2012 Payments	Remaining Prospective Adjustment
-3.90%	-2.9%	-6.8%	-2.0%	-2.9%	-1.9%

FY 2013 proposed rule adjustments to the standardized amounts. For FY 2013, CMS proposed to complete the prospective portion of the statutorily required adjustment by applying a -1.9 percent adjustment to the standardized amount for FY 2013. This adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix from FY 2008 and FY 2009, as estimated by CMS.

Following a similar analysis to the analyses applied in previous years' rulemaking to examine CMI changes in FY 2008 and FY 2009, CMS analyzed CMI changes in FY 2010 for the FY 2013 proposed rule. The analysis showed an estimated increase in documentation and coding-related CMI of 0.8 percentage points in FY 2010. To eliminate the effect of coding or classification changes that do not reflect real changes in case-mix, the proposed rule applied a prospective adjustment of -0.8 percent to the standardized amounts. As shown in the table below, the proposed FY 2013 adjustment equaled -1.90 percentage points plus -0.80 percentage points for a total adjustment of -2.70 percentage points. The proposed rule also removed the FY 2012 one-time recoupment adjustment of 2.90 percentage points resulting in a net documentation and coding adjustment for the FY 2013 proposed rule of 0.2 percentage points.

Proposed Rule, FY 2013 MS-DRG Documentation and Coding Adjustment (Operating Standardized Amounts)

	Remaining Prospective Adjustment for 2008-2009	Prospective Adjustment for FY 2010	Proposed Prospective Adjustment for FY 2013	Removal of Onetime Recoupment Adjustment in FY 2013	Combined Proposed Documentation & Coding Adjustment for FY 2013
Level of Adjustments	-1.9%	-0.8%	-2.7%	2.9%	0.2%

With respect to hospital-specific rates, in the FY 2012 final rule CMS applied a prospective documentation and coding adjustment of -2.0 percent leaving an additional -0.5 percent adjustment to the hospital-specific payment rates to complete prospective adjustments required to

remove CMS' estimate of the documentation and coding-related changes in FY 2008 and FY 2009. In past rulemaking, CMS had determined that a -5.4 percent adjustment was required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. For FY 2011, an adjustment of -2.9 percent was made. For FY 2013, CMS proposed to apply the remaining -0.5 percent adjustment necessary to complete removal of the FY 2008 and FY 2009 CMI effects as well as to apply an additional adjustment of -0.8 percentage points to remove the FY 2010 documentation and coding-related effect discussed above.

For FY 2013, CMS determined, as it had for FY 2012, that no further adjustment was needed to correct the Puerto-Rico specific rate for FY 2013 for CMI changes in FY 2008, FY 2009 and FY 2010. CMS made an adjustment of -2.6 percent for FY 2011, which CMS estimates is the entire adjustment required to eliminate the effects of documentation and coding changes on future payment under the Puerto Rico rate.

FY 2013 final rule adjustments to the standardized amounts. The final rule applies a -1.9 percentage point adjustment to the FY 2013 standardized amounts, as proposed, to complete the prospective portion of the statutorily required adjustments for case-mix changes in FY 2008 and FY 2009 that did not reflect real increases in case mix. The FY 2013 standardized amounts also increase 2.9 percentage points to restore the one-time recoupment adjustment.

Commenters continue to disagree with the CMS analysis, believing that it overstates the extent of documentation and coding-related case-mix increase. They cited a MedPAC analysis suggesting that "negative documentation and coding" may have occurred using the previous CMS-DRGs, creating an overestimation of documentation and coding due to the introduction of MS-DRGs. MedPAC estimated that the magnitude of this effect could reach 0.36 percent in FY 2008, 0.36 percent in FY 2009, and 0.25 percent in FY 2010. CMS had responded to these findings previously, stating that the MedPAC point could not be corroborated with any specific examples or analysis. Commenters further stated that if MedPAC's estimates are true, hospitals are due an additional +0.72 percent adjustment to account for overestimated recoupment (as well as similar positive adjustments to the hospital-specific and Puerto Rico-specific rate).

Commenters provided several specific examples of changes in documentation and coding that may have decreased the CMI under the CMS-DRGs and contribute to an over-estimate of documentation and coding-related change: atrial fibrillation; chronic blood loss anemia; mitral valve disorder; and aortic valve disorder. For example, after 10 years in which the proportion of IPPS cases that included atrial fibrillation as a secondary diagnosis increased each year, the proportion decreased by 20 percent immediately upon implementation of the MS-DRGs in FY 2008. Commenters argue that the decrease in coding of atrial fibrillation (and the other cited conditions) causes the CMI as measured by the FY 2007 DRG Grouper to go down and, since this is the base against which CMIs under MS-DRGs are compared, results in an over-estimate of documentation and coding effects.

CMS responds that it disagrees with commenters but acknowledges that the methodological issues raised are complex and may merit further consideration. Therefore, the agency does not finalize the proposed -0.8 percent prospective adjustment for FY 2010 case-mix change to the FY 2013

standardized amounts until more analysis is completed. The table below summarizes the FY 2013 adjustments.

	Remaining Prospective Adjustment for 2008-2009	**Prospective Adjustment to Account for FY 2010**	**Prospective Adjustment Applied in FY 2013**	**Removal of Onetime Recoupment Adjustment in FY 2013**	**Combined Documentation & Coding Adjustment for FY 2013**
Level of Adjustments	-1.9%	-0. 0%	-1.9%	+2.9%	+1.0%

Similarly, the remaining -0.5 percentage point adjustment for case-mix change in FYs 2008-2009 is applied to the hospital-specific rate in FY 2013 but the proposed -0.8 percent prospective adjustment for FY 2010 case-mix change is not applied.

C. Refinement of the MS-DRG Relative Weight Calculation

The cost of each MS-DRG is determined from hospitals claims and cost report data using national cost-to-charge ratios (CCRs) for 15 cost centers to convert billed charges to costs. The final IPPS rules for FY 2007 (71 FR 47882) and FY 2008 (72 FR 47199) describe the details of the cost-based weight calculation methodology and the FY 2013 final rule includes a summary of the methodology, with a table showing the lines on the cost report and the corresponding revenue codes used to create the 15 national cost center CCRs (pp. 297-308 of display copy).

The FY 2013 proposed rule again addressed the issue of charge compression affecting the level of charges billed for high cost services and the accuracy of costs determined for these services. CMS did not, however, propose to use the refined cost data available from new cost centers established for Implantable Devices Charged to Patients, CT, MRI, and Cardiac Catheterization through the cost report changes made in recent years. Although CMS had anticipated being able to consider FY 2010 cost report data for Implantable Devices Charged to Patients in calculating relative weights for FY 2013, the proposed rule reported that technical difficulties with the cost report data (noted in section II.F. below) precluded use of the new cost center data even though FY 2010 HCRIS includes these data for a sizeable number of hospitals.

CMS reported a compounding problem; the corresponding information regarding charges for implantable devices on hospital claims is not yet available in the MedPAR file. Missing a breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, CMS proposed to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices.

The proposed rule stated that CMS may have the necessary data to create distinct CCRs for supplies and implantable devices in FY 2014 when it also hopes to be able to consider creating distinct CCRs for MRI, CT scans, and cardiac catheterization using data from the new cost centers for these services. Any changes would be made after thorough analysis and through rulemaking.

Commenters were concerned about the continued delays in the utilization of the new cost center data for "Implantable Devices Charged to Patients" and stated that such delays only prolong the

payment inaccuracies associated with charge compression. Some comments included detailed suggestions for short-term fixes to account for the lack of data and to create a CCR for implantable devices. Other commenters requested that the FY 2013 IPPS final rule include an action plan to assure availability of the necessary data and its use for calculating MS-DRG relative weights for FY 2014.

CMS responded that it would be inappropriate to finalize a specific CCR for implantable devices charged to patients for FY 2013 using one of the short-term fixes without an opportunity for the public to review and comment. CMS expresses optimism that it will have the necessary data for FY 2014 rulemaking to consider using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. It says that if additional delays are encountered, the agency will consider informing stakeholders and hosting a national conference call to consider alternative solutions for establishing additional CCRs.

Commenters expressed continued concern about the accuracy of establishing new CT and MRI cost centers using cost report and claims data because, they stated, a large portion of the capital costs for CT and MRI equipment may have been allocated across the entire hospital, rather than to the radiology cost center, which would result in the understatement of costs of CT and MRI reported in the radiology cost center. The final rule reiterates long-standing Medicare policy that CT and MRI equipment are 'major moveable equipment' and not a building cost or a building equipment cost. According to the rule, hospitals with accounting systems that include the cost of CT scanning and MRI equipment in the 'Capital Related Costs –Building and Fixtures' cost center should correct their cost reporting practices to come into compliance with CMS' longstanding policy – and they *"should do so soon."*

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). Thus, the case will be paid as though the secondary diagnosis was not present. The selected HACs that CMS determines, in consultation with the Center for Disease Control and Prevention (CDC), are conditions that: (1) are high cost, high volume or both, (2) would result in the assignment of a case to a MS-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. Under CMS' policy, Medicare does not pay at the higher complication or comorbidity (CC) or major complication or comorbidity (MCC) amount when a selected HAC diagnosis code is reported with a POA indicator of "N" (condition not present on admission) or "U" (documentation is insufficient to determine if condition was present on admission). HACs coded with a POA indicator of "Y" (condition was present on admission) or "W" (hospital has determined that based on data and clinical judgment it is not possible to document when the onset of the condition occurred) are considered POA and the condition can cause an increase in payment at the CC/MCC level.

In the final rule, CMS notes that effective January 1, 2011, hospitals using the new 5010 format (Version 5010 of the electronic transaction standards) no longer need to report a POA indicator of "1" for codes exempt from POA reporting (the field should be left blank). For claims that

continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of "1" is still required.

CMS translated the current ICD-9-CM HAC list into codes using the ICD-10-CM and ICD-10-PCS classification system. The translation list is available on the CMS Web site: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html. CMS continues to encourages comments on these translations through the HACs Web page using the CMS ICD-10-CM/PCS HAC Translation Feedback Mailbox under the Related Links section titled "CMS HAC Feedback." CMS will subject the final HAC translation list to formal rulemaking.

Changes to the HAC Policy for FY 2013

a. *Additional Diagnosis Codes to Existing HACs*. **CMS finalizes its proposal to add two diagnosis codes, 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter), to the Vascular Catheter-Associated Infection HAC Category for discharges occurring on or after October 1, 2012.**

Several commenters supported the addition of these two codes. A State program commented that they use these codes in a statewide HAC payment incentive program.

Some commenters opposed the addition of these two codes and also urged CMS to remove the one existing HAC code (999.31) in the Vascular Catheter-Association Infection HAC category. Commenters were concerned that hospitals could be "penalized twice" by having the same measure as a HAC as well as a quality measure (i.e. central line associated bloodstream infection, CLABSI). CMS states that the HAC-POA Program is part of an array of tools used to promote increased quality and efficiency of care. Because of their importance, CMS states it is appropriate to include HACs in the multiple tools used to measure quality of services provided and to determine payment adjustments. Since under the IPPS hospitals have an incentive to treat patients efficiently and avoid unnecessary costs, such as the costs associated with complications, CMS does not consider this an example of "penalizing a hospital twice."

One commenter supported the addition of diagnosis code 993.32 (Bloodstream infection due to central venous catheter) but did not believe that diagnosis code 993.33 (Local infection due to central venous catheter) should be included in the HAC category. The commenter did not think infections related to the soft tissues should be included in the HAC category for central blood infections. The commenter also recommended that CMS publish data analyses for the Vascular Catheter-Associated Infection HAC category. In response, CMS notes that the correct title of the HAC category is Vascular Catheter-Associated Infection; therefore, the category is not restricted to catheter-associated central blood infections and would include the patient with a central venous catheter who subsequently developed an infection due to the presence of the catheter. CMS believes that local infections resulting from a central venous catheter are also important and deserve surveillance and prevention efforts. CMS also notes that they have provided results for each selected condition within each HAC category beginning with FY 2009 data analysis presented in FY 2011; the information for years FY 2009 through FY 2011 are on the following website: http://www.rti.org/reports/cms.

b. *New Candidate HAC Condition: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures*. **CMS modifies its proposal to add SSI Following CIED Procedures as a HAC condition and finalizes that SSI Following CIED Procedures is a sub-HAC condition within the SSI HAC category subject to the HAC payment provision for discharges occurring on or after October 1, 2012.**

The majority of commenters supported the addition of this condition. A State program commented that they use this condition and the proposed ICD-9-CM codes in a statewide HAC payment incentive program.

Several commenters raised concerns that the inclusion of SSI Following CIED Procedures as a HAC candidate does not meet the statutory conditions of section 1886(d)(4)(D) of the Act because the incidence of these conditions does not meet the high-volume criterion and therefore, should not be included as a HAC. CMS notes that the Act specifies that a condition on the HAC list may be high-volume or high-cost or both; a condition that is only high-cost would meet this statutory criterion. As discussed in the proposed rule, the average cost per case of SSI Following CIED Procedures is $51,795 which would meet the high-cost criterion. CMS also notes that while 859 cases of SSI Following CIED Procedures during FY 2011 may seem like a small number of cases, CMS had similar numbers for HACs, such as in FY 2008, where there were 764 cases of an object left in during surgery reported as a secondary diagnosis.

Some commenters were opposed to the SSI Following CIED Procedures becoming a HAC because they believed that this HAC selection "will result in hospitals dedicating time and effort to avoiding this extremely low-incidence adverse event (when resources could have been devoted to more highly prevalent safety concerns)." CMS notes that SSIs are an established HAC category and that a similar concern had been identified by public commenters in prior rule making. In the FY 2008 IPPS final rule with comment period (72 FR 47213), SSIs were identified as a broad category for consideration. Because coding of SSIs with only ICD-9-CM code 998.59 (Other postoperative infection) did not meet the statutory criteria of being able to uniquely identify SSIs, CMS finalized only one SSI, mediastinitis after coronary artery bypass graft surgery and asked for public input to identify additional specific SSIs. In FY 2009, additional specific SSIs were added and at that time a commenter provided information supporting a recommendation adding SSI following implantation of cardiac devices as a HAC. In the FY 2009 final rule, CMS noted that they expected to propose SSI following certain cardiac device procedures as future candidates. In response to these comments, CMS modified their proposal so that, instead of a new HAC category for this procedure, they finalized a new subcategory under SSIs: HAC 9D, SSI Following Cardiac Implantation.

Some commenters also raised the concern that the addition of this HAC would "put hospitals at risk of being penalized twice for the same event." As discussed above, CMS disagrees.

CMS finalizes its proposal to identify the condition by using a subset of discharges with ICD-9-CM diagnosis code 996.61 (Infection and inflammatory reaction due to cardiac device, implant and graft) or 998.59 (Other postoperative infection) that also have one or more of a specified list of 21 ICD-9-CM procedure codes associated with CIED procedures (see table below). Some commenters opposed the use of administrative/claims data and the use of a combination of codes

because this did not provide precise identification of hospital-associated infections (HAIs) and did not provide information in a timely manner to provide effective treatment. CMS agrees with these comments. They state, however, the statute established a payment policy which is implemented on a per claim basis by adjusting the MS-DRG assignment and requires that the conditions on the HAC list must be identifiable through ICD-9-CM codes. CMS notes this payment policy was not intended to provide information in a timely manner to impact patient treatment.

c. *New Candidate HAC Condition: Iatrogenic Pneumothorax with Venous Catherization.* **CMS finalizes its proposal to add Iatrogenic Pneumothorax with Venous Catherization as a condition subject to the HAC payment provision for discharges on or after October 1, 2012.**

Some commenters supported this proposal because it aligns with and encourages use of "widely recognized" guidelines based on research evidence, including an AHRQ published report. Commenters also listed additional supporting guidelines such as guidance from the CDC, the American College of Emergency Physicians and the 2012 practice guidelines from the American Society of Anesthesiologists. A few commenters stated that even when evidence-based guidelines are followed, the occurrence rates for many conditions on the HAC list cannot be reduced to "zero or near zero". CMS agrees that it may be difficult to reduce the incidence of conditions to zero but that the incidence of conditions on the HAC list can be significantly reduced in cases where evidence-based guidelines for the prevention of the condition exist and are used. Some commenters expressed concerns that there was not enough evidence to demonstrate that ultrasound guidance, required for the procedure, is used in small community medical centers and is often impossible to use in trauma cases. CMS believes that in applying evidence-based guidelines, hospitals will have appropriately trained hospital personnel. It also notes that the lesser paying MS-DRG is not assigned when additional nonselected CC/MCCs also appear on a claim and that trauma cases may likely involve additional nonselected CC/MCCs.

A few commenters recommended that CMS add exclusion criteria and exclusion codes. CMS notes that by limiting this condition to include Iatrogenic Pneumothorax only in the context of venous catherization, they have improved the ability to accurately identify cases and that no further exclusion criteria are needed. They note that this condition is indexed to ICD-9-CM 512.1, Iatrogenic pneumothorax, and that this would not include the codes for spontaneous pneumothorax because a spontaneous pneumothorax is not a complication of medical intervention and therefore it is not iatrogenic.

Some commenters also raised the concern that the addition of this HAC would "put hospitals at risk of being penalized twice for the same event." As discussed above, CMS disagrees. As with SSI Following CIED Procedures, some commenters also opposed the inclusion of Iatrogenic Pneumothorax with Venous Catherization as a HAC candidate condition because they did not believe this proposal is high-volume; CMS notes that this condition is high-cost and high-volume with analysis showing 4,467 cases and an average cost of $39,128.

A few commenters expressed concern that this HAC may lead providers toward using alternative sites for central line placement, such as internal jugular or femoral veins, that are less prone to pneumothorax, but carry increased risk of mechanical and infectious complications. CMS notes that this HAC condition will apply to patients who have iatrogenic pneumothorax as

a complication of a catheter in the jugular vein. It also disagrees that hospitals will consider alternative, suboptimal sites for central venous access because of this addition to the HAC list.

The table below reflects the current HAC categories, with the additions and changes summarized above identified in italics.

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	999.60 (CC) 999.61 (CC) 999.62 (CC) 999.63 (CC) 999.69 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Other Injuries	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
Vascular Catheter Associated Infection	999.31 (CC) *999.32 (CC)* *999.33 (CC)*
Manifestations of Poor Glycemic Control - Diabetic Ketoacidosis - Nonketotic Hyperosmolar Coma - Hypoglycemic Coma - Secondary Diabetes with Ketoacidosis - Secondary Diabetes with Hyperosmolarity	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, 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 - Spine - Neck - Shoulder - Elbow	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 (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures	*996.61(CC)* *998.59(CC)* *And one of the following procedure co* *00.50-00.54, 37.80-37.83, 37.85-37.87, 37.94, 37.96, 37.98, 37.74-37.77, 37.79, or 37.89*
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures - Total Knee Replacement - Hip Replacement	415.11 (MCC) 415.13 (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
Iatrogenic Pneumothorax with Venous Catherization	*512.1(CC) with procedure code 38.93*

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

Year	Savings In Millions
FY 2013	$24
FY 2014	$26
FY 2015	$28
FY 2016	$30
FY 2017	$33

Research Triangle Incorporated (RTI) Program Evaluation Summary

CMS uses the final rule to summarize some of the findings of an ongoing evaluation of the HAC-POA policies being conducted by RTI. Additional details of RTI's analysis of the FY2011 MedPAR data file for the HAC-POA program evaluation can be found at the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html and the RTI Web site at http://www.rti.org/reports/cms.

Using MedPAR claims data from October 2010 through September 2011, RTI found a total of approximately 89.3 million secondary diagnoses across approximately 8.94 million diagnoses. The chart below shows the distribution of these secondary diagnoses by POA indicator. As

noted on the chart, 77.57 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		8,941,507	
Total Number of Secondary Diagnoses Across Total Discharges		89,252,194	100.00
POA	**Indicator Description**		
Y	Condition present on admission	69,231,189	77.57
W	Status cannot be clinically determined	21,796	0.02
N	Condition not present on admission	5,748,769	6.44
U	Documentation not adequate to determine if condition was present on admission	207,258	0.23
1	Exempted ICD-9-CM code	14,043,182	15.73

Source: RTI Analysis of MedPAR IPPS Claims, October 2010 through September 2011.

RTI also evaluated POA indicator reporting for specific HAC-associated secondary diagnoses and the results of this analysis are shown in the following chart.

CHART B.—POA STATUS OF CURRENT HACS: OCTOBER 2010 THROUGH SEPTEMBER 2011

Selected HAC	Frequency as a Secondary Diagnosis	Not Present on Admission				Present on Admission			
		POA = N		POA = U		POA = Y		POA = W	
		No.	Percent	No.	Percent	No.	Percent	No.	Percent
1. Foreign Object Retained After Surgery (CC)	606	283	46.7	1	0.2	321	53.0	1	0.2
2. Air Embolism (MCC)	45	34	75.6	0	0.0	11	24.4	0	0.0
3. Blood Incompatibility (CC)	22	10	45.5	1	4.5	11	50.0	0	0.0
4. Pressure Ulcer Stages III & IV (MCC)	102,172	1,742	1.7	75	0.1	100,328	98.2	27	0.0
5. Falls and Trauma (MCC & CC)	181,157	4,738	2.6	510	0.3	175,831	97.1	78	0.0
6. Catheter-Associated UTI (CC)	16,807	3,906	23.2	32	0.2	12,835	76.4	34	0.2
7. Vascular Catheter-Associated Infection (CC)	11,324	5,910	52.2	25	0.2	5,366	47.4	23	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.	Percent	No.	Percent	No.	Percent	No.	Percent
8. Poor Glycemic Control (MCC)	15,360	612	4.0	7	0.0	14,734	95.9	7	0.0
9A. Surgical Site Infection Mediastinitis CABG (CC)	58	50	86.2	0	0.0	8	13.8	0	0.0
9B. Surgical Site Infection Following Certain Orthopedic Procedures (CC)	356	247	69.4	0	0.0	109	30.6	0	0.0
9C. Surgical Site Infection Following Bariatric Surgery for Obesity (CC)	25	24	96.0	0	0.0	1	4.0	0	0.0
10. Pulmonary Embolism & DVT Orthopedic (MCC)	3,368	2,715	80.6	20	0.6	611	18.1	22	0.7
Total *	331,300	20,271	6.1	671	0.2	310,166	93.6	192	0.1

* More than one HAC-associated diagnosis code can be reported per discharge; therefore, frequency of HAC-associated diagnosis codes may be more than the actual number of discharges that have a HAC-associated diagnosis code reported as a secondary diagnosis.

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

RTI's analyses also yield the following findings:

- Of the total 287,993 discharges with a HAC-associated diagnosis as a secondary diagnosis, 19,839 discharges (6.54 percent) were HACs reported with a POA indicator of "N" or "U" that were identified as a HAC discharge. Of these 19,839 discharges, the number of discharges resulting in MS-DRG reassignments was 3,006 (15.96 percent). (See Chart C in final rule for detailed information.)

- RTI found 207 cases in which at least two different HAC categories were reported on the same discharge. (See Chart D in the final rule for detailed information.)

- A total of 16,833 discharges did not have a change in MS-DRG assignment, regardless of the presence of a HAC. 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 (12,335 cases); (2) the relevant MS-DRG is subdivided solely by the presence or absence of an MC and the HAC does not impact MS-DRG assignment (1,922 cases); (3) the MS- DRG is not subdivided by severity levels (2,570 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 (6 cases). (See Chart E in the final rule for detailed information.)

- The estimated net savings of current HACs, based on MedPAR claims from the 12-month period of October 2010 through September 2011, were roughly $19.4 million ($6,478 per discharge), with most of the savings associated with the following HAC categories: Falls and Trauma ($7.4 million), Pulmonary Embolism & DVT Orthopedic ($8.3 million) and Pressure Ulcer Stages III & IV ($1.85 million). (See Chart F in the final rule for detailed information.)

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

Finally, RTI found a total of 219,397 discharges with at least one of 7 previously considered candidate HACs (including clostridium difficile-associated disease and ventilator-associated pneumonia) reported as a secondary diagnosis. Of those, 60,025 discharges were reported with a POA indicator of "N" or "U" and 3,544 discharges could have resulted in MS-DRG reassignments. (See Charts H and I in the final rule for detailed information.) However, CMS says these findings do not provide additional information that would require the agency to change its determinations regarding current HACs, new HACs for FY 2013, and previously considered candidate HACs.

E. Changes to Specific DRG Classifications

CMS received a number of public comments regarding MS-DRG issues that were outside the scope of the proposals included in the FY 2013 proposed rule and is not addressing them in this final rule. CMS will consider these comments for possible proposals in future rulemaking.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Ventricular Assist Devices (VADs): CMS received a request to restructure MS-DRGs 001 (Heart Transplant or Implant of Heart Assist System with MCC) and 002 (Heart Transplant or Implant of Heart Assist System without MCC) by removing all of the procedure codes that describe the insertion of a VAD, leaving only procedure codes 33.6 (Combined heart-lung transplantation) and 37.51 (Heart transplantation) in the heart transplant DRGs and to create new MS-DRGs for the remaining device codes. **CMS is finalizing its proposal not to make any changes to the structure of MS-DRG's 001 and 002.**

Several commenters agreed with CMS' proposal. In response to a commenter's concern about the potential problem for beneficiary access to VAD implantations and heart transplants, CMS plans to continue to monitor these MS-DRGs as additional VADs come into the market and technologies change.

b. Allogenic Bone Marrow Transplant: During the comment period for the FY 2012 IPPS proposed rule, CMS received a comment recommending that MS-DRG 014 be subdivided into two MS-DRGs based on related and unrelated transplant donor source. **CMS is finalizing its proposal not to make any changes to MS-DRG 014.** Several commenters agreed with CMS' proposal.

2. MDC 4 (Diseases and Disorders of the Respiratory System)

Influenza with Pneumonia: CMS received a request during the comment period for the FY 2012 IPPS proposed rule related to reassignment of cases with a combined diagnosis of influenza and pneumonia that was not addressed because CMS considered it out of the scope of the FY 2012 proposed rule. **CMS is finalizing its proposal to reassign cases with a principal diagnosis code 487.0 (Influenza with pneumonia) and an additional secondary diagnosis code of one of the following pneumonia codes listed as a secondary diagnosis code from MS-DRGs 193, 194, and 195 to MS-DRGs 177, 178, and 179: 482.0, 482.1, 482.40 – 482.42, 482.49, 482.81 – 482.84, and 482.89**. Several commenters agreed with CMS' proposal.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair with Implant: CMS received a request to reassign procedure code 35.97 (Percutaneous mitral valve repair with implant) from MS-DRGs that involve percutaneous cardiovascular procedures to a set of MS-DRGs for cardiac valve and other major cardiothoracic procedures, MS-DRGs 216 - 221). **CMS is finalizing its proposal not to reassign procedure code 35.97.**

Several commenters supported the reassignment request. A number of commenters recommended that CMS reassign code 35.97 to MS-DRGs 216, 217, and 218 because percutaneous mitral valve repair offers an alternative to open surgery and is used in high risk patients. Commenters also stated the procedure requires a team approach, is complex and has a lengthy procedure time. In response, CMS reiterates that the claims data do not support reassigning this procedure. Although the costs of the percutaneous mitral valve implantations are more than the average for MS-DRGs

250 and 251, the volume is low, and it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. CMS' clinical advisors also supported not reassigning percutaneous mitral valve repairs.

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta: CMS received a request to reassign procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) that was created for use beginning October 1, 2011 from MS-DRGs 252 - 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) because the clinical coherence and consumption of resources were more similar to the major cardiovascular procedures. Upon further review and consideration of comments, **CMS is finalizing reassignment of procedure code 39.78 from MS-DRGs 252 - 254 to MS-DRGs 237 and 238.**

Many commenters agreed or did not have any specific objection to CMS' proposal not to reassign the procedure code. Numerous commenters representing various professional organizations and devices manufacturers disagreed and stated that the assignment for procedure code 39.78 was not clinically correct. Commenters noted that the implantation of fenestrated grafts is more similar, from a clinical and resource perspective, to the other endovascular graft procedures within MS-DRGs 237 and 238 than it is to the vascular procedures assigned to MS-DRGs 252 - 254. CMS agrees with these commenters.

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

Disorders of Porphyrin Metabolism: CMS received a request to create a new MS-DRG for cases reporting a principal diagnosis of 277.1 (Disorders of porphyrin metabolism) instead of the current assigned MS-DRG 642 (Inborn and Other Disorders of Metabolism). **CMS is finalizing its proposal not to create a new MS-DRG or to reassign cases reporting a principal diagnosis code of 277.1.** They will continue to monitor this issue and determine how to better account for the variation in resource utilization for these cases.

Several commenters agreed with the request. Two commenters, representing organizations dedicated to disorders of porphyrin metabolism expressed concern that CMS' proposal would negatively impact beneficiary access to necessary treatments. CMS disagrees with the comments and notes that it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs.

5. Proposed 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.

a. Length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more: **CMS is finalizing its proposal to make a change to the MCE edits to include the creation of a new edit for procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) when reported on a claim with a length of stay less than 4 days.** A change request with instructions will be issued prior to the implementation date.

Commenters urged CMS to reconsider the proposed new edit. Several commenters agreed with the concept of the edit but expressed concern about the associated administrative burden for hospitals. CMS believes that recent programming enhancements will eliminate the concern regarding additional administrative burden.

b. Sleeve Gastrectomy Procedure for Morbid Obesity: Effective June 27, 2012 CMS revised their coverage for this procedure and the noncovered procedure edit for procedure code 43.82 (Laproscopic vertical (sleeve) gastrectomy) is no longer valid and is being removed from the MCE for FY 2013. A change request will be issued prior to October 1, 2012.

6. 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 2013, CMS is finalizing its proposal to not make any changes to the surgical hierarchy for the Pre-MDCs and MDCs for FY 2013. Several commenters agreed with CMS' proposal.

7. Complications or Comorbidity (CC) Exclusions List

The CC Exclusions List: (1) precludes coding of CCs for closely related conditions; (2) precludes duplicative or inconsistent coding from being treated as CCs; and (3) ensures that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. **For FY 2013, CMS is finalizing its proposal not to make any revisions to the CC Exclusion list.**

Suggested Changes to the MS-DRG Severity Levels for Diagnosis Codes for FY 2013

a. *Protein-Calorie Malnutrition:* CMS received a request to change the severity level for three protein-calorie nutrition diagnosis codes: 263.0 (Malnutrition of moderate degree), 263.1 (Malnutrition of mild degree), and 263.9 (Unspecified protein-calorie malnutrition). Specifically, the request was to change the severity level for diagnosis codes 263.0 and 263.1 from a non-CC to a CC and change the severity level for diagnosis code 263.9 from a CC to a non-CC. **CMS is finalizing its proposal for FY 2013 to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC. CMS is**

finalizing its proposal not to make any change to the severity level for diagnosis code 263.9. Several commenters agreed with CMS' proposal.

b. *Antineoplastic Chemotherapy Induced Anemia:* CMS received a request to change the severity level for diagnosis code 285.3 (Antineoplastic chemotherapy induced anemia) from a non-CC to a CC. **CMS is finalizing its proposal not to make any changes to the severity level for this diagnosis code.** Several commenters agreed with CMS' proposal.

c. *Cardiomyopathy and Congestive Heart Failure, Unspecified:* CMS received a request to change the severity level for diagnosis code 428.0 (Congestive heart failure, unspecified) from a non-CC to a CC. **CMS is finalizing its proposal not to make any changes to the severity level for this code.** Several commenters supported this proposal.

d. *Chronic Total Occlusion of Artery of the Extremities:* CMS received a request to change the severity level for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) from a non-CC to a CC. **CMS is finalizing its proposal not to change the severity level for diagnosis code 440.4 from a non-CC to a CC.** Several commenters agreed with CMS' proposal. One commenter stated that the additional time, intensity of work and resources justified the proposed increase in severity level.

e. *Acute Kidney Failure with Other Specified Pathological Lesion in Kidney:* CMS received a request to change the MCC severity level for diagnosis code 584.8 (Acute kidney failure with other specified pathological lesion in kidney). **CMS is finalizing its proposal to change the severity level of this diagnosis code from a MCC to a CC.** Several commenters agreed with CMS' proposal. One commenter opposed the proposal because the downgrade would penalize hospitals willing to take on sicker patients because additional care is required to treat patients with this condition. CMS responds that their clinical analysis and claims data support the change. In addition, CMS does not agree that this change will hurt hospitals.

f. *Pressure Ulcer, Unstageable:* CMS received a request to change the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from a non-CC to a MCC. **CMS is finalizing its proposal not to make any change.** Several commenters agreed with CMS' proposal. Some commenters noted that the National Pressure Ulcer Advisory Panel defines unstageable pressure ulcers as at least a stage III pressure ulcer and would meet the definition of an MCC. CMS' clinical advisors recommend that unstageable pressure ulcers should be classified as a non-CC because the stage is not clearly designated as a stage III or IV.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the CMS Web site at: http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

8. 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 2013, CMS is finalizing its decision not to make any changes to the procedures assigned among these MS-DRGs. CMS did not receive any public comments on their proposal.

9. Proposed 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 proposed rule (CMS-0040-P) published on April 17, 2012 would delay the implementation of the ICD-10 coding system applicable to hospital inpatient services from October 1, 2013 to October 1, 2014. The comment period for this proposed rule closed on May 17, 2012.

a. ICD-9-CM Coding System: For FY 2013, there were no changes to the ICD-9-CM coding system due to the partial code freeze because of the planned implementation of the ICD-10 coding system on October 1, 2013. Consequently, there are no new, revised, or deleted diagnosis and procedure codes.

b. Code Freeze: In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule, there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes. After multiple public meetings and opportunities for public comment, CMS announced at the September 15-16, 2010 and September 13, 2011 ICD-9-CM Coordination and Maintenance Committee meetings that a partial freeze of both ICD-9-CM and ICD-10 codes would be implemented as follows:

- The last regular annual update to both ICD-9-CM and ICD-10 code sets was on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD-9-CM and ICD-10 code sets to capture new technology and new diseases.
- On October 1, 2013, there will be only limited code updates to ICD-10 code sets to capture new technology and diagnosis. There were to be no updates to the ICD-9-CM, as the system would no longer be a HIPAA standard. With the proposed ICD-10 implementation delay, there would be only limited codes updates to both ICD-9-CM and ICD-10 to capture new technology and new diagnoses on October 1, 2013.

- On October 1, 2014, regular updates to ICD-10 were to begin. If the compliance date of ICD-10 is delayed from October 1, 2013 to October 1, 2014, there would be only limited ICD-10 code updates to capture new technology and diagnosis. There would be no updates to ICD-9-CM on October 1, 2014, as the system will no longer be a HIPAA standard. Full ICD-10 updates would begin on October 1, 2015, one year after the implementation of ICD-10.

Several commenters expressed concern about the delay and some commenters supported a delay. CMS notes that proposals on ICD-10 implementation are being addressed as part of a separate rulemaking at which time these comments will be addressed.

CMS notes the ICD-9-CM Coordination and Maintenance Committee will continue to meet twice a year.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims: CMS will continue to process up to 25 diagnosis codes and 25 procedure codes when received in the 5010 format.

d. ICD-10 MS-DRGs: CMS plans to post the final version of the ICD-10 MS-DRGs which will be subject to notice and comment rulemaking. They will provide updated information on this activity through the ICD-9-CM Coordination and Maintenance Committee.

During FY 2012, CMS finalized the ICD-10 MSG-DRGs Version 29.0 and posted a Definitions Manual of ICD-10 MS-DRGs Version 29.0 on the CMS ICD-10 MS-DRG Web site. CMS also posted a paper , "Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments" on the CMS web site at http://www.cms.goc/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp.

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 2013 final rule, CMS used two data sources:

- FY 2011 MedPAR data for discharges occurring on October 1, 2009, through September 30, 2010, based on bills received by CMS through March 31, 2012, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which is under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2011 MedPAR file used in calculating the proposed relative weights includes data for approximately 10.8 million Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from the analysis. The data also exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken; and

- Medicare cost report data files from HCRIS, principally for FY 2010 cost reporting periods (that is, cost reporting periods beginning on or after October 1, 2009, and before October 1, 2010). FY 2010, which precedes the start of FY 2013 by three years, typically would represent the most recent full set of cost report data available. CMS found, however, that

cost reports in the FY 2010 HCRIS database with fiscal year start dates that are on or after May 1, 2010, and before October 1, 2010, are not accessible because they were filed on the new cost report Form 2552-10, and cost reports filed on Form 2552-10 are not currently accessible in the HCRIS. To assure adequate data for calculating the relative weights, CMS finalizes its proposal to calculate the FY 2013 MS-DRG relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of October 1, 2009 through May 1, 2010, and to backfill with data from FY 2009 cost reports for those providers that have fiscal year begin dates of May 1, 2010 through September 30, 2010. CMS used cost report data for the March 31, 2012 update of the HCRIS for FY 2009 and FY 2010 in calculating the final FY 2013 relative cost-based weights.

Adhering to the process used to calculate the weights for FY 2012, charges were converted to costs using national average CCRs. The resulting 15 national average CCRs used for the FY 2013 final rule are shown in the table below (for comparison, the FY 2012 final rule CCRs also are shown):

Group	**CCR FY 2012 Final Rule**	**CCR FY 2013 Final Rule**
Routine Days	0.539	0.514
Intensive Days	0.473	0.442
Drugs	0.202	0.199
Supplies & Equipment	0.345	0.335
Therapy Services	0.403	0.370
Laboratory	0.155	0.143
Operating Room	0.272	0.238
Cardiology	0.169	0.145
Radiology	0.152	0.136
Emergency Room	0.263	0.226
Blood and Blood Products	0.415	0.389
Other Services	0.416	0.397
Labor & Delivery	0.470	0.450
Inhalation Therapy	0.200	0.189
Anesthesia	0.128	0.109

The new cost-based relative weights were normalized by an adjustment factor of 1.5916044904 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 does not increase or decrease total payments under the IPPS, as required by the statute.

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. CMS first determines whether a medical service or technology meets the newness criteria before making a determination about cost and substantial clinical improvements.

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 in the FY 2012 IPPS/LTCH PPS final rule contains the final thresholds that were used to evaluate applications for new technology add-on payments for FY 2013
(http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp - TopOfPage).

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

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

For an approved new technology, if the costs of the discharge (determined by applying cost to charge ratios) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case

including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology. Add-on payments for new medical services or technologies for FY 2005 and later years are not subject to budget neutrality.

Applicants for add-on payments for new medical services or technologies for FY 2014 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.

CMS received public comments on the proposed rule relating to topics such as marginal cost factors for new technology add-on payments and the use of external data in determining the cost threshold and mapping new technologies to the appropriate MS-DRG. Because it did not request public comments nor propose to make any changes to these issues, CMS is not summarizing nor responding to these comments.

2. FY 2013 Status of Technologies Approved for FY 2012 Add-On Payments

AutoLaser Interstitial Thermal Therapy (AutoLITT™) System: AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. **CMS considers the AutoLITT™ to be new for FY 2013 and will continue to make new technology add-on payments for the AutoLITT™ in FY 2013.**

In the proposed rule, CMS noted that in "close proximity" to publication of the proposed rule, the manufacturer provided information on the delayed market release of the product and CMS anticipated receiving further information on the delayed market release date from the manufacturer. The manufacturer's comments provided additional information demonstrating that the AutoLITT™ was first available on May 11, 2010. The manufacturer explained that because some of the sterile disposable products were not released from quarantine until May 11, 2010 the technology was not actually introduced to the market in December 2009 and that the first time the AutoLITT™ was available on the market was May 11, 2010. This date would make the AutoLITT™ eligible for new technology add-on payments in FY 2013 because the 3-year anniversary date of AutoLITT™ would take place in the latter half of the FY. Several additional commenters also recommended extending the new technology add-on payments for the AutoLITT™ in FY 2013.

CMS agrees, stating that its practice is to begin and end new technology add-on payments on the basis of a fiscal year following a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether or not to extend the new technology add-on

payment for an additional fiscal year. In general, it extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

3. FY 2013 Applications for New Technology Add-On Payments

CMS received six applications for new technology add-on payments for FY 2013; two applicants withdrew their applications prior to the publication of the proposed rule.

a. Glucarpidase (Trade Brand Voraxaze®): BTG International, Inc. submitted an application for the new technology add-on payments for Glucarpidase for FY 2013. Glucarpidase is used in the treatment of toxic methotrexate (MTX) concentrations as a result of renal impairment and causes a rapid and sustained reduction of toxic MTX concentrations. **CMS finalizes that Voraxaze® meets all three criteria for new technology add-on payments and is eligible for these payments in FY 2013.** Cases of Voraxaze® will be identified with ICD-9-CM procedure code 00.95 (Injection or infusion of glucarpidase). The cost of Voraxaze® is $22,500 per vial. Since the applicant stated that an average of four vials is used per Medicare beneficiary, the average cost per case for Voraxaze® is $90,000. Because new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS-DRG payment for the case, the maximum new technology add-on payment for Voraxaze® is $45,000 per case.

Newness Criterion

Voraxaze® is an orphan drug that received FDA approval on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment using Voraxaze® as an investigational drug and, since 2007, the company has been authorized to recover the costs of making Voraxaze® available through its expanded access program. In the proposed rule, CMS raised concerns that Voraxaze® may no longer be considered "new". Although it generally believes that the newness period begins on the date that FDA approval is granted, which for Voraxaze® was January 2012, it noted that the applicant has been authorized to recover certain costs of making Voraxaze® available through its expanded access program since 2007 and expressed concerns that the cost of the drug was already reflected within the MS-DRG relative weights.

The applicant's comments documented that Voraxaze® was approved by the FDA in January 2012 and that marketing of the drug did not begin until April 2012. They also commented that the FDA's Office of Prescription Drug Promotion (OPDP) considers a product new from the point of initial marketing and promotion and that the FDA recognizes a time delay between approval and commercial availability as standard in the pharmaceutical industry. Several public commenters supported that Voraxaze® should be considered new for the purposes of the new technology add-on payment. CMS states, in general, its policy is to begin the newness period on the date of FDA approval/clearance or, if later, the date of market availability. Since availability under the expanded access program neither represents the date of FDA approval nor the date of market availability, it considers Voraxaze® to be "new" as of April 30, 2012, the date of market availability.

Cost Criterion
The applicant submitted public comments supporting that Voraxaze® met the cost criterion including the fact that the commercial costs of Voraxaze® are not reflected in the MS-DRG relative weights and that hospitals were not allowed to submit for reimbursement of Voraxaze® because it was an investigational drug. Further, if hospitals attempted to submit for reimbursement, the cost recovery price was substantially lower than the commercial price and the data used to determine MS-DRG relative weights would not capture a price difference and would largely underestimate the cost of Voraxaze®. Several public commenters also supported that Voraxaze® met the cost criteria. CMS agrees.

Substantial Clinical Improvement Criterion
The application's submitted public comments stated that Voraxaze® met the substantial clinical benefit criterion because the FDA approved the biological licenses application for the drug on an accelerated timeline and that this happens when a "high unmet need exists and when an applicant has a product that may qualify as a substantial clinical improvement". Several other public comments also provided support demonstrating that Voraxaze® meets the substantial clinical improvement criteria.

CMS agrees that Voraxaze® represents a substantial clinical improvement for Medicare beneficiaries; it is less time intensive and allows select patient populations to avoid risk associated with current treatment options. CMS notes however, that they remain interested in seeing clinical endpoints that show that reduction in MTX levels lead to improved renal function.

b. DIFICID™ (Fidaxomicin) Tablets: Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for DIFICID™ (Fidaxomicin) for FY 2013. According to the company, Fidaxomicin is a major clinical advancement in treatment of *Clostridium difficile-associated diarrhea* (CDAD). As indicated on the labeling submitted to the FDA, Fidaxomicin is taken twice a day as a daily dosage as an oral antibiotic. **CMS finalizes that DIFICID™ meets all three criteria for new technology add-on payments and is eligible for these payments in FY 2013.** Cases of DIFICID™ will be identified with ICD-9-CM procedure code 008.45 in combination with NDC code 52015-0080-01; CMS will issue final guidance about how to code the NDC code on the 837i Health Care Claim Institutional form. The average cost per day for DIFICID™ is $280 and, based on CMS' determination that an average does within the inpatient setting is 6.2 days, CMS calculates an average cost per case for DIFICID™ of $1,736. Since new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS-DRG payment for the case, the maximum new technology add-on payment for DIFICID™ is $868.

Newness criterion
Fidaxomicin was approved by the FDA on May 27, 2011 for the treatment of CDAD in adult patients, 18 years of age and older, and was commercially available on the market within 7 weeks after the FDA approval was granted. In the proposed rule, CMS noted there are not any ICD-9-CM diagnosis or procedure codes that exist to uniquely identify the use of Fidaxomicin, or any oral drug, as a procedure. CMS discussed that under its current new technology add-on payment policy, eligibility for consideration for new technology add-on payments is limited to

new technologies associated with procedures described by ICD-9-CM codes. CMS established the framework for this policy in the FY 2002 IPPS final rule (66 FR 46907 through 46915). Accordingly, CMS did not consider drugs that are only taken orally to be eligible for consideration for new technology add-on payments, because there is no procedure code associated with these drugs, and therefore, no ICD-9-CM code(s).

A number of commenters, including the applicant, stated that the technology meets the newness criterion and discussed various issues including the statutory authority for the policy in relation to coding of oral therapies and coding options for this new technology. In response to comments, CMS notes that under its current policy, eligibility for new technology add-on payments is limited to new technologies associated with procedure codes described by ICD-9-CM codes (77 FR 27939). CMS agrees, however, that the statute does not preclude new technology add-on payments for oral medications that have no inpatient procedure, i.e. an infusion, when the oral medication meets the other aspects of the newness criterion in addition to meeting the cost and substantial clinical improvement criteria. **In the final rule, CMS is revising its policy to allow for the use of an alternative code set for the purposes of new technology add-on payments to identify oral medications where no inpatient procedure is associated. It is establishing the use of NDCs as the alternative code set for this purpose, effective for payments for discharges occurring on or after October 1, 2012.** CMS states that oral medications for which no inpatient procedure is associated may be considered self-administered drugs under Part B and are not payable under the OPPS and reminds hospitals that they may not include services that are not payable under the OPPS within the 3 days prior to and on the day of inpatient admission as part of the inpatient claim.

Cost Criterion

The applicant submitted public comments supporting that DIFICID™ meets the cost criterion and addressed the concerns that CMS raised in the proposed rule. In its comments, the applicant noted that although it determined an average use of DIFICID™ is 6.2 days within the inpatient setting based on a sample of 116 claims, it recommended that CMS consider 6.5 days for inpatient administration of DIFICID™. CMS agrees that the sample of claims the applicant submitted supports the average use of DIFICID™ within the inpatient setting but believes it is appropriate to use an estimate of 6.2 days rather than the 6.5 days the applicant recommended. CMS states that the applicant can submit additional data for FY 2014.

Substantial Clinical Improvement Criterion

The applicant's submitted public comments addressed the concerns that CMS raised in the proposed rule. The applicant noted that DIFICID™ is the only agent proven to provide a superior sustained clinical response versus Vancomycin and it they had demonstrated the low potential for patients to develop resistance to DIFICID™. Several other public comments provided support demonstrating that DIFICID™ meets the substantial clinical improvement criteria. After reviewing the evidence and the comments, CMS agrees that DIFICID™ represents a substantial clinical improvement over existing technologies.

c. Zilver® PTX® Drug Eluting Stent: Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. This technology is used for the treatment of peripheral artery disease (PAD) of superficial

femoral arteries (SFA). The applicant indicates that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel (Paclitaxel is approved for use as an anticancer drug and for use with coronary artery stents to reduce the risk of renarrowing of the coronary arteries after the stenting procedure). **Because the Zilver® PTX® has not yet received FDA approval it does not meet the newness criterion and is not eligible for the IPPS new technology add-on payments for FY 2013**.

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft: Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated AAA Endovascular Grant (Zenith® F. Graft) for FY 2013. This technology is an implantable device designed to treat patients with an AAA and that are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The Zenith® F. Graft is custom-made for each patient and is a modular system consisting of three components. **CMS finalizes that Zenith® F. Graft meets all three criteria for new technology add-on payments and is eligible for these payments in FY 2013.** Cases of Zenith® F. Graft will be identified with ICD-9-CM procedure 39.78. CMS calculates the total maximum cost for the Zenith® F. Graft as $16,343. Since new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS-DRG payment for the case, the maximum new technology add-on payment for Zenith® F. Graft is $8,171.50.

Newness Criterion

Because the Zenith® F. Graft was approved by FDA on April 4, 2012, CMS believes the technology meets the newness criterion. CMS did not receive any public comment about this criterion.

Cost Criterion

The applicant submitted multiple analyses of the FY 2010 MedPAR data and CMS believes that they addressed the concerns raised in the proposed rule. CMS notes that in the application, the total cost of the Zenith® F. Graft utilizing bare metal (renal) alignment stents was $17,264 and that this included $921 for components that are used in a standard Zenith AAA Endovascular Graft procedure. Because the costs for these components are already reflected within the MS-DRGs, CMS does not believe it is appropriate to include them in the determination of the maximum cost for the add-on payment for the Zenith® F. Graft and subtracted these costs in making its determination.

Substantial Clinical Improvement Criterion

The applicant's submitted public comments addressed the concerns that CMS raised in the proposed rule. The applicant cited the FDA indications of the device and noted that while the application referred to medical management, they did not intend to suggest that medical management was a reasonable alternative treatment option for AAAs at heightened risk of rupture. The applicant noted that they assumed that medical management had already been maximized and some type of surgical intervention was necessary. In response to CMS' concerns that the studies conducted were not randomized, the applicant commented that a randomized trial was not conducted because it was anticipated that the clinical trial conducted for FDA registration would primarily enroll high risk patients in whom open surgical repair would present

an unacceptably high risk of operative mortality and that this precluded a randomized study design.

After reviewing the evidence and the comments, CMS agrees that the Zenith® F. Graft represents a substantial clinical improvement over existing technologies because it offers a treatment option to a patient population that would otherwise require an open procedure or a treatment option to those patients who are ineligible for an open procedure.

4. Regulatory Impact Analysis

Section 1886(d)(5)(K) of the Act does not require add-on payments for new technology to be budget neutral.

In FY 2013, CMS is continuing to make new technology add-on payments for AutoLITT™. Based on the applicant's estimate from FY 2011, CMS currently estimates that the new technology add-on payments for the AutoLITT™ will increase overall FY 2013 payments by $900,000.

In FY 2013, CMS is approving three new technology add-on payments and estimates that the total increase in FY 2013 payments due to the new technology add-on payment is $46,125,534. For Voraxaze®, for FY 2013, the applicant estimates that approximately 140 Medicare beneficiaries will be eligible for this treatment and CMS estimates that new technology add-on payments for Voraxaze® will increase overall FY 2013 payments by $6,300,000. For DIFICID™, for FY 2013, the applicant estimates that approximately 40,138 Medicare beneficiaries will be eligible for this treatment and CMS estimates that new technology add-on payments for DIFICID™ will increase overall FY 2013 payments by $34,839,784. For Zenith® F. Graft, for FY 2013, the applicant estimates that approximately 500 Medicare beneficiaries will be eligible for this new technology and CMS estimates that the new technology add-on payments for Zenith® F. Graft will increase overall FY 2013 payments by $4,085,750.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Reports on the Medicare Wage Index. Please see section IX below for a description of the reports proposing wage index methodology reforms, and associated comments and responses.

B. Core-Based Statistical Areas for the Hospital Wage Index

CMS will use the same labor market areas in FY 2013 that it used for the FY 2012 wage index because OMB will not announce before CY 2013 new area delineations based on the OMB 2010 standards and 2010 census data.

C. Worksheet S-3 Wage Data

The FY 2013 wage index values are based on data from FY 2009 submitted cost reports, and include categories of costs paid under the IPPS (and outpatient costs) for salaries and hours from short term, acute care hospitals, home office costs and hours, contract labor costs and hours (including direct and certain indirect patient care, pharmacy, lab, and nonteaching physician Part

A services), and wage related costs (including pension costs). Consistent with the FY 2012 wage index methodology, excluded categories of costs are direct and overhead salaries and hours for services not subject to IPPS payment (e.g., SNF and home health services), hospital-based RHCs and FQHCs, and CAHs. CMS uses the data to calculate wage indices for other providers of services as well as for prospective payments to IRFs, IPFs, and LTCHs but notes that comments for wage indices applicable to IRFs and IPFs should be made in response to those separate proposed rules.

The FY 2013 wage index calculation is based on data from 3,447 hospitals; CMS excludes 34 providers due to excessively aberrant data. CMS includes data from IPPS hospitals in 2009 even if they terminated program participation as hospitals, but excludes data from CAHs and IPPS hospitals that converted to CAH status, 6 in this instance. For a multicampus hospital, CMS uses the same methodology as it did for the FY 2012 wage index to allot wages and hours data among the different labor market areas where the campuses are located. Table 2, available from the CMS website, includes separate wage data for multicampus hospitals.

D. Method to Compute FY 2013 Unadjusted Wage Index

Using the same methodology employed to calculate the unadjusted FY 2012 wage index, CMS calculates a national average hourly wage, unadjusted for occupational mix, of $37.4855 ($15.8643 for Puerto Rico). CMS uses the employment cost index (ECI) as its data source for wages, salaries and other price proxies in the IPPS market basket. The factors used to adjust a hospital's data were based on the midpoint of the applicable cost reporting period, as shown in the table on pages 421 and 422 of the display copy.

E. Occupational Mix Adjustment for the FY 2013 Wage Index

Again using the same methodology employed to calculate the occupational mix adjustment factor for the FY 2012 wage index, the final FY 2013 occupational mix-adjusted national average hourly wage is $37.4608; the FY 2013 occupational mix-adjusted Puerto Rico-specific average hourly wage is $15.9019.

The Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. The FY 2013 hospital wage index is based on data collected on the new 2010 Medicare Wage Index Occupational Mix Survey. Additionally, hospitals that fail to submit this data are required, effective with the 2010 survey, to explain why the data were not submitted; CMS appears to be considering penalties for hospitals that fail to submit this data.

As it did for FY 2012, CMS applies the occupational mix adjustment to 100 percent of the FY 2013 wage index. The FY 2013 national average hourly wages for each occupational mix nursing subcategory are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wag
National RN	$37.43580
National LPN and Surgical Technician	$21.77974
National Nurse Aide, Orderly, and Attendant	$15.33436
National Medical Assistant	$17.23252
National Nurse Category	$31.85257

The FY 2013 wage index values are included in Tables 4A, 4B, 4C, and 4F of the Addendum to the final rule (available on the CMS website), and include the national rural and imputed floor budget neutrality adjustments as well as the outmigration adjustment for eligible hospitals. Tables 3A (urban areas) and 3B (rural areas) list the 3-year average hour wage for each labor market area before hospital redesignation or reclassification based on FYs 2007 through 2009 cost reporting periods.

CMS observes that, based on its analysis of the occupational mix data, the national percentage of hospital employees in the nurse category is slightly more than 43 percent, and that the wage index values for FY 2013 will increase for 70.8 percent of rural areas and for slightly more than half of urban areas.

Rural Floor. 454 hospitals will receive an increase in their FY 2013 wage index due to the application of the rural floor. Commenters opposed the rural floor national budget neutrality adjustment which benefits hospitals in certain areas (such as Massachusetts) at the expense of hospitals across the nation; CMS responds that the requirement is statutory.

CMS projects that, in aggregate, rural hospitals will experience a 0.3 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.2 percent increase in payments; and urban hospitals in the New England region can expect a 3.6 percent increase in payments primarily, due to the application of the rural floor in Massachusetts. CMS expects that all 60 urban providers in Massachusetts will receive a rural floor wage index value, including rural floor budget neutrality, of 1.3047 and will receive approximately a 5.7 percent increase in IPPS payments due to the application of the rural floor.

Imputed Floor. CMS finalizes its proposal to create an alternative, temporary imputed floor methodology for the benefit of Rhode Island (which has only one CBSA) for FY 2013. CMS rejects a suggestion to continue the policy for three fiscal years. Thus, the lowest post-reclassified wage index assigned to a hospital in Rhode Island will be increased by a factor equal to the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (absent rural floor budget neutrality). Four hospitals in Rhode Island would benefit from the alternative temporary methodology; CMS estimates an additional $2.5 million in payments in FY 2013. All 29 hospitals in New Jersey will receive an increase in their FY 2013 wage index from the previously established temporary methodology. CMS estimates an aggregate increase in payments of roughly $29 million in FY 2013. CMS

plans to evaluate any further need for the imputed floor policy and will address those issues in the FY 2014 proposed rule.

Frontier Floor. Montana, North Dakota, South Dakota, and Wyoming will receive the frontier floor value of 1.0000. Nevada, which qualifies as a frontier State, will receive its higher rural floor value of 1.0256 in lieu of the frontier floor. Overall, CMS estimates an increase of approximately $69 million in IPPS operating payments in FY 2013 by reason of the frontier floor; the frontier floor adjustments are not budget neutral.

F. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

193 hospitals were approved for wage index reclassifications for FY 2013 by the Medicare Geographic Classification Review Board (MGCRB), and, because such reclassifications are effective for 3 years, a total of 663 hospitals are in a reclassification status for FY 2013 (including those initially approved by the MGCRB for FY 2011 and FY 2012). Applications for FY 2014 reclassifications are due to the MGCRB by September 4, 2012 which is also the deadline for canceling a previous wage index reclassification withdrawal or termination. Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process are incorporated in the final FY 2013 wage index values.

The final rule notes that a "Lugar" hospital may apply to the MGCRB to reclassify to a different area; could have compared the impact of any such reclassification in Table 4C of the proposed rule; and had 45 days from the date of publication of the proposed rule to withdraw from an MGCRB reclassification. Additionally, an eligible hospital that waives its Lugar status to receive the rural wage index in addition to the out-migration adjustment is treated as rural for all purposes (including for the rural DSH adjustment) for each fiscal year for which it receives the out-migration adjustment. A Lugar hospital may submit a single, written notice to automatically waive its deemed urban status for the 3-year period of the out-migration adjustment, though the hospital is permitted before its second or third year of eligibility to notify CMS in writing to return to its deemed urban status.

Section 508 hospital reclassifications expired at the end of March 2012; thus, the FY 2013 wage index does not reflect any section 508 reclassifications or special exception wage indices.

Given the expiration of the MDH program, commenters asked CMS to permit hospitals to revisit any geographic reclassification decisions that could impact their ability to participate in the MDH program were it to be extended by Congress. CMS declines to do so and indicates that in the event of legislation extending the program, it would address specific issues at that time.

G. FY 2013 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

Table 4J (available from the CMS Web site) lists the out-migration wage index adjustments for FY 2013. CMS uses the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment, and it estimates increased payments of approximately $53 million for 287 providers receiving the out-migration adjustment in FY 2013.

H. Process for Requests for Wage Index Data Correction

CMS reiterates the process and deadlines by which a hospital may submit to its fiscal intermediary or Medicare Administrative Contractor (FI/MAC) requests to change or revise wage index data for FY 2013. June 4, 2012 was a hospital's last opportunity to request a correction to an error the hospital determines was made after review of the CMS final wage index data public use files (made available in early May 2012). CMS reiterates that it will only make a change to wage and occupational mix data under very limited circumstances, namely that 1) the error was made by the FI/MAC or CMS; and 2) the hospital could not have known about the error before its review of the final wage index data files. A hospital that can meet these two requirements should have sent a letter to both its FI/MAC and CMS explaining the error and providing full documentation to support its claim, including when it became aware of the error.

Date/Deadline	Wage Index Data Related Action
October 4, 2011	Preliminary unaudited wage data and occupational mix survey data available on CMS Web site
December 5, 2011	Deadline to submit corrections with detailed explanation to FI/MAC for desk review
Mid-February 2012	FI/MAC notifies hospitals of any changes due to desk review and submits revised data to CMS
February 21, 2012	CMS publishes proposed wage index public use files, including hospital revised wage index data
March 5, 2012	Deadline to submit to FI/MAC request for reconsideration of adjustment made by FI/MAC due to desk review
April 11, 2012	Deadline for FI/MAC to transmit additional revisions due to hospital reconsideration request
April 18, 2012	Deadline for hospital to seek CMS intervention where hospital disagrees with FI/MAC policy interpretation
Early May, 2012	CMS to release final wage index data public use files: only purpose for review is to identify potential CMS or FI/MAC errors in the entry of final wage index data from the correction process (e.g., revisions submitted to CMS by FI/MACs by April 11, 2012)
June 4, 2012	Deadline for receipt of hospital letters to FI/MAC and CMS describing and explaining erroneous wage or occupational mix data (with supporting information)

Verified corrections that were timely received by CMS are incorporated in the final wage index and are effective October 1, 2012. Hospitals that failed to meet the procedural timelines may not appeal to the PRRB any CMS failure to make the requested data revision. However, CMS does reserve the right (but no obligation) to make mid-year corrections to errors that hospitals bring to its attention after the June 4, 2012 deadline under limited circumstances as follows: 1) the FI/MAC or CMS erred in tabulating its data; and 2) the hospital could not have known about the error, or could not have had an opportunity to correct the error, by the June 4 deadline. If a mid-year correction changes the wage index value for an area, the revised wage index is effective prospectively from the correction date.

CMS will only under very limited circumstances make wage index value changes retroactive to the beginning of the fiscal year involved, as follows: 1) the FI/MAC or CMS erred in tabulating data; 2) the hospital knew and requested a correction before June 4; and 3) CMS agreed that the error was made and should be corrected. However, this does not apply for a hospital that seeks to revise another hospital's data; further, the correction may not be used to revise a prior fiscal year's wage index data. CMS notes that there is retroactive effect where a judicial decision reverses a CMS denial of a hospital's wage index revision request.

I. Labor-Related Share for the FY 2013 Wage Index

As proposed, CMS continues to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012 (the same labor-related share used in FY 2012). Tables 1A and 1B in section VI. of the final rule Addendum reflect this labor-related share. Also as proposed, CMS applies the wage index to the labor related-share of 62 percent of the national standardized amount for hospitals with wage indices less than 1.0000 and 68.8 percent of the national standardized amount for hospitals with wage indices greater than 1.0000. CMS does not make any further changes to the national average proportion of operating costs attributable to wages and salaries, fringe benefits, contract labor, other labor-related services, etc.

For Puerto Rico hospitals, CMS continues to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2012. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 percent or 62 percent, whichever results in higher payments to the hospital. Table 1C published in section VI. of the final rule Addendum reflects the Puerto Rico labor-related share of 62.1 percent.

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

A. Hospital Readmissions Reduction Program

Beginning October 1, 2012, IPPS payments are reduced for Medicare PPS hospitals with risk-adjusted readmissions exceeding an expected level in three conditions selected by CMS as required by the statute. For FY 2013, CMS uses three NQF-endorsed, risk-standardized hospital readmission measures that are currently in the IQR program: Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF #0505); Heart Failure 30-Day Risk Standardized Readmission Measure (NQF #0330); and Pneumonia 30-day Risk Standardized Readmission Measure (NQF #0506). The measures, as endorsed by the NQF, include a 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions.

CMS chose to develop and promulgate implementing regulations for the hospital readmissions reduction program over 2 years, FY 2012 and FY 2013. CMS established definitions and polices in several areas in the FY 2012 IPPS final rule:

- Selection of applicable conditions;
- Definition of "readmission;"
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the excess readmission ratio;

- Definition of "applicable period;"
- Index hospitalizations;
- Risk adjustment;
- Risk standardized readmission rate;
- Data sources; and
- Exclusion of certain readmissions.

The policies are summarized in this final rule along with a discussion of additional comments received by CMS on the finalized policies and CMS' responses to them, a few of which are noted later in this summary. CMS does not make any changes in the FY 2013 final rule in response to these additional comments but it indicates that it will consider them in the future. (See pp. 460-484 of the display copy of the final rule for a discussion of the policies established in FY 2012.)

The FY 2013 proposed and final regulations set policies related to the payment adjustment and other issues:

(i) Base operating DRG payment amounts, including policies for SCHs and MDHs;
(ii) Adjustment factor (both the ratio and the floor adjustment factor);
(iii) Aggregate payments for excess readmissions and aggregate payments for all discharges;
(iv) Applicable hospital;
(v) Limitations on review; and
(vi) Reporting of hospital-specific information, including the process for hospitals to review and submit corrections.

In future years' rulemaking, CMS plans to expand the list of applicable conditions beyond the initial 3 conditions and add 4 conditions that have been identified by MedPAC for the Program.

Provisions in the FY 2013 Regulations. The readmissions reduction program determines the "excess readmission ratio" for each selected clinical condition (such as heart failure). As finalized in the FY 2012 rule, CMS uses the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the excess readmission ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

The payment adjustment formula calculates the amount of aggregate payments due to excess readmissions for each condition by multiplying:

- the total number of admissions for the condition *times*
- the average base operating DRG payment for the condition *times*
- the excess readmission ratio for the condition.

Under the readmissions reduction program, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and an "adjustment factor" based on the aggregate payments for excess readmissions. The FY 2013 final rule establishes regulatory definitions of these terms largely repeating the statutory definitions.

Base operating DRG payment amount is the DRG payment for operating costs excluding adjustments for VBP, IME, DSH, low-volume hospitals, and outliers. It includes new technology payments and is wage-adjusted, including COLA adjustments for Alaska and Hawaii. For SCHs that receive payments based on their hospital-specific payment rate, the base operating DRG payment amount excludes the difference between a hospital's hospital-specific payment rate and the Federal payment rate. (A similar policy applies to MDHs prior to the scheduled termination of that program effective October 1, 2012.)

The "base operating DRG payment amount" is used to calculate both the "aggregate payments for excess readmissions" and "aggregate payments for all discharges," which are used to determine the readmission adjustment factor as well as the payment amounts to be adjusted for excess readmissions. CMS uses MedPAR claims data to determine the base operating DRG payment amounts; it uses the MedPAR file as updated 6 months after the end of each federal fiscal year (that is, the March updates of the respective federal fiscal year MedPAR files). These are the same MedPAR files that are used in the annual IPPS rulemaking.

Readmissions adjustment factor is defined as equal to the greater of: (i) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges or (ii) the floor adjustment factor. The statute specifies that the floor adjustment factor is 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. Thus, the floor adjustment factor limits the payment reduction applicable to the base operating DRG payments to 1 percent in FY 2013, 2 percent in FY 2014, and 3 percent in FY 2015 and subsequent years. The applicable payment formulas are:

> **Aggregate payments for excess readmissions** = [sum of base operating DRG payments for AMI x (Excess Readmission Ratio for AMI-1)] + [sum of base operating DRG payments for HF x (Excess Readmission Ratio for HF-1)] + [sum of base operating DRG payments for PN x (Excess Readmission Ratio for PN-1)]
>
> **Aggregate payments for all discharges** = sum of base operating DRG payments for all discharges
>
> **Ratio** = 1-(Aggregate payments for excess readmissions/Aggregate payments for all discharges)
>
> **Readmissions Adjustment Factor** for FY 2013 is the higher of the ratio or 0.99

Applicable hospital includes both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid based on a waiver under section 1814(b)(3) and that, absent the waiver, would have been paid under the IPPS, unless CMS approves an

application from Maryland establishing an equivalent program, as discussed below. The following hospitals are not applicable hospitals: CAHs; Puerto Rico hospitals or hospitals in the Territories; and hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, and IPFs. An Indian Health Service hospital enrolled as a Medicare provider is an applicable hospital.

As specified in the statute, excess readmission ratios calculated for the hospital readmissions reduction program include only admissions and readmissions to "applicable hospitals." Thus, readmissions to non-PPS hospitals such as LTCHs are not counted as readmissions. The excess readmission ratios under the readmissions reduction program will differ from the readmission rates reported on Hospital Compare for the Hospital IQR Program since excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals.

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Impact on hospitals. Many commenters during the FY 2012 IPPS rulemaking cycle expressed concern that hospitals treating a high proportion of low-income patients may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program. The proposed rule included a table showing the estimated distribution of the readmission adjustment factors among hospitals ranked by their DSH patient percentage (DPP). CMS made no proposal or conclusions based on the table, but invited public comment. Commenters presented different results and reported that they could not replicate the CMS results. One commenter found that high DSH hospitals located in large urban areas are nearly two times more likely to be penalized for heart attack than other hospitals, 2.6 times more likely for heart failure, and 2.2 times more likely for pneumonia. CMS commits to work with MedPAC and other stakeholders to complete a more sophisticated analysis.

The proposed rule included a table showing the distribution of proposed readmission adjustment factors modeled using 2007-2010 data. The proposed rule table was reprinted in the final rule, but it was not updated to show the final rule adjustments with the 2008-2011 data that CMS used to calculate the actual FY 2013 adjustments. The final FY 2013 adjustment factors, however, are available on the CMS website. Health Policy Alternatives created the table below using the actual adjustment factors published by CMS. The table shows that about 77 percent of hospitals would receive either no adjustment or an adjustment that would reduce their base operating DRG payments by less than 0.5 percent and that about 8 percent of hospitals would have their base operating DRG payments reduced by the maximum 1.0 percent.

DISTRIBUTION OF READMISSION ADJUSTMENT FACTORS

Percent Reduction	Number of Hospitals	Percent of Hospitals
No Adjustment	1285	36.7%
Up to -.09 Percent	408	11.7%
-0.1 Percent to -0.19 Percent	354	10.1%
-0.20 Percent to -0.29 Percent	268	7.7%
-0.30 Percent to -0.39 Percent	215	6.1%
-0.40 Percent to -0.49 Percent	169	4.8%

-0.50 Percent to -0.59 Percent	144	4.1%
-0.60 Percent to -0.69 Percent	115	3.3%
-0.70 Percent to -0.79 Percent	115	3.3%
-0.80 Percent to -0.89 Percent	88	2.5%
-0.90 Percent to -0.99 Percent	61	1.7%
-1.0 Percent	278	7.9%
Total	3,393	100.0%

Reporting Hospital-Specific Information, Including Opportunity to Review and Submit Corrections. For FY 2013, CMS delivered confidential reports and accompanying confidential discharge-level information to applicable hospitals containing their excess readmission ratios for the three applicable conditions in June 2012 and hospitals were given 30 days to review the report and submit corrections. The discharge-level information accompanying the excess readmission ratios included the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges (such as dates, provider numbers, and diagnosis upon readmission). CMS incorporated appropriate corrections to the excess readmission ratio calculations for the final rule. The final FY 2013 payment adjustment factors and excess readmission ratios for each of the three conditions are available to the public in a table that can be downloaded via the Internet on the CMS Web site.

CMS creates data extracts using claims in the Common Working File (CWF) 90 days after the last discharge date in the applicable period which is used for the calculations. For example, for FY 2013 the last discharge date in the applicable period for a measure was June 30, 2011, CMS created the data extract on September 30, 2011, and used that data to calculate the ratios for that applicable period. CMS does not allow hospitals to submit corrections related to the underlying claims data used to calculate the ratios, or allow hospitals to add new claims to the data extract used to calculate the ratios.

PPS Waiver Hospitals Paid under Section 1814(b)(3) of the Act. The statute allows the Secretary to exempt Maryland waiver hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings. The final rule provides that (1) CMS will not evaluate Maryland's Admission-Readmission Revenue Program (ARR) on measureable health outcomes and cost savings for the first year; (2) beginning in FY 2014, CMS will evaluate whether Maryland's readmissions program can demonstrate similar decreases in potential preventable readmissions and similar cost savings on an annual basis; (3) Maryland's annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually; (4) for FY 2013, all acute care hospitals in Maryland paid under the waiver and that absent the waiver would have been paid under the IPPS are exempt from the Hospital Readmissions Reduction Program.

Limitations on Review. The statute provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for the determination of base operating DRG payment amounts or the methodology for determining the adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges, and applicable periods and applicable conditions.

CMS response to comments on FY 2013 proposals:

- Fix flawed formula for calculating the adjustment factor: Commenters urged CMS to modify the proposed rule's methodology for calculating the readmission payment adjustment factor to correct a problem in the formula. They recommended that CMS replace the words "number of admissions" in the formula with "number of expected readmissions" so that the formula for the aggregate payments for excess readmissions would calculate the number of expected readmissions for each condition and not the total number of admissions. As proposed by CMS, the formula produces penalties that are higher than Medicare payments for excess readmissions. CMS responds that the statutory language is prescriptive and that the agency cannot make the recommended change.

- Exclude certain admissions in calculating the amount of a hospital's aggregate payments for excess readmissions: CMS agrees with commenters that the index admissions that are not considered admissions for the purpose of the readmissions measures and are thus excluded from the calculation of the excess readmission ratio also should not be considered admissions for the purposes of determining a hospital's aggregate payments for excess readmissions. CMS will modify its methodology accordingly. CMS finalizes a methodology to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2008 to June 30, 2011, to identify applicable conditions based on the same ICD-9-CM codes used to identify the conditions for the readmissions measures and to apply the exclusions for the types of admissions discussed above, which are currently identifiable on the claim in MedPAR.

- Modify the payment adjustment factor to account for socioeconomic conditions: Commenters made several alternative suggestions for CMS to refine the calculation of the readmissions payment adjustment factor to avoid penalizing hospitals that treat a high proportion of patients of low socioeconomic status or that have a high proportion of dual-eligible patients. Two commenters suggested stratification of the hospital calculations by the percentage of dual-eligible patients (that is, patients who are eligible for both Medicare and Medicaid). CMS commits to tracking this issue and evaluating disparities in care and the impact of the readmissions reduction program on providers of vulnerable populations, but it notes that there is a statutory requirement to use NQF-endorsed measures, which do not risk-adjust for socioeconomic factors. It observes that applying an adjustment to the readmissions payment adjustment factors to account for socioeconomic status rather than determining whether a risk adjustment for socioeconomic status would be appropriate for the readmissions measures could appear as circumventing the NQF's position on the application of a risk adjustment for socioeconomic status on the readmissions measures. CMS also does not want to establish different standards for the outcomes of patients of low socioeconomic status (which CMS

argues would occur if calculations were stratified by percent of dual-eligible patients). It does not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations.

- Adjust calculation of base operating DRG payment for transfer cases: In response to a comment, CMS clarifies that the base operating DRG payment amount accounts for any applicable transfer adjustment for cases that are paid as either an acute care transfer or post-acute care transfer. If a case is paid as a transfer resulting in a reduced IPPS payment, the reduced transfer-adjusted payment amount is also reflected in the base operating DRG payment amount.

- Adjust calculation of base operating DRG payment for MDHs if program is extended: In response to a comment, CMS clarifies that the difference between the applicable hospital-specific payment rate and the Federal payment rate for both SCHs and for MDHs, should the MDH provision be extended beyond FY 2012, is excluded from base operating DRG payment amount for these hospitals.

CMS response to selected comments on FY 2012 final rule policies (which is codified as part of the FY 2013 rule):

- Planned readmissions: Commenters urged CMS to identify and exclude planned readmissions for the AMI, HF, and PN readmission measures and to consider implementing codes that hospitals could use to designate when a readmission is planned. CMS responds that intends to update the condition-specific readmissions measures to permit more planned readmissions, which would not be counted as readmissions, and that it will analyze the reliability, validity, and usability of any discharge status codes proposed by the National Uniform Billing Committee (NUBC). Commenters suggested that CMS exclude readmissions that occur for reasons such as transplants and device implantation, trauma, psychoses, substance use, end-stage renal disease, maternity and neonatal readmissions, rehabilitation, sepsis, natural disease or treatment progression, acute decompensated heart failure, the result of nonhospital community factors, and disaster relief. CMS says that many of these suggestions are among the planned readmission updates it intends to submit for the AMI, HF and PN measures as part of annual maintenance review by NQF.

- Potential overcrowding in hospital emergency departments: Commenters expressed concern that the hospital readmissions reduction program may induce unintended consequences of overcrowding hospital emergency departments as hospitals seek to avoid readmitting patients. CMS responds that it will monitor the measures and assess unintended consequences over time.

- Exclude patients under "extreme circumstances": Patients under "extreme circumstances" such as transplants, end-stage renal disease, burn, trauma, psychosis and substance abuse should not be considered an index hospitalization (that is, a hospitalization included in the readmissions measure calculation). CMS responds that the measures address clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure. The only exclusions are patients who died during the first

admission, patients who have not spent at least 30 days post-discharge enrolled in Medicare fee-for-service (FFS), patients who are discharged against medical advice, and patients who are under the age of 65.

- Use shorter timeframe for measuring performance: CMS should consider a shorter timeframe for measuring performance for readmissions such as a 1-year or 2-year period rather than three years. CMS notes that using a 3-year period of index admissions increases the number of cases per hospital used for measure calculation, which improves the precision of each hospital's readmission estimate.

B. Sole Community Hospitals (SCH)

Generally, classification of a hospital as an SCH remains in effect unless a change specified in regulations (clauses (A) through (E) of § 412.92(b)(3)(ii)) occurs or unless the hospital becomes aware of a change that would affect its status. Failure to report a change will result in retroactive loss of SCH status to the date of the change or the hospital's awareness of the change and recoupment of overpayments, subject to cost report reopening rules at §405.1885 (the 3-year reopening period). However, CMS also clarifies that any reopening limitation does not apply in the case of fraud, such as where a hospital knowingly misled CMS or deliberately submitted incorrect information in its initial classification.

As its regulations were silent on circumstances where a hospital that never met the criteria was nonetheless granted SCH status, and CMS clarifies what it describes as its current authority to make the withdrawal of SCH status for such a hospital retroactive for the entire time period of its SCH classification, again subject to reopening rules. In determining whether the hospital meets its initial SCH classification criteria, CMS means requirements for SCH status in effect at the time of the hospital's initial classification, including for hospitals grandfathered at different times. CMS confirms it will not apply criteria, standards or interpretations not in effect at the time of the hospital's initial classification.

In response to comments concerning inadvertent errors by a hospital, or by CMS or its contractors of which a hospital is unaware, CMS modifies its proposal such that, effective October 1, 2012, CMS provides for a prospective effective date (30 days from the date of the CMS determination) for cancellation of SCH status for a hospital that subsequently reports factors or information to CMS that could have affected its initial classification, and CMS determines, based on that information, that the hospital should not have qualified for SCH status. This modification does not apply in the case of fraud.

CMS further believes that a hospital with SCH status is under an obligation to report not just changes that may affect SCH status but also any relevant factor or other information. In response to comments asserting these requirements impose undue burdens on hospitals, CMS states it is not requiring hospitals to continuously monitor data or to report data not within their control; the information CMS seeks is that which is germane to the hospital's initial SCH classification and which must be reported to CMS. CMS continues to believe there will not be any significant impact of these policies because they will only affect hospitals incorrectly classified as SCHs.

As the current Medicare-dependent, small rural hospital (MDH) program will expire on September 30, 2012, CMS will offer a seamless transition for an MDH hospital that seeks to apply for SCH classification effective October 1, 2012. An MDH hospital must apply by August 31, 2012, and specifically request that, if approved, SCH classification be effective with the expiration of the MDH program. If its application is approved, the hospital's SCH status would be effective October 1, 2012. CMS again declines to quantify any payment impact due to lack of any data from hospitals regarding their intentions to use this authority.

C. Rural Referral Centers

The finalized 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 for FY 2013 are based on FY 2011 bills received through March 2012. These factors are among those used to determine whether a given hospital qualifies for RRC status.

More specifically, to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, a rural hospital with fewer than 275 beds available for use must, among other things:

- Have a CMI value for FY 2011 that is at least 1.5378 or the newly updated median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) calculated by CMS for the census region in which the hospital is located.
- Have as the number of discharges for its applicable cost reporting period (described below) a figure that is at least 5,000 (3,000 for an osteopathic hospital) or the newly updated median number of discharges for urban hospitals in the census region in which the hospital is located. However, since the 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).

Due to a transition in the CMS cost reporting system for cost reporting periods beginning on or after May 1, 2010, CMS reports using FY 2009 cost report data for those providers with fiscal years beginning during the 5-month period beginning on May 1, 2010, in addition to FY 2010 cost report data for providers with fiscal years beginning during the October 1, 2009 through April 30, 2010 period.

D. Payment Adjustment for Low-Volume Hospitals

The ACA-revised criteria for the low-volume payment adjustment expires at the end of FY 2012; thus, for discharges occurring during FY 2013, the criteria for this adjustment revert back to those in effect before FY 2011: the road mileage qualifying criterion reverts to 25 road miles from the nearest subsection (d) hospital and the discharge qualifying criterion reverts to no more than 200 total (Medicare and non-Medicare) discharges. A hospital seeking this adjustment must provide sufficient documentation to its FI/MAC that it meets the discharge and distance

requirements by not later than September 1, 2012, for the adjustment to apply to discharges made on or after the beginning of FY 2013. CMS indicates that a Web-based mapping tool may be used for the mileage criterion. For requests submitted after September 1, 2012 that are approved, the adjustment will apply prospectively to discharges beginning on or after the date that is 30 days after the FI/MAC approval date. CMS notes that hospitals must meet the requirements with respect to the fiscal year involved; the adjustment is not based on a "one-time" qualification.

Concerned by the financial impact of the expiration of the ACA adjustments, commenters believe CMS should increase the maximum number of discharges to qualify for the low-volume payment adjustment from 200 to 800 discharges. CMS relies on its regression analyses to justify the policy to apply the adjustment only for those hospitals with fewer than 200 total discharges, but indicates it may reevaluate its low-volume adjustment criteria in the future.

CMS estimates approximately 600 hospitals that qualified as low-volume hospitals for FY 2012 will no longer meet the mileage and discharges criteria to qualify in FY 2013, resulting in a projected reduction in payments of roughly $318 million in FY 2013 compared to the payments that those providers would have otherwise received had the ACA-revised criteria not expired.

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.

CMS finalizes its proposals that claims submitted by hospitals for costs associated in providing services to Medicare Advantage (MA) enrollees for IME and direct GME, as well as for nurse and allied health education programs, must meet the claims filing requirements, including timely filing requirements, applicable under regulations at § 424.44 for fee-for-service claims. CMS rejects commenters' assertions that this represents a new policy rather than a clarification, observing that the issue had been previously addressed in two final rules as well as in a 1998 program memorandum, and rejecting a commenter's citation of a court holding in Loma Linda vs. Sebelius because the issue was not directly addressed in that case. CMS finds that because it is clarifying an existing requirement in lieu of implementing a new one, there is no new cost or administrative burden associated with it.

CMS adopts the same policy of meeting the fee-for-service timely claims filing requirements in the case of no pay bills used to calculate the DSH disproportionate patient percentage (DPP) for services furnished on a prepaid capitation basis by an MA organization or through cost settlement with an HMO, competitive medical plan, health care prepayment plan, or a demonstration. Because providers are already submitting no pay bills for purposes of the DPP, CMS does not believe this policy will have any impact.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education

To be consistent with its policy change in the FY 2010 IPPS/RY 2010 LTCH PPS final rule which included in the DPP of the Medicare DSH adjustment all *patient days* associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as

an inpatient, CMS applies the same policy in the *bed day count* for IME and DSH payment adjustments. CMS finds this to be consistent with its policy on observation, swing bed, and hospice days, which are excluded from both the patient day count and available bed count. CMS will amend cost reporting instructions to carry out the change.

Some commenters disagree with the change, indicating that it is appropriate for a discrepancy in treatment of labor and delivery for the patient day count and the bed day count because labor and delivery services are not typically paid for under Medicare (i.e., only 1 percent of all U.S. births). CMS believes that because costs for services provided in a labor and delivery room are generally payable under IPPS, the low volume of those services is not relevant in determining whether patients are receiving IPPS-level of care. Other commenters pointed to the current policy for patient stays in newborn nursery units and the different treatment for patient day and bed counts in those circumstances. CMS responds by indicating it will consider addressing the issue in future rulemaking.

In response to commenter confusion about treatment of maternity suites, or separate labor and delivery and postpartum rooms, CMS indicates that it considers whether the unit in which the bed is located provides services generally payable under IPPS, and if so, whether the beds in that unit (be they maternity suite beds or ancillary labor and delivery beds) are furnishing services generally payable under IPPS. CMS also clarifies that it counts all beds in a unit that is providing such services because they are available for IPPS-level acute care hospital services, regardless of whether they are occupied. CMS will review whether to count labor and delivery patient days for purposes of the direct GME patient load, and if so the changes required to the cost report.

CMS agrees with commenters that the inclusion of beds associated with ancillary labor/delivery services might impact qualification of certain hospitals (hospitals with 100 or fewer beds) for hold harmless payments under the hospital outpatient PPS, but declines to make a special rule to exclude those beds from the bed count of those hospitals.

CMS reminds readers of its policy under which days are excluded of labor and delivery patients who are not admitted to the hospital, and its continued application under this revised policy.

CMS estimates that the impact of including labor and delivery beds in the available bed day count would likely be negligible for DSH purposes (other than for those hospitals that do not currently meet the minimum threshold who may satisfy that criteria by reason of the change). The impact on IME payments will be to increase the number of available beds, decrease the resident-to-bed ratio, and depending on the number of those beds, decrease IME payments to teaching hospitals; CMS estimates an aggregate decrease of $40 million in FY 2013. This estimate is significantly less than the $170 estimated decrease CMS provided in the proposed rule which it attributes to an error in adding its estimate of labor and delivery bed days to hospitals' total bed day count, instead of their bed day count used to determine IME payments.

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

CMS notes that the MDH program will expire at the end of FY 2012 by operation of the statute, and hospitals will be paid based on the Federal rate beginning October 1, 2012. CMS reminds commenters that absent statutory authority it may not continue the MDH program.

CMS estimates that MDHs may expect a 7.8 percent decrease in payments. CMS also estimates that 98 MDHs, which are paid under the blended payment of the federal standardized amount and hospital specific rate, will lose approximately $183 million in payments when paid only under the Federal standardized amount in FY 2013.

H. Changes in the Inpatient Hospital Update

The applicable percentage increase to the FY 2013 operating standardized amount for hospitals that submit required quality data is 1.8 percent. This is based on an estimated 2.6 percent market basket increase reduced by 0.7 percentage points for the multifactor productivity (MFP) adjustment and further reduced by 0.1 percentage point under the Act. For hospitals that fail to submit the requisite quality data, the applicable percentage increase would be reduced by an additional 2.0 percentage points resulting in a -0.2 percent increase.

For SCHs, the FY 2013 applicable percentage increase is 1.8 percent, or -0.2 percent for an SCH that fails to submit requisite quality data.

For Puerto Rico hospitals the FY 2013 applicable percentage increase to the Puerto-Rico-specific operating standardized amount is 1.8 percent.

As the MDH program is set to expire at the end of FY 2012, CMS would not include MDHs in the update to the hospital specific rates.

CMS continues to use its methodology to calculate and apply the MFP adjustment, and bases its market basket update on the second quarter 2012 forecast of the 2006-based IPPS market basket with historical data through the first quarter 2012, and its MFP adjustment on IHS Global Insight, Inc. (IGI) second quarter 2012 forecasts.

I. Payment for Graduate Medical Education Costs

<u>New Teaching Hospitals: 5-Year New Program Growth Period (5-Year Window)</u>

For hospitals that begin training residents in a new program for the first time on or after October 1, 2012, CMS provides a 5-year window in which the hospital may establish and grow new programs for purposes of direct GME and IME payments. A new teaching hospital's resident cap is determined at the end of the fifth year and set permanently effective with the beginning of the sixth program year. The hospital's cap is adjusted by the product of 1) the highest number of residents training in any program year during the fifth academic year of the first new program's existence for all new residency programs, and 2) the number of years residents are expected to complete the program, based on the minimum accredited length for the program type involved.

The final rule contains several examples of how the methodology is to be implemented. CMS reminds hospitals that filling a program with transfer students from another hospital's existing residency training program(s) could jeopardize its program status as new. Commenters were very supportive of the policy change generally, though some objected to the prospective effective date observing that hospitals within their current 3-year window were facing the very challenges the policy change sought to address.

For new residency training programs where residents are rotating to more than one hospital, CMS calculates the cap adjustment for each new program started within the 5-year window by determining the product of 1) the highest FTE resident count for residents training in any program year during the fifth academic year at all participating hospitals, and 2) the number of years residents are expected to complete the program (again based on the minimum accredited length for the program type involved). Additionally, CMS apportions the overall FTE cap among the participating hospitals by taking that product and multiplying it by each hospital's ratio of A) the number of FTE residents in the new program training over the course of the 5-year period at each hospital, to B) the total number of FTE residents training at all participating hospitals over the course of the 5-year period. Thus, CMS looks to the fifth academic year of the first new program to calculate the aggregate cap for the participating hospitals, but considers all 5 years in distributing the aggregate cap among those participating hospitals. While commenters supported this methodology, some believe that considering all 5 years in distributing the aggregate cap could result in lost cap slots if residents rotate to a new program of another hospital during that 5-year window. CMS firmly believes that all 5 years must be considered in apportioning resident caps among participating hospitals and declines to adopt suggested alternative methodologies to determine the cap adjustment should hospitals disagree with the CMS cap calculation. CMS also makes certain technical changes to the regulation text at 42 CFR 413.79(e)(1)(i).

CMS does not change regulations for the treatment of the rolling average and the intern-to-resident bed (IRB) ratios for new programs, thus exempting new program FTE residents from the rolling average and cap on IRB ratios for the minimum accredited length for the type of residency training program involved.

Some commenters asked CMS to establish a bright line policy for the definition of a new program, citing confusion among teaching hospitals, and offered suggestions such as clarifying that prior experience and status of program directors and teaching faculty are irrelevant in determining whether a program is new. CMS considers these comments outside the scope of the proposed rule and may address them in future rulemaking. CMS clarifies that its reference to "accredited length of a 'type' of program" is a reference to a specific specialty program, meaning the number of years of residency training required to be board certified in that specialty.

Assuming 20 possible new teaching hospitals each year, CMS estimates an impact of approximately $175 million over the next 10 years; however, because the policy only affects new programs beginning on or after October 1, 2012, CMS believes that no cost would be incurred before FY 2016.

Policies and Clarification Related to 5-Year Period Following Implementation of ACA Section 5503 GME FTE Resident Cap Reductions and Increases

In order for a hospital to receive an increase to its FTE resident cap pursuant to redistribution rules enacted in section 5503 of the ACA, the hospital must, among other requirements, 1) maintain the number of primary care residents at or above its average level during the 3 most recent cost reporting periods ending before the enactment of section 5503 (i.e., the primary care average); and 2) ensure that at least 75 percent of the positions attributable to the redistributions are in primary care or general surgery residencies (i.e., the 75-percent threshold). In response to early hospital queries whether and if so how CMS would enforce the primary care average and 75-percent threshold requirements, CMS responded that the 75-percent threshold requirement applies once the hospital uses any of the section 5503 slots and the primary care average requirement applies on July 1, 2011, regardless of whether the hospital uses its additional slots in year 1 of the 5-year period (July 1, 2011 through June 30, 2016).

Taking into account public comment, CMS significantly modifies its proposal for determining hospital compliance with section 5503 requirements. The final rule drops the CMS proposal to remove all section 5503 slots (direct GME and IME, respectively) from a hospital that fails to fill at least half of those slots in the first, second and/or third cost reporting period of the 5-year period. Instead, Medicare contractors will review section 5503 slots 1) in the case of a program expansion, in the fourth 12-month cost reporting period, or 2) in the case of a new program, in the fifth 12-month cost reporting period. The contractor will remove unused (not all) slots from the hospital prospectively, effective for portions of cost reporting periods beginning on or after July 1, 2016. Thus the "draconian penalty", as one commenter put it, of potentially losing all slots for failure to entirely fill them by the cost reporting period in question has been substantially modified, and CMS in effect provides additional time for a hospital to meet the statutory mandate that it demonstrate the likelihood of filling the awarded section 5503 slots. However, a teaching hospital still risks losing all section 5503 slots retroactively for failure to meet the 75 percent test and primary care average requirement.

For the section 5503 residents, hospitals must indicate on their cost reports the number in new programs (and the program specialty) and the number in expanded programs (and the program specialty) for contractors to determine the number of unused slots. Though CMS is clearly uncomfortable with the policy, it acknowledges that hospitals may use 25 percent of their section 5503 slots for cap relief, and hospitals must also indicate the numbers of slots used for that purpose on their cost reports. CMS warns that this requirement, in conjunction with the other reporting requirements, carries pitfalls for the unwary because slots used for cap relief count for purposes of the 75-percent test and the primary care average requirement. CMS further states that the policy is not new and will apply to cost reports already filed after July 1, 2011 as well as to future cost reports. Thus, a hospital should not automatically report all of its slots awarded under the section 5503 cap increase; it should only report a portion that is at least equal to the additional primary care/general surgery FTEs added, with no more than an additional 25 percent permitted for other purposes (e.g., cap relief). CMS warns that use of slots for cap relief in excess of the 25 percent permitted may result in the loss of all section 5503 cap slots, retroactive to the earliest cost reporting period which may be reopened and in which the hospital failed to meet the requirements. For contractors to perform the analysis, CMS will establish a hospital's

baseline FTE count as the total unweighted allopathic and osteopathic FTE count from the hospital's 12-month cost reporting period that precedes the cost report that includes July 1, 2011.

With respect to contractor review of a hospital's final full or partial cost reporting period of the 5-year period, for those hospitals that comply with the 75-percent test and the primary care average requirement, contractors will assess the number of unused slots and permanently remove them for portions of cost reporting periods beginning on or after July 1, 2016. Unused slots for these hospitals would be slots above the sum of 1) the number of slots filled for primary care/general surgery and 2) 25 percent of filled slots used for other purposes (i.e., cap relief). In the case of program expansions, rather than new programs, the contractor will perform the calculation of unused slots based on the number of slots reported in the fourth 12-month cost reporting period.

CMS emphasizes that a contractor may remove all section 5503 slots in any year of the 5-year evaluation period if the hospital fails to meet the 75-percent test or the primary care average requirement, and reiterates that the primary care average is effective July 1, 2011. CMS also notes that the 75-percent test and the primary care average are determined separately with respect to direct GME and IME. Given its revised methodology, CMS does not believe it would be useful for a hospital to submit a revised 5-year plan describing how it intends to fill its slots; CMS also does not believe it is necessary to extend the 5-year evaluation period beyond June 30, 2016.

CMS does not project any additional costs or savings due to budget neutrality.

ACA Section 5506: Preservation of Resident Cap Positions from Closed Hospitals

Generally, section 5506 of the ACA permits the redistribution of residency positions of teaching hospitals that close to other teaching hospitals. The redistribution is to be done in the following priority order: first to hospitals in the same, or contiguous, CBSA; second to hospitals in the same state; third to hospitals in the same region of the country; and, fourth, if necessary, based on redistribution rules under ACA section 5503 (described above). The statute requires that hospitals demonstrate that the positions will likely be filled within the three academic years that follow the application deadline to receive slots after a particular hospital closes, and any increases are limited to the number of slots from the closed teaching hospital.

In response to comments, CMS finalizes a 90-day application period that begins when CMS provides public notice of a hospital's closing and availability of resident slot cap increases. CMS formally provides public notice in this final rule of the closure of three teaching hospitals and announces a new round of the section 5506 application and selection process. Applications must be received (not postmarked) by the CMS Central Office (not a Regional Office) by no later than October 29, 2012.

CMS established seven ranking criteria for each category in its November 24, 2010 final rule with comment period to rank applications, and the vast majority of applications from the first section 5506 process fell under the lowest ranking criterion. CMS revises the seventh ranking criterion and adds an eighth as follows:

- *Ranking criterion seven:* The hospital 1) will use the slots to establish or expand a primary care or general surgery program; and 2) will also apply under ranking criterion eight to establish or expand a nonprimary care or non-general surgery program and/or for cap relief.
- *Ranking criterion eight:* The hospital will apply to establish or expand a nonprimary care or non-general surgery program or for cap relief.

The change is intended to distinguish ranking criterion seven from criteria five (hospitals in a Health Professional Shortage Area (HPSA)) and six (hospitals outside a HPSA) which both require the hospital to use all additional slots to establish or expand a primary care or general surgery program. CMS makes no changes to ranking criteria one through six. CMS dismisses commenter objections to granting higher ranking to applications only for primary care or general surgery, believing that the priority is consistent with the goals of the ACA.

CMS clarifies the effective dates for slots awarded under section 5506, and modifies some of its proposals. The final rule contains a table describing both the requirements for each ranking criterion as well as the relevant effective date rule. Below is an abbreviated table describing the effective dates for future section 5506 slot redistributions:

Ranking Criteria	**Effective Date**
One and Three	The day after the graduation date(s) of the actual displaced resident(s)
One and Three *(no temporary c*	Hospital closure
adjustment)	
Two	Hospital closure
Four through Seven; Eight *for new or expanded nonprimary care or non-genera surgery slots*	The later of 1) when a hospital demonstrates to its contractor slots for a new/expanded program are actually filled as of a c (usually July 1—could be retroactive); or 2) July 1 *after* the displaced resident(s) complete training.
Eight *for Cap Relief*	The later of 1) the CMS award announcement effective date, 2) July 1 *after* the displaced resident(s) complete training.

Based on comments emphasizing the importance of seamless awards under ranking criteria one and three, CMS finalizes a policy to make these effective dates apply with the expiration of the temporary cap adjustment (i.e., the date of graduation of the displaced resident(s)). Hospitals applying under either of these criteria must list the names and graduation dates of the displaced residents who will be "seamlessly" replaced with new PGY1 residents. CMS also states where a teaching hospital closes after December 31 of an academic year, for a hospital to qualify under ranking criterion one or three for slots associated with displaced residents that will graduate June 30 of the academic year the applying hospital took those residents, the applying hospital must be able to demonstrate it will fill slots vacated by those displaced residents by July 1 of the second academic year following the hospital closure. Where the teaching hospital closes before (and presumably on though the preamble does not state this) December 31 of the academic year, the applying hospital must demonstrate it will seamlessly fill the slots by the day immediately after the June 30 that the displaced residents graduate.

CMS believes that the effective date of slots awarded under ranking criteria four through seven, and eight in the case of establishment or expansion of a nonprimary care or non-general surgery program, should be when those slots are actually needed. Thus, while the CMS award letter will indicate the program for which slots were added, whether the program is new or expanded, the number of slots awarded and the applicable ranking criterion, it will not specify an effective date (but may indicate a "no earlier than" date). The hospital must submit documentation to its Medicare contractor proving it "needs" the applicable slots as of a certain date because it actually filled that number of positions in its resident recruitment process above its prior academic year number. The hospital may not report the additional slots on its cost report until its contractor grants permission to do so.

CMS does not believe there is a justifiable policy reason for a retroactive effective date for slots awarded for cap relief under ranking criterion eight.

CMS agrees with comments arguing for the continuation of the regulatory temporary cap adjustment for FTE residents displaced from closed hospitals and makes no changes to the regulations at §413.79(h) or to the attending exemptions from the 3-year rolling average or IRB ratio cap for the duration of the training of the displaced residents in the program from which they were displaced. CMS notes for ranking criterion two (Medicare GME affiliation agreement hospitals), the prior year numerator of the IME intern and resident-to-bed ratio for the hospital will only be adjusted to reflect the portion of affiliated FTEs that the hospital received prior to the other hospital's closure and termination of the affiliation agreement.

Having received no comments, CMS finalizes its clarification that, in the case of a closed hospital that is training residents in excess of its FTE resident cap, it will not prorate slots among applicant hospitals that qualify under the first, second and third ranking criteria. Rather, it will follow the priority under those criteria even in the case where the hospital with ranking criterion one is assigned all the slots to the detriment of a hospital with an affiliation agreement with the closed hospital. CMS believes that a hospital that assumes responsibility for the entire program(s) of a closed hospital (ranking criterion one) is showing a higher degree of commitment than a hospital with an affiliation agreement with the closed hospital (ranking criterion two) which in turn shows a higher degree of commitment than a hospital that seeks to assume part of an entire program because it does not have the capacity to assume the entire program (ranking criterion three).

CMS makes numerous changes to the section 5506 application form itself, including changing its name; revising ranking criteria seven and eight (described above); providing prompts to specify whether the application is for a particular program, general cap relief, or for Medicare GME affiliation agreement slots; changing titles for the various Demonstration Likelihood Criteria; specifying documentation requirements for unfilled positions; adding requirements for the names and graduation dates of specific displaced graduates whom, upon graduation, the applying hospital must seamlessly replace with new residents under ranking criterion one or three; and making other, non-substantive changes. The final rule contains a copy of the revised and renamed CMS Section 5506 Application Form.

CMS does not project any financial impact for these section 5506 policies and clarifications.

J. Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

CMS makes its proposed conforming changes to regulations governing general cost reporting rules under §§ 413.24 and 413.100 to account for the exception for recognizing actual pension contributions funded during the cost reporting period on a cash, rather than on an accrual, basis. Because the changes are largely conforming in nature, CMS does not project any financial impact on hospitals for FY 2013.

K. Rural Community Hospital Demonstration Program

For the 23 hospitals participating in the budget neutral, rural community hospital demonstration program in FY 2013, CMS finalizes its 3-step methodology to calculate the budget neutrality offset amount that is applied across aggregate IPPS payments. Under the methodology, CMS calculates the budget neutrality offset amount by subtracting the sum of the estimated aggregate amount of payments to all 23 hospitals participating in the demonstration program for covered inpatient hospital services (including swing bed services) that would otherwise be made in the absence of the demonstration (calculated under Step 2 of the methodology) from the aggregate reasonable cost amount payments to all 23 hospitals for those services estimated to be made under the demonstration (calculated under Step 1 of the methodology).

CMS:

1. Uses hospital data for all participating hospitals from "as submitted" cost reports rather than a mix of "as submitted" and "settled" cost reports, as had been used for FY 2012;
2. Updates the estimated reasonable cost amounts for all 23 hospitals under the demonstration by the IPPS market basket percentage increase (under Step 1 of the methodology); and
3. Updates the estimated payments that would otherwise be made to those 23 hospitals absent the demonstration by the applicable percentage increase, rather than by the market basket percentage increase (under Step 2 of the methodology).

CMS estimates that the amount of the adjustment to the national IPPS rates during FY 2013 is $34,288,129, and notes that updated data was not available for the final rule. CMS also notes that, because of a delay affecting the settlement process for IPPS hospital cost reports, it was unable to include in the budget neutrality offset for FY 2013 any additional amounts by which the final settled cost reports for all hospitals participating in the demonstration in FYs 2007 through 2010 exceeded the budget neutrality offset amount for the fiscal year involved. CMS expects to be able to perform this calculation for the FY 2014 budget neutrality offset amount.

CMS notes that it has calculated excess readmission ratios and readmission payment adjustment factors for hospitals participating in the demonstration because they are subsection (d) or specified Maryland hospitals and thus are included in the hospital readmissions reduction program. If a demonstration hospital is subject to a readmissions payment reduction, its base operating DRG amount will be reduced as if it were paid under the IPPS, and at cost report settlement, the amount will be reduced from payments received under the demonstration.

L. Hospital Routine Services Furnished under Arrangements

As proposed, CMS delays by one year the implementation date of its revised policy (viz., that hospitals may only furnish therapeutic and diagnostic services under arrangements—not routine services) to cost reporting periods beginning on or after October 1, 2013.

Commenters continue to object to the revised policy, advocating for its rescission or absent that a longer delay to its implementation. CMS continues to maintain that the policy is consistent with the statute and that, for example, it is inconsistent with efficiency goals to move an inpatient between hospitals without discharge to furnish routine services unavailable at the first hospital. CMS acknowledges that a few providers may incur additional costs for construction or reconfiguration but observes these providers may receive inappropriately higher payments as non-IPPS providers in furnishing routine services under arrangements. CMS also expresses strong concern about collocation arrangements between a host IPPS hospital and a non-IPPS hospital within hospital (HwH) and declines to make an exemption, or to discontinue its revised policy generally or for these particular entities. CMS also disagrees with commenters representing cancer hospitals that Medicare costs will necessarily rise due to a greater number of discharges from a HwH to an ICU unit back to the HwH after ICU services are no longer needed, in part because those ICU services would be payable at the IPPS rate in lieu of the reasonable cost rate for the cancer HwH. CMS also discounts concerns about the impact of the revised policy on hospital readmission rates, noting that cancer hospitals are not included in the hospital readmission reduction program and that transfers to other providers are not included when calculating the excess readmission rate. CMS also rejects requests 1) to permit those hospitals currently furnishing routine services under arrangements to continue to do so, and 2) to provide an exception for cancer hospitals.

CMS believes the financial impact of the effective date change will be negligible.

M. Technical Change

CMS makes a technical, conforming change to the text of its regulations at § 413.79(f)(7) with respect to the length of emergency Medicare GME affiliation agreements which was increased to 5 years in the aftermath of Hurricanes Katrina and Rita. CMS received no comments on this provision.

V. Changes to the IPPS for Capital-Related Costs

Capital Standard Rate for FY 2013. The annual update to the payment rates for capital-related costs for FY 2013 is 1.2 percent based on the capital input price index (CIPI), as detailed below. As with CMS' final rule decision with respect to the operating standardized amounts, the agency does not finalize its proposal to apply a 0.8 percentage point reduction in the national capital federal rate to reflect changes which occurred in FY 2010 in documentation and coding changes that do not reflect real changes in case mix following the adoption of MS-DRGs. Referring to comments raising technical questions with its analysis, CMS acknowledges that the methodological issues are complex and require further analysis and consideration.

CMS finalizes the national capital federal rate for FY 2013 at $425.49, representing a 0.97 percent change from FY 2012, as shown in the table below:

	FY 2012	FY 2013	Change	Percent Change
Update Factor[1]	1.015	1.012	1.012	1.2
GAF/DRG Adjustment Factor[1]	1.004	0.9998	0.9998	-0.02
Outlier Adjustment Factor[2]	0.9382	0.9362	1.0019	-0.21
Capital Federal Rate	$421.42	$425.49	1.0097	0.97

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital federal rates. Thus, for example, the incremental change from FY 2012 to FY 2013 resulting from the application of the 0.9998 GAF/DRG budget neutrality adjustment factor for FY 2013 is a net change of 0.9998 (or -.02 percent).

[2] The outlier reduction factor is not built permanently into the capital federal rate; that is, the factor is not applied cumulatively in determining the capital federal rate. Thus, for example, the net change resulting from the application of the FY 2013 outlier adjustment factor is 0.9362/0.9382, or 0.9979 (or -0.21 percent).

For Puerto Rico hospitals, the final FY 2013 special capital rate is $207.25 compared to $203.86 in FY 2012.

The table below compares the proposed rule and final rule update factors and adjustments. Note that the documentation and coding adjustments shown in the table reflect cumulative adjustments. The proposed rule included a cumulative documentation and coding adjustment of 0.9404, reflecting the proposed 0.79 percent decrease compared to the FY 2012 cumulative documentation and coding adjustment of 0.9479. The final rule retains the FY 2012 cumulative documentation and coding adjustment of 0.9479

	Proposed* FY 2013	Final FY 2013	Change	Percent Change
Update Factor	1.013	1.012	0.999	-0.1
GAF/DRG Adjustment Factor	1.0002	0.9998	0.9997	-0.03
Outlier Adjustment Factor	0.9357	0.9362	1.0005	0.05
MS-DRG Documentation and Coding Adjustment Factor	0.9404	0.9479	1.008	0.8
Capital Federal Rate	$422.47	$425.49	1.0071	0.71

* The proposed FY 2013 capital federal rate reflects the correction to the outlier adjustment factor presented in the FY 2013 IPPS/LTCH PPS correction notice (77 FR 34328).

Exception Payments. The IPPS for capital-related costs was first implemented in FY 1992 with a 10-year transition period. CMS notes that while the exception payments were first instituted during the 10-year transition period which ended in 2001 (referred to as regular exceptions), for eligible hospitals these exception payments are available within the subsequent 10 years following the end of the transition period (referred to as special exceptions). CMS notes that there are no

hospitals remaining that qualify for special exceptions payments in FY 2012, and that after FY 2012 no payments may be made to any hospital under the special exceptions authority.

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.

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 is paid 85% of its Medicare allowable capital-related reasonable costs 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

Using more recent data available after publication of the proposed rule (IHS Global Insight, Inc.'s 2012 second quarter forecast with historical data through the first quarter of 2012), CMS provides a 2.6 rate-of-increase percentage to the target amount for cancer hospitals, children's hospitals, and religious nonmedical health care institutions (RNHCIs). CMS uses the percentage increase in the IPPS operating market basket because the number of cancer hospitals, children's hospitals, and RNHCIs is too small and cost report data too limited to create a market basket for them. These hospitals and institutions are not subject to the ACA-mandated percentage point reductions for the MFP or the statutory 0.1 percentage point reduction applicable to IPPS hospitals.

The total amount of adjustment payments (operating costs in excess of the hospital's ceiling) made to excluded hospitals and hospital units, aggregated by class of hospital, under section 1886(b)(4) adjudicated during fiscal year 2011 is as follows:

Class of Hospital	Number	Excess Cost over Ceiling	Adjustment Payments
Children's	2	$1,362,705	$1,303,381
Cancer	1	$7,805,148	$1,743,053
RNHCI	1	$ 72,154	$ 72,154
Total			$3,118,588

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

Overview

The table below summarizes key data for the LTCH PPS for FY 2013 in the proposed and final rule.

Summary of Key Data for Changes to LTCH PPS for FY 2013		
	Proposed	**Final**
Key update factors		
Market basket change	+3.0%	+2.6%
Multi-factor productivity adjustment	-0.8%	-0.7%
Additional adjustment required by statute	-0.1%	-0.1%
Net market basket update	**+2.1%**	**+1.8%**
One-time budget neutrality adjustment for base year estimates (1st year of 3-year proposed phase-in: 0.98734 each year) for discharges on or after 12/29/2012	-1.3%	-1.3%
Standard Federal Rate		
FY 2012	$40,222.05	
FY 2013		
Discharges from 10/1/2012 – 12/28/2012 (without the 0.98734 budget neutrality adjustment)	$41,026.88	$40,915.95
Discharges from 12/29/2012 – 9/30/2013 (with the 0.98734 budget neutrality adjustment)	$40,507.48	$40,397.96
Fixed-loss amount for High Cost Outlier (HCO) cases	$15,728	$15,408
Estimated percent change in payments per discharge*		
All LTCH providers (428 LTCH providers in final rule)	+1.9%	+1.7%
Rural (27 LTCH providers in final rule)	+3.6%	+3.3%
Urban (401 LTCH providers in final rule)	+1.9%	+1.6%
Voluntary (82 LTCH providers in final rule)	+2.6%	2.3%
Proprietary (323 LTCH providers in final rule)	+1.8%	1.6%
Government (14 LTCH providers in final rule)	+1.8%	1.7%
Unknown ownership (9 LTCH providers in final rule)	+3.0%	2.5%
*More detail on the changes in payments per discharge is available in Table IV of Appendix, Effects of Payment Rate Changes and Policy Changes under the LTCH PPS" for the proposed and final rules		

CMS finalizes its updates for LTCHs using a process generally consistent with prior regulatory policy, but finalizes several changes:

- LTCH-specific market basket. CMS finalizes its proposal to implement a new LTCH-specific market basket for FY 2013.
- 25 percent threshold moratorium. CMS finalizes its proposal to continue for one additional year, starting October 1, 2012, the moratorium on full implementation of the "25 percent threshold" payment adjustment. CMS includes in the final rule an additional supplemental moratorium for a select group of LTCHs and LTCH satellites: grandfathered hospitals within hospitals under section 412.22(f); grandfathered hospitals structured as satellite facilities under section 412.22(h)(3)(i); and freestanding LTCHs described in section 412.23(e)(5). The existing moratorium expires for such facilities with cost-reporting periods starting on or after July 1, 2012 and before October 1, 2012, before the new moratorium is put in place for cost reporting periods starting October 1, 2012. The proposed rule made no adjustment for this July 1 to September 30, 2012 period for these facilities. CMS in the final rule establishes a *discharge-based supplemental moratorium* for such facilities: the moratorium will apply to discharges occurring beginning October 1, 2012.
- IPPS Comparable Per Diem Payment Option moratorium. CMS finalizes its proposal to not extend the moratorium on use of the IPPS Comparable Per Diem Amount Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy, for discharges occurring on or after December 29, 2012.
- One-time budget neutrality adjustment: CMS finalizes its proposed adjustment (of approximately -3.75 percent) to the standard federal rate to be phased-in over a three-year period starting FY 2013 through the application of a 0.98734 percent adjustment (a reduction of about 1.3 percent in FY 2013). This reflects the agency's determination that the initial budget neutrality calculation for FY 2003 was not sufficient, and its standing policy that any discrepancies in the initial budget neutrality calculation for that year not be perpetuated for future years. This proposed adjustment had been delayed by regulation and statute in the past. Under the final rule, it is applicable for discharges occurring on or after December 29, 2012 upon expiration of the current moratorium.

A. Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2013

CMS continues to use the same Medicare Severity Diagnosis-Related Groups (MS-DRG) classification system used for the IPPS payments for the LTCH PPS (MS-LTC-DRG), although the relative weights are different.

Patient Classification into MS-LTC-DRGs

As noted elsewhere in this summary, CMS finalizes its proposal to not add or delete any MS-DRGs this year, retaining the 751 in place in FY 2012 for FY 2013. The other updates to the MS-DRG system described elsewhere in this summary would be reflected in the MS-LTC-DRG system since it is the same classification system.

Relative weights in the MS-LTC-DRGs

In computing the relative weights, CMS finalizes its proposal to continue its prior policy to exclude data from 14 all-inclusive rate providers, 2 LTCHs that are paid in demonstration projects, and all Medicare Advantage claims.

CMS finalizes its proposal to continue two long-standing policies for setting the relative weights of the MS-LTC-DRGs in a manner different from the IPPS.

- CMS continues to calculate the relative weights based on LTCH facilities alone (rather than using the IPPS relative weights) to reflect the different resource use and costs of such patients compared with the broader IPPS system.
- CMS continues to set the relative weights based on a hospital-specific relative-value (HSRV) methodology, because CMS finds that LTCH facilities often specialize in certain services that have the potential to distort charge differences among facilities.

Volume-related adjustments

CMS finalizes its proposal to continue to account for low-volume MS-LTC-DRG cases in updating the MS-LTC-DRG relative weights as follows:

- If an MS-LTC-DRG has at least 25 cases, it is assigned its own relative weight (there are 233 such MS-LTC-DRGs).
- If an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges (CMS finds that there are 306 such MS-LTC-DRGs). CMS then determines a relative weight and average length of stay of the MS-LTC-DRGs in the quintile and applies it to each MS-LTC-DRG in the quintile. Table 13A in section IV of the Addendum to the final rule lists these low-volume quintiles (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/Downloads/CMS-1588-F-Tables-13A.zip).
- If an MS-LTC-DRG has zero cases (CMS finds that there are 212 such MS-LTC-DRGs), it is cross-walked to another MS-LTC-DRG based on clinical similarities in intensity of use and costliness of resources, in order to assign an appropriate relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG would be assigned to that same quintile. CMS further notes that it will assign a 0.0 relative weight for eight transplant MS-LTC-DRGs because Medicare coverage policy covers these procedures only in a certified hospital, and no LTCH has been so certified. Table 13B in section IV of the Addendum to the final rule lists each of these zero case MS-LTC-DRGs and the MS-LTC-DRG to which it is assigned (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/Downloads/CMS-1588-F-Tables-13B.zip).

Determining the Relative Weights

After grouping the cases as noted, CMS finalizes its proposal to continue its policy of calculating the relative weights by first removing statistical outliers (charges outside of 3.0 standard

deviations from the mean) and cases with a length of stay of 7 days or less. It then adjusts for the effect of short-stay outlier (SSO) cases. SSO cases are cases with a length of stay that is less than or equal to five-sixths of the average length of stay of the MS-LTC-DRG to which it is assigned. CMS continues to adjust for SSO cases by counting an SSO as a fraction of a discharge based on the ratio of the length of stay of the SSO case to the average length of stay for the MS-LTC-DRG for non-SSO cases.

CMS finalizes its proposal to continue to adjust for "nonmonotonically" increasing relative weights. These are situations in which a base MS-LTC-DRG has two or three severity levels, but the relative weights do not increase with severity. CMS continues to adjust for those situations by combining the severity levels within such an MS-LTC-DRG to ensure that monotonicity is maintained.

Budget Neutrality Factor

Consistent with prior policy, CMS finalizes the budget neutrality adjuster for the annual update to the MS-LTC-DRG classifications and relative weights. That adjuster first includes a normalization adjustment of 1.12412 that CMS applies to the recalculated relative weights to ensure that the recalibration does not change the average case mix index. CMS then finalizes a budget neutrality adjustment of 0.9880413.

Table

Table 11 in Section VI of the Addendum to the final rule lists detailed information for each of the MS-LTC-DRGs: the relative weight, average length of stay, short stay outlier threshold, and IPPS comparable threshold (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/Downloads/CMS-1588-F-Tables-11.zip).

B. Use of a LTCH-Specific Market Basket under the LTCH PPS

CMS notes that the initial market basket for the LTCH PPS in FY 2003 was the "excluded hospital with capital" market basket. Starting with rate year 2007, CMS updated LTCH PPS payments using a market basket reflecting operating and capital costs of Inpatient Rehabilitation Facilities, Inpatient Psychiatric Facilities, and LTCHs (this is referred to as the Rehabilitation, Psychiatric and LTCH market basket, or the RPL market basket). CMS previously (in 2010) noted its interest in exploring a stand-alone LTCH market basket.

CMS proposed for comment such an LTCH market basket for FY 2013 in the proposed rule, and responds to comment and finalizes that proposal in the final rule.

CMS finalizes its proposal to use FY 2009 Medicare LTCH cost reports for development of the LTCH-specific market basket, but only from facilities that have a Medicare average length of stay within a comparable range (+/- 15 percent) of the facility's total average length of stay.

CMS finalizes its proposal to calculate cost weights for six cost categories based on the cost reports:

- Wages and Salaries
- Employee Benefits
- Contract Labor
- Professional Liability Insurance
- Pharmaceuticals
- Capital, and
- All other (Residual)

CMS finalizes its proposal to supplement the data using the Bureau of Economic Analysis 2002 Benchmark Input-Out Tables to create more detailed hospital expenditure category shares. CMS notes that these are the same data used to derive most of the other PPS market baskets.

CMS finalizes its proposal to assign price proxies as with other market baskets, using, as appropriate for the category, Producer Price Indexes (PPI), Consumer Price Indexes (CPI), and Employment Cost Indexes (ECIs).

Table VII.C-2 in the final rule details the categories and weights (which are the same in the proposed and final rule), and how they compare with the current RPL weights, along with the proposed price proxies for each of the cost categories. The summary table below sets out differences between the current weights for major categories (not all subcategories) based on the FY 2008-Based RPL market basket and the final FY 2009-Based LTCH market basket. Table VII.C-2 should be consulted for detail on all the categories and subcategories and the proposed price proxies.

Final FY 2009-Based LTCH Specific Weights for Major Cost Categories, Compared Current FY 2008-Based RPL Weights		
Major Cost Categories	**Proposed FY 2009-Based LTCH Specific Weights**	**Current FY 2008-Based RPL Weights**
Compensation	**54.338**	**62.278**
Wages and Salaries*	46.330	49.447
Employee Benefits*	8.008	12.831
Utilities	**1.751**	**1.578**
Professional Liability Ins.	**0.830**	**0.764**
All Other Products and Services	**33.252**	**26.988**
All Other Products	19.531	15.574
All Other Services	13.721	11.414
Capital-Related Costs	**9.829**	**8.392**
Total	**100.0**	**100.0**
Summarized from Table VII.C-2 *Note: contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents		

CMS sets out detailed specifications for each cost category and each price proxy for the LTCH-specific market basket.

FY 2013 Market Basket Update for LTCHs

For FY 2013, using the final LTCH-specific market basket, CMS finalizes a market basket update of 2.6 percent based on the IHS Global Insight (IGI) 2011 and second quarter 2012 forecast. This is a change from the 3.0 percent market basket update projected in the proposed rule, which was based on the IGI first quarter 2012 forecast. The update in the final rule reflects CMS' standing policy (stated in the proposed rule) to use the most recent data available for the final rule. IGI is the same firm that forecasts components of other market baskets for CMS.

CMS sets out in Table VII.C-5 a comparison between the FY 2008-based RPL market basket previously used for the LTCH market basket and the final FY 2009-Based LTCH-specific market basket. That table is summarized below, along with a comparison with the market basket update initially set out in the proposed rule based on the earlier data.

Proposed and Final 2008-Based RPL Market-Basket Index and FY 2009-Based LTCH Market Basket, Percent Changes				
Fiscal Year	**Market-Basket Index Percent Change**			
	RPL Index		**LTCH Index**	
	Proposed FY 2008-Based RPL Index	**Final FY 2008-Based Index**	**Proposed FY 2009-Based LTCH Index**	**Final FY 2009-Based LTCH Index**
Historical Average, 2008-2011	2.8	2.9	2.9	2.9
Forecast				
2012	2.4	2.2	2.5	2.5
2013	3.0	2.7	3.0	2.6
2014	3.1	2.8	3.1	2.7
2015	3.2	3.2	3.1	3.0
Forecast Average 2012-2015	2.9	2.	2.9	2.7
Summarized from Table VII.C-5, with comparable information from the proposed rule				

CMS notes that the 2.6 percent LTCH-specific market basket update for 2013 is 0.1 percentage points lower than the 2.7 percent update under the RPL index in use through 2012. The reason is that the new LTCH-specific market basket has a lower total compensation weight than the RPL market basket (54.338 percent compared with 62.278 percent) as shown in the previous table on weights for major cost categories. That is partially offset by the relatively higher weights for pharmaceuticals and all other services.

FY 2013 Labor-Related Share

CMS finalizes a labor-related share of 63.096 percent based on the new LTCH-specific market basket. That share is based on the most recent IGI projection for the second quarter of 2012 for

purposes of applying the area wage index. CMS reviews the detailed categories included, and sets out in Table VII.C-6 a comparison with the labor-related share of 70.199 percent for FY 2012 based on the RPL market basket. CMS' final labor-related share is just slightly lower than the labor-related share of 63.217 percent projected in the proposed rule, which, like the rest of the LTCH market basket, had been based on IGI projections though the first quarter of 2012. That table, along with the comparable data from the proposed rule, is reproduced below.

Comparison: FY 2012 Relative Importance Labor-Related Share Based on the FY 2008-Based RPL Market Basket and Proposed and Final FY 2013 Relative Importance Labor-Related Share Based on FY 2009-Based LTCH Market Basket			
	FY 2012 Relative Importance Labor-Related Share	**Proposed FY 2013 Relative Importance Labor-Related Share**	**Final FY 2013 Relative Importance Labor-Related Share**
Wages and Salaries	48.984	45.604	45.470
Employee Benefits	12.998	8.143	8.146
Professional Fees: Labor-Related	2.072	2.216	2.217
Administrative and Business Support Services	0.416	0.502	0.503
All Other: Labor-Related Services	2.094	2.513	2.507
Subtotal	66.564	58.978	58.843
Labor-Related Portion of Capital Costs (46%)	3.635	4.239	4.253
Total Labor-Related Share	**70.199**	**63.217**	**63.096**
Table VII.C-6 of proposed and final rules.			

CMS responds to several comments and concerns expressed about the reduction in the labor-related share. The concerns focused on the impact on LTCHs in urban areas and in high wage index areas, and included recommendations to completely reconsider the change, to phase it in over three years, and to update the computation based on more recent data.

CMS responds by noting that the use of LTCH-specific data for computation of the market basket and labor-related share is an improvement over the prior RPL market basket and more accurately reflects the costs of LTCH providers. CMS notes that it does not typically phase-in changes to the labor-related share. CMS' analysis is that about 20 percent of LTCHs will experience a decline in LTCH PPS payments as a result of the change in the labor-related share, and will experience an average 0.5 percent decrease as a result of the change. CMS notes that a change of that magnitude is similar to changes due to past updates to the adjustment for area wage levels, for which CMS has not provided a phase-in. Finally, CMS notes that the final rule uses updated IGI data.

C. Changes to the LTCH Payment Rates for FY 2013 and Other Changes to the LTCH PPS for FY 2013

Annual Market Basket Update

CMS finalizes the update as follows, based on the most recent IGI projections for the new LTCH market basket. The final updates for 2013 and comparison with the proposed rule are presented below. This table does not include the impact of the one-time budget neutrality adjuster described below.

Annual market basket update for 2013	Proposed	Final
Full market basket increase	3.0%	2.6%
Multi-factor productivity adjustment under the ACA	-0.8%	-0.7%
Adjustment of 0.1 percentage point called for under the ACA	-0.1%	-0.1%
Market basket update	2.1%	1.8%

COLA Updates for Alaska and Hawaii

CMS finalizes its proposal to continue to use "frozen" COLA factors used in FY 2012 for FY 2013, and to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii with the growth in the CPI for the average U.S. city. The approach will continue to use the statutorily mandated cap of 25 percent on the adjustments. Finally, CMS finalizes its proposal to update the COLA factors every four years, starting with FY 2014.

Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

CMS continues to make outlier payments for any discharge if the estimated cost of the case exceeds the adjusted LTCH PPS payment for the MS-LTC-DRG plus a fixed-loss amount. CMS makes an additional payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold, which is the sum of the adjusted federal PPS for the MS-LTC-DRG and the fixed loss amount. CMS determines the fixed-loss amount so that it results in expected outlier payments being equal to 8 percent of projected total LTCH PPS payments.

The fixed loss amount for FY 2012 was $17,931. CMS proposed a fixed loss amount of $15,728 for FY 2013, and finalizes a fixed loss amount, based on updated data, of $15,408. CMS notes that the decrease from the FY 2012 level is necessary to maintain outlier payments at the level of 8 percent of total LTCH PPS payments.

D. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

The 25 Percent Payment Adjustment Threshold

CMS finalizes with one change its proposal to extend the existing moratorium on full implementation of the 25 percent payment adjustment threshold for an additional year (for cost

reporting periods beginning on or after October 1, 2012, and before October 1, 2013.) CMS notes that the threshold was put in place because research revealed a strong correlation between growing numbers of discharges from IPPS hospitals, after short-stays, to onsite or neighboring LTCHs, yielding costs to Medicare. CMS again notes in finalizing this extension that it believes that it could be in a position in the near future to propose revisions to payment policy that would render that threshold unnecessary, based in part on prior MedPAC and CMS research.

The one change incorporated in the final rule responds to concerns about a select group of LTCHs and LTCH satellites: grandfathered hospitals within hospitals under section 412.22(f); grandfathered hospitals structured as satellite facilities under section 412.22(h)(3)(i); and freestanding LTCHs described in section 412.23(e)(5). The existing moratorium expires for such facilities for cost-reporting periods starting on or after July 1, 2012 and before October 1, 2012, before the new moratorium is put in place for cost reporting periods starting October 1, 2012. The concern expressed in response to the proposed rule is that such facilities would be subject to the 25 percent payment adjustment threshold just for a brief period of time (one, two or three months, depending on the facility) before October 1, 2012. CMS responds in the final rule by establishing a *discharge-based supplemental moratorium* for such facilities: the moratorium will apply to discharges occurring beginning October 1, 2012. CMS believes that, while such facilities will still be technically subject to the payment adjustment during the gap period, "very few, if any, LTCHs will actually be disadvantaged because these LTCHs would rarely, if ever admit more than 25 percent of their discharges from any one referring hospital during the limited period of 1 to 3 months … that the 25 percent payment adjustment threshold policy would technically be in effect." CMS further notes that because the policy would have virtually no impact on those hospitals for that 1 to 3 month period, it does not intend to allocate limited audit dollars to pursue the issue.

<u>The "IPPS Comparable Per Diem Amount" Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy</u>

CMS finalizes its proposal to not extend the 5-year moratorium on application of the IPPS comparable per diem amount as one option under the SSO payment adjustment when it expires, which is for discharges occurring on or after December 29, 2012. At that point, this option will become one of the payment options from which CMS selects the least costly alternative in paying for an SSO discharge. While a number of commenters expressed concerns about the impact of the expiration of the moratorium, CMS finalizes the policy and notes that it will address the comments when it considers changes to the SSO policy in the future. CMS also finalizes its proposal to clarify that the IPPS comparable per diem amount is capped at an amount comparable to what would have been full payment under the IPPS.

<u>One-Time Prospective Adjustment to the Standard Federal Rate</u>

In the August 2002 Final Rule, CMS set LTCH PPS rates to achieve budget neutrality for FY 2003 with the prior TEFRA-based system, and also stated its intent to provide for a prospective, one-time adjustment if future data indicated that the original budget neutrality calculation for payments in FY 2003 was inadequate. The original deadline for that adjustment has been

extended, and subsequently the Congress set and then extended a moratorium on implementing the adjustment. The current moratorium expires on December 28, 2012.

CMS finalizes its proposal to implement this adjustment at the end of the current moratorium, starting during FY 2013, for discharges occurring on or after December 29, 2012. The methodology has been discussed in previous proposed rules and the methodology and specific calculation steps, and adjustments, are set out in detail in the proposed and final rules.

CMS finds that the budget neutrality adjustment originally built into the FY 2003 payment rates was not adequate, and finalizes its proposal to apply a permanent factor of 0.9625 (a reduction of about 3.75 percent) to payments to assure that the original miscalculation is not retained in future payment rates. CMS finalizes its proposal to phase-in this adjustment over three years, applying a factor of 0.98734 in each of the next three years starting in FY 2013 (a reduction of about 1.3 percent in FY 2013) to payments for discharges occurring on or after December 29, 2012.

CMS responds to a number of concerns set out by commenters on the proposed rule. It notes that the one-time permanent adjustment is necessary to achieve the regulatory goal of budget neutrality, based on updated data, in the original transition from the pre-2003 TEFRA system to the new LTCH PPS system. It states that this goal was not met by other policy changes since 2003 which have different policy justifications. It states that this adjustment is not inconsistent with one-time adjustments across other prospective payment systems. CMS notes specifically that the IRF policy adjustment to account for coding changes identified by one commenter, while labeled "one-time," should not be confused with this one-time adjustment to correct the earlier budget neutrality calculation. Finally, it notes that this one-time budget neutrality adjustment is different from the annual budget neutrality calculation for annual changes to the MS-LTC-DRG classifications and recalibrations of weighting factors.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

This section of the rule addresses several different quality-related programs. Changes are made to the existing inpatient hospital quality reporting program and the inpatient hospital value-based purchasing program which will begin implementation in FY 2013. Requirements are added to the long-term care hospital quality reporting program which will be implemented in FY 2014 and the ambulatory surgical center quality reporting program which will begin in CY 2014. Finally, two new quality reporting programs are adopted in this rule, one for PPS-exempt cancer hospitals and the other for inpatient psychiatric facilities.

A. Hospital Inpatient Quality Reporting (IQR) Program

This section of the rule discusses requirements for the Hospital IQR Program, including a number of changes. (An IPPS hospital that chooses not to participate in the IQR program or one that fails to meet the requirements of the program for a fiscal year will receive an update factor reduction of 2.0 percentage points.) Removals and additions to the Hospital IQR Program measure set are made beginning with the FY 2015 payment determination along with changes to the procedures for hospital reporting**. A table displaying the measures for the FYs 2014, 2015 and 2016 payment determinations appears at the end of this section**.

Maintenance of Technical Specifications for Quality Measures

Many quality measures adopted for use in the Hospital IQR Program have been endorsed by the National Quality Forum (NQF) and subject to NQF's regular measure maintenance procedures. CMS finalizes its proposal to use a subregulatory process to incorporate non-substantive NQF updates into the measure specifications used in the IQR program. Under this process, the Specifications Manual will be revised and updates will be posted on the QualityNet.org website. CMS states that where changes to hospital data collection systems are needed, hospitals will be given sufficient lead time to implement the changes. CMS will continue to use the rulemaking process to adopt any changes that result from the NQF measure maintenance process that substantially change the nature of the measure.

In response to comments, CMS indicates that decisions about which changes to measures will be subject to the subregulatory process versus rulemaking will be made on a case-by-case basis, but examples of substantive and non-substantive changes to measures are provided. Non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, measure exclusions and updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. Substantive changes might include changes to the standard of performance such as timing of medication or test administration and extension of a previously endorsed measure to a new setting.

In discussing comments on this provision, CMS includes a link to the NQF website that includes information on the status of NQF-endorsed measures:
http://www.qualityforum.org/Measures_List.aspx.

Removal and Suspension of Hospital IQR Program Measures

CMS finalizes its proposal to remove 17 measures from the Hospital IQR Program beginning with the FY 2015 payment determination. The measures removed are "SCIP-VTE-1: Surgery patients with recommended VTE prophylaxis ordered"; the eight hospital acquired condition (HAC) measures; and eight AHRQ measures, five of which are patient safety indicator (PSI) measures and three of which are inpatient quality indicators (IQIs). The summary table at the end of this section identifies all 17 individual measures that are removed.

The practical effects of the removal of these measures are discussed. Data collection for SCIP-VTE-1 will end with December 31, 2012 discharges. New calculations of the 16 other measures will not be displayed on Hospital Compare after July 2012 for the purposes of the Hospital IQR Program. However, CMS notes that the AHRQ PSI composite measure that continues as part of the IQR program includes four of the five PSI measures that are being removed, and information on these individual measures can be provided on the Hospital Compare website in "drill down" pop –up displays for users seeking more information on the composite measure. CMS also indicates that although hospital performance on the HACs will no longer be publicly reported as part of the IQR program, in the future some or all of the HAC measures may be reported on Hospital Compare under the public reporting authority provided under section 3008 of the Affordable Care Act.

With respect to the four "topped-out" measures for which data collection was previously suspended, CMS responds to questions for clarification of the methods it will use to determine whether performance has declined and the criteria for reinstatement of a measure. CMS indicates that it will review published literature for evidence of performance and examine national performance trends in data collected by other parties. CMS intends that any reinstatement of data collection for these suspended measures will be aligned with IQR program timelines to provide sufficient notice to hospitals. (The four measures are AMI-1: Aspirin at arrival; AMI-3: ACEI/ARB for left ventricular systolic dysfunction; AMI-5: ACEI/ARB for left ventricular systolic dysfunction; and SCIP INF-6: Appropriate Hair Removal.)

Measures for the FY 2015 and FY 2016 Hospital IQR Program Payment Determination

The criteria CMS uses in adopting measures for use in the IQR program are reviewed, emphasizing support for the National Quality Strategy triple aims (better health care for individuals, better health for populations, and lower health care costs) and indicating that the statutory requirements under section 1890A(a)(4) of the Act, as added by the ACA, required the Secretary to consider input from multi-stakeholder groups in selecting measures. The MAP is a partnership of multi-stakeholder groups convened by NQF to provide input on measures and CMS will consider the recommendations of the MAP in selecting quality and efficiency measures. Among other considerations is selection of measures that will meet the VBP program inclusion criteria.

Retention of Measures. As proposed, once a measure is adopted for the Hospital IQR Program for a payment determination year it will automatically be adopted for subsequent years until CMS proposes to remove, suspend or replace it. Until now, CMS has proposed to retain previously adopted measures on a year-by-year basis. In responding to comments on this change, CMS notes that automatic retention of measures does not preclude the public from submitting comments on program measures.

CMS responds to comments on specific existing measures. As part of this discussion, CMS indicates that it is working to address concerns regarding ED-1: Median time from ED arrival to departure from the emergency room for patients admitted to the hospital. The concern involves cases where a patient may appear to have an ED visit that spans 2 calendar days due to Medicare billing processes. CMS will review the issue in technical expert panel meetings and determine the frequency of this type situation. In addition, CMS will evaluate recent changes to NQF specifications for SCIP-INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose. Finally, CMS has decided that public reporting for the Healthcare Personnel Influenza Vaccination measure will begin in December 2014 with the second data submission to span the flu season from October 1, 2013 through March 30, 2014. That is, the first submission of data for the flu vaccine measure for October 1 through December 31, 2012 will be voluntary and will not be publicly reported on Hospital Compare.

Addition of Measures. Several measures are added to the Hospital IQR Program for the FY 2015 payment determination and future years, without change from the proposed rule. These include expansion of the Hospital Consumer Assessment of Healthcare Providers and Systems

(HCAHPS) patient experience survey, and addition of new measures for complications of hip and knee surgery, hip/knee readmissions, hospital-wide readmissions, and elective delivery prior to 39 completed weeks gestation. In addition to these new measures, CMS finalizes a proposal regarding two current IQR program measures for which NQF specifications have been changed. The measures involved are Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-associated urinary tract infections (CAUTI).

Expansion of HCAHPS to include Care Transitions Measure. The HCAHPS survey is expanded to include a 3-part Care Transition Measure (referred to as CTM-3) beginning with January 2013 discharges. This measure was endorsed by the NQF and recommended by the MAP for immediate inclusion to the Hospital IQR Program. The addition of this measure adds the following items to the HCAHPS:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
- When I left the hospital, I clearly understood the purpose for taking each of my medications.

For each item, the patient may respond "strongly disagree," "disagree," "agree," or "strongly agree." For the last item regarding medications, the patient may also answer that they were not given any medications when they left the hospital.

Addition of "About You" Questions to HCAHPS. Two questions are added to the "About You" section of the HCAHPS required for collection also beginning with January 2013 discharges. One yes/no question asks "During this hospital stay, were you admitted to this hospital through the Emergency Room?" and the other asks "In general, how would you rate your overall mental or emotional health." The question about admission through the emergency room is added so that CMS can use it as a patient adjustment variable. Until June 2010 this information was collected from hospitals as an administrative code and was used as a patient-mix adjustment for HCAHPS scores. CMS adds the question on mental health status in response to numerous requests from hospitals and researchers.

In response to comments, CMS states that the emergency room self-report question was included in the HCAHPS three-state pilot study in 2003. At that time CMS was able to compare patient self-reports with administrative data and found that the patient self-report is a valid indicator of whether the patient was admitted through the ED. CMS identifies the mental health status question, which has been fielded in the CAHPS surveys since 2002 as "one of the oldest and best-validated items in patient surveys."

Hip/Knee Surgical Complications. CMS finalizes as proposed the addition of a new measure, "Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthoplasty (THA) and Total Knee Arthoplasty (TKA)" (NQF #1550). CMS believes this addition is important because of the high and rising volume and cost of these procedures and findings in the clinical literature of high rates of serious post-operative complications for these procedures.

The measure uses Medicare claims data to assess complications occurring after THA and TKA surgery from the date of the index admission and 90 days thereafter. One or more of the following complications are measured: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The measure includes Medicare beneficiaries age 65 and older who have had continuous enrollment fee-for-service Medicare coverage in the 12 months prior to the index admission. For the clinical exclusions and further details of the measure, CMS refers readers to the Surgical Consensus Standards Endorsement Maintenance project on the NQF website. Alternatively readers may find the specifications via this link http://tinyurl.com/7lzzje5, which is the product of a search for measure NQF #1550 on the NQF Quality Positioning System (QPS) beta website.

Risk adjustment is performed using the same hierarchical logical modeling (HLM) methodology that is specified for other outcome measures included in the Hospital IQR Program, namely the readmission and mortality measures for heart attack, heart failure and pneumonia. Risk factors are defined using the Hierarchical Condition Categories (CC). CMS indicates that the CCs used in the risk adjustment model for this measure are available on the qualitynet.org website. (The link provided in the rule is broken, but a search on qualitynet.org for measure NQF 1550 will produce a text file ICD-9-CM and CC crosswalk for the measure which is used to adjust for patient risk factors.)

CMS responds to concerns of commenters regarding the lack of risk adjustment for socioeconomic status. Readers are referred to a study of disparities in hip/knee complication rates by SES which found that although SES (as measured by Medicaid eligibility status) is an independent predictor of readmission risk, adding it to the risk model did not improve the model's overall ability to predict readmission risk. That is, clinical variables appear to adequately account for differences in patient risk of readmission. The link provided in the rule is: http://www.nysna.org/images/pdfs/practice/nqf_ana_outcomes_draft10.pdf.

CMS also reports that it has found a high level of consistency in complications found in claims with those found in medical records; 99 percent of patients were found to have a complication in the claims as well as the medical record. The preamble includes a discussion clarifying why complications attributable to processes of care and unrelated complications are included.

Hip/Knee Readmissions. CMS also finalizes as proposed the addition of another hip/knee related measure (NQF #1551): Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthoplasty (THA) and Total Knee Arthoplasty (TKA). The final rule clarifies that the hospital performance rate on this measure that will be reported on *Hospital Compare* will be calculated using data for three years, like the existing readmission measures for heart attack, heart failure and pneumonia.

The measure is a Medicare claims based measures similar to the existing readmission measures. Like the other readmission measures and the proposed hip/knee complications measure, the HLM methodology for risk adjustment is used for this hip/knee readmissions measure. (The qualitynet.org website includes a crosswalk to CCs used in the risk adjustment model for this

measure.) Readmissions associated with a subsequent planned THA/TKA procedure within 30 days of discharge from the index hospitalization are excluded from this measure. In the rule CMS discusses other exclusions and further details of the measure specifications, which can be found on the NQF QPS beta website via this link http://tinyurl.com/cy37xon.

CMS responds to numerous comments on the methodology underlying the measure, including discussion of planned and unplanned readmissions, related and unrelated readmissions, and the use of a 30-day post-discharge time period. In doing so, CMS states its view that greatly expanding the list of exclusions would result in a measure that is less meaningful because it would reflect the care of fewer patients.

Hospital-wide Readmissions. CMS finalizes as proposed the addition of a hospital-wide readmissions to the Hospital IQR Program. The specific Hospital-wide Readmission (HWR) measure (NQF #1789)was developed by CMS using 2008 Medicare fee-for-service data, which was endorsed by the NQF subsequent to publication of the proposed rule. Specifications for the measure are detailed in the rule. Briefly, the measure reflects all-cause unplanned readmissions for Medicare beneficiaries age 65 and older within 30 days following an index admission. Exclusions, which are detailed in the rule and specifications, include patients undergoing medical treatment for cancer and primary psychiatric disease as well as deaths and transfers. An algorithm is used to identify admissions that are likely to be planned. It is based on the assumption that, depending on the discharge condition, readmissions which include any of a specified list of procedures or for maintenance chemotherapy are considered to be a planned readmission while readmissions for acute illness or complications of care are unplanned readmissions. The measure specifications can be found on the NQF QPS beta website at http://tinyurl.com/bovd2lb.

CMS describes in the rule how, in calculating this measure, Medicare claims data is used to compute a single summary score that is derived from scores for five separate specialty cohorts: medicine, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology. For each cohort, risk adjusted predicted and expected readmissions are calculated for each hospital. A single summary score is calculated as the volume-weighted log average of the predicted over expected ratios from each cohort, multiplied by the national average readmission rate. CMS states that because this measure applies to Medicare discharges broadly, only one year of claims data is required to calculate this measure rather than the three years used for the condition-specific readmission measures.

In responding to comments, CMS indicates that it intends to track use of ED and observation services three days prior to hospitalization as increased use of these services is a potential unintended consequence of implementation of this measure. Further, CMS notes that because there will be a one year lag when hospital performance data on this measure are posted on *Hospital Compare*, it is considering options for providing hospitals with unadjusted all-hospital readmission data on a more frequent basis to assist them in their quality improvement efforts.

Various methodological issues are also addressed in the response to comments, and more broadly, CMS reiterates its view that hospitals can reduce readmission rates by ensuring that patients are clinically ready for discharge, reducing risk of infection, reconciling medications,

improving communication with community providers, and educating patients at discharge. While CMS recognizes the role of patient compliance, it believes that the current rate of one in five admissions resulting in readmissions is too high and hospitals can take steps that will reduce these rates.

Perinatal Care Measure. As proposed, the measure "Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation" (NQF# 0469) is added to the IQR program. The measure assesses the percent of patients with deliveries (vaginal and Cesarean) at >= 37 and < 39 weeks completed gestation with a procedure code for 1) medical induction of labor or 2) Cesarean section while not in active labor or experiencing spontaneous rupture of membranes. Detailed measure specifications are available at http://manual.jointcommission.org/releases/TJC2012A/MIF0166.html.

Although this is a chart- abstracted measure, it will be reported in the aggregate using a web-based tool. Hospitals will provide aggregate numerator, denominator and exclusion counts, as discussed below in the section on form, manner and timing of quality data submission. In responding to comments CMS clarifies that like all other chart-abstracted measures included in the Hospital IQR Program, this measure applies to all births, not just births to Medicare patients.

Specifications of CLABSI and CAUTI Measures. As part of NQF measure maintenance review, two existing IQR program measures have recently been re-specified. The CLABSI and CAUTI measures which were limited to ICU cases have been expanded to include non-ICU hospital locations and other care settings. CMS finalizes its proposal that the current specifications for these measures on ICU locations only be continued for the Hospital IQR Program. CMS intends to propose collection of data on non-ICU patients for these measures in the future.

CMS responds to reports of difficulties with uploading data to the NHSN data systems and indicates that CDC relies on input from users and field studies to improve the usability of the NHSN web-based interface. According to CMS, the NHSN accepts comma separated value files for importation of patient demographic data, procedure data and surgeon data which eliminates the need for manual data entry.

Additional Hospital IQR Program Measure for the FY 2016 Payment Determination and Subsequent Years

A safe surgery checklist measure is added to the Hospital IQR Program for the FY 2016 payment determination and subsequent years, bringing to 60 the total number of measures included in the program for that year. This addition is a yes/no measure of whether the hospital uses a safe surgery checklist during three periods: prior to administration of anesthesia, prior to skin incision and from the closure of incision prior to the patient leaving the operating room. The measure has previously been adopted for use in the hospital outpatient and ambulatory surgical center quality reporting programs. Measure specifications are available on the qualitynet.org website in the specifications manuals for these programs.

Possible New Quality Measures for Future Years

In the proposed rule, CMS indicated its intention to propose the addition of a smoking cessation measure set and an alcohol cessation measure set developed by The Joint Commission to the Hospital IQR Program once an EHR-based data collection for these measure sets is possible. Each measure set consists of four measures addressing screening, provision or offer of treatment/intervention, steps at discharge and assessing status after discharge. These measure sets were recommended by the MAP for inclusion in the IQR program provided they are NQF-endorsed prior to inclusion. CMS indicates that comments on the addition of these measures were equally divided between those in support and those in opposition.

CMS repeats its intention to propose six measurement domains for the Hospital IQR Program: clinical quality, care coordination, patient safety, patient and caregiver experience of care, population/community health, and efficiency.

Form, Manner, and Timing of Quality Data Submission

With some changes, the data submission requirements for hospitals participating in the Hospital IQR Program are continued. These are codified at 42 CFR 412.140 and further details are available at the QualityNnet.org website. Changes, which are finalized as proposed, are:

- Hospitals joining the Hospital IQR Program for a payment determination year must submit a participation form by December 31st of the year prior preceding the 1st quarter of the calendar year for which chart-abstracted data submission is required for that year. For example, for participation in FY 2015, a hospital must submit a participation form by December 31, 2012 and submit data beginning with January 1, 2013 discharges.
- A hospital withdrawing from the IQR program must submit a withdrawal form by May 15th prior to the start of the payment year. For example, to withdraw for FY 2015, the withdrawal form is due by May 15, 2014.
- As noted earlier, data submission for the proposed new chart-abstracted measure on elective delivery prior to 39 completed weeks gestation will be made via a web-based tool. Hospitals will submit aggregate numerator, denominator and exclusion counts for this measure. CMS clarifies that the quarterly data submission deadlines for this measure are the same as those for other chart-based measures, but the timing of reporting is somewhat different. For the elective delivery measure hospitals must necessarily wait until after the end of the quarter to submit the aggregate counts, whereas hospitals may submit data on other chart-abstracted measures as cases occur. Data submission for all chart-based measures is 4 ½ months after the discharge quarter, which for first calendar quarter 2013 discharges is August 15, 2013. For this quarter, data submission on the elective delivery measure must occur between July 1, 2013 and August 1, 2013.
- Data submission for the structural measures (on registry participation) for the FY 2015 payment determination via the web-based tool will be from April 1, 2014 to May 15, 2014 with respect to calendar year 2013.
- A reporting exception is provided for hospitals with respect to several of the measures reported through the National Healthcare Safety Network, specifically the measures on CLABSI, CAUTI and surgical site infection (SSI). Under the process, hospitals without

an ICU do not have to report the CLABSI and CAUTI measures, and those with fewer than 10 total combined cases of colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year are not be required to report the SSI measure. A single exception form for this purpose will be provided on the QualityNet.org website.

In responding to suggestions that the CDC manage validation of the HAI measures collected through the NHSN, CMS clarifies that the CDC is unable to use the regulatory authority that is used to require hospitals to submit medical record documentation, (42 CFR 476.78(c)) and for this and other reasons CMS will retain control over the HAI validation process, while collaborating closely with CDC

Supplements to the Chart Validation Process

CMS finalizes with modifications several proposals related to the validation process for chart abstracted measures for FY 2015 and subsequent years. In general, previously adopted validation requirements and methods will continue, but a separate process is established for the HAI measures and changes are made to the criteria for selection of hospitals for validation.

Validation of HAI measures. A separate process is finalized for validation of the HAI measures, with a few modifications from the proposed rule. These measures (CLABSI, CAUTI and SSI) are reported differently from other chart abstracted measures (through the NHSN). The latter two measures were added to the Hospital IQR Program beginning with the FY 2014 payment determination year and no data validation approach had previously been adopted or proposed for them. A validation approach was finalized in the FY 2012 IPPS/LTCH final rule for validation of the CLABSI measure involving abstraction of CLABSI data from the records selected for other chart-abstracted measures; this will be discontinued in favor of the new approach for all HAI measures. In addition, the policy of abstracting emergency department and immunization cases from CLABSI records will be discontinued.

Under the new process for validation of the three HAI measures, CMS will construct a list of candidate events for each of the measures, and then create a combined list of candidate HAI events which will be used to generate a random sample of medical records for evaluation of the presence or absence of one or more of the HAI events. In combining the three lists, CMS will remove duplicates for a given episode of care. Once the combined unduplicated list is created, a random sample of 12 candidate events per quarter will be drawn, or a total of 48 events per year. In a quarter where a hospital has fewer than 12 candidate events, all candidates will be selected for validation. The rule describes the process for developing the three candidate event lists.

- For CLABSI, the approach that was finalized in last year's rulemaking is modified, including a change from the proposed rule. Sampled hospitals must submit to CMS a listing of positive blood cultures drawn from ICU patients, with an annotation to indicate whether the patient had a central venous catheter. As proposed, hospitals must add the Medicare health insurance claim (HIC) number (if there is one) to the positive blood culture list to allow matching of the candidate event lists for CLABSI with those for SSI, which will be identified through claims data. In a change from the proposed rule, CMS redefines "positive blood cultures drawn from ICU patients" to include only those drawn

during the actual ICU stay. This is in response to comments on reporting burden with which CMS agrees although this will exclude from the validation sample a limited number of CLABSI cases which must be reported to NHSN because of results within 48 hours after ICU discharge. For the FY 2014 payment, hospitals will not be penalized for any cases reported under the old definition, which will be required for the FY 2015 payment determination.

- A process similar to that for CLABSI is adopted for CAUTI. Hospitals targeted for validation will be asked to submit a list of positive urine cultures among ICU patients adding the Medicare claim number when there is one. A CMS contractor will review the list to eliminate urine cultures not consistent with an ICU-associated CAUTI and to reduce the list to one entry per ICU patient. In response to comments, CMS limits the list of positive urine cultures to those with concentrations greater than or equal to 10^3 CFUs/ml during the actual ICU stay. Hospitals will not be required to submit specific data on the concentration of colony forming units (CFUs).
- For SSI, a different process will be used because SSIs are reported more frequently in claims data. Claims for Medicare patients who had colon or abdominal hysterectomy surgery will be reviewed including the index admission and readmissions within 30 days to the index hospital to identify discharge diagnoses that indicate infection. The final rule includes the list of ICD-9 codes that will be used to identify candidate SSI events; the proposed rule had referenced the codes used in a published paper by Platt and others. Responding to comments, CMS states that this separate process is needed because the sample of SSI events drawn from the normal validation sample for chart-based measures would be insufficient. The rule finalizes the proposal to exclude from SSI validation cases identified during readmission to hospitals other than the index hospital.

When an SSI is identified based on a readmission diagnosis, the hospital is required to submit records for both the readmission and the surgical admission. (For CLABSI and CAUTI evaluation is limited to the index hospitalization.) CMS discusses issued raised by commenters regarding post-discharge surveillance reporting, and indicates that it will use claims data to identify the frequency of SSI readmissions occurring at other than the index hospital. CMS agrees it is premature to develop validation processes for this situation and will consider using Conditions of Participation to require post-discharge surveillance.

Scoring for the HAI measures will follow the process previously finalized for the CLABSI measure. If a record includes one event that was reported to NHSN, a full score will be awarded for that record. If a record includes multiple events (e.g., CLABSI and CAUTI), both events will have had to have been reported to NHSN to receive a full score for validation. If a record includes no events and none were reported, a full score will be awarded. No points will be awarded if the wrong infection was reported or if an infection was reported and the validation data does not support the event. A mean HAI score will be computed as the number of HAI records correctly classified divided by the total number of HAI records scored. CMS modifies the method for calculating variance from what was proposed to adjust for the change from separate scoring to a single score. The total variance and confidence interval will be calculated for the combined weighted score.

CMS does not adopt its proposal to require that hospitals receive two separate passing scores of 75 percent, one for the HAI measures and one for the other chart-abstracted measures. It agrees with commenters that for FY 2015 this would overweight the scores for the 3 HAI measures compared with the 21 other chart-abstracted measures. The final rule provides instead that for the FY 2015 payment determination and subsequent years, CMS will calculate a single score that is a weighted average of the validation score for HAI measures and the score for other measures. The scores will be weighted proportionate to the number of measures validated in each set. So, for FY 2015 the HAI validation score will receive a weight of 12.5% (3/24) and the other measures 87.5% (21/24). If the HAI measures are not applicable because there were no events or the hospital was excepted from NHSN reporting, only the other score will apply. CMS clarifies that scores are computed over the four quarters rather than for each quarter. A two-tailed 90 percent confidence interval will replace the current standard of a one-tailed 95 percent confidence interval. The passing score remains 75 percent.

The process for validating ED throughput measures that assess time from admission to discharge (ED-1 and ED-2) is modified in response to a comment that a discrepancy of even 1 minute between the time reported to the Hospital IQR Program and the time identified during data validation is a failure. Beginning with the FY 2014 payment determination, a 5 minute variation will be permitted between the timed abstracted by the hospital and the data validator for these measures.

In responding to other comments, CMS states that pilot testing the validation process for CLABSI and CAUTI is not necessary because hospitals and CMS are learning from the previously adopted process for submission of CLABSI blood culture templates. With respect to comments on the reporting burden associated with validation of the HAI measures, CMS acknowledges the concerns but believes that the importance of HAI reduction as well as the statutory requirement for validation of IQR Program data justifies some added burden. Although some states that use NHSN data may have rigorous validation systems in place these are not standardized and CMS has responsibility for ensuring the validity of Hospital IQR Program data. CMS indicates that it is considering requiring hospitals to submit HIC information to NHSN which would allow for linkage with Medicare claims data and therefore reducing the information required on the blood and urine culture lists.

Reduced Base Sample Size and Targeted Sampling. CMS finalizes its proposal to reduce from 800 to 400 the annual random sample of hospitals selected for validation and to add criteria for targeted sampling of up to 200 additional hospitals. Any IQR-program eligible hospital submitting at least one IQR case during the third quarter of calendar year 2012 will be eligible for selection in the base random sample, which would occur in early 2013 for the FY 2015 payment determination. A random sample of hospitals meeting other targeting criteria will be chosen as a supplemental validation group. Criteria include whether the hospital was not selected as part of the base random sample for the previous 3 years; hospitals with abnormal or conflicting data patterns; rapidly changing data patterns; hospitals submitting data to the NHSN after the IQR deadline has passed; and hospitals that joined the IQR program within the past 3 years and have not been selected for validation. Beginning with the FY 2016 payment determination, another criterion will be added: hospitals that passed validation in the previous

year but, under the new proposed scoring, had a two-tailed confidence interval that included 75 percent.

Other Provisions

For participation in the Hospital IQR Program for the FY 2015 payment determination, hospitals must submit the electronic Data Accuracy and Completeness Acknowledgement by May 15, 2014 with respect to calendar year 2013 reporting.

The rule includes discussion of comments on the relationship between the Hospital IQR Program and the Medicare payment incentives for the use of EHR technology provided under the HITECH Act. CMS reiterates its goal of aligning the two program requirements, noting that not all IQR program measures, such as HCAHPS, lend themselves to electronic reporting. Importantly, CMS does not believe it is practical to allow some hospitals to use EHR-based reporting while others report based on chart abstracted measures. That is, CMS envisions that all hospitals will transition to EHR-reporting at the same time.

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016			
	2014	**2015**	**2016**
Acute Myocardial Infarction (AMI) Measures			
AMI-2 Aspirin prescribed at discharge	X	X	X
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival	X	X	X
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)	X	X	X
AMI-10 Statin Prescribed at Discharge	X	X	X
Heart Failure (HF) Measures			
HF-1 Discharge instructions	X	X	X
HF-2 Evaluation of left ventricular systolic function	X	X	X
HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction	X	X	X
Stroke (STK) Measure Set			
STK-1 VTE prophylaxis		X	X
STK-2 Antithrombotic therapy for ischemic stroke		X	X
STK-3 Anticoagulation therapy for Afib/flutter		X	X
STK-4 Thrombolytic therapy for acute ischemic stroke		X	X
STK-5 Antithrombotic therapy by the end of hospital day 2		X	X
STK-6 Discharged on Statin		X	X
STK-8 Stroke education		X	X
STK-10 Assessed for rehabilitation services		X	X
Venous Thromboembolism (VTE) Measure Set			
VTE-1 VTE prophylaxis		X	X
VTE-2 ICU VTE prophylaxis		X	X
VTE-3 VTE patients with anticoagulation overlap therapy		X	X
VTE-4 VTE patients receiving un-fractionated Heparin with doses/labs monitored by protocol		X	X

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016			
	2014	**2015**	**2016**
VTE-5 VTE discharge instructions		X	X
VTE-6 Incidence of potentially preventable VTE		X	X
Pneumonia (PN) Measures			
PN-3b Blood culture performed before first antibiotic received in hospital	X	X	X
PN-6 Appropriate initial antibiotic selection	X	X	X
Surgical Care Improvement Project (SCIP) Measures			
SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision	X	X	X
SCIP-INF-2: Prophylactic antibiotic selection for surgical patients	X	X	X
SCIP-INF 3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)	X	X	X
SCIP-INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose	X	X	X
SCIP–INF-9: Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero	X	X	X
SCIP-INF-10: Surgery patients with perioperative temperature management	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
SCIP-VTE-1: Surgery patients with Venous thromboembolism (VTE) prophylaxis ordered	X	Removed	
SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery	X	X	X
Mortality Measures (Medicare Patients)			
AMI 30-day mortality rate	X	X	X
Heart Failure 30-day mortality rate	X	X	X
Pneumonia 30-day mortality rate	X	X	X
Patients' Experience of Care Measures			
HCAHPS survey	X	X	Expanded[1]
Readmission Measures (Medicare Patients)			
AMI 30-Day Risk Standardized Readmission	X	X	X
Heart Failure 30-Day Risk Standardized Readmission	X	X	X
Pneumonia 30-Day Risk Standardized Readmission	X	X	X
30-Day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty		X	X
Hospital-Wide All Cause Unplanned Readmission		X	X
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures			
PSI 06: Iatrogenic pneumothorax, adult	X	Removed	
PSI 11: Post Operative Respiratory Failure	X	Removed	
PSI 12: Post Operative PE or DVT	X	Removed	
PSI 14: Postoperative wound dehiscence	X	Removed	
PSI 15: Accidental puncture or laceration	X	Removed	

IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)	X	Removed	
IQI 19: Hip fracture mortality rate	X	Removed	
Complication/patient safety for selected indicators (composite)	X	X	X
Mortality for selected medical conditions (composite)	X	Removed	
PSI 04 Death among surgical inpatients with serious, treatable complications	X	X	X
Structural Measures			
Participation in a Systematic Database for Cardiac Surgery	X	X	X
Participation in a Systematic Clinical Database Registry for Stroke Care	X	X	X
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	X	X	X
Participation in a Systematic Clinical Database Registry for General Surgery	X	X	X
Safe Surgery Checklist Use			X
Healthcare-Associated Infections Measures			
Central Line Associated Bloodstream Infection (CLABSI)	X	X	X
Surgical Site Infection	X	X	X
Catheter-Associated Urinary Tract Infection (CAUTI)	X	X	X
MRSA Bacteremia		X	X
Clostridium Difficile (C.Diff)		X	X
Healthcare Personnel Influenza Vaccination		X	X
Surgical Complications			
Hip/Knee Complication: Hospital-Level Risk Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty		X	X
Hospital Acquired Condition (HAC) Measures			
Foreign Object Retained After Surgery	X	Removed	
Air Embolism	X	Removed	
Blood Incompatibility	X	Removed	
Pressure Ulcer Stages III & IV	X	Removed	
Falls and Trauma (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)	X	Removed	
Vascular Catheter-Associated Infection	X	Removed	
Catheter-Associated Urinary Tract Infection (UTI)	X	Removed	
Manifestations of Poor Glycemic Control	X	Removed	
Emergency Department (ED) Throughput Measures			
ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital	X	X	X
ED-2 – Median time from admit decision to time of departure from the ED for ED patients admitted to the inpatient status	X	X	X
Prevention			
Immunization for Influenza	X	X	X
Immunization for Pneumonia	X	X	X

Cost Efficiency			
Medicare Spending per Beneficiary	X	X	X
Perinatal Care			
Elective delivery < 39 completed weeks gestation		X	X

[1]HCAHPS expanded to include one 3-item care transition set and two new About You items on mental health status and admission through the ED.

B. PPS-Exempt Cancer Hospital Quality Reporting Program

This section of the rule establishes a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals (PCHs) as required under section 3005 of the ACA. The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) program follows many of the policies established for the Hospital IQR Program, including the principles for selecting measures and the procedures for hospital participation in the program. No policy is adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS plans to address this issue in future rulemaking.

As proposed, five measures are included in the new cancer hospital quality reporting program for FY 2014. Two measures (CLABSI and CAUTI) are healthcare associated infection measures that are already adopted for the Hospital IQR Program and other quality reporting programs. The other three measures are process of care measures specific to cancer that were developed by the American College of Surgeons/Commission on Cancer accreditation program. The five measures are:

1. NHSN CLABSI outcome measure (NQF #0139)
2. NHSN CAUTI outcome measure (NQF #0138)
3. Adjuvant chemotherapy is considered or administered with 4 months (120 days) of surgery to patients < 80 with AJCC T1c (lymph node positive) colon cancer (NQF #0223)
4. Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis to women < 70 with AJCC T1c or Stage II or III hormone receptor negative breast cancer. (NQF #0559)
5. Adjuvant hormonal therapy (NQF #0220) (Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year of diagnosis to women > 18 with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer.)

The NHSN CLABSI and CAUTI measures will apply to both ICU and non-ICU locations in a PPS-exempt cancer hospital. As noted earlier, for the Hospital IQR Program, CMS will continue to apply this measure only for ICU locations, as it was originally specified. PCHs will report these measures through the NHSN. Data on the three cancer-specific measures will be reported by PCHs to a CMS contractor that will collect the data, calculate measure rates and report them to CMS. Responding to comments, CMS indicates that it intends to align as much as possible with the American College of Surgeons data infrastructure and reporting format for these measures because most PCHs are already reporting them to the College.

The rule sets forth procedures for PCH participation in the quality reporting program. These parallel the procedures in place for the Hospital IQR Program. PCHs will register with the QualityNet.org website, which will be used to make available the information that PCHs need to participate in the program, including measure specifications and instructions for data submission. For PCHs that file a notice of participation, performance on the measures will be posted on the *Hospital Compare* website and PCHs will have 30 days to review the data before it is posted. PCHs would be required to electronically submit an annual data accuracy and completeness acknowledgment.

Data submission deadlines are finalized with changes from the proposed rule. For all measures, the initial quarterly reporting period will begin on January 1, 2013 instead of October 1, 2012 as proposed. The deadline for reporting these data is August 15, 2013 for the NHSN measures; November 15, 2013 for two of the process of care cancer measures and May 15, 2014 for the adjuvant hormonal therapy measure. The rule also sets forth a similar schedule for subsequent reporting periods. Quarterly reporting is required on all measures. For a fiscal year CMS will look at data quarter submitted during the 12 months preceding the start of the fiscal year. So, for FY 2014 program, CMS will assess only the CLABSI and CAUTI data which will be reported by August 15, 2013. For FY 2015, CMS will assess quarterly data submissions occurring during fiscal year 2014.

With respect to measure maintenance, CMS finalizes the same policy on use of a subregulatory process described earlier for the Hospital IQR Program. That is, NQF updates to program measure specifications that CMS believes do not substantially change the measure will be incorporated into the program through a subregulatory process.

Responding to comments, CMS states that PCHs should become familiar with the quality reporting program before CMS will consider establishing a data validation process, and indicates that this is consistent with the approach taken with respect to data validation in the hospital outpatient quality reporting program.

C. Hospital Value-Based Purchasing (VBP) Program

1. Overview

FY 2013 is the first year of payment adjustments under the Hospital VBP Program established by the ACA. CMS will base each hospital's VBP percentage on its Total Performance Score (TPS) for a specified performance period. The total amount available for value-based incentive payments for a fiscal year is equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool equals 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary; the funding pool increases to 1.25 percent of base-operating DRG payments for FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

The VBP program includes all subsection (d) hospitals (i.e., IPPS hospitals), with three exclusions with respect to a particular fiscal year: (1) a hospital that is subject to the Hospital IQR payment reduction under section 1886(b)(3)(B)(viii)(I) for the fiscal year; (2) a hospital for

which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

CMS published a final rule in April 2011 (76 FR 26490 through 26547) establishing the VBP program and setting program requirements for the FY 2013 Hospital VBP Program. The final rule adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the HCAHPS, and categorized them into two domains: a clinical process of care domain with 12 measures and a patient experience of care domain with the HCAHPS survey measure. CMS adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for the measures, and performance standards for evaluating hospital performance. To determine whether a hospital meets or exceeds the performance standards for these measures, CMS will assess each hospital's achievement during the performance period, as well as its improvement during this period compared to its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010.

CMS will calculate a TPS for each hospital by summing the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights are 70 percent for clinical process of care and 30 percent for patient experience of care), and adding together the weighted domain scores. CMS will convert each hospital's TPS into a value-based incentive payment percentage using a linear exchange function.

2. FY 2014 Hospital VBP Measures

CMS adopted 17 measures for the Hospital VBP Program for FY 2014, including the 12 clinical process of care measures and the HCAHPS measure that were adopted for the FY 2013 program. The FY 2014 VBP measures include:

- 1 new clinical process of care measure (SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and
- 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate).

The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP-Inf-9 is discussed in more detail in the CY 2012 OPPS/ASC final rule (76 FR 74530).

In the CY 2012 OPPS/ASC final rule, CMS suspended the effective date of several other measures that it had adopted for the FY 2014 program: 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending per Beneficiary Measure; these measures are not included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530). A table at the end of this section displays all the VBP Program measures.

3. Other Previously Finalized Requirements for the Hospital VBP Program

In the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74547), CMS adopted a number of other policies for the FY 2014 Hospital VBP Program including: the minimum number of cases that a hospital must report to receive a score on a mortality measure; the minimum number of measures that a hospital must report in order to receive a score on the outcome domain; the baseline and performance periods; the performance standards for the clinical process of care and patient experience of care measures (CMS had previously finalized the performance standards for the 3 mortality outcome measures in the Hospital Inpatient VBP Program final rule (76 FR 26513)); the scoring methodology; and the domain weighting methodology. CMS also finalized for all years of the program a process whereby hospitals may review and correct the data that they submit to the QIO Clinical Warehouse on clinical process of care measures, their clinical process of care measure rates, their HCAHPS data, and their patient-mix and mode adjusted HCAHPS scores.

4. Hospital VBP Payment Adjustment Calculation Methodology

For purposes of the Hospital VBP Program, CMS defines the term "base operating DRG payment amount" as the wage-adjusted DRG operating payment plus any applicable new technology add-on payment. This definition is the same as the one adopted in this rule for the Hospital Readmissions Reduction Program. The definition excludes adjustments for IME, DSH, low-volume hospitals, outliers and the readmissions reduction program adjustment. In addition to the wage adjustment, it includes the COLA adjustments for Alaska and Hawaii. For SCHs that receive payments based on their hospital-specific payment rate, the base operating DRG payment amount excludes the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate. (A similar policy applies to MDHs prior to the scheduled termination of that program effective October 1, 2012; the final rule clarifies that the policy would continue to apply to MDHs if payments under that program are extended.) For Maryland waiver hospitals paid under section 1814(b)(3), CMS defines the term "base operating DRG payment amount" to be the payment amount under that section, as provided by section 1886(o)(7)(D)(ii)(II) of the Act.

The final rule accepts a comment that transfer adjustments should be included in the definition of base-operating DRG payment amount. The transfer adjustment is the reduction applied to the payment amount when a patient leaves the hospital before the average length of stay for their DRG, and continues to receive treatment in either another acute hospital or a post acute setting.

The final rule notes that hospitals in Maryland have been granted an exemption from the VBP program for FY 2013 based on the state's submission of a report describing how a similar state program achieves or surpasses the measured results in terms of patient health outcomes and cost savings under the VBP program.

To create the funding pool for value-based incentive payments for each fiscal year, beginning with FY 2013 discharges, every hospital eligible for the VBP program will have its base operating DRG payment amount reduced by the "applicable percent" for each discharge in a fiscal year, regardless of whether CMS has determined that the hospital has earned a value-based

incentive payment for that fiscal year. The applicable percent is 1.0 percent in FY 2013, increasing gradually to 2.0 percent in FY 2017. The total amount of reductions over all hospitals constitutes the pool from which CMS will make VBP incentive payments. CMS will determine these amounts from MedPAR data in December of the previous fiscal year for development of preliminary estimates for the annual proposed rule and in March for the final rule estimates. Using FY 2011 MedPAR data inflated to FY 2013 dollars, the available amount for FY 2013 value-based incentive payments under the Hospital VBP Program is $963 million.

Beginning with the FY 2014 Hospital VBP Program, CMS will make the value-based incentive payments to hospitals as part of the claims payment process, beginning at the start of the fiscal year. CMS will notify hospitals of the net result of the base operating DRG payment amount reduction and the value-based incentive payment adjustment no later than 60 days prior to the start of the fiscal year, as required by the statute.

The "value-based incentive payment percentage" is the percentage of the total base operating DRG payment amount that a hospital has earned back, based on its TPS for a fiscal year. CMS will calculate a value-based incentive payment percentage for each hospital that receives a TPS greater than zero with respect to a fiscal year. A hospital may earn a value-based incentive payment percentage that is less than, equal to, or more than the applicable percent.

CMS will use the linear exchange function that it finalized in the Hospital Inpatient VBP Program final rule (76 FR 26534) to convert each hospital's TPS into a value-based incentive payment factor to be applied to each discharge in the fiscal year. A hospital with no net percentage change to its total base operating DRG payment amount percentage would have a value-based incentive payment adjustment factor of 1.0: its base operating DRG payment amount for each discharge is multiplied by 1.0 so that its base-operating DRG payment amount would be equal to what it would have been in the absence of the Hospital VBP Program. A hospital with a negative net percentage change to its total base-operating DRG payment amount percentage would have a value-based incentive payment adjustment factor that is less than 1.0 and a hospital with a positive net percentage change would have a value-based incentive payment adjustment factor that is greater than 1.0.

Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Amount Adjustment. CMS will incorporate the value-based incentive payment adjustment into the claims processing system in January 2013, and the adjustment will apply to all FY 2013 discharges, including those occurring in the first quarter of the fiscal year. CMS is delaying application of the 1.00 percent applicable reduction to the base operating DRG payment amount until it applies the value-based incentive payment adjustment factor. Beginning in January 2013, a hospital will receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment adjustment factor. In FY 2014 and future years, these adjustments will begin on October 1.

For FY 2013, CMS finalizes it proposal to reprocess claims submitted prior to January 2013, which is when it expects to incorporate the VBP adjustments into the claims processing system. Although hospitals are not required to resubmit claims, CMS recognizes the burden which

reprocessing places on hospitals for tracking and accounting of these claims. The proposed rule had invited comment on an alternative approach that would modify the slope of the exchange function as necessary so that it could be used to calculate a value-based incentive payment adjustment for each hospital such that the equivalent of the full fiscal year effect is achieved between January and September 30, 2013. Most commenters preferred the reprocessing of claims.

5. Review and Corrections Process

CMS adopts as proposed a process by which hospitals will have the opportunity for confidential review and correction of the claims-based measure rates and scores calculated by CMS in developing the VBP total performance score. For claims-based measure calculations, CMS will create data extracts of claims 90 days after the end of the performance period to be used in calculating measure rates. Hospitals will be provided with a confidential report containing the measure rates calculated and relevant discharge-level details for review. Similar to the process used to allow hospitals review of Hospital IQR Program data prior to its public release, these reports will be made available to hospitals through their secure QualityNet accounts, and hospitals will have 30 days to review the information and submit corrections. If CMS agrees that a correction is needed a new confidential report would be prepared for the hospital. Hospitals may not submit corrections to the claims data that was originally submitted and may not submit additional claims data for the performance period.

Separate from the claims-based measures calculation report, CMS will provide hospitals, via their QualityNet account, with a confidential report that includes the hospital's score for each condition, domain scores, and the TPS. Hospitals will have 30 days to review these scores and submit corrections. Submitting a correction on a score is a prerequisite to appealing the score, which is discussed below.

In responding to comments requesting more than 30 days to review and submit corrections, CMS states that allowing more time would delay CMS's ability to make VBP payments, and 30 days is the same time period allowed for measure rate previews under *Hospital Compare*.

6. Appeal Process

The ACA requires the Secretary to establish a process for a hospital to appeal the calculation of the hospital's performance related to the performance standards or the calculation of the total performance score. Other elements of the VBP program are specifically excluded in the statute from administrative or judicial review. These include the calculation of the VBP payment amounts, the total amount available for distribution, and the methodology for calculating the performance score.

CMS finalizes its proposal that a hospital that has requested a correction to a score for a measure, dimension, or total score under the review and corrections process and that request was rejected, may seek an appeal through the QualityNet website within 30 days after receipt of the rejection. Appeals on other matters may be submitted within 30 days after the corrections period ends.

Appeals may be sought on the following specific items:

- CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;
- Whether the achievement/improvement points were calculated correctly;
- Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the TPS;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the TPS; and,
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

7. Measures for the FY 2015 Hospital VBP Program

For FY 2015, CMS retains all but one of the 17 measures adopted for the FY 2014 VBP program and adds three additional measures; one measure that CMS had proposed for addition is not finalized because it has been found to be "topped out". The measure previously adopted for FY 2014 that is dropped for FY 2015 is SCIP-VTE-1: Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered. As discussed earlier in this summary, this measure is being removed from the Hospital IQR Program in FY 2015. The measure that was proposed for addition but is not finalized because it is topped out is AMI-10: Statin Prescribed at Discharge.

The three measures added for FY 2015 include two measures that will be added to outcome domain: PSI-90, the AHRQ patient safety composite measure, and CLABSI. The third measure is Medicare spending per beneficiary, which will become the only measure in a new efficiency domain. **A summary table showing the VBP measures previously adopted for FY 2014 and those finalized in this rule for FY 2015 appears the end of this section.**

As proposed, CMS will automatically continue measures once they are adopted for the VBP program. CMS intends to re-evaluate the entire measure set annually. Measures will be monitored and proposed for removal if they are topped out or for other reasons, and these changes will be subject to rulemaking.

CMS responds to numerous comments on specific VBP measures, especially with respect to the Medicare spending per beneficiary measure. CMS states that this is a measure of cost efficiency that is not intended itself to measure both costs and quality. Further, CMS believes that care furnished to Medicare beneficiaries after they are discharged from the hospital is not wholly outside the hospital's control, and hospitals can work to improve care that is provided post-discharge even if furnished at distance. CMS acknowledges that some services included in this measure may be unrelated to the initial admission and these and others may extend beyond the

30 day period, but because all hospitals are subject to the same calculation of this measure it believes that none will be disadvantaged by these features. CMS does not believe that this measure should be adjusted for demographic or socioeconomic factors, citing NQF's position on these types of adjustments. The lack of claims data on patient functional status makes it impossible to adjust for these factors. CMS reviews the data on Medicare spending per beneficiary that was provided to hospitals before this measure was posted on *Hospital Compare* in April 2012, and indicates that it has made available through the *Hospital Compare* and the Hospital VBP website data that will allow hospitals and the public to view data on average Medicare spending per beneficiary episodes at the individual hospital, state, and national levels. The final rule includes a discussion of CMS's views and data on the reliability of this measure which includes links to a number of studies. An overall reliability of 0.951 with a 10-case minimum is calculated; the final rule includes a link to the underlying analysis

Among its response to public comments on other measures, CMS discusses the reliability of the AHRQ composite, CLABSI and mortality measures. Among other issues, CMS states that is takes reliability into account when considering performance periods, case minimums and other policies. Regarding CLABSI, in response to comments that the number of hospitals for which data was first posted on *Hospital Compare* in January 2012 was insufficient to meet the requirement for reporting prior to adoption in the VBP, CMS indicates that the May *Hospital Compare* posting includes data on 1,500 hospitals and another 500 indicated they had insufficient ICU cases to require reporting. CMS also reiterates findings with respect to HCAHPS that once patient mix adjustments are applied, the performance of safety net hospitals is similar to other hospitals.

8. Measures and Domains for FY 2016

For the FY 2016 VBP program, all FY 2015 measures will be continued except for the CLABSI measure, although CMS anticipates proposing continuation of the this measure next year. Adopting these measures now permits a longer performance period. (As discussed below the performance period for these measures for the FY 2016 VBP program will begin on October 1, 2012.) CMS expects to propose additional measures for FY 2016 in future rulemaking.

CMS does not finalize its proposal to revise the domain structure for the VBP program beginning in FY 2016. The proposal would have replaced the current four domains (Clinical Process of Care, Patient Experience of Care, Outcomes and Efficiency), with six domains that reflect the National Quality Strategy priorities. These are: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/ Population Health. CMS plans to consider re-proposing this approach once it has information about hospital performance on the program. Commenters suggested proceeding cautiously with these changes and expressed concerns that the proposed restructuring would dilute focus on the outcome measures.

9. Performance Periods and Baseline Periods for FY 2015 and 2016

The baseline and performance periods for FY 2015, which include some changes from the proposed rule, are shown in the table below. FY 2015, CMS states that a performance period of 9

months is the longest one possible for the claims-based mortality and AHRQ measures given the time constraints that result from the requirement for publishing performance standards at least 60 days prior to the start of the performance period. In responding to concerns of commenters in particular with respect to the AHRQ measure, CMS indicates that maximizing reliability should not be used to the exclusion of other criteria in considering the appropriateness of measures for the VBP Program, such as the measure topic, alignment with quality priorities and the number of hospitals receiving a score on the measure. For the CLABSI measures, the final rule provides for calendar year baseline and performance periods. The proposed rule would have begun these periods for CLABSI on January 26 instead of January 1, but CDC indicated to CMS that the data submission may not easily be disaggregated to the day. CMS anticipates providing hospitals this fall with preview reports of their baseline data, which will be posted on *Hospital Compare* in January 2013. For the AHRQ measure, CMS sets October 15 as the start of the baseline and performance periods rather than the proposed date of October 1. Because these data were first posted on *Hospital Compare* on October 15, 2011, CMS does not believe it can set the initial performance period prior to October 15, 2012.

For FY 2016, CMS adopts its proposal to provide 21 month baseline and performance periods for the mortality and AHRQ composite measures for FY 2016. The baseline periods will be unchanged from those used for FY 2015. CMS seeks to establish a 24-month performance period for future years, but notes the constraints that result from the requirement that performance standards be published at least 60 days prior to the start of the performance period. As noted above, the baseline and performance periods for the AHRQ measure will begin on October 15 instead of October 1 as proposed. Some commenters expressed concern that use of longer timeframes means that hospitals continue to be held accountable for older data. CMS believes that this is unavoidable at this time.

CMS finalizes its proposal to update performance periods and performance standards outside the rulemaking process using methodologies finalized during rulemaking. The periods and standards will be posted in a notice on the CMS website or other public website.

Domain/Measures	Baseline Period	Performance Period
FY 2015		
Clinical Process of Care	Jan. 1, 2011 – Dec. 31, 2011	Jan.1, 2013 – Dec. 31, 2013
Patient Experience of Care		
HCAHPS	Jan. 1, 2011 – Dec. 31, 2011	Jan. 1, 2013 – Dec. 31, 2013
Outcomes		
Mortality	Oct. 1, 2010 – June 30, 2011	Oct. 1 2012 – June 30, 2013
AHRQ composite	Oct. 15, 2010 – June 30, 2011	Oct. 15, 2012 – June 30, 2013
CLABSI	Jan. 1, 2011 – Dec. 31, 2011	Feb. 1, 2013 – Dec. 31, 2013
Efficiency		
Medicare spending per beneficiary	May 1, 2011 – Dec. 31, 2011	May 1, 2013 – Dec. 31, 2013
FY 2016		
Outcomes		
Mortality	Oct. 1, 2010 – June 30, 2011	Oct. 1, 2012 – June 30, 2014
AHRQ composite	Oct. 15, 2010 – June 30, 2011	Oct. 15, 2012 – June 30, 2014

10. Performance Standards for FY 2015 and FY 2016

The proposed rule includes tables with the performance standards for all measures for FY 2015 and FY 2016, which CMS has calculated using the methodology finalized in previous VBP rulemaking. The calculations have been updated from the proposed rule. The tables are not reproduced in this summary.

CMS received comments asking that numerical values be displayed on *Hospital Compare* for the Medicare spending per beneficiary measure. CMS notes that the median value of the measure will be 1.0 because it is the ratio of a hospital's score to the national median. While numerical equivalents will be provided at the conclusion of the performance period, CMS does not believe that it is helpful to provide this information for the baseline period because of changes in market forces, utilization practices and possible Medicare policy changes. For hospitals' information, CMS reports that the median value for the Medicare spending per beneficiary measure for the period May 15, 2010 to February 14, 2011 is $17,988.04. (This is the time period for which data were first displayed on *Hospital Compare* in April 2012.*)* The benchmark ratio, or mean of the lowest decile, was 0.806, corresponding to a per-beneficiary amount of $14,495.

The proposed rule noted that the future transition to ICD-10-CM/PCS coding will result at some point in time in comparison of performance to performance standards calculated for a period in which ICD-9-CM/PCS coding was used. CMS reports that commenters urged that the data be run on a single coding set to ensure fair comparisons. CMS will consider these comments in future rulemaking and plans to monitor the effects of the adoption of ICD-10 on measure rates.

As noted above, for future years, updates to performance standards will be made outside the rulemaking process using methodologies finalized in rulemaking. The periods and standards will be posted in a notice on the CMS website or other public website.

11. FY 2015 VBP Program Scoring Methodology

The VBP scoring methodology previously finalized will continue for FY 2015 without change, as proposed.

FY 2015 domain weights are finalized as proposed and are shown in the table below. Domain weighting for FY 2013 and FY 2014 is shown for comparison purposes.

VBP Program Weighting (Fiscal Year)			
Domain	**2013**	**2014**	**2015**
Clinical process of care	70%	45%	20%
Patient experience of care	30%	30%	30%
Outcomes		25%	30%
Efficiency			20%

In discussing comments on domain weighting, CMS reiterates its desire to move away from clinical process of care measures toward outcome and efficiency measures. CMS indicates that some commenters supported the proposed weighting, two thought the efficiency domain should

be increased to 30% over time, and others called on CMS to eliminate or reduce the weight for this domain. In response to comments that the patient experience of care (HCAHPS) domain weight is too high, CMS discusses analysis by the Cleveland Clinic referenced by commenters. This analysis shows a greater than expected impact of severity of illness on HCAHPS scores. CMS says that its understanding is that this analysis does not take into account the patient mix adjustments that are applied to raw HCAHPS to calculate hospital performance. CMS expects that most or all of the association between severity and HCAHPS scores would be removed by the adjustments built into the HCAHPS measure.

The minimum number of domains for which a hospital must have a score in order to receive a total performance score under the hospital VBP program is changed. For FY 2015, Hospitals must have scores for at least two domains in order to receive a total score for the VBP program. Currently, hospitals must have a score for each domain (i.e., all three domains for FY 2014), and specific requirements apply to the minimum number of cases and measures that a hospital must have in order to receive a score for a domain. As discussed below, CMS in this rule increases the number of cases that a hospital must have to receive a mortality measure score. Under the new policy, scores will be reweighed so that the total possible points are always 100 and the relationship between the domains is consistent. CMS believes that this change will increase participation of low-volume hospitals in the VBP Program.

12. Applicability of the VBP Program to Hospitals

Modifications are made to the requirements for a state with a waiver under section 1814(b)(3), namely Maryland, to seek an exemption for its hospitals from the VBP program if certain conditions are meant. Under the process established in previous rules, Maryland hospitals are exempt from the VBP program for FY 2013. For FY 2014 and beyond, the state will need to submit a required report supporting an exemption request by November 15 prior to the effective fiscal year.

13. Minimum Cases and Measures for FY 2015

Under the VBP program, a hospital must meet a minimum number of cases to receive a score on a measure and must have scores on a minimum number of measures to receive a score for a domain. For FY 2014, a hospital must have a minimum of 10 cases for a clinical process of care measure score and scores on 4 measures for a clinical process of care domain score. For HCAHPS, a 100-completed survey minimum applies, and for the 30-day mortality measures a 10-case minimum applies for each measure and a minimum of 2 measures is required for an outcomes domain score.

Beginning in FY 2015, CMS modifies the minimum number of cases required for a hospital to receive a score on the 30-day mortality measures, and a minimum is set for the new efficiency domain. A minimum number of 25 cases will be required for a score on the mortality measures, replacing the current 10-case minimum. In light of the 9-month performance period adopted for these measures for FY 2015, CMS believes an increase in the minimum number of cases will ensure more reliable data given the shorter time period. Although fewer hospitals will receive a

mortality domain score, hospitals need only have a score for two domains to receive a total VBP score.

For the new efficiency measure, a minimum of 25 cases is required for a score. Because it is the only Efficiency measure, this is also the minimum for a score for the Efficiency domain. In the proposed rule CMS described an independent analysis it used to determine the appropriate minimum, and says that at 25 cases, 97.8 percent of hospitals would meet the minimum to receive a score, and the 95 percent confidence interval for a hospital with an efficiency score of 1.0 is from 0.81 to 1.23. In this rule, CMS discusses additional reliability analysis of the Medicare spending per beneficiary measure which it believes provides additional support for the 25 case minimum. It is available at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/MSPBReliabilityAnalysis-Jul-18-12.pdf. (Note: The link published in the pre-publication version of the final rule is broken.)

14. Immediate Jeopardy Citations

The statute requires that a hospital be excluded from the VBP program if it has been cited by the Secretary during the performance period for deficiencies that pose an immediate jeopardy to the health or safety of patients. In this rule, CMS finalizes without change its proposal that for purposes of the VBP program, the definition of the term "immediate jeopardy" found under 42 CFR Part 489 and used for the purposes of survey, certification, enforcement and termination procedure with respect to provider agreements will apply. In addition, CMS defines the phrase "cited for deficiencies that pose immediate jeopardy" for the purposes of the VBP program as the identification of an immediate jeopardy noted on the Form CMS-2567, Statement of Deficiencies and Plan of Correction that is issued to a hospital after a survey. A hospital must be cited for immediate jeopardy on two surveys during the performance period and each time noted on the Form CMS-2567 in order to be considered having multiple deficiencies that pose immediate jeopardy and thus excluded from the VBP program for the applicable fiscal year. Because performance periods can vary by measure, CMS indicates that a hospital cited for multiple deficiencies as defined here during any of the performance periods for a VBP program year will be subject to exclusion.

CMS responds to comments regarding wide variation across states and CMS regional offices regarding findings of immediate jeopardy. CMS cites requirements for consultations before an immediate jeopardy finding can be declared which it believes reduces the risk of subjectivity in making these determinations. Additionally, CMS indicates that because of the link between immediate jeopardy citations and the VBP program, it has undertaken special training for surveyors and regional office staff to ensure consistency across regions and state. Data will be monitored and used for further training if needed.

Most subsection (d) hospitals are deemed in compliance with Medicare conditions of participation on the basis of accreditation, and CMS states that although it does not issue immediate jeopardy citations on the basis of an accrediting organization's findings, there is no advantage to having deemed status. This is because the Secretary may authorize state survey agencies to conduct representative validation surveys or substantial allegation validation surveys

of deemed facilities. Accrediting organizations are required to notify CMS promptly if they identify a situation in a deemed facility that constitutes immediate jeopardy, which may trigger a substantial allegation validation survey.

In a clarification, CMS indicates that it will consider only those Form 2567s which are issued to a hospital based on a federal survey both for general enforcement purposes and for determining immediate jeopardy citations for the Hospital VBP Program. Some states use this federal form in conducting surveys under state licensure authority, but a reference to immediate jeopardy in such a case is not a report resulting from a federal survey.

CMS makes two clarifications with respect to operative dates. The first clarification is with respect to determining the performance period to which an immediate jeopardy citation will be applied. The survey end date, which is tracked in an automated system, will be used to assign the citation to a performance period. Given the possibility of simultaneous federal surveys, two Form 2567s with immediate jeopardy citations and the same survey end date will be counted as one instance of an immediate jeopardy citation. CMS acknowledges that the survey end date will often be earlier than the date on which Form CMS-2567 is issued to the hospital. The second clarification is that the definition of immediate jeopardy is in effect and applied to the performance period for the FY 2013 Hospital VBP Program even though that performance period occurred prior to the start of the fiscal year.

While some commenters asked that hospitals be able to appeal immediate jeopardy citations, CMS states that this is not possible under current regulations. It will consider future rulemaking on this issue.

Some commenters expressed concern about the possibility of immediate jeopardy citations resulting in a hospital's exclusion from the VBP Program for a long period of time because of the range of performance periods that apply to VBP Program measures for any given year. CMS believes that under the statute it must exclude hospitals cited during any finalized performance period regardless of its length.

VBP Program Quality Measures for FYs 2014 and 2015			
Measure ID	**Measure Description**	**2014**	**2015**
Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	X	X
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	X	X
HF-1	Discharge Instructions	X	X
PN-3b	Blood Cultures Performed in the Emergency Department Prior to I Antibiotic Received in Hospital	X	X
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	X	X
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	X	X
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	X	X
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	X	X

VBP Program Quality Measures for FYs 2014 and 2015			
Measure ID	**Measure Description**	**2014**	**2015**
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	X	X
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2	X	X
SCIP–Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received Beta Blocker During the Perioperative Period	X	X
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	X	Removed
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	X	X
Patient Experience of Care Measures			
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)			
Communication with Nurses		X	X
Communication with Doctors		X	X
Responsiveness of Hospital Staff		X	X
Pain Management		X	X
Communication About Medicines		X	X
Cleanliness and Quietness of Hospital Environment		X	X
Discharge Information		X	X
Overall Rating of Hospital		X	X
Outcome Measures			
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	X	X
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	X	X
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate	X	X
AHRQ PSI 90	Complication/patient safety for selected indicators (composite)		X
CLABSI	Central Line-Associated Blood Stream Infection		X
Efficiency Measures			
MSPB-1	Medicare spending per beneficiary		X

D. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

This rule finalizes measures and data collection timelines for the LTCH quality reporting program that was established in the FY 2012 IPPS/LTCH final rule. Under the FY 2012 IPPS/LTCH final rule, three measures were adopted for the LTCH quality reporting program for the FY 2014 payment determination, the initial year of the quality reporting program. Two of them, CAUTI (NQF #0138) and CLABSI (NQF #0139), are measures in use in the Hospital IQR Program and other quality reporting programs. The third (NQF # 0678) measures the percent of residents with pressure ulcers that are new or worsened.

CMS finalizes several proposals regarding measures previously adopted for the LTCH quality reporting program:

- The three measures previously adopted for the FY 2014 payment determination will continue into FYs 2015 and 2016.

- For the future, once a quality measure is adopted, it will be retained in future years unless otherwise stated.
- The changes to the CLABSI and CAUTI measures made in the NQF measure maintenance process subsequent to the adoption of these measures for the FY 2014 payment determination are adopted for the LTCHQR program. Because the NQF has not yet expanded its endorsement of the Pressure Ulcer measure to the LTCH setting, CMS retains the measure previously finalized in the FY 2012 IPPS/LTCH PPS final rule for the 2014 LTCHQR Program. CMS clarifies that with respect to the pressure ulcer measure, LTCHs will only be required to complete a subset of data elements from the LTCH CARE Data Set. CMS also notes that Office of Management and Budget approval was received for the use of the LTCH CARE Data Set for collection of data for the pressure ulcer measure on April 24, 2012 (OMB Control Number 0938-1163).
- Changes to measure specifications made in the NQF measure maintenance process that do not substantially change the nature of the measure will be made through a subregulatory process. Rulemaking will continue to be used to adopt substantial changes to measures. CMS gives as examples of non-substantive changes updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. Examples of changes CMS might consider substantive would be those in which changes are so significant that the measure is no longer the same measure, when a standard of performance assessed by a measure becomes more stringent, or where the NQF has extended its endorsement of a previously endorsed measure to a new setting.

CMS finalizes the addition of only the following two of the five additional measures it had proposed for inclusion in the LTCHQR program for the FY 2016 payment determination.

1. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680, which is re-titled as a result of NQF endorsement).
2. Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which is now NQF-endorsed.

CMS notes that the specifications for NQF #0680 are written to account for cases when the patient refuses the vaccine or when the medical provider documents that the vaccine was not given due to a contraindication. For purposes of NQF #0431, health care personnel refers to all paid and unpaid persons working in health care settings, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from health care personnel. Also, the numerator for this measure includes healthcare personnel who declined influenza immunization.

The following measures were <u>not</u> adopted for the reasons discussed below.

Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)(NQF #0682): The NQF expanded its endorsement of this measure to the LTCH setting and changed its title to Percent of Residents or Patients Who Have Been

Assessed and Appropriately Given the Pneumococcal Vaccine. However, the Centers for Disease Control and Prevention (CDC) has advised CMS that the Advisory Committee on Immunization Practices (ACIP) guidelines for adult and pediatric pneumococcal vaccination are currently being re-evaluated, and that the measure specifications might change as a result. For this reason, CMS is not finalizing this measure.

Ventilator Bundle (NQF #0302): The measure steward, the Institute for Healthcare Improvement (IHI) decided to withdraw the Ventilator Bundle measure from consideration for NQF re-endorsement, and thus CMS is not finalizing this measure, but notes that it plans to propose an updated version of the measure during future rulemaking.

Restraint Rate per 1,000 Patient Days (not NQF endorsed): While some commenters supported the measure, others were concerned that it was not NQF-endorsed, that the specifications for the measure were flawed, and that the measure failed to recognize that restraint use is often necessary and medically appropriate in the LTCH setting. Thus CMS does not finalize this measure but notes that it intends to propose a patient restraint measure for the LTCHQR Program in future rulemaking.

Taking into account the above decisions, the quality measures for the FY 2016 LTCHQR Program are the five measures listed in the following table, along with the previously finalized measures for FY 2015.

NQF Measure	Measure Title	FY 2015	FY 2016
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcomes Measure	X	X
NQF #0139	NHSN Central line-associated Blood Stream Infection (CLABSI) Outcomes Measure	X	X
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)	X	X
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)		X
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel		X

CMS finalizes the data submission deadlines as proposed and shown in the table that follows. For the FY 2015 payment determination, LTCHs will have about 135 days after the end of the reporting quarter to submit data to CMS. For FY 2016 and subsequent years, the time frame will be 45 days after the end of the reporting quarter.

Timelines for Data Submission for the LTCH Quality Reporting Program	
FY 2014 Payment Determination (finalized in FY 2012 IPPS/LTCH rulemaking)	
Data Collection Timeframe (CY 2012)	**Final Submission deadline**
Q4 (October 1-December 31, 2012)	May 15, 2013
FY 2015 Payment Determination	
Data Collection Timeframe (CY 2013)	**Final Submission deadline**
Q1 (January -March 2013)	August 15, 2013
Q2 (April- June 2013)	November 15, 2013
Q3 (July –September 2013)	February 15, 2014
Q4 (October –December 2013)	May 15, 2014
FY 2016 Payment Determination	
Data Collection Timeframe (CY 2014)	**Final Submission deadline**
Q1 (January -March 2014)	May 15, 2014
Q2 (April- June 2014)	August 15, 2014
Q3 (July –September 2014)	November 15, 2014
Q4 (October –December 2014)	February 15, 2015

Several commenters urged CMS to propose use of the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System as the submission mechanism through the regulatory process so that the public can be afforded a proper notice and comment period. In response, CMS notes that the QIES ASAP System is a secure, intranet-based data submission and data storage system that it has adopted for a variety of purposes, and that this system was selected to support the data submission of LTCHQR quality measures into the QIES national data base. CMS adds that it will release a demonstration-version of the LTCH Assessment Submission Entry & Reporting (LASER) software, a free, JAVA-based application that provides an option for facilities to collect and maintain their LTCH CARE Data Set for subsequent submission to the QIES ASAP System, in the middle of August to provide LTCHs the opportunity to familiarize themselves with the LASER software and the features of the tool. Further, the production version of LASER will be released on the QIES Technical Support Office Web site by the end of August. CMS notes that the LASER software is currently undergoing critical and rigorous testing by quality assurance staff. CMS also says that it has revised Chapter 2 of the draft LTCHQR Program Manual relating to assessment of patient's "usual status," assessment time frame for admission assessment, and relevant approaches to completing each item on the LTCH CARE Data Set. The revised manual will be posted at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html

In response to comments expressing concern about the ability of the NHSN to handle LTCHQR Program data collection (for the CAUTI and CLABSI measures), CMS says that the CDC has given assurances that the NHSN system is adequate and will be able to handle the LTCHQR Program data reporting. CMS adds that over 300 of the 450 LTCHs in the nation are already enrolled and reporting into the NHSN.

Public Display of Data Quality Measures. CMS had not proposed any procedures or timelines for public reporting of data reported under the LTCH quality reporting program. In the final rule,

CMS says it is continuing to undertake efforts to establish such procedures and timeline and will communicate this information as soon as it is available (no mention is made of an opportunity for public comment on the procedures and timeline). CMS adds that it will provide a preview period of quality reports under the LTCHQR Program prior to making quality data public.

E. Quality Reporting Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A quality reporting program for ASCs was finalized in the 2012 OPPS/ASC Final Rule for initial implementation in CY 2014. At that time CMS indicated that the FY 2013 IPPS/LTCH rulemaking process would be used to further address elements of the program regarding administrative requirements, data validation, and reconsiderations and appeals. The IPPS/LTCH rule was chosen for this purpose because it will be finalized at an earlier date than the OPPS/ASC rule.

The measures previously adopted for the ASC quality reporting program for 2014 include several measures which are to be reported by ASCs by adding a Quality Data Code (QDC) to the claim. For 2015, these measures will continue as part of the program and two structural measures will also be required to be reported by participating ASCs.

CMS now finalizes without modification proposals regarding ASC quality reporting as follows:

- ASCs are encouraged to maintain a QualityNet administrator as a point of contact for security purposes for the program, but this is only a requirement for the purpose of reporting the structural measures required for 2015, which must be submitted between July 1, 2013 and August 15, 2013 (CMS cautions ACSs not to wait until the deadline to apply for a QualityNet user account and acknowledges that such accounts are automatically deactivated after a 120-day period of inactivity but can be reactivated by contacting the QualityNet Help Desk).
- ASCs are considered to be participating in the quality reporting program for a payment determination year if they submit any quality data during the reporting period for that year, and participation will be assumed to continue until the ASC formally withdraws from the program. Withdrawal must be done by August 31 of the year prior to the payment determination year. Once an ASC withdraws for a payment year, the 2.0 percentage point reduction in the annual payment update will take effect for that year.
- All quality data submitted by an ASC will be publicly available unless the ASC withdraws from the program.
- Administrative requirements will apply to ASCs designated as open in the Certification and Survey Provider Enhanced Reports (CASPER) system before January 1, 2012 for the 2014 payment determination, and open for at least 4 months prior to January 1, 2013 for the 2015 payment determination.
- Claims for the time period October 1, 2012 to December 31, 2012 that are paid by April 30, 2013 will be included in the data used for the 2014 payment determination.
- To be considered complete for the 2014 and 2015 payment determinations, ASCs will have to report QDCs on at least 50% of claims meeting measure specifications. CMS expects to propose increasing this threshold for future years as ASCs become more

familiar with the quality reporting requirements. CMS specifies that only claims where Medicare is the primary payer will be used in the calculation of data completeness for the 2014 payment determination because private payers will not have access to files with the ASCQR Program-related G-codes until January 1, 2013; CMS adds that it intends to finalize what claims would be included in calculating data completeness for the 2015 payment determination in the CY 2013 OPPS/ASC final rule with comment period.

- There will be no data validation involving independent medical record review. CMS believes this is consistent with other quality reporting programs, where claims-based and structural measures are not subject to such data validation. Several commenters urged CMS to reconsider the need for data validation to ensure standardization and accuracy, but CMS responds that it does not believe there is a method for effectively validating structural measure data and that it does not believe that any results that could be obtained from independent validation of claims-based measures justify the associated burden. CMS adds that as it gains more experience with the ASCQR Program, it will reassess whether a data validation process for structural and claims-based measures is needed.
- A process is adopted for obtaining waivers or extensions of the ASC reporting requirements under extraordinary circumstances (such as a natural disaster). The process parallels the one used for the hospital OQR program. A request form will need to be submitted within 45 days of the date that the extraordinary circumstance occurred, notwithstanding comments urging CMS to give ASCs more time, such as 90 days. Note that under the adopted process, CMS has the discretion to grant waivers or extensions to ASCs that have not been formally requested when CMS determines that an extraordinary circumstance affects an entire region or locale. In response to comments, CMS says it is aware of situations where clearinghouses are removing QDCs from claims as well as of non-Medicare payers rejecting claims with QDCs as having invalid codes. CMS would consider inappropriate removal or rejection of QDCs an extraordinary circumstance "if the ASC was able to sufficiently document refusal by a clearinghouse or private payer to follow [CMS'] HCPCS usage standards that could result in the ASC suffering substantial risk of having a payment reduction under the ASCQR Program;" this documentation must include substantive efforts made by the ASC to inform the clearinghouse or private payer of the need to follow CMS' usage standards.
- A process for reconsideration of quality reporting program payment determinations is adopted similar to the ones in effect for the hospital IQR and OQR programs. Reconsideration requests must be submitted by March 17 of the affected payment year, notwithstanding comments urging CMS to give ASCs more time. CMS notes that an automated reporting system with feedback reports will begin during 2013, with CMS intending to provide feedback on the October 1, 2012 to December 31, 2012 claims-based measures through a report that will be supplied via an ASC's QualityNet account on the QualityNet Web site, http://www.QualityNet.org.

F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

CMS finalizes its proposal to implement an inpatient psychiatric facilities (IPF) quality reporting program beginning in FY 2014 for psychiatric hospitals and units that are reimbursed under Medicare's IPF PPS. Covered entities that do not meet the requirements of the IPF quality reporting program for a fiscal year will be subject to a 2.0 percentage point reduction in the applicable annual update factor, and this reduction may result in a negative update factor. CMS notes that the IPF PPS is applicable to freestanding psychiatric hospitals, including government-operated psychiatric hospitals, and distinct part psychiatric units of acute care hospitals and CAHs, but that it does not apply to inpatient psychiatric units within a children's hospital.

Quality Measures

For the IPF quality reporting program in FY 2014 and subsequent years, CMS finalizes the six NQF-endorsed quality measures it had proposed. As proposed, CMS will require reporting of data for four age groups (children, adolescents, adults, and older adults) and will collect aggregate data rather than patient-level data to minimize reporting burden on IPFs. CMS intends to provide a template in a commonly available spreadsheet format to assist providers in entering and computing measure rates. This template will be available on the QualityNet Web site. Technical specifications for the six measures can be found on the website of The Joint Commission (TJC), the measure steward, at: https://manual.jointcommission.org/bin/view/Manual/WebHome,

The six adopted measures are as follows:

Patient Safety

HBIPS-2 Hours of Physical Restraint Use (NQF #0640)
This measure is the total number of hours that all psychiatric inpatients were maintained in physical restraints, expressed as a percentage of the total number of psychiatric inpatient hours, excluding leave days.

HBIPS-3 Hours of Seclusion Use (NQF #0641)
The total number of hours that all psychiatric inpatients were held in seclusion, expressed as a percentage of the total number of psychiatric inpatient hours, excluding leave days. One commenter recommended that the amount of time be measured in minutes rather than in hours but CMS responds that this would require additional user testing before it could be implemented.

Clinical Quality of Care

HBIPS-4 Patients Discharged on Multiple Antipsychotic Medications (NQF #0552)
HBIPS-5 Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560)

These two measures were developed to be used together. HBIPS-4 measures the percentage of all psychiatric patients discharged on two or more routinely scheduled antipsychotic medications among patients discharged on at least one antipsychotic medication, while HBIPS-5 measures the rate of patients discharged on multiple

antipsychotic medications with appropriate justification. CMS believes that while lower rates of multiple antipsychotic medication use are indicative of higher quality care, there is no expectation that a zero rate is the desired outcome. CMS acknowledges that some consumers may misinterpret low rates on HBIPS-4 as poor performance and says it intends to test displays of performance data with target audiences and incorporate feedback into the display before public reporting. CMS also acknowledges that it did not correctly describe the denominator for HBIPS-4 in the proposed rule and clarifies that the denominator includes only patients discharged on one or more antipsychotic medications. In terms of HBIPS-5, CMS notes that TJC has identified the following justifications for discharging a patient on multiple antipsychotics: (1) the medical record contains documentation of a history of a minimum of three failed trials of monotherapy; (2) the medical record contains documentation of a recommended plan to taper to monotherapy or to cross-taper drugs (that is, decreasing the dosage of one while increasing the dosage of the other to a level that manages the patient's symptoms with one medication); and (3) the medical record contains documentation of augmentation of Clozapine. CMS also notes that this measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement or failing to return from leave, and patients with a length of stay of 3 days or less.

Care Coordination

HBIPS-6	Post-Discharge Continuing Care Plan Created (NQF #0557)
HBIPS-7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge (NQF #0558)

These two measures were also developed as a pair. HBIPS-6 measures the percentage of all psychiatric discharges for whom a post-discharge continuing plan is created and contains the reason for hospitalization, principal discharge diagnosis, discharge medications and next level of care recommendations. HBIPS-7 measures the percentage of all psychiatric discharges for whom the post-discharge plan of care was transmitted to the next level of care. Both measures exclude patients who died, patients with an unplanned departure resulting in discharge due to elopement or failing to return from leave, patients who refused (or whose guardians refused) aftercare, and patients who refused to sign (or whose guardians refused to sign) authorization to release information. In response to a commenter recommending that patient lab results and pending tests should be included in care plans, CMS agrees that, when appropriate, this information should be provided in care plans but declines to make this a requirement for purposes of the HBIPS-6 and HBIPS-7 measures. Commenters recommended expanding the exclusions to cover other possible reasons for a lack of post-discharge care, such as out of jurisdiction, no psychiatric care required, admission for observation with pre-arranged discharge back to sending provider or to another facility, such as a jail, and instances where the next level of care is unavailable, such as for uninsured homeless patients, but CMS simply says it will consider these suggestions during the measure maintenance process. CMS also acknowledges receiving one comment recommending that the timeframe for transmittal of the discharge plan be changed from "by the fifth post-discharge day" to "within one post-discharge day" but declines to adopt this recommendation.

CMS will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism knows as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted at https://www.QualityNet.org. As is the case for other quality reporting systems, CMS will adopt non-substantive measure changes through a subregulatory process and continue to use notice-and-comment rulemaking to adopt substantive changes.

CMS says it is considering initiating a call for future measures to solicit input to assess the following measure domains: clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. In response to CMS' request for input on possible additional measure topics, CMS received the following suggestions: measures with regard to the monitoring of patients on antipsychotic medications for metabolic syndrome, primary care follow-up, treatment adherence post acute care, and coordination of care between psychiatric care and alcohol/substance abuse treatment; measures assessing patients' experience with care, such as the National Association of State Mental Health Program Directors' Inpatient Consumer Survey; and HBIPS-1: Admission Screening for Violence Risk, Substance Use, Psychological Trauma History and Patient Strengths Completed. CMS simply thanks the commenters for their input, which it promises to take into consideration for future measure development and selection.

Data Submission Requirements for the FY 2014 Payment Determination and Subsequent Years

CMS finalizes the reporting and submission requirements for the FY 2014, FY 2015 and FY 2016 payment determinations as proposed. IPFs will need to meet the specific data collection and submission requirements as described on the QualityNet website and TJC's Specifications Manual for Joint Commission National Quality Measures. In addition, IPFs will need to submit aggregate data on the measures on an annual basis (with data reported separately for each quarter). The data submission deadlines are shown in the following table.

Timelines for Data Submission for the IPF Quality Reporting Program	
FY 2014 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**
Q4 2012 (October 1-December 31, 2012)	July 1, 2013- August 15, 2013
Q1 2013 (January 1-March 31, 2013)	
FY 2015 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**
Q2 (April- June 2013)	July 1, 2014- August 15, 2014
Q3 (July –September 2013)	
Q4 (October –December 2013)	

FY 2016 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**
Q1 (January -March 2014)	July 1, 2015-August 15, 2015
Q2 (April- June 2014)	
Q3 (July –September 2014)	
Q4 (October –December 2014)	

CMS declines to delay the first reporting period, arguing that the 9-month lag time between October 1, 2012 and the beginning of the data submission period (July 1, 2013) should give IPFs sufficient time to be prepared. CMS also declines to grant "deemed" status to those IPFs that are already submitting the data to TJC, saying that this would make the agency's data collection incomplete. In response to a comment urging CMS to establish a process for automatic data exchange between CMS and TJC, CMS says it will consider establishing such a process through future rulemaking. CMS also notes that it may consider modifying the IPFQR Program to require patient-level data through future rulemaking. Further, no data validation is being required by CMS at this time.

CMS finalizes as proposed the requirements for population, sampling, and minimum case thresholds, which will be those specified for the adopted measures in TJC's Specifications Manual. Data must be reported on all patients, not just Medicare beneficiaries. IPFs must submit data on all measures, even when the population is zero or small or if no cases apply (e.g., no hours of physical restraint use). CMS acknowledges that it erroneously noted that the Specifications Manual does not require sampling procedures for measures HBIPS-2 and HBIPS-3, whereas the manual actually does not allow such sampling; IPFs are required to submit data on all cases for these two measures. Further, if the initial patient population stratum size is below a certain number of cases for measures HBIPS-4, HBIPS-5, HBIPS-6 and HBIPS-7, IPFs must submit all applicable measure data rather than sample data.

CMS finalizes as proposed the data accuracy and completeness acknowledgement requirements for the FY 2014 payment determination and subsequent years. IPFs must submit a data accuracy and completeness acknowledgement by August 15th each year via the QualityNet website. For example, for the FY 2014 payment determination, the acknowledgement deadline is August 15, 2013.

CMS notes that the opportunity to utilize electronic health records (EHRs) for automatic data collection is not applicable under the IPFQR Program because the proposed measures will be submitted as aggregate data. The agency adds that it will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

Other Procedural Requirements

Procedural requirements for IPF participation adopted in the final rule parallel those of the Hospital IQR Program, and involve registering with QualityNet, completing a notice of participation, and so forth. Reconsideration and appeals procedures will be available to an IPF that believes its annual payment update was incorrectly reduced for failure to meet the quality reporting program requirements, and waivers from the quality reporting program requirements

will be available to IPFs under extraordinary circumstances. Requests for such waivers must be submitted within 30 days of the date that the extraordinary circumstances occurred.

Public Display of Quality Data

CMS finalizes as proposed the public display requirements for preview and public display procedures for the 2014 payment determination and subsequent years. More specifically, CMS will make the data publicly available on its website beginning in the first quarter of the calendar year following the payment determination year. For example, data for the FY 2014 payment determination year will be displayed during the first quarter of CY 2014. And IPFs will have the opportunity to preview the data between September 20 and October 19 of the payment determination year before it is publicly displayed (for example, between September 20, 2013 and October 19, 2013 for the FY 2014 payment determination year). For public reporting purposes, commenters suggested that a footnote should be used in cases where a hospital has a small sample size and that rates should not be reported, and that CMS establish a minimum number of cases. CMS thanks the commenters for their suggestions and says it will take them into consideration when it gains experience from this coming year's data.

IX. MedPAC Recommendations and Other Related Studies and Reports for the IPPS and the LTCH PPS.

Studies and Reports on Reforming the Hospital Wage Index. On April 11, 2012, the Secretary submitted to Congress a report to reform the Medicare Wage Index using the concept of a Commuting Based Wage Index (CBWI) to replace the current Medicare wage index methodology. The CBWI would use commuting data of hospital employees commuting from home to work to define hospital labor market areas thereby aggregating wage data based on worker residence rather than a CBSA-based area where a hospital is located. A CBWI methodology would use commuting flows to identify specific areas, with a potential specificity of zip codes or rural census tracts, to determine the proportion of hospital employees hired from each area, using either hospital cost report data or, perhaps, Bureau of Labor Statistics (BLS) Occupational Employment Survey data. A hospital's benchmark wage level would be calculated as the weighted average of hiring proportions by area and area wage levels and then divided by the national average.

The Secretary believes that a CBWI methodology "would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on [BLS] data for health care industry workers"; further, while the CBWI methodology would permit variation within a CBSA, those variations would likely be less severe and less likely to result in large differences (i.e., cliffs) among hospitals within adjacent CBSAs. However, stakeholders expressed concerns in an April 12, 2011, open door forum over the availability of commuting data, continuation of certain current law exceptions and adjustment policies, and the impacts of the CBWI upon other nonhospital payment systems; concerns were also raised that a CBWI may encourage providers to manipulate hiring practices in order to improve wage index calculations. While CMS is not

convinced that providers will alter hiring practices, the agency agrees that a CBWI may not be appropriate or even calculable for non-hospital payment systems.

MedPAC expressed several concerns with the CBWI methodology. MedPAC believes that

- It is preferable to apply a method that uses a broader definition of labor inputs (i.e., not limited to hospital workers), and it worries about a great circularity risk of the CBWI because of its reliance on hospital-specific employment patterns;
- CBWI contradicts IOM report principles that geographic adjustment should reflect 1) input prices faced, not costs incurred, by providers and 2) areawide input prices faced by all employers operating in the same local market;
- CBWI ignores well-established relationships between wage rates and commuting costs, and assumes workers will ask for the same wage from a job without regard to the length of commute;
- Using a correlation of wage index and actual wages is a poor measure of wage index validity; and
- CMS should publish simulated data on a hospital-by-hospital basis to ensure hospitals in the same city would not have different wage indexes under the CBWI system.

CMS disagrees that the CBWI contradicts the IOM principles and notes that those principles apply with respect to the construction of the wage index--not the method used to group data into wage areas that reflect the boundaries of labor markets. CMS argues that a main advantage of CBWI is its ability to refine those boundaries, and it points out that CBWI may use many different sources of data. CMS also notes that the circularity concerns raised by MedPAC exist in the current system, as well as current single provider MSAs, and believes that relatively minor adjustments can be made to mitigate any effects under a CBWI system. CMS also believes that while it is possible to adjust CBWI for commuting costs, it may be impractical and would add a great deal of complexity; additionally, CMS is not convinced that failing to account for commuting costs is more problematic under a CBWI that it is for an MSA-based wage index.

CMS agrees with MedPAC that wage index methodologies should not be measured solely on their correlation with observed wages but still believes the comparison provides useful information, for example, in identifying whether sharp differences exist between actual and fitted wages which would arise if an index created artificial cliffs across boundaries that do not reflect actual circumstances.

MedPAC also noted errors in the wage index reform proposal comparison table contained in the proposed rule which CMS corrects; CMS did not intend to give the impression that a separate occupational mix adjustment was necessary under the MedPAC or IOM methodology.

The Secretary commissioned the Institute of Medicine (IOM) to recommend changes to the wage index. The IOM recommends:

- Changing the "current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live."
- Assigning each hospital within a county in an MSA the county area wage index determined by:

→ 1) first computing a wage index for each MSA using the current methodology (before hospital reclassification); and
→ 2) computing an area wage for each county within the MSA equal to the weighted average of MSA-level average hourly wages (using the BLS Occupational Employment Survey) for all health care workers, where the weight for each MSA would measure the share of all hospital workers living in the county who commute to hospitals located in that MSA.

The wage indices would then be normalized for budget neutrality.

While the IOM recommendations would reduce the cliffs among wage levels in adjacent areas, the Secretary is concerned about the limitation of the average hourly wage computation to only those health care workers who live near a hospital versus those who could be employed there. The Secretary also reflects concerns expressed by hospitals and hospital associations on the operational and other challenges of using the BLS Occupational Employment Survey.

CMS notes that the American Hospital Association has created an Area Wage Index Task Force to review the CMS, IOM, and MedPAC wage index reform proposals and that it plans to review the findings of this Task Force.

X. Quality Improvement Organization (QIO) Regulation Changes Related to Provider and Practitioner Medical Record Deadlines and Claims Denials

Medical records are critical for Quality Improvement Organizations (QIOs) to determine that services were reasonable and medically necessary, meet professionally recognized quality standards, and were provided in the appropriate settings. CMS states that the responsibility of practitioners and providers to supply information to QIOs for use in completing their review activities is implicit throughout the QIO program. **CMS is finalizing its proposal to make several changes to the regulations at § 476.1, 476.78, and 476.90 to more clearly convey the responsibilities of providers and practitioners in submitting medical information and to specify the QIO's authority should the information not be received.** CMS did not receive any comments about their proposals.

CMS finalized changes related to the definition of "providers":

- Add a definition of "providers" under § 476.1 to clearly denote that certain requirements in Part 476 apply to health care facilities, institutions, and organizations involved in the delivery of health care services to Medicare beneficiaries.
- Change the section heading of § 476.78 from "Responsibilities of health care facilities" to "Responsibilities of providers and practitioners".

CMS finalized changes related to the timeframes for practitioners and providers to follow in submitting medical information:

- Add references to "practitioners" in § 476.78(b)(2) so that the 21-day and 30-day timeframes for submittal of information apply equally to practitioners and providers.

CMS finalized changes to § 476.90 that will provide improved instructions to QIOs when attempting to resolve issues associated with practitioners and providers that fail to submit medical information within the timeframes set forth in § 476.78. These include:

- Changing the section heading from "Lack of cooperation by a health care facility or practitioner" to "Lack of cooperation by a provider or practitioner".
- Incorporating the broader term "provider" (as reflected in the proposed changes to § 476.1) within § 476.90 as well as references to "practitioners", where appropriate.
- Adding references to "practitioners" in § 476.90(a)(2) to denote that the QIO's authority includes the ability to make financial liability determinations for both providers and practitioners and adding the word "may" to clarify that the QIO has the discretion to report to the Inspector General a provider's or practitioner's failure to provide evidence of the medical necessity or quality of care provided.
- Modifying § 476.90(b) to denote that QIOs will also deny claims if practitioners fail to submit medical information as requested. This proposed change is based on the fact that a QIO cannot make a determination about whether payment shall be made on the basis of its reviews (section 1154(a)(2) of the Act) if the QIO does not have the medical records it needs to determine that payment would be appropriate.
- Adding new language to § 476.90(b) to convey the right of providers and practitioners to request a reconsideration by the QIO of its decision to deny the claim based on the failure to receive the medical information, and that no further appeal rights exist beyond the QIO.

CMS finalized technical changes:

- A technical correction to a cross-reference to "§ 474.30(c)" that appears in § 476.90(a)(1). This cross-reference is to the Office of Inspector General regulations that convey the obligations of providers and practitioners; these regulations are now located in 42 CFR 1004.10(c).
- A minor technical change to § 476.78, that is unrelated to the application of time frames. CMS proposes to delete the sentence, "QIOs pay providers paid under the prospective payment system for the costs of photocopying records required by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first-class postage for mailing the records to the QIO", because it is merely a reference to paragraph (c) of § 476.78 and does not provide substantive information.

CMS believes that the impact of these changes will be insignificant. However, at this time, they cannot determine the precise number of claim denials that will occur for practitioners as a result of these changes. CMS did not receive any public comments on their proposed statement of impact.

TABLE I.— REGULATORY IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2013

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
All Hospitals	3,423	2.7	0	0	0	0	0	0.1	0	-0.2	-0.3	2.3
By Geographic Location:												
Urban hospitals	2,497	2.7	0	0	0.1	-0.2	0	0.1	0	0	-0.3	2.4
Large urban areas	1,373	2.7	0	0.2	0.2	-0.3	0	0	0.1	0	-0.3	2.4
Other urban areas	1,124	2.7	0	-0.2	-0.1	-0.1	0.2	0.2	0	-0.1	-0.2	2.6
Rural hospitals	926	2.3	-0.1	-0.3	-0.3	2.1	-0.3	0.1	0.1	-1.4	-0.3	2.3
Bed Size (Urban):												
0-99 beds	633	2.7	0	0.2	0.2	-0.6	0.2	0.2	0	-0.4	-0.2	2.1
100-199 beds	780	2.8	0	0.1	0.2	-0.1	0.3	0.1	0.1	-0.1	-0.3	3
200-299 beds	448	2.7	0	0.1	0.1	-0.2	0	0.1	0.1	0	-0.3	2.5
300-499 beds	430	2.7	0	0	0	-0.2	0.1	0.1	0	0	-0.2	2.5
500 or more beds	206	2.7	0	-0.1	0	-0.3	-0.1	0	0	0	-0.3	2
Bed Size (Rural):												
0-49 beds	321	2.3	-0.1	-0.4	-0.4	0.8	-0.3	0.1	0.2	-2.6	-0.3	-0.2
50-99 beds	347	2.2	-0.1	-0.3	-0.4	1.3	-0.3	0.1	0.2	-3.3	-0.2	-0.4
100-149 beds	153	2.3	-0.1	-0.3	-0.4	2.6	-0.3	0	0	-0.7	-0.3	3.2
150-199 beds	58	2.3	-0.1	-0.2	-0.3	2.3	-0.3	0.2	0	-0.2	-0.2	3.8

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
200 or more beds	47	2.2	0	-0.2	-0.2	3	-0.3	0	0	0	-0.2	4.5
Urban by Region:												
New England	120	2.7	0	0.9	0.9	0.7	3.6	0	0.3	0	-0.3	7.9
Middle Atlantic	318	2.8	0	-0.1	0	0.1	-0.3	0	0.1	0	-0.4	2.3
South Atlantic	380	2.7	0	-0.4	-0.4	-0.4	-0.4	0	0	0	-0.2	1.3
East North Central	399	2.7	0	0.2	0.2	-0.2	-0.4	0	0	0	-0.3	2
East South Central	151	2.7	0	-1	-0.8	-0.3	-0.4	0	0	0	-0.3	0.9
West North Central	165	2.6	0	0.4	0.4	-0.7	-0.4	0.8	0	-0.1	-0.2	2.4
West South Central	372	2.7	0	-0.3	-0.3	-0.6	-0.4	0	0	-0.1	-0.1	1.2
Mountain	159	2.6	0	-0.3	-0.3	-0.3	0.6	0.2	0	0	-0.1	2.7
Pacific	382	2.7	-0.1	0.8	0.7	-0.2	0.6	0	0	0	-0.1	3.7
Puerto Rico	51	2.6	0	0.2	0.2	-0.8	0.1	0	0	0	0	2.1
Rural by Region:												
New England	23	2.4	-0.1	-0.3	-0.4	2.7	-0.4	0	0	-3.4	0	0.9
Middle Atlantic	69	2.1	-0.1	-0.3	-0.4	1.8	-0.3	0	0	-1.6	-0.3	1.3
South Atlantic	166	2.4	-0.1	-0.5	-0.6	2.7	-0.4	0	0.1	-1.2	-0.3	2.7
East North Central	120	2	-0.1	0	-0.1	1.4	-0.2	0	0.1	-1.6	-0.2	1.4
East South Central	173	2.7	-0.1	-0.5	-0.5	2.9	-0.4	0	0.1	-1.3	-0.4	3.1
West North Central	98	1.7	-0.1	-0.2	-0.3	1.3	-0.2	0.2	0.1	-1.2	-0.1	1.5

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
West South Central	181	2.5	-0.1	-0.1	-0.1	2.3	-0.4	0	0.1	-1.7	-0.4	2.3
Mountain	65	1.6	-0.1	0	-0.1	0.4	-0.2	0.8	0	-0.5	-0.1	1.9
Pacific	30	1.8	-0.2	-0.1	-0.2	1.2	-0.2	0	0	-0.3	-0.1	2.2
Puerto Rico	1	2.6	0	0.7	0.6	-0.9	-0.4	0	0	0	0	1.9
By Payment Classification:												
Urban hospitals	2,512	2.7	0	0	0.1	-0.2	0	0.1	0	0	-0.3	2.4
Large urban areas	1,383	2.7	0	0.2	0.2	-0.3	0	0	0.1	0	-0.3	2.4
Other urban areas	1,129	2.7	0	-0.2	-0.1	0	0.2	0.2	0	0	-0.2	2.8
Rural areas	911	2.2	-0.1	-0.2	-0.3	1.8	-0.3	0.1	0.1	-1.5	-0.2	1.9
Teaching Status:												
Nonteaching	2,392	2.7	0	-0.1	-0.1	0.3	0.1	0	0.1	-0.4	-0.3	2.4
Fewer than 100 residents	789	2.7	0	0.1	0.1	-0.1	-0.1	0.1	0	0	-0.2	2.5
100 or more residents	242	2.7	0	0.1	0.1	-0.2	0	0	0	0	-0.3	2.3
Urban DSH:												
Non-DSH	700	2.7	-0.1	0.2	0.1	-0.2	0.1	0.1	0.1	-0.3	-0.3	2.3
100 or more beds	1,558	2.7	0	0	0	-0.2	0	0.1	0	0	-0.3	2.3
Less than 100 beds	345	2.7	0	0.2	0.2	-0.1	0.2	0.1	0	-0.4	-0.2	2.5
Rural DSH:												
SCH	258	1.6	-0.2	-0.1	-0.3	0.4	-0.1	0	0	-1.8	-0.2	-0.4

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
RRC	232	2.3	-0.1	-0.2	-0.2	2.6	-0.3	0.1	0	-0.5	-0.2	3.8
100 or more beds	34	2.8	-0.1	-0.3	-0.4	2.3	-0.5	0	0.1	-0.9	-0.4	3
Less than 100 beds	296	2.8	-0.1	-0.6	-0.6	1	-0.4	0	0.4	-3.7	-0.4	-0.9
Urban teaching and DSH:												
Both teaching and DSH	825	2.7	0	0	0.1	-0.3	-0.1	0.1	0	0	-0.3	2.2
Teaching and no DSH	139	2.7	-0.1	0.4	0.3	-0.1	0.2	0	0.2	0	-0.3	3
No teaching and DSH	1,078	2.7	0	-0.1	-0.1	0	0.3	0	0	0	-0.3	2.6
No teaching and no DSH	470	2.8	0	0	0	-0.4	0	0.1	0.1	-0.1	-0.3	2.2
Special Hospital Types:												
RRC	203	2.8	0	-0.1	-0.1	3	-0.4	0.4	0	-0.7	-0.2	4.8
SCH	326	1.6	-0.2	-0.1	-0.3	0.1	-0.1	0.1	0.1	0	-0.2	1.3
Former MDH	195	2.8	-0.1	-0.4	-0.4	0.6	-0.2	0	0.3	-7.8	-0.4	-5.1
SCH and RRC	118	1.6	-0.1	0	-0.2	1.1	-0.1	0.1	0	0	-0.2	2.3
Former MDH and RRC	18	2.8	0.1	0	0.1	2	-0.5	0	0.1	-13.7	-0.3	-9.5
Type of Ownership:												
Voluntary	1,971	2.7	0	0.1	0.1	0	0	0.1	0.1	-0.1	-0.3	2.6
Proprietary	868	2.7	0.1	-0.3	-0.3	0	-0.1	0	0.1	-0.3	-0.3	1.8
Government	563	2.6	0	-0.2	-0.2	0	-0.1	0	0	-0.2	-0.2	1.9

	No. of Hospitals[1] (1)	Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	FY 2013 MGCRB Reclassifications[6] (6)	Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Application of the Frontier Wage Index[8] (8)	FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status[10] (10)	Hospital Readmissions Reduction Program[11] (11)	All FY 2013 Changes[12] (12)
Medicare Utilization as a Percent of Inpatient Days:												
0-25	376	2.7	0.1	0.1	0.2	-0.3	0.1	0	0	0	-0.2	2.5
25-50	1,834	2.7	0	0	0	-0.2	0	0.1	0	0	-0.2	2.4
50-65	974	2.6	0	0	0	0.7	0	0	0.1	-0.5	-0.3	2.6
Over 65	166	2.5	-0.1	-0.4	-0.4	0.3	0	0.1	0.1	-1.3	-0.4	0.9
FY 2013 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	654	2.6	0	0	0	2.9	0.1	0.1	0	-0.2	-0.3	5.2
Non-Reclassified Hospitals	2,769	2.7	0	0	0	-0.7	0	0.1	0.1	-0.1	-0.2	1.9
Urban Hospitals Reclassified	320	2.7	0	0.1	0.1	2.8	0.3	0.1	0	0	-0.3	5.7
Urban Nonreclassified Hospitals, FY 2013:	2,137	2.7	0	0	0	-0.7	0	0.1	0.1	0	-0.2	2
All Rural Hospitals Reclassified FY 2013:	334	2.3	-0.1	-0.3	-0.3	3.1	-0.3	0	0	-0.8	-0.3	3.7
Rural Nonreclassified Hospitals FY 2013:	531	2.2	-0.1	-0.3	-0.4	-0.1	-0.3	0.1	0.3	-2.5	-0.3	-1
All Section 401 Reclassified Hospitals:	46	2	-0.1	0.2	0.1	0.3	0	0	0.1	-2.5	-0.2	-0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	2.5	-0.1	-0.2	-0.2	2.8	-0.4	0	0.1	-3.3	-0.2	1.3
Specialty Hospitals												
Cardiac Specialty Hospitals	19	2.8	0.1	-0.2	-0.2	-0.8	0.1	0.6	0	0	-0.1	2.4

Note: Column 12 showing the impact of all changes was not readable in the public display copy of the regulation downloaded from the Federal Register. Health Policy Alternatives calculated column 12 as the sum of the relevant prior columns. The actual total impact may vary due to rounding and interaction effects, but these elements are usually minimal.

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 2011, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.
2 This column displays the payment impact of the hospital rate update and documentation and coding adjustment including the 1.8 percent adjustment to the national standardized amount (the 2.6 percent market basket update reduced by the 0.7 percentage point for the multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the 1.0 percent documentation and coding adjustment to the national standardized amount (-1.9 documentation and coding adjustment and 2.9 percent return to the rate to account for the one-time documentation and coding recoupment from FY 2012). In addition, it displays the payment impact of the hospital rate update of 1.8 percent and the documentation and coding adjustment of -0.5 percent to the hospital-specific rate.
3 This column displays the payment impact of the changes to the Version 30.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2011 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.998431 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 2009 cost report data. This column also displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000331.
5 This column displays the combined payment impact of the changes in Columns 3 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 0.998761 is the product of the wage index budget neutrality factor and the recalibration budget neutrality factor.
6 Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2013 payment impact going from no reclassifications to the reclassifications scheduled to be in effect for FY 2013. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.991276.
7 This column displays the effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. This column does not reflect the alternative temporary methodology beginning in FY 2013; we note that the impact of that methodology is discussed separately and will have negligible impact on budget neutrality. The rural floor and imputed floor budget neutrality factor is 0.991340.
8 This column shows the impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.
9 This column displays the impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
10 This column displays the impact of the expiration of MDH status, under section 3124 of the Affordable Care Act, a non-budget neutral payment provision.

11 This column displays the impact of the implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.
12 This column shows the changes in payments from FY 2012 to FY 2013. It reflects the impact of the FY 2013 hospital update and adjustments due to the documentation and coding. It reflects changes in hospitals' reclassification status in FY 2013 compared to FY 2012. It incorporates all of the changes displayed in Columns 2, 5, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 3 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.