FINAL RULE: MEDICARE INPATIENT HOSPITAL OPERATING AND CAPITAL PAYMENT FOR FISCAL YEAR 2016

SUMMARY

On July 31, 2015, the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2016 policies and rates for Medicare's prospective payment systems for acute inpatient hospital care (IPPS) and long-term care hospitals (LTCH). The payment rates and policies described in the rule would 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. The rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions, which are paid based on reasonable costs subject to limits.

Other provisions establish or modify policies affecting quality reporting requirements for acute care hospitals, PPS-exempt cancer hospitals, and LTCHs; set policies for eligible hospitals and critical access hospitals participating in the Medicare Electronic Health Record (EHR) Incentive Program; and update policies pertaining to the Hospital Value-Based Purchasing (VBP), the Hospital Readmissions Reduction, and the Hospital-Acquired Condition (HAC) Reduction programs. The regulatory document also includes an interim final rule, with comment period closing on September 29, to implement statutory extensions of the Medicare-dependent, small rural hospital (MDH) Program and changes to the payment adjustment for low-volume hospitals under the IPPS.

The final rules will be published in the *Federal Register* on August 17, 2015, with the rates and policy changes generally taking effect on October 1, 2015.

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I. PPS Rate Updates and Impact of the Rule; Outliers

CMS estimates that policies and rates in the final rule will increase combined operating and capital payments to the approximately 3,400 acute care hospitals paid under the IPPS by about $272 million (about 0.2 percent) in FY 2016 compared to FY 2015. The increase is comprised of increases of about $85 million in IPPS operating payments and $187 million in IPPS capital payments. Although the annual update and other policies would increase operating payments in FY 2016 by approximately $378 million, Medicare disproportionate share hospital (DSH) payments are projected to fall about $303 million stemming from the growing impact of the Affordable Care Act (ACA) reductions in DSH; expiring new technology add-on payments for three technologies and the additional approval of add-on payments for two technologies combine for an increase of $9.5 million in hospital operating payments.

A. Inpatient Hospital Operating Update for FY 2016

The final rule increases IPPS operating payment *rates* by 0.9 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The increase reflects an "applicable percentage increase" of 1.7 percentage points combined with a reduction of 0.8 percentage points due to continued implementation of the documentation and coding recoupment adjustment required by the American Taxpayer Relief Act of 2012 (ATRA) (described in section II.D. below).

The 1.7 percent "applicable percentage increase" is the net result of a market basket update equal to +2.4 percentage points, an annual multi-factor productivity (MFP) adjustment of -0.5 percentage points[1] and a statutory update adjustment of -0.2 percentage points. Both the annual productivity adjustment and the 0.2 percentage point reduction are required by the ACA. The payment rate update factors are summarized in the table below.

Factor	Percent Change
FY 2016 inflation (market basket) update	2.4
Multifactor productivity adjustment	-0.5
Additional -0.2 percentage point update adjustment required by the ACA	-0.2
Subtotal – "applicable percentage increase"	*1.7*
Documentation and coding recoupment required by ATRA	-0.8
Net increase in national standardized amounts (before application of budget neutrality factors)	*0.9*

[1] 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 MFP for IPPS payment updates are developed by IHS Global Insight, Inc. an economic forecasting firm which also prepares the market basket forecasts, using a methodology described in the proposed rule. More technical information on the MFP is available from BLS: http://www.bls.gov/mfp/mprtech.pdf. The final rule reflects more recent projections of the market basket and productivity adjustments.

Hospitals that choose not to participate in the Hospital Inpatient Quality Reporting (IQR) Program or do not successfully submit the required quality data will not receive the full "applicable percentage increase." Similarly hospitals that are not meaningful users of EHR also will not receive the full "applicable percentage increase." See section IV.A. below for a discussion of the annual update and of the reductions pertaining to the IQR program and EHR meaningful use.

In FY 2015, 50 hospitals are not receiving the full market basket rate-of-increase because they failed the quality data submission process or chose not to participate in IQR; 24 of these 50 hospitals also are not meaningful users of EHR; and 153 hospitals are not meaningful EHR users but do satisfy the quality reporting requirements. CMS reports that sufficient information is not available at this time to determine which hospitals will not receive the full update in FY 2016.

The IPPS "applicable percentage increase" applies to the national and Puerto Rico operating standardized amounts and also to the hospital-specific rates on which some sole community hospitals (SCHs) and Medicare-dependent hospitals are paid. As discussed in section II.D. below, the documentation and coding recoupment adjustment does not apply to the Puerto Rico-specific amount or to the hospital-specific rates of SCHs resulting in a 1.7 percent increase for these amounts rather than the 0.9 percentage points increase applicable to the national standardized operating amounts.

B. Payment Impacts

While CMS applied an "applicable percentage increase" of 1.7 percent to the FY 2015 standardized amounts and a documentation and coding adjustment of -0.8% for a net update of 0.9%, the regulatory impact analysis shows average per case operating payments increasing 0.4 percent. The additional factors affecting the impact of the final rule are summarized in the table below:

Contributing Factor	**National Percent Change**
FY 2016 increase in final rule payment rates	+0.9
Additional FY 2016 reduction in the DSH uncompensated care payment pool as required by the ACA (described in section IV.F. below)	-1.0*
Frontier hospital wage index floor and out-migration adjustment	+0.1**
FY 2016 outlier payments at 5.1 percent compared to FY 2015 outlier payments being underpaid at 4.6 percent	+0.48
Hospital Readmissions Reduction Program (HRRP)	0.0
Total	*+0.4***

*The effect of the DSH reduction is not displayed in any of the columns of Table I, the published impact analysis included in the final rule, nor is it mentioned in the table's footnote describing column 9, the "all changes" column. The 1.0 percent reduction is, however, identified in the narrative portion of the impact analysis. Also, the detailed Excel spreadsheet for the impact analysis, which can be downloaded from the CMS website, includes this factor.
**The frontier hospital wage index floor increases payments about $60 million to 48 hospitals in Montana, North Dakota, South Dakota and Wyoming and the out-migration adjustment increases payments about $45 million to 336 providers.
*** The effect of the HRRP is not displayed in any of the columns of the impact analysis, but the narrative portion of the impact analysis indicates that the program reduces FY 2016 payments to an estimated 2,666 hospitals by about $420 million, an increase of $6 million over the estimated FY 2015 savings.
****Total varies due to rounding.

Table I Impact Analysis

Detailed impact estimates are displayed in Table I of the final rule (reproduced in the Appendix to this summary). The following table shows the impact by major hospital category.

Hospital Type	All Proposed Rule Changes
All Hospitals	0.4%
Large Urban	0.4%
Other Urban	0.4%
Rural	0.2%
Major Teaching	0.4%

Hospitals in rural areas gain 1.5 percent from geographic reclassification and the frontier wage index combined and 1.3 percent from the annual update because the documentation and coding adjustment does not apply to the hospital-specific portion of payments to SCHs and MDHs. They also are affected less by the HRRP and DSH changes. Rural hospitals, however, lose 0.7 percent from DRG recalibration and wage index changes combined, including a reduction of 0.2 percent due to budget neutrality of the rural and imputed rural floors. CMS estimates that 371 hospitals will benefit from these floors in FY 2016, while the remaining 2,998 urban and rural IPPS hospitals will have their wage index reduced by the rural floor budget neutrality adjustment of 0.990298, (or 0.99 percent). The final rule impact analysis includes a table showing the state-level payment impact of the rural and imputed rural floors including budget neutrality.

The effect of several significant policies are not included in the rule's impact analysis:

- Expiring new technology add-on payments for three technologies and the additional approval of add-on payments for two technologies. Net increase in payments of about $9.5 million. (See section II.I. below.)
- The hospital Value-Based Purchasing (VBP) program is budget neutral but will redistribute about $1.50 billion based on hospitals' total performance scores.
- The Hospital Acquired Condition (HAC) Reduction Program. (See section IV.G. below for details.) The impact analysis does not include an estimate of the impact of this provision in FY 2016. HAC penalties for FY 2015 were previously estimated by CMS to total about $373 million.
- The HAC payment provision that precludes higher payment for certain secondary diagnoses unless they were present at the time of admission. The provision will reduces payments about $28 million in FY 2016.

The net aggregate effect of these policies is similar to their impact in FY 2016 but their effect on payments to a particular hospital or to types of hospitals could vary significantly.

C. IPPS Standardized Amounts for FY 2016

As in FY 2015, there are four rate categories in FY 2016:

- Hospital Submitted Quality Data and is a Meaningful EHR User (applicable percentage increase [i.e., before adjustments] = 1.7 percent)
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.1 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.5 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.1 percent)

The applicable percentage increases shown above are prior to application of the documentation and coding adjustment and several budget neutrality factors. The updated standardized amounts for the proposed rule were calculated applying the additional -0.8 percentage point adjustment for documentation and coding and these budget neutrality adjustments totaling about 1.5 percentage points:

- MS-DRG recalibration and wage index, 0.997150, a reduction of 0.3 percent;
- geographic reclassification, 0.987905, a reduction of 1.2 percent;
- rural community demonstration program, 0.999861, a reduction of 0.0 percent; and
- new labor market areas transition, 0.999996, a reduction of 0.0 percent.

The outlier offset factor is 0.949000, the same as for FY 2015.

The net increase in the operating standardized amounts from FY 2015 to FY 2016 after applying all adjustments is about 0.52 percent for hospitals satisfying quality reporting and EHR meaningful use requirements in both years. Including the proposed FY 2016 capital payment rate, which increases 0.85 percent in the final rule, the total operating standardized amount plus capital increases 0.54 percent in FY 2016 compared to FY 2015.

FY 2016 FINAL RULE TABLES 1A-1E

TABLE 1A. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (69.6 PERCENT LABOR SHARE/30.4 PERCENT NONLABOR SHARE IF WAGE INDEX GREATER THAN 1)

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 1.7 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.1 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.5 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = - 0.1 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,804.40	$1,661.69	$3,781.96	$1,651.89	$3,759.51	$1,642.08	$3,737.07	$1,632.28

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

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 1.7 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.1 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.5 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = - 0.1 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,388.98	$2,077.11	$3,368.99	$2,064.86	$3,348.99	$2,052.60	$3,329.00	$2,040.35

TABLE 1C. ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1; PUERTO RICO: 63.2 PERCENT LABOR SHARE/36.8 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1 OR 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1				
	Rates if Wage Index Greater Than 1		Rates if Wage Index Less Than or Equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,388.98	$2,077.11
Puerto Rico	$1,648.66	$959.98	$1,617.36	$991.28
[1]For FY 2016, there are no CBSAs in Puerto Rico with a national wage index greater than 1.				

TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE	
	Rate
National	$438.65
Puerto Rico	$212.56

Note that the standardized amounts do not include the -2 percent Medicare sequester reduction that began in 2013 and will continue in 2016 and through 2024 absent new legislation. The sequester reduction is applied as the last step in determining the payment amount for submitted claims and it does not affect the underlying methodology used to calculate MS-DRG weights or standardized amounts.

D. Outlier Payments and Threshold

To qualify for outlier payments for high cost cases, a case must have costs greater than the sum of the prospective payment rate for the DRG, plus IME, DSH and new technology add-on payments, plus the "outlier threshold" or "fixed-loss" amount, which is $24,626 in FY 2015. The sum of these components is the outlier "fixed-loss cost threshold" applicable to a case. To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's total covered charges billed for the case are converted to estimated costs using the hospital's cost-to-charge ratio (CCR). An outlier payment for an eligible case is then made based on a marginal cost factor, which is 80 percent of the estimated costs above the fixed-loss cost threshold.

FY 2016 outlier threshold. CMS sets the outlier fixed-loss cost threshold for FY 2016 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $22,544 (compared to $24,485 in the proposed rule). CMS determined the final threshold following the process (described below) used to set the FY 2015 outlier

threshold, with no methodological changes. As in the proposed rule, CMS notes that the outlier fixed-loss threshold for FY 2016 is lower than in FY 2015 and believes that the decrease is explained by the decrease in the FY 2016 charge inflation factor (compared to the FY 2015 charge inflation factor). Lower charges lead to a lower amount of outlier payments and consequently a lower threshold is needed to reach the 5.1 percent outlier pool target.

CMS projects that the final outlier threshold for FY 2016 will result in outlier payments equal to 5.1 percent of operating DRG payments and 6.35 percent of capital payments based on the respective federal rates, and it adjusts the respective operating and capital standardized amounts using the different percentages.

FY 2016 outlier threshold methodology. CMS finalizes its proposal to set the target for total outlier payments at 5.1 percent of total operating DRG payments (including outlier payments but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program). To calculate the final FY 2016 outlier threshold, CMS simulated payments by applying FY 2016 payment rates and policies using cases from the FY 2014 Medicare Provider Analysis and Review File (MedPAR), with the hospital charges on the MedPAR claims inflated by 2 years, from FY 2014 to FY 2016 to account for charge inflation. CMS determined the 1-year average annualized rate-of-change in charges per case for FY 2016 by comparing the average covered charge per case of $48,927 ($480,593,255,007/9,822,564) from the third quarter of FY 2013 through the second quarter of FY 2014 (April 1, 2013, through March 31, 2014) to the average covered charge per case of $50,768 ($463,248,162,670/ 9,124,821) from the third quarter of FY 2014 through the second quarter of FY 2015 (April 1, 2014, through March 31, 2015). This rate-of-change is 3.7 percent (1.037616) or 7.7 percent (1.076647) over 2 years. [See table below copied from the final rule.]

Quarter	Covered Charges (April 1, 2013, through March 31, 2014)	Cases (April 1, 2013, through March 31, 2014)	Covered Charges (April 1, 2014, through March 31, 2015)	Cases (April 1, 2014, through March 31, 2015)
1	$126,565,555,412	2,486,502	$100,567,278,074	1,932,720
2	$118,792,100,497	2,505,875	$121,989,001,463	2,444,426
3	$115,796,137,233	2,424,262	$118,516,052,865	2,351,444
4	$119,439,461,865	2,405,925	$122,175,830,268	2,396,231
Total	$480,593,255,007	9,822,564	$463,248,162,670	9,124,821

CMS used hospital CCRs from the March 2015 update to the Provider-Specific File (PSF) – the most recent data available for the final rule – and applied an adjustment factor to the CCRs to account for cost and charge inflation. The adjustment methodology, used since FY 2014, compares the national average case-weighted operating and capital CCRs from the most recent (March 2015) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (March 2014 update of the PSF). The methodology uses total transfer-adjusted cases from FY 2014 to determine the national average case-weighted CCRs for both sides of the comparison.

CMS calculated a March 2014 operating national average case-weighted CCR of 0.287139, a March 2015 operating national average case-weighted CCR of 0.278565, and the percentage change of 0.970141, which is the final national operating CCR adjustment factor. The same methodology applied to the capital CCRs produces a March 2014 capital national average case-weighted CCR of 0.024879 and a March 2015 capital national average case-weighted CCR of 0.024243. The percentage change results in a national capital CCR adjustment factor of 0.974442.

CMS finalizes its proposal to continue the policy adopted in the FY 2014 final rule to include the section 1886(r)(2) DSH uncompensated care payments in determining the outlier threshold and in calculating outlier payments. CMS uses the estimated per-discharge uncompensated care amount established for distribution in a fiscal year divided by the average number of discharges, or claims, in the most recently available three fiscal year Medicare claims datasets.

The final rule also 1) continues to apply only a 1-year adjustment factor to the CCRs; 2) in outlier simulations, account for the second year of the 3-year transitional wage index due to implementation of the adoption of the new OMB labor market area delineations; and 3) make no adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled at cost report settlement.

Comments on the proposed rule. Several commenters raised concerns about the transparency and availability of data to replicate CMS calculations, about the accuracy of the methodology which leads to frequently missing the outlier target, and other data or calculation issues. CMS responds at length to the comments but makes no methodological changes in the final rule.

One commenter said that information provided in the proposed rule was not useful in assessing the accuracy of the charge inflation figure that CMS used to calculate the outlier threshold. The absence of these data and of details concerning how they were edited by CMS to arrive at the totals used in the proposed rule charge inflation calculation was asserted to be a violation of the Administrative Procedure Act by not providing adequate notice to allow for meaningful comment. CMS responds that it is optimal to use the most recent period of charge data available to measure charge inflation and that the most recent publicly available data was 10 months old whereas it was able to use data internally available that was 4 months old. It also believes that sufficient data were provided to facilitate meaningful comment. It does, however, commit to two actions:

i. make available on the CMS Web site a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor (go to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html click the link "FY 2016 Final Rule Data Files"); and
ii. work with CMS systems teams and privacy office to explore expanding the information available in the current limited data set (LDS), perhaps through the provision of a supplemental data file for future rulemaking.

CMS also notes that the rate calculation Addendum included in the proposed and final rules describes the inclusion and exclusion of claims and charges used in the outlier calculation and charge inflation calculation.

Other commenters expressed concern, as commenters have previously, with CMS' decision not to consider outlier reconciliation in developing the outlier threshold and they stated that CMS has not provided objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process. One of these commenters cited a 2013 OIG report which stated "that high-outlier hospitals had similar average CCRs, compared to all other hospitals, which means that the higher charges by the hospitals directly resulted in larger and more frequent outlier payments." The commenter stated that it is not consistent with the outlier statute nor reasonable for CMS, in modeling outlier payments for the upcoming fiscal year, to include outlier payments that were based on excessively high charges for particular MS-DRGs and not based on truly unusually high costs.

CMS responds that the OIG report used CCRs from 2008-2011 and that the CCRs are updated in the PSF at the time the Medicare Administrative Contractor (MAC) tentatively settles the hospital cost report, which is about 6 to 7 months after the cost report has been submitted. Thus, there is a lag in CCRs with the possibility that a CCR may be 18 months old from the time the cost report is submitted by the provider to the MAC until it is updated at the following tentative settlement. CMS says that it is encouraging transparency with respect to hospital charges by posting hospital charge data on the CMS Web site at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data. It also notes that the agency and the MACs have authority to specify an alternative CCR to avoid outlier overpayments or underpayments.

FY 2014 and FY 2015 Outlier Payments. CMS' current estimate, using available FY 2014 claims data, is that actual outlier payments for FY 2014 were approximately 5.38 percent of actual total MS-DRG payments. Although actual payments exceeded projected payments, following long-standing policy the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2014 are equal to 5.1 percent of total MS-DRG payments.

Similarly, CMS currently estimates that actual outlier payments for FY 2015 will be approximately 4.65 percent of actual total MS-DRG payments, about 0.45 percentage points below the 5.1 percent the agency projected when setting the outlier policies for FY 2015. The final rule projections are based on the latest CCRs from the March 2015 update of the PSF and simulations using FY 2014 MedPAR claims data.

II. Changes to MS-DRG Classifications and Relative Weights

A. to C. Background; MS-DRGs for FY 2016

The FY 2016 final rule continues the Medicare severity diagnosis-related group (MS-DRG) classification system used beginning in FY 2008. For general information about the MS-DRG system, including yearly reviews and changes to the MS-DRGs, the rule refers readers to previous discussions in these IPPS/LTCH PPS final rules: FY 2010 (74 FR 43764 through 43766), FY 2011 (75 FR 50053 through 50055), FY 2012 (76 FR 51485 through 51487), FY 2013 (77 FR 53273), FY 2014 (78 FR 50512), and FY 2015 (79 FR 49871). For information on the adoption of the MS-DRGs in FY 2008, CMS refers readers to the FY 2008 IPPS/LTCH final rule (72 FR 47140 through 47189).

Changes in specific MS-DRGs for FY 2016, including modifications for the implementation of ICD-10 on October 1, 2015, are described in section II.G below.

D. FY 2016 Documentation and Coding Adjustment

The FY 2016 rule continues the process of documentation and coding adjustments begun in FY 2008 when the transition to MS-DRGs began. Under this process, CMS has adjusted the standardized amounts based on the actuaries' estimates that a portion of the increases in the average case-mix index (CMI) are due to improved medical record documentation and more complete and accurate coding which are not related to real increases in the severity of cases requiring additional hospital resources. A series of adjustments were made in FY 2008 through FY 2012 to eliminate the effects of documentation and coding changes on future payments as well as to recoup the additional payments made in FY 2008 and FY 2009 attributable to documentation and coding improvements. In general, these adjustments were required by the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Pub. L. 110-90 (referred to as the TMA).

Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Delaying full implementation of the prospective adjustment related to FY 2008 and FY 2009 case-mix change until FY 2013 resulted in higher IPPS payments in FY 2010 through FY 2012. CMS could not recover these "overpayments" because its statutory recoupment authority under the TMA was limited to overpayments made in FY 2008 and FY 2009. Section 631 of the ATRA, however, requires the Secretary to make a recoupment adjustment or adjustments totaling $11 billion, the estimated amount of the increase in aggregate payments in FYs 2010, 2011, and 2012 due to delaying the prospective adjustments; the $11 billion amount is written into the law. The adjustments are to be made over the period FY 2014 through FY 2017. The required ATRA recoupment adjustment is a one-time recovery of prior payments, not a permanent reduction in payment rates.

In FY 2014 rulemaking, CMS actuaries estimated that a -9.3 percent adjustment to the standardized amount would have been necessary if CMS were to recover the full $11 billion in

FY 2014. In its March 2013 Report to Congress, MedPAC estimated that a -2.4 percent adjustment made in FY 2014, and not removed until FY 2018, also would recover the required recoupment amount.

In the FY 2014 final rule, CMS chose to phase in the adjustment. It applied a -0.8 percent offset to the FY 2014 standardized amounts and estimated that this level of adjustment would recover up to $0.96 billion in FY 2014, with at least $10.04 billion remaining to be recovered by FY 2017. CMS further estimated that the entire $11 billion would be accounted for, using standard inflation factors, by the end of the statutory 4-year timeline if additional adjustments of -0.8 percent were implemented in FYs 2014, 2015, 2016, and 2017, leaving all prior year adjustments in place through FY 2017. The FY 2014 rule did not, however, finalize specific adjustments for FYs 2015, 2016, or 2017. The FY 2015 IPPS/LTCH final rule reduced the standardized amounts to reflect the second -0.8 percent installment, keeping the 0.8% FY 2014 reduction in place, for a cumulative reduction of 1.6% in FY 2015.

For FY 2016, CMS finalizes its proposal to make an additional -0.8 percent adjustment to the standardized amounts, bringing the cumulative reduction to 2.4 percent. In the proposed rule, CMS estimated that this adjustment, combined with leaving in place the -0.8 percent adjustments made for FY 2014 and FY 2015, would recover up to $3 billion in FY 2016 and, with the approximately $3 billion recovered in FY 2014 and FY 2015 combined, would result in the recovery of a total of approximately $6 billion of the $11 billion in overpayments required to be recovered by section 631 of the ATRA. In this final rule, CMS states that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016.

The final rule does not indicate a specific reduction level for FY 2017, an issue that CMS intends to address in FY 2017 IPPS rulemaking. In response to a comment in the DSH section of the FY 2015 IPPS/LTCH final rule regarding the actuaries' estimates of the level of DSH payments, CMS agreed with commenters that "the documentation and coding numbers for future years could be more than a 0.8 percent reduction to comply with the $11 billion requirement, but those figures have not yet been determined. The reason for the higher possibility is that the number of discharges has decreased significantly."

The FY 2016 final rule states that CMS had anticipated that any ATRA adjustment made to reduce payment rates in one year would eventually be offset by a single positive adjustment in FY 2018, once the necessary amount of overpayment was recovered, but notes that section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Pub. L. 114-10, enacted on April 16, 2015, replaces the single positive adjustment, estimated to be 3.2 percent when MACRA was enacted, with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. CMS intends to address the MACRA provision in future rulemaking.

Section 414 of MACRA also removed the Secretary's authority to make an additional prospective adjustment to IPPS rates to offset payment increases resulting from documentation and coding changes for discharges occurring during fiscal year 2010. (This amount has been estimated to be 0.55 percent.)

E. Refinement of the MS-DRG Relative Weight Calculation

Since FY 2009, the MS-DRG relative weights have been fully cost-based and not determined by hospitals' billed charges; CCRs are used to estimate costs from charges. The FY 2014 final IPPS rule added four new cost centers: Implantable Devices Charged to Patients, Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and Cardiac Catheterization. CMS asserted that using distinct CCRs calculated with data from these new cost centers would address the issue of charge compression and improve the accuracy of the costs allocated to specific services, especially higher cost services most affected by charge compression. Breaking out these four additional CCRs increased the number of CCRs used to calculate the MS-DRG relative weights from 15 to 19. No changes were made for FY 2015.

In the FY 2016 IPPS/LTCH proposed rule, CMS expressed concern about inconsistencies in hospitals' use of nonstandard codes in reporting costs, coupled with differences in the way hospitals and CMS map these nonstandard cost center codes to standard cost center lines. To view how CMS rolls up the codes to create the Hospital Cost Report Information System (HCRIS) files, CMS referred readers to http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form.html.[2]

CMS indicated that these reporting issues may affect the calculation of the 19 CCRs and aspects of the IPPS that rely on the CCRs, including calculation of the MS-DRG relative weights. Its simulations showed these possible effects on four cost centers, with minimal differences in the other 15 cost centers:

Cost Center	FY 2016 Proposed Rule CCR*	CCR Simulated by CMS**
Anesthesiology	0.108	0.084
Cardiology	0.0119	0.113
Radiology	0.159	0.161
"Other Services"	0.367	0.291

* Calculated based on the December 31, 2014 update of the FY 2013 HCRIS. (See section II.H below.)
** Computed by applying CMS' current rollup procedures of assigning nonstandard codes to specific standard cost centers in contrast to hospitals' general practice of reporting nonstandard codes "en masse" on line 76 "Other Ancillary." The version of the HCRIS used by CMS to calculate the 19 CCRs for the proposed rule is available on the FY 2016 IPPS/LTCH proposed rule Home Page at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Proposed-Rule-Home-Page.html.

Comments. CMS received several comments in response to its solicitation of public input concerning how to improve the use of nonstandard cost center codes. Commenters requested that CMS provide more cost reporting instruction so that the accuracy and validity of the CCRs could be improved through more detailed examples of how cost report and claims data are used

[2] On this page, click on "Hospital-2010-SAS.ZIP (SAS datasets and documentation)", and from the zip file, choose the Excel spreadsheet "2552-10 SAS FILE RECORD LAYOUT AND CROSSWALK TO 96.xlsx". The second tab of this spreadsheet is "NEW ROLLUPS", and shows the standard and nonstandard 5-digit codes (columns B and C) that CMS rolls up to each standard line (column G).

for rate-setting, identifying what revenue codes and services should be associated with specific cost centers, and providing detailed instructions regarding cost allocation methods. Several commenters supported more specific guidance and data processing on cost reporting and supported CMS' idea in the proposed rule to "lock in" certain nonstandard codes with specific cost centers in the cost reporting software, but wanted to retain flexibility in terms of available options. Commenters requested that CMS work with stakeholders and possibly convene a technical workgroup to receive stakeholder input.

CMS expressed appreciation for the suggestions, noted that it had not made specific proposals, and agreed with some commenters' caution that the desire for more specific direction in how to report should be balanced by the need for flexibility in cost reporting and cost allocation methodologies based on each hospital's own internal charge structure. CMS intends to continue to explore ways to improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process.

CMS finalizes its proposal to use the 19 CCRs for FY 2016 that were calculated from the March 2015 update of the FY 2013 HCRIS, created based on CMS' longstanding procedures for mapping and rolling up nonstandard cost center codes. The version of the HCRIS from which CMS calculated the 19 CCRs is available on the FY 2016 IPPS/LTCH final rule Home Page at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html.

F. Adjustment to MS-DRGs for Preventable Hospital-Acquired Conditions (HACs)

Section 1886(d)(4)(D) required the Secretary, by October 1, 2007, to select at least two clinical conditions, including infections, that: (a) are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. Effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is not present on admission (POA).

A complete list of the 14 current categories of HACs is included on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee- for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html. CMS finalizes its proposal not to add or remove categories of HACs for FY 2016. It will continue to monitor contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute hospital setting and may use this information in future rulemaking.

Research Triangle Institute, International (RTI) annually provides a summary report of the contemporary evidence-based guidelines for selected, candidate, and previously considered HACs that provide specific recommendations for the prevention of the corresponding conditions in the acute care hospital setting. RTI's 2015 report is available on the CMS Hospital-Acquired Conditions Web page in the "Downloads" section at: http://www.cms.gov/Medicare/Medicare-Fee- for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/.

Comments. Two commenters suggested that CMS expand the current HAC category of Iatrogenic Pneumothorax with Venous Catheterization to include Iatrogenic Pneumothorax with Thoracentesis and also to add Accidental Puncture/Bleeding with Paracentesis as a HAC category. CMS responds that it will consider the recommendations for future rulemaking and notes that RTI has developed a separate excerpt report that summarizes the two conditions in a document titled, "Evidence-based Guidelines Pertaining to Select Thoracentesis- and Paracentesis-Related Conditions," which is available on the CMS Hospital-Acquired Conditions Web page in the "Downloads" section at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/.

In response to other comments:

- CMS disagrees with a commenter that it should remove the Falls and Trauma HAC category from the HAC program because falls do not meet the statutory criterion of being reasonably preventable through the application of evidence-based guidelines; and
- CMS agrees to consider for future rulemaking a commenter's recommendation to incorporate untreated malnutrition, including disease-related malnutrition, as a HAC category.

Transition to ICD-10-CM and ICD-10-PCS. In the FY 2014 IPPS/LTCH PPS final rule, CMS stated that the final HAC list translation from ICD-9-CM to ICD-10-CM/ICD-10-PCS would be subject to formal rulemaking. In the FY 2016 proposed rule, CMS proposed to designate the ICD-10 MS-DRGs Version 33 as the replacement logic for the ICD-9-CM MS-DRGs Version 32 (see section II.G below). As part of the HAC update for FY 2016, CMS proposed that the ICD-10-CM/ICD-10-PCS Version 33 HAC list would replace the ICD-9-CM Version 32 HAC list. CMS solicited public comments on how well the ICD-10-CM/PCS Version 32 HAC list replicates the ICD-9-CM Version 32 HAC list.[3] CMS did not receive any public comments on ICD-10 translations for the HAC list and finalizes its proposal to implement the ICD-10-CM/PCS Version 33 HAC list to replace the ICD-9-CM Version 32 HAC list.

POA indicator reporting. The POA indicator reporting requirement currently applies only to IPPS hospitals because they are subject to the HAC provision. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting. Beginning in FY 2014, Maryland hospitals, which formerly operated under a waiver under section 1814(b)(3) of the Act, are no longer exempted from the POA indicator reporting requirement. The Maryland All-Payer Model, effective January 1, 2014, does not change the POA indicator reporting requirement for Maryland hospitals.

[3] CMS prepared this ICD-10 MS-DRGs Version 32 based on the FY 2015 MS-DRGs (Version 32) finalized in the FY 2015 IPPS/LTCH final rule. In November 2014, CMS posted a Definitions Manual of the ICD-10 MS-DRGs Version 32 on the ICD-10 MS-DRG Conversion Project Web site at: http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html. The HAC code list translations from ICD-9-CM to ICD-10-CM/PCS are located in Appendix I of the ICD-10-CM/PCS MS-DRG Version 32 Definitions Manual. The link to this Manual (available in both text and HTML formats) is located in the Downloads section of the ICD-10 MS-DRG Conversion Project Web site.

The POA indicator reporting process does not change with the conversion to ICD-10-CM and ICD-10-PCS on October 1, 2015. The four POA indicator reporting options are:

Indicator	Descriptor
Y	Indicates that the condition was present on admission
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred
N	Indicates that the condition was not present on admission
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission

Under the HAC payment policy, CMS treats HACs coded with "Y" and "W" indicators as POA and allows the condition on its own to cause an increased payment at the CC and MCC level. CMS treats HACs coded with "N" and "U" indicators as Not Present on Admission and does not allow the condition on its own to cause an increased payment at the CC and MCC level. CMS estimates the HAC payment provision savings for the next 5 fiscal years as follows:

Year	Savings (in millions)
FY 2016	$28
FY 2017	$29
FY 2018	$31
FY 2019	$32
FY 2020	$34

CMS emphasizes that the provision only applies when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that would lead to higher payment.

G. Changes to Specific MS-DRG Classifications

This section of the rule contains many tables with ICD-9-CM to ICD-10-PCS comparable code translations. In general, for ICD-9-CM codes that result in greater than 50 ICD-10-PCS comparable code translations, CMS refers readers to Table 6P, ICD-10-PCS Code Translations for Final MS-DRG Changes, which is available on the CMS web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. The table includes the MDC topic, the ICD-9-CM code, and the ICD-10-PCS code translations.

1. Discussion of Changes to Coding System and Basis for MS-DRG Updates

a. *Conversion of MS-DRGs to the ICD-10 Coding System*

CMS discusses the process used to convert the ICD-9-CM based MS-DRGs to ICD-10 MS-DRGs, including posting updated versions of the ICD-10 MS-DRGs for comments. Information on the ICD-10 MS-DRG conversion project, including the impact study, is available on the ICD-10 MS-DRG Conversion Project Web site at: http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.

CMS finalizes using:

- The MS-DRG code logic in the ICD-10 MS-DRGs Version 32 along with any finalized updates to Version 32 for the final ICD-10 MS-DRGs Version 33 and
- ICD-10 MS-DRGs Version 33 as the replacement logic for the ICD-9-CM based MS-DRGs Version 32 as part of the proposed MS-DRG updates for FY 2016.

CMS invited comments on how well the ICD-10 MS-DRGs Version 32 replicates the logic of the MS-DRGs Version 32 based on ICD-9-CM codes. CMS agrees with the comments that identified ICD-10 MS-DRG replication errors and reassigns these identified procedure codes.

b. *Basis for FY 2016 MS-DRG Updates*

CMS encourages input from stakeholders concerning the annual IPPS updates; CMS notes this input should be made to CMS by December 7 of the year prior to the next annual proposed rule update. **Thus, to be considered for any updates or changes in FY 2017, comments should be submitted by December 7, 2015.**

For the proposed rule, CMS' MS-DRG analysis was based on claims data from the December 2014 update of the FY 2014 MedPAR file, which contains hospital bills received through September 30, 2014 for discharges occurring through September 30, 2014. For the final rule, CMS calculated the final relative weights based on claims data from the March 2015 update of the FY 2014 MedPAR file, which contains hospital bills received through December 31, 2104, for discharges occurring through December 31, 2014.

CMS reminds readers that in deciding on modifications to the MS-DRGs for particular circumstances, it considers whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG (discussed in greater detail in previous rulemaking, 76 *FR* 51487). CMS evaluates patient care costs using average costs and lengths of stay. CMS uses its clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In addition, CMS considers the number of patients who will have a given set of characteristics and notes it generally prefers not to create a new MS-DRG unless it would include a substantial number of cases.

CMS uses the following criteria established in FY 2008 (*72 FR 47169*) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups.

CMS notes that in order to warrant the creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the criteria.

2. MDC 1 - Diseases and Disorders of the Nervous System: Endovascular Embolization (Coiling) Procedures

CMS received a request to create four new MS-DRGs for endovascular intracranial embolization procedures. According to the requestor, endovascular intracranial and endovascular embolization procedures are not similar to the open craniotomy procedures they are grouped within the MS-DRGs. (CMS notes that this topic had been discussed in the FY 2015 IPPS proposed and final rules and for FY 2015, they did not change the MS-DRG assignment for these procedures.) The requestor suggested the following new MS-DRGs:

- MS-DRG XXX (Endovacular Intracranial Embolization Procedures with Principal Diagnosis of Hemorrhage);
- MS-DRG XXX (Endovacular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with MCC);
- MS-DRG XXX (Endovacular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage with CC); and
- MS-DRG XXX (Endovacular Intracranial Embolization Procedures without Principal Diagnosis of Hemorrhage without CC/MCC)

The requestor also recommended several ICD-9-CM codes, which include endovascular embolization procedures and additional intracranial procedures, that should be removed from MS-DRG 020 through 027 and included in the new MS-DRGs. (CMS provides the ICD-10-PCS codes for endovascular embolization assigned to MS-DRGs 020 through 027 in ICD-10 MS-DRGs Version 32.) Based on the findings from CMS' data analysis and the recommendations from their clinical advisors, CMS proposed to maintain the current MS-DRG assignments, for endovascular embolization and other percutaneous and endovascular procedures within MS-DRGs 023 through 027. CMS also proposed not to create three new MS-DRGs for endovascular intracranial procedures without a principal diagnosis of hemorrhage with MCC, with CC, and without CC/MCC.

A number of commenters supported CMS' proposal. CMS agrees with the comment that the data demonstrates that the average cost of the endovascular coils exceeds the average cost of all the cases in MS-DRGs 023 through 027, but CMS reiterates that they expect some procedures within an MS-DRG to have higher average costs and other procedures to have

lower average costs. In addition, the clinical advisors recommend maintaining the current MS-DRGs assignments because they believe all the procedures are clinically similar and treat the same clinical problem. **CMS finalizes its proposal to maintain the current MS-DRG assignments, MS-DRGs 023 through 027, for endovascular intracranial embolization and other endovascular procedures.**

3. MDC 5- Diseases and Disorders of the Circulatory System

a. *Adding Severity Levels to MS-DRGs 245 through 251*

During the comment period for the FY 2015 IPPS proposed rule, CMS received a comment that recommended establishing additional severity levels for MS-DRG 245 through 251 and establishing severity levels for MS-DRG 245. CMS considered this comment to be outside the scope of the FY 2015 proposed rule and indicated they would consider the comment in future rulemaking.

For the FY 2016 IPPS proposed rule, CMS received a separate but related request and both requests are discussed below.

b. *Percutaneous Intracardiac Procedures*

CMS received a request to create new MS-DRGs for percutaneous intracardiac procedures that would differentiate percutaneous intracardiac procedures from percutaneous intracoronary procedures. CMS' data analysis for this request also included the request to add severity levels to MS-DRGs 245 and 251. CMS proposed to:

- Create two new MS-DRGs to classify percutaneous intracardiac procedures;
- Not to create severity levels for MS-DRGs 245 (AICD Generator Procedures); and
- Not to create additional severity levels for MS-DRGs 246 through 251.

CMS invited public comments on these proposals. CMS also invited comments on the ICD-10-PCS code translations for the ICD-9-CM procedure codes discussed with this request (ICD-9-CM procedure code 35.52, 35.96, 35.97, 37.26, 37.27, 37.34, 37.36, 37.90) and the proposed assignment of these procedure codes to the new proposed MS-DRGs.

CMS finalizes its proposal to create two new MS-DRGs for the 2016 ICD-10 MS-DRG Version 33 for percutaneous intracardiac procedures:

- **MS-DRGs 273, entitled "Percutaneous Intracardiac Procedures with MCC and**
- **MS-DRG 274, "Percutaneous Intracardiac Procedures without MCC).**

CMS examined claims data from the December 2014 update of the 2014 MEdPAR file to determine if including additional severity levels in MS-DRG 246 through 251 was warranted. CMS found that the criterion that there be a $2,000 difference in average costs between subgroups was not met. **CMS finalizes its proposal not to create additional severity levels for MS-DRG 264 through 251.**

CMS used the same MedPAR claims data and separately examined cases in MS-DRG 245 to determine whether to subdivide this MS-DRG into severity levels. Based on analysis of the

data, CMS found that the results supported creating a "with MCC" and a "without MCC" severity level split. CMS agreed with the concerns of their clinical advisors that the analysis only included one year and that it would not be clinically appropriate to add severity levels based on an isolated year's data because of the possibility of yearly fluctuations. CMS' analysis of the FY 2013 claims data for MS-DRG 245 did not support creating any severity levels because the data did not meet all of the five required criteria. **CMS finalizes its proposal not to create severity levels for MS-DRGs 245 (AICD Generator Procedures).** CMS does agree with a commenter's recommendation that follow-up analysis should be conducted for the FY 2017 proposed rule.

c. *Zilver® PTX Drug-Eluting Peripheral Stent (Zilver® PTX®)*

Zilver® PTX® was approved for new-technology add-on payments in FY 2014. Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by the ICD-9-CM procedure code 00.60.

CMS received a request from the manufacturer for an extension of new technology add-on payments for Zilver® PTX® in FY 2016. The manufacturer also asked CMS to consider the following options:

- Establish a new family of MS-DRGs for drug-eluting stents used in the peripheral (noncoronary) vasculature.
- Assign all Zilver® PTX® cases to MS-DRG 252 even if there is no MCC.

CMS determined that the small number of cases did not provide justification to create a new set of MS-DRGs specifically for angioplasty of peripheral arteries using drug-eluting stents. CMS also noted that the data did not support assigning all the drug-eluting stents to the highest severity level (MS-DRG 252), even when there is not an MCC. CMS' clinical advisors state that the cases are clinically similar to other cases within the MS-DRGs. CMS proposed to maintain the current MS-DRG assignment for these cases.

A number of commenters supported CMS' proposal. One commenter, the manufacturer, expressed concerns with the proposal and requested CMS to reconsider the request that all Zilver® PTX® cases be assigned to MS-DRG 252 even if there were no MCC. In response to this comment, CMS notes that even the commenter acknowledges that the data do not support assigning all the drug-eluting stents to the highest severity level (MS-DRG 252), even when there is not an MCC. CMS notes that the MS-DRGs are comprised of a distinct structure with respect to the types of patients within each severity level; the highest severity levels are those patients who are generally sicker, consume an increased utilization of resources, and require more complex services. CMS believes that disregarding this structure solely for the purpose of increasing payment for patients who are not similar in terms of their severity of illness and resource utilization would be inconsistent with how MS-DRGs are defined. **CMS finalizes its proposal to maintain the current MS-DRG assignments for procedures involving drug-eluting stents in MS-DRG 252, 253, or 254.**

d. *Percutaneous Mitral Valve Repair System – Revision of ICD-10-PCS Version 32 Logic*

CMS received a comment that the ICD-10 MS-DRGs Version 32 assignment for ICD-10-PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) does not accurately replicate the ICD-9-CM MS-DRGs Version 32. CMS agrees with the commenter. For the proposed FY 2016 ICD-10 MS-DRGs Version 33, CMS proposed assigning ICD-10 PCS procedure code 02UG3JZ to MS-DRGs 231 and 232, and MS-DRGs 246 through 251.

CMS agrees with comments that this code would group to the proposed new MS-DRGs 273 and 274 (see discussion above). **CMS finalizes that ICD-10 PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) will be assigned to new ICD-10 MS-DRGs 273 and 274 and will continue to be assigned to MS-DRGs 231 and 232.**

e. *Major Cardiovascular Procedures: Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Graft (Zenith® F. Graft)*

The new technology add-on payment for the Zenith® F. Graft will end on September 30, 2015. Cases involving the Zenith® F. Graft are identified by ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) in MS-DRGs 237 and 238.

CMS received a request to consider the following options:

- Reassign procedure code 39.78 to the highest severity level in MS-DRGs 237 and 238, even if there is no MCC.
- Establish a new MS-DRG that would contain all endovascular aneurysm repair procedures.

CMS notes that in addition to procedure code 39.78, ICD-9-CM procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta) also describes endovascular aneurysm repair procedures.

CMS proposed to:

- Delete MS-DRGs 237 and 238
- Create five new MS-DRGs (268 through 272) and assign more complex cardiovascular procedures to MS-DRGs 268 and 269 and assign the less complex, less invasive procedures to MS-DRGs 270, 271, and 272.

CMS also invited comments on the ICD-10-PCS code translations for the ICD-9-CM procedure codes discussed with this request (ICD-9-CM procedure codes 39.71, 39.78, 37.41, 37.49, 37.55, 37.64, 38.04, 38.14, 38.34, 38.44, 38.64, 38.84, 39.24, 39.71, and 39.78). Several commenters supported CMS' proposal to delete MS-DRGs 237 and 238 and to create five new proposed MS-DRGs to distinguish the more complex procedures from the less complex, less invasive procedure.

CMS received several comments about the ICD-10 PCS code translations. In response to a comment requesting clarification on some of the ICD-10-PCS code translations that were listed for ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta), CMS reviewed the translations for this specific ICD-9-CM procedure code and all the comparable ICD-10-PCS translations that CMS proposed to assign to the proposed new MS-DRGs 268 through 272. CMS agrees with the commenter that dilation codes are not necessary code translations for ICD-9-CM procedure code 39.78 and that they would assign dilation codes to their own separate and clinically appropriate ICD-10 MS-DRG. CMS identified that the ICD-10-PCS translations for ICD-9-CM procedure code 37.49 (Other repair of heart and pericardium) displayed in Table 6P.1a of the proposed rule were incomplete (an omission of 78 ICD-10-PCS comparable code translations) and provides an updated Table 6P for this final rule.

CMS' clinical advisors also determined that ICD-9-CM procedure code 37.49 and the corresponding ICD-10-PCS comparable code translations would be more appropriately classified under proposed MS-DRGs 270 through 272 instead of the proposed new MS-DRGs 268 and 269. In addition, the clinical advisors determined that ICD-9-CM procedure code 39.54 (Re-entry operation (aorta)) and the corresponding ICD-10-PCS comparable code translations would be more appropriately classified under proposed new MS-DRGs 268 and 269 instead of MS-DRGs 270 through 272.

In response to a commenters request for clarification on certain ICD-10-PCS code translations for the proposed new DRGs and how they relate to the General Equivalency Maps (GEMs) and ICD-10-PCS to ICD-9-CM Reimbursement Mappings files, CMS notes that the GEMs and Reimbursement Mappings files are resources for the public and are updated separate from the IPPS rulemaking. The GEMS were developed to provide users with a code to code translation reference tool for both ICD-9-CM and ICD-10 code sets and to offer acceptable translation alternatives where possible. The GEMS have been updated on an annual basis as part of the ICD-10 Coordination and Maintenance Committee meetings process and will be continued to be updated for approximately 3 years after ICD-10 is implemented. Information about GEMS update can be found at: http://www.cms.gov/Medicare/Coding.ICD9PRoviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html. The Reimbursement Mappings have been updated on an annual basis and the 2016 files will be posted later this month.

CMS finalizes its proposal to delete ICD-9-CM MS-DRGs 237 and 238 and add the following five new MS-DRGs to ICD-10 MS-DRGs Version 33:

- MS-DRG 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC);
- MS-DRG 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC);
- MS-DRG 270 (Other Major Cardiovascular Procedures with MCC);
- MS-DRG 271 (Other Major Cardiovascular Procedures with CC);
- MS-DRG 272 (Other Major Cardiovascular Procedures without CC/MCC).

These finalized ICD-10 MS-DRGs will include the update assignments related to the ICD-10 code translations for ICD-9-CM codes 37.49 (Other repair of heart and pericardium) and 39.54 (Re-entry operation (aorta)). CMS also refers the reader to the updated Table 6P for this final rule. CMS will consider if further modifications to the titles of these MS-DRGs are warranted in future rulemaking.

4. MDC 8 – Diseases and Disorders of the Musculoskeletal System and Connective Tissue

a. *Revision of Hip or Knee Replacements: Revision of ICD-10-PCS Version 32 Logic*

CMS received two comments that the logic used for ICD-10 MS-DRGs Version 32 is not the same as the logic used for ICD-9-CM based MS-DRGs Version 32 for joint revisions. One of the commenters requested that CMS change the MS-DRG structure for joint revisions within the ICD-10 MS-DRGs 446, 467 and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC respectively) so that cases with a spacer removed prior to the insertion of a new joint prosthesis are assigned to MS-DRG 466, 467, and 468, as is the case with the ICD-9-CM MS-DRGs. The second commenter requested that joint revision cases that involve knee revisions involving cemented and uncemmented qualifiers be assigned to MS-DRG 466, 467, and 468.

CMS agreed with the commenters. CMS also examined joint revision combination codes that are not currently assigned to MD-DRGs 466, 467, and 468 in ICD-10 MS-DRGs Version 32 and identified additional combinations that should be included so that the joint revision MS-DRGs would have the same logic as the ICD-9-CM MS-DRGs.

CMS finalizes its proposal to add joint revision code combinations for MS-DRGs 466, 467, and 468 and finalizes comparable joint revision code combinations for ICD-10-MS-DRGs 628, 629, and 630. These joint revision combination updates will be incorporated into the Version 33 MS-DRG structure and will be implemented effective October 1, 2015. The final rule includes over 350 hip revision ICD-10-PCS combinations and 36 knee revision ICD-10-PCS combinations.

b. *Spinal Fusion*

CMS received a request to revise the titles of MS-DRGs 456, 457 and 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or 9+ Fusion with MCC, with CC, and without CC/MCC, respectively) for the ICD-10 MS-DRGs so they would more closely correspond to the terminology used to describe the ICD-10-PCS procedure codes without changing the ICD-10 MS-DRG logic. CMS agreed with the request.

CMS finalizes its proposal and modifies the titles for MS-DRG 457 through 458 for the 2016 ICD-10 MS-DRG Version 33 as follows:

- **MS-DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with MCC).**
- **MS-DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion with CC).**

- **MS-DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusion without CC/MCC.**

5. MDC 14 – Pregnancy, Childbirth and the Puerperium: MS-DRG 775 (Vaginal Delivery Without Complicating Diagnosis)

CMS received a request to modify the logic for ICD-10 MS-DRG 775 so that the procedure code for the induction of labor with a cervical ripening gel would not group to the incorrect MS-DRG when a normal delivery has occurred. CMS reviewed how the code (ICD-10-PCS code 3E0P7GC) is classified under the ICD-10 MS-DRGs Version 32 and agreed with the requestor that the current logic for the ICD-10-PCS procedure code does not result in the appropriate MS-DRG assignment. CMS' analysis suggested that this code should not be designated as an OR code. CMS' clinical advisors agreed that this procedure does not require the intensity or complexity of service and resource utilization for an OR designation under ICD-10. CMS also reviewed 8 additional, similar ICD-10-PCS procedure codes that are currently designated as OR codes and determined that these codes are non-OR codes, which would affect their MS-DRG assignments.

CMS finalizes its proposal to designate the following ICD-10-PCS procedure codes as non-OR for the 2016 ICD-10 MS-DRGs Version 33: 3E0P76Z, 3E0P77Z, 3E0P7SF, 3E0P83Z, 3E0P86Z, 3E0P8GC, and 3E0P8SF.

6. MDC 21 – Injuries, Poisonings and Toxic Effects of Drugs: CroFab Antivenin Drug

CMS received a request that CMS change the MS-DRG assignment for antivenin cases from MS-DRG 917 and 918 (Poisoning & Toxic Effects of Drugs with and without MCC, respectively). CMS examined claims data for injections for snakebites reported in MS-DRGs 917 and 918 from the FY 2014 MedPAR file and identified only 19 cases reported in MS-DRG 918. CMS notes that basing a new MS-DRG on only 19 cases would lead to distortions in the relative payment weights for the MS-DRG because several expensive cases could impact the overall relative payment weight.

CMS finalizes its proposal to maintain the current MS-DRG assignments for procedures involving the CroFab antivenin drug for snakebites to MS-DRGs 917 and 918.

7. MDC 22 – Burns: Additional Severity of Illness Level for MS-DRG 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation 96+ Hours with Skin Graft)

CMS received a request to add an additional severity level to MS-DRG 927. The requestor was concerned that payment for severe burn cases that used dermal regenerative grafts (captured by procedure code 86.67, Dermal regenerative graft) was significantly greater than the average total costs for all cases in the MS-DRG.

CMS notes that ICD-10-PCS provides more detailed and specific codes for skin grafts. Table 6P.2a shows the comparable ICD-10-PCS codes for ICD-9-CM 86.67. (Table 6P.2a is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.)

CMS examined claims data for cases reported in MS-DRG 927 from the FY 2014 MedPAR file and identified only 171 cases reported in MS-DRG 927. The request for severity levels does not meet the criterion that there are at least 500 cases in the CC or MCC group. CMS also noted that the long-term mechanical ventilation cases are contributing more to the costs than the graft cases. CMS' clinical advisors believed that the dermal regenerative graft cases are appropriately assigned to MS-DRG 927 because they are clinically similar to other cases in this DRG.

CMS finalizes its proposal to maintain the current MS-DRG 927 structure without additional severity levels.

8. 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 an MS-DRG.

In November 2014, CMS made available a Definitions Manual of the ICD-10 MS-DRGs Version 32 and the MCE Version 32 on the ICD-10 MS-DRG Conversion Project Web site at: http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html/.

For FY 2016, in order to be consistent with the ICD-9-CM MS-DRG GROUPER and MCE Version 32, CMS finalizes its proposal to add ICD-10-CM codes listed in the final rule (Table in the final rule titled ICD-10-CM Codes Proposed To Be Added to the Version 33 MCE "Manifestation Codes Not Allowed as Principal Diagnosis" Edit) to the ICD-10 MCE Version 33 of the "Manifestation codes not allowed as principal diagnosis" edit. CMS notes that because these codes describe manifestation of an underlying disease and do not describe the disease itself, they should not be used as principal diagnoses.

CMS also proposed to revise the language describing the "Procedure inconsistent with LOS (Length of stay)" edits which lists ICD-10-POS code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours), effective for the FY 2016 ICD-10 MCE Version 33. Because the code description of the ICD-10-PCS code is for ventilation that occurs greater than 96 hours, CMS proposed to revise the language for the edit to read: "The following procedure code should only be coded on claims with a length of stay greater than 4 days".

CMS finalizes its proposal to revise the language describing the "Procedure inconsistent with LOS edit which lists ICD-10-PCS code 5A1955Z. Consistent with this revision, CMS is also revising, effective for FY 2016, the ICD-10 MS-DRG Version 33 titles for MS-DRGs 003, 004, 007, 870, 871, 872, 927, and 933 to include >96 hours in the titles.

9. Changes to Surgical Hierarchies

The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive and its application ensures that cases involving multiple surgical

procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class. Because the relative resource intensity of surgical classes can shift as a function of MS-DRG reclassification and recalibrations, for FY 2016, CMS reviewed the surgical hierarchies of each MDC, to determine if the ordering of classes coincides with the intensity of resource utilization.

Based on the finalized proposals discussed above for MDC 5 (Diseases and Disorders of the Circulatory System), **CMS finalizes to revise the surgical hierarchy for MDC 5 as follows:**

- Delete MS-DRG 237 and MS-DRG 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) from the surgical hierarchy.
- Sequence new MS-DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively) above new MS-DRGs 270, 271 and 272 (Other Major Cardiovascular Procedures without MCC, with MCC, and with CC, respectively).
- Sequence new MS-DRGs 270, 271, and 272 above MS-DRG 239 (Amputation for Circulatory System Disorders Except Upper Limb & Toe with MCC).
- Sequence new MS-DRGs 273 and 274 (Percutaneous Intracardiac Procedures with MCC and without MCC, respectively) above MS-DRG 246 (Percutaneous Cardiovascular Procedure with Drug-eluting Stent with MCC or +4 Vessels/Stents).

10. Changes to the MS-DRG Diagnosis Codes for FY 2016

CMS notes that the complete updated MCC list (Table 6I), CC list (Table 6J) and Non-CC Exclusion list (Table 6K) is available on the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

a. *Coronary Atherosclerosis Due to Calcified Coronary Lesion*

CMS received a request to change the severity level for ICD-9-CM diagnosis codes 414.2 (Chronic total occlusion of coronary artery) and 414.4 (Coronary atherosclerosis due to calcified coronary lesion) from a non-CC to an MCC. (This issue was also discussed in the FY 2014 and 2015 IPPS proposed and final rules). The ICD-10-CM codes for these diagnoses are I25.82 (Chronic total occlusion of coronary artery) and I25.84 (Coronary atherosclerosis due to calcified coronary lesion); these codes are currently classified as non-CCs. Based on an analysis of claims data and the advice of its clinical advisers, who do not believe the diagnosis would increase the severity level of patients, CMS proposed to maintain theses codes as non-CCs.

CMS finalizes its proposal to maintain ICD-10-CM diagnosis codes I25.82 and I25.84 as non-CCs. In response to a commenter, CMS notes that these codes are not restricted only to patients who have severe calcified lesions.

b. *Hydronephrosis*

CMS received a request that the ICD-10-CM combination codes for hydronephrosis due to ureteral stricture and urinary stone (N13.1 and N13.2) be flagged as principal diagnosis that can act as their own CC for MS-DRG grouping purposes. CMS agreed.

CMS finalizes its proposal to add diagnosis codes N13.1 and N13.2 to the list of principal diagnoses that act as their own CC in Appendix J of the ICD-10 MS-DRG Definitions Manual Version 32.

11. Complications or Comorbidity (CC) Exclusions List for FY 2016

A substantial complication or comorbidity is defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. CMS created a CC Exclusions List to: (1) preclude coding of CCs for closely related conditions; (2) preclude duplicative or inconsistent coding from being treated as CCs; and (3) ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. In previous years, CMS has made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

For FY 2016, CMS does not make any changes to the CC Exclusion List. A complete list of CC Exclusions (Table 6K) is available on CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

Because there are no proposed, new, revised, or deleted diagnosis or procedure codes for FY 2016, CMS did not develop Tables 6A (New Diagnosis Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles) or 6F (Revised Procedure Codes) for this proposed rule. CMS developed Table 6B (New Procedure Codes) for new ICD-10-PCS codes which will be implemented on October 1, 2015.

CMS did not propose additions or deletions to the MS-DRG MCC List or the MS-DRG CC List for FY 2016. Therefore, CMS has not developed the corresponding tables for FY 2016. CMS developed Tables 6L (Principal Diagnosis Is Its Own MCC List) and 6M (Principal Diagnosis Is Its Own CC List).

CMS also reminds readers that the complete documentation of the GROUPER logic will be available on the CMS Acute Inpatient PPS web page after the issuance of the final rule.

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

These MS-DRGs are reserved for those atypical cases in which none of the O.R. procedures performed are related to the principal diagnosis. CMS is not making any changes relating to these MS-DRGs for FY 2016. CMS is also not adding any diagnosis or procedure codes to MDCs for FY 2016.

Review of Cases with Endovascular Embolization Procedures for Epistaxis

During the comment period for the FY 2015 IPPS proposed rule, CMS received a comment related to the specific procedure codes that are assigned to MS-DRGs 981 through 983; 984 through 986, and 987 through 989 for epistaxis. CMS considered this comment outside the scope of the FY 2015 IPPS proposed rule and indicated it would consider the comment in future rulemaking.

Based on an analysis of claims data (including a list of ICD-10-PCS codes for endovascular embolization or occlusion of vessel(s) of head or neck using bare coils and bioactive coils) and the advice of its clinical advisers, CMS proposed to maintain the current MS-DRG structure for epistaxis cases receiving endovascular embolization procedures. CMs did not identify a sufficient number of cases to base a change of MS-DRG assignment.

CMS finalizes its proposal to maintain the current MS-DRG structure for epistaxis cases receiving endovascular embolization procedures and not make any updates to MS-DRGs 981, 982 and 983.

13. Changes to the ICD-9-CM Coding System in FY 2016

a. *ICD-10 Coordination and Maintenance Committee*

The ICD-10-CM Coordination and Maintenance Committee is responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-10-CM to reflect newly developed procedures and technologies and newly identified diseases. The National Center for Health Statistics (NCHS) has lead responsibility for the ICD-10-CM diagnosis codes and CMS has lead responsibility for the ICD-10-PCS procedure codes.

The Committee held its 2015 meeting on March 18-19, 2015. For FY 2016, there were no new, revised, or deleted ICD-10-CM diagnosis codes. For FY 2016, there are new ICD-10-PCS procedure codes that are included in Table 6B (New Procedure Codes).

CMS provides the following contact information for questions and comments concerning coding issues:

- For diagnosis codes contact Donna Pickett, Co-Chairperson, ICD-10 Coordination and Maintenance Committee, at dfp4@cdc.gov
- For procedure codes contact Patricia Brooks, Co-Chairperson, ICD-10 Coordination and Maintenance Committee, at patricia.brooks2@cms.hhs.gov

b. *Code Freeze*

CMS discusses how the partial code freeze has dramatically decreased the number of codes created each year and has gone from creating several hundred new codes each year to creating only a limited number of new ICD-9-CM and ICD-codes.

Regular updates to ICD-10 will begin one year after the implementation of ICD-10 on October 1, 2016.

14. Other Policy Change: Recalled/Replaced Devices

In the FY 2008 final rule with comment period (72 FR 47246 through 47251), CMS discussed Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. CMS specified that if a hospital received a credit for a recalled device equal to 50 percent or more of the cost of the device, CMS would reduce a hospital's IPPS payment for those MS-DRGs. In the FY 2012 IPPS final rule (76 FR 51556 and 51557), CMS clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device.

After publication of the FY 2015 IPPS final rule, CMS received a request to clarify the list of "device-dependent" MS-DRGs subject to this policy. Specifically, ICD-9-CM procedure codes that previously grouped to MS-DRGs 216 through 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, without CC/MCC, respectively and were subject to this policy had been reassigned to new MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with MCC and without MCC, respectively) but MS-DRGs 266 and 267 were not on the list of "device-dependent" MS-DRGs. CMS agreed and proposed to add MS-DRGs 266 and 267 to the list.

CMS also proposed deleting MS-DRGs 237 and 238 and adding MS-DRGs 268 through 272 to the list, if the related proposal were finalized.

CMS finalized its proposals. The final list of MS-DRGs subject to the IPPS policy for replaced devices without cost or with a credit for FY 2016 is below.

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
MDC 03	130	Major Head & Neck Procedures without CC/MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 05	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 05	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 05	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 05	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC
MDC 05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
MDC 05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
MDC 05	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 05	243	Permanent Cardiac Pacemaker Implant with CC
MDC 05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 05	245	AICD Generator Procedures
MDC 05	258	Cardiac Pacemaker Device Replacement with MCC
MDC 05	259	Cardiac Pacemaker Device Replacement without MCC
MDC 05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
MDC 05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
MDC 05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
MDC 05	265	AICD Lead Procedures
MDC 05	266	Endovascular Cardiac Valve Replacement with MCC
MDC 05	267	Endovascular Cardiac Valve Replacement without MCC
MDC 05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
MDC 05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
MDC 05	270	Other Major Cardiovascular Procedures with MCC
MDC 05	271	Other Major Cardiovascular Procedures with CC
MDC 05	272	Other Major Cardiovascular Procedures without CC/MCC
MDC 08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
MDC 08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
MDC 08	466	Revision of Hip or Knee Replacement with MCC
MDC 08	467	Revision of Hip or Knee Replacement with CC
MDC 08	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 08	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC
MDC 08	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC

15. Out of Scope Public Comments

CMS received comments regarding two MS-DRG issues that were outside of the scope of proposals in the proposed rule and they will consider these comments for possible proposals in future rulemaking. These comments requested:

- Creation of a new MS-DRG for primary total ankle replacements and revisions of total ankle replacement procedures; and
- Creation of a new MS-DRG for hip fractures for individuals who receive total hip replacements.

H. Recalibration of MS-DRG Weights

The Secretary is required by statute to revise the MS-DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. In developing relative weights for the FY 2016 final rule, CMS used two data sources:

- FY 2014 MedPAR data for discharges occurring on October 1, 2013, through September 30, 2014, based on bills received by CMS through March 31, 2015, from all hospitals subject to the IPPS as well as short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2014 MedPAR file used to calculate the final relative weights includes data for approximately 9.7 million Medicare discharges these 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. To the extent possible, all the claims were regrouped using the final FY 2016 MS-DRG classifications discussed in section II.G. above.

- Medicare cost report data files from HCRIS, principally for FY 2013 cost reporting periods, using the March 31, 2015 update of the FY 2013 HCRIS. As in the past, CMS used the HCRIS dataset that is three years prior to the IPPS fiscal year.

Following the process used to calculate the relative weights for FY 2015, hospitals' FY 2014 billed charges were converted to costs using national average CCRs calculated by CMS for the 19 cost centers. The cost report lines used to create the 19 national cost center CCRs and the corresponding revenue codes for each of the 19 cost centers are shown in the final rule (see unnumbered table on pp. 398-414 of the display copy). The final FY 2016 CCRs are shown in the table below and compared to FY 2015.

Group	FY 2015 CCR	Final FY 2016 CCR
Routine Days	0.489	0.480
Intensive Days	0.407	0.393
Drugs	0.192	0.191
Supplies & Equipment	0.292	0.297
Implantable Devices	0.349	0.337
Therapy Services	0.344	0.332
Laboratory	0.128	0.125
Operating Room	0.212	0.199
Cardiology	0.123	0.118
Cardiac Catheterization	0.133	0.124
Radiology	0.165	0.159
MRIs	0.087	0.085
CT Scans	0.043	0.041
Emergency Room	0.195	0.183
Blood and Blood Products	0.360	0.336
Other Services	0.405	0.368
Labor & Delivery	0.398	0.404
Inhalation Therapy	0.181	0.177
Anesthesia	0.114	0.106

The final cost-based relative weights were normalized by an adjustment factor of 1.678947 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 section 1886(d)(4)(C)(iii) of the Act.

Using data from the FY 2014 MedPAR file, there were 7 MS-DRGs, all pertaining to newborns, which contain fewer than 10 cases, the minimum number CMS has established to assure accurate and stable cost weights. For these 7 newborn MS-DRGs, CMS finalizes its proposal to compute FY 2016 relative weights by adjusting their FY 2015 weights by the percentage change in the average weight of the cases in other MS-DRGs – the same procedure used previously.

Discussion and Acknowledgment of Public Comments Received on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

CMS, through its Center for Medicare and Medicaid Innovation (CMMI), is currently testing four models of bundled payments as part of the Bundled Payments for Care Improvement (BPCI) initiative. Organizations voluntarily enter into payment arrangements that include financial and performance accountability for episodes of care. The BPCI initiative is currently in the testing phase and must be evaluated, as required by statute, before implementation can be expanded.

Section 1115A(c) of the Act, as added by section 3021 of the ACA, gives the Secretary authority to expand the duration and scope of successful models tested under section 1115A(b), including implementation on a nationwide basis. Such expansion must go through rulemaking and is only applicable to models for which these findings are made, taking into account the evaluation of the model required under section 1115A(b)(4):

1) the Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending;
2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and
3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits.

The FY 2016 IPPS/LTCH proposed rule sought public input on an extensive list of issues affecting possible expansion but did propose expansion pending completion of an evaluation of the program and decision by the Secretary to expand.

CMS reports that it received over 75 public comments addressing a range of issues such as the evaluation of the BPCI models, further testing of the BPCI initiative, target pricing methodologies, data collection and reporting, quality measures, episode definitions, payment methodologies, and precedence rules. No detail about the comments is provided and CMS does not respond, merely stating it will consider the public comments if the BPCI initiative is expanded in the future through rulemaking.

I. Add-On Payments for New Services and Technologies for FY 2016

1. Background

The regulations at 42 CFR 412.87 specify three criteria for a new medical service or technology to receive add-on payments under the IPPS: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. CMS notes that 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 or 3 years. For purposes of the cost criterion, Table 10 released with the FY 2016 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2016[4]. CMS considers a new technology a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to available technologies.

Under the new technology add-on payment policy, 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. Further, unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology. Add-on payment for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

Applicants for new technology add-on payments must have FDA approval or clearance 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. CMS also notes that for FY 2017, complete application information, along with final deadlines for submitting an application, will be posted as it becomes available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. This web site will also post the tracking forms completed by each applicant and will be available before the publication of the proposed rule for FY 2017. CMS invites any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence needed in the agency's coverage decisions.

[4] Table 10 is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/AcuteInpatientPPS/FY2016-IPPS-Final -Rule-Home-Page-Items/FY2016-Final-Rule-Tables.html.

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

On February 3, 2015, CMS held a town hall meeting at the CMS Headquarters Office in Baltimore, MD for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications. In their evaluations, CMS considered the applicants' presentation made at the town hall meeting and written comments received by January 19, 2015. Where applicable, CMS summarized comments at the end of each discussion of the individual applications for FY 2016 in the proposed rule.

3. Implementation of ICD-10-PCS Section "X" Codes for Certain New Medical Services and Technologies for FY 2016

As part of the September 2014 ICD-10 Coordination and Maintenance Committee meeting, CMS received a request to create a new section within the ICD-10-PCS to capture new medical services and technologies that might not appropriately align with the current structure of the ICD-10-PCS codes. The requestor indicated that there might be a need to identify and report new medical services and technologies, including drugs, biologicals and medical devices, for purposes of new-technology add-on payments or tracking and analyzing the use of new technologies and services. CMS agreed with this suggestion and created a new section within the ICD-10-PCS codes, labeled Section "X" codes, to identify new medical services and technologies that are not usually captured by coders, or do not have the desired specificity within the current ICD-10-PCS structure required for new technology. Further information regarding "X" codes can be found on the CMS web site at http://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.

The new "X" codes will be implemented on October 1, 2015 and will be used to identify new technologies and medical services approved for the new technology add-on payment policy for payments beginning October 1, 2015[5]. CMS notes that after section "X" codes have served their purpose, proposals to delete them and create new codes in the body of ICD-10-PCS would be addressed at subsequent ICD-10 Coordination and Maintenance Committee meetings. CMS also notes that codes for new technologies that are consistent with the current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure. The FY 2016 ICD-10-PCS, which includes Section "X" codes were posted in June on the CMS web site at http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html.

Several commenters supported the creation of ICD-10-PCS Section "X" codes. In response to concerns about the decision to create new codes during the partial code freeze, CMS acknowledges the challenges with implementation of the ICD-10-PCS coding system, including the partial code freeze and several implementation delays, and believes that during this time it has been important to make updates to the ICD-10-CM/PCS in a manner that results in less burden on the majority of users. Several commenters expressed concern that payers may mistakenly consider ICD-10-PCS Section "X" codes as interchangeable with CPT Category III

[5] The slides from CMS' June 2015 teleconference, National ICD-10 Teleconference for Implementation and New ICD-10-PCS Section "X" MLN Connects National Provider Call, are available at http://www.cms.gov?Outreach-and-Education/Outreach?NPC/National-Provider-Calls-and-Events-Items/2015-06-18-ICD10.html?DLPage=1&DLSort=0&DLSortDir=descending.

codes. CMS states that Section "X" codes were not created, or intended to be used, to identify experimental or investigational procedures.

4. FY 2016 Status of Technologies Approved for FY 2015 Add-On Payments

As discussed below, **CMS is continuing new technology add-on payments in FY 2016 for Kcentra™, the Argus® II System, the CardioMESH™ HF System, the MitraClip® System, and the RNS® System**.

a. Glucarpidase (Voraxaze®)

Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as a result of renal impairment. Its administration causes a rapid and sustained reduction of toxic MTX concentrations. Voraxaze® was available as a commercial product on the market as of April 30, 2012; CMS considers Voraxaze® "new" as of April 30, 2012. Relevant cases are identified with ICD-9-CM procedure code 00.95 (Injection or infusion of glucarpidase).

CMS explains that, 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; the 3-year anniversary date for Voraxaze® (April 30, 2015) will occur prior to the beginning of FY 2016. **CMS finalizes its proposal to discontinue the new technology add-on payment for Voraxaze® for FY 2016.**

b. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

The Zenith® F. Graft is an implantable device designed to treat patients who have an abdominal aortic aneurysm (AAA) and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. Cases involving the technology are identified by ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). The 3-year anniversary date of the Zenith® F. Graft on the US market (April 4, 2015) will occur prior to the beginning of FY 2016.

CMS finalizes its proposal to discontinue the new technology add-on payments for the Zenith® F. Graft technology for FY 2016.

c. Kcentra™

Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Cases involving the technology are identified by ICD-9-CM procedure code 00.96.

CMS reiterates from the FY 2104 IPPS final rule (78 *FR* 50579) that new technology add-on payments for Kcentra™ are not available for discharges for which the hospital received an add-on payment for a blood-clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. The 3-year anniversary date of Kcentra™ will occur in the second half of FY 2016 (April 29, 2016).

CMS finalizes its proposal to continue the new technology add-on payment for Kcentra™ for FY 2016. For FY 2016, CMS will identify cases involving Kcentra™ with ICD-10-PCS procedure code 30283B1 (Transfusion of nonautologous-4-factor prothrombin complex concentrate into vein, percutaneous approach). The maximum new technology add-on payment for a case involving the Kcentra™ would remain at $1,587.50 for FY 2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $5.4 million.

d. Argus® II Retinal Prosthesis System

The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). It is intended to be implanted in a single eye, typically the worse seeing eye. It consists of three primary components: (1) an implant which is an epiretinal prosthesis that is fully implanted on and in the eye (that is, there are no percutaneous leads); (2) external components worn by the user; and (3) a "fitting" system for the clinician that is periodically used to perform diagnostic tests with the system and to custom-program the external unit for use by the patient. The stimulation pulses delivered to the retina via the electrode array of the Argus® II Retinal Prosthesis System are intended to mimic the function of degenerated photoreceptor cells in patients with RP. The Argus® II System is a Class III device and has an IDE number of G050001. Cases involving the implantation of this technology are identified by ICD-9-CM procedure code 14.81, which uniquely identifies the Argus® II System. The 3-year anniversary date of the Argus® II System will occur in the first half of FY 2017 (December 20, 2013).

CMS finalizes its proposal to continue the new technology add-on payment for the Argus® II System for FY 2016. For FY 2016, CMS will identify cases involving the Argus® II System with ICD-10-PCS procedure codes 08H005Z or 08H105Z (Insertion of epiretinal visual prosthesis into right eye, open approach or Insertion of epiretinal visual prosthesis into left eye, open approach, respectively). The maximum new technology add-on payment for a case involving the Argus® II System would remain at $72,028.75 for FY 2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $3.6 million.

e. Zilver® PTX® Drug Eluting Peripheral Stent

The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above-the-knee femoropopliteal arteries (superficial femoral arteries). A stent is percutaneously inserted in the artery(s), usually by accessing the common femoral artery in the groin. The stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Cases involving the Zilver® PTX® are identified by ICD-9-CM procedure code 00.60. The 3-year anniversary date of the Zenith® PTX® (November 15, 2015) will occur in the first half of FY 2016.

CMS finalizes its proposal to discontinue the new technology add-on payments for this technology.

f. CardioMESH™ HF (Heart Failure) System

The CardioMESH™ HF System is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery (PA); pulmonary artery hemodynamic monitoring is used in the management of HF. The hemodynamic data, including a detailed waveform, are transmitted to a secure web site that serves as the PA pressure database and can be accessed by health care providers. The 3-year anniversary date of the CardioMESH™ HF System on the US market will occur in FY 2017 (May 28, 2017).

CMS finalizes its proposal to continue the new technology add-on payments for the CardioMESH™ HF System for FY 2016. For FY 2016, CMS will identify cases involving the CardioMESH™ HF System with ICD-10-PCS procedure code 02HQ30Z or 02HR30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach or Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach, respectively). The maximum new technology add-on payment for a case involving the CardioMESH™ HF System would remain at $8,875 for FY 2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $11.3 million.

g. MitraClip® System

The MitraClip® System is a transcatheter mitral valve system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral heart valve for high-risk patients who are not candidates for conventional open mitral valve surgery. As discussed in the FY 2015 IPPS final rule, the approval for new technology add-on payment is based on using MitraClip® with the NCD. The 3-year anniversary date of MitraClip® System on the US market will occur in FY 2017 (October 24, 2016).

CMS finalizes its proposal to continue the new technology add-on payments for MitraClip® for FY 2016. For FY 2016, CMS will identify cases involving the MitraClip® System with ICD-10-PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach). The maximum new technology add-on payment for a case involving the MitraClip® System would remain at $15,000 for FY 2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $27 million.

In response to a comment, CMS notes they are maintaining their current policy to use the thresholds issued with each final rule for the upcoming FY when making a determination to continue the add-on payment for new technologies that were approved for the new technology add-on payment from the prior FY (e.g. for FY 2017, CMS will use the thresholds for the updated MS-DRG assignments in Table 10 for the FY 2016 final rule).

h. Responsive Neurostimulator (RNS®) System

The RNS® is an implantable medical device developed by NeuroPace, Inc. for treating people with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical

stimulation through the leads to interrupt those patterns. The 3-year anniversary date of the RNS® System on the US market will occur in FY 2017 (November 14, 2016).

CMS finalizes its proposal to continue the new technology add-on payments for the RNS® System for FY 2016. For FY 2016, CMS will identify cases involving the RNS® System with ICD-10-PCS procedure code 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator generator into brain, open approach). The maximum new technology add-on payment for a case involving the RNS® System would remain at $18,475 for FY 2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $12.9 million.

5. FY 2016 Applications for New Technology Add-On Payments

CMS received nine applications for new technology add-on payments for FY 2016. Two applicants, the Angel Medical Guardian® Ischemia Monitoring Device and Ceftazidime Avibactan (AVYCAZ) withdrew their applications prior to the publication of this final rule. In addition, Idarucizumab, did not receive FDA approval by July 1, 2015 and in accordance with the regulations under §412.87(c) is ineligible for consideration for new technology add-on payments for FY 2016.

The summary below provides a high level discussion of the six remaining new technology applications. **CMS is approving two of the six applications for new technology add-on payments for FY 2016: Blinatumomab (BLINCYTO™) and LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter.**

a. Blinatumomab (BLINCYTO™)

Amgen, Inc. submitted an application for BLINCYTO™, a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), a rare aggressive cancer. The BLINCYTO™ technology attaches to a CD19 cell, which is present on all of the cells of the malignant transformations that cause ALL and helps attract the cell into close proximity to the CD3 T cell with the intent of allowing the T-cell to inject toxins that destroy the tumorous cell. BLINCYTO™ is administered as a continuous IV infusion and a course of treatment consists of two phases.

CMS finalizes that the BLINCYTO™ technology meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2016. Cases with BLINCYTO™ will be identified by ICD-10-PCS procedure codes XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1) and XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1). The applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35 mcg at a cost of $3,187.57 per vial; the applicant

noted that all vials are single-use. CMS determined that cases involving the BLINCYTO™ would incur an average cost per case of $54,035.69 (1 vial/day x 17 days x $3,178.57). As 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 BLINCYTO™ is $27,017.85 for FY2016. CMS estimates the FY 2016 add-on payments for this technology at approximately $4.6 million.

CMS determined that cases involving the BLINCYTO™ would incur an average cost per case of $54,035.69 based on treatment involving 1 vial/day for a 17 day treatment cycle at a cost of $3,178.57 per vial. CMS disagrees with the applicant's assumption that the maximum new technology add-on payment for a case is an estimated 28 day treatment cycle. CMS notes that it is historical practice to base new technology add-on payments based on the average cost and the maximum cost of the technology.

Newness criterion BLINCYTO™ received FDA approval on December 4, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry on the US market on December 17, 2014. The applicant states that BLINCYTO™ is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

In the proposed rule, CMS evaluated BLINCYTO™ against the three established criteria (discussed in 74 FR 43813 – 43814) for evaluating whether a new technology is substantially similar to an existing technology and would therefore not be considered "new" for purposes of the new technology add-on payment:

1. Whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome;
2. Whether a product is assigned to the same or a different MS-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.

CMS was concerned that BLINCYTO™ may be similar to other technology currently available to treat the same patient population and invited public comment on "if, and how", BLINCYTO™ meets the newness criterion

In response to comments, including comments provided by the applicant, CMS concludes that the BLINCYTO™ technology meets the newness criterion. Commenters noted that there are no other FDA-approved bi-specific T cell engager constructs currently marketed and its mechanism of action is unique and distinguishable from all other FDA-approved therapies because it redirects the patient's immune system toward the cancerous cells, which leads to the target destruction of these cells. Commenters also noted that although other bi-specific T cell-engager constructs are in the development stage, these products have not reached the advanced stages of development and that the BLINCYTO™ technology is FDA approved. CMS also agrees with comments that the technology would be used in the treatment of a different patient population than those currently treated with existing technologies.

Cost criterion In response to CMS' concerns discussed in the proposed rule, the applicant submitted additional information. After reviewing this additional information, CMS agrees with the applicant that the technology meets the cost criterion.

Substantial clinical improvement criterion In response to comments, including comments provided by the applicant, CMS concludes that the BLINCYTO™ technology meets the substantial clinical improvement criterion. Comments noted that the small sample size and lack of a control arm in the BLINCYTO™ study is due to the rarity and fatality of the disease and that MedPAR data demonstrates that 60 percent of the inpatient stays for patients in relapse were Medicare patients under the age of 65. CMS also agrees with comments that treatment of patients using currently available combination chemotherapy or the standard treatment for this disease, has an equivalent or lower rate of complete or partial remission, as well as excessively exposes patients to severe toxicities. CMS notes that they will continue to monitor ongoing Phase III studies to determine if the substantial clinical improvement demonstrated in the BLINCYTO™ study MT 103-211 continues.

b. DIAMONDBACK 360® Coronary Orbital Atherectomy System

Cardiovascular System, Inc. submitted an application for the DIAMONDBACK 360® Coronary Orbital Atherectomy System (OAS), a percutaneous orbital atherectomy system used to facilitate stent delivery in patients diagnosed with coronary artery disease and severely calcified coronary artery lesions. The system uses an electrically driven, diamond-coated crown to reduce calcified lesions in coronary blood vessels.

CMS finalizes that the DIAMONDBACK® Coronary OAS is not eligible for new technology add-on payments for FY 2016 because it does not meet the newness and substantial clinical improvement criteria for new technology add-on payments.

Newness criterion In response to additional comments provided by the applicant, CMS notes they remain concern that the DIAMONDBACK® Coronary OAS is substantially similar to other atherectomy devices currently available. CMS also noted that although the applicant stated that the FDA did not grant approval for a trial comparing approved versus non-approved technologies, the FDA does not prohibit manufacturers performing other trials outside of the trials included under the FDA approval process. In response to the applicants comments that CMS' concerns about the newness criteria for the DIAMONDBACK® Coronary OAS are similar to issues raised about the Zilver® PTX technology that was approved for a new technology add-on payment, CMS agrees but notes that the Zilver® PTX was the first drug-eluting stent technology at the time it was approved. After reviewing all the information, CMS concludes that the DIAMONDBACK® Coronary OAS does not meet the newness criterion.

Cost criterion In response to CMS' concerns discussed in the proposed rule, the applicant submitted additional information. After reviewing this additional information, CMS agrees with the applicant that the technology meets the cost criterion.

Substantial clinical improvement criterion In response to comments, including comments provided by the applicant, CMS still does not believe that the safety and efficacy endpoints in the ORBIT II study represent a substantial clinical improvement over existing atherectomy

devices available to the Medicare population. CMS notes that the requirement that a technology demonstrates a substantial clinical improvement is not inherent in FDA's regulatory process. CMS concludes that the technology does not meet the substantial clinical improvement criterion.

c. CRESEMBA® (Isavuconazonium)

Astellas Pharma Us, Inc. submitted an application for CRESEMBA®, an IV and oral-broad antifungal used for the treatment of adults with severe invasive and life-threatening fungal infections, including invasive aspergillosis and mucormycosis.

CMS finalizes that the CRESEMBA® technology is not eligible for new technology add-on payments for FY 2016 because it does not meet the newness and substantial clinical improvement criteria for new technology add-on payments.

Newness criterion In response to additional comments provided by the applicant, CMS notes they remain concern that CRESEMBA® is substantially similar to other azole antifungal drugs; it uses the same mechanism of action, inhibiting the enzyme lanosterol 14 α-demethylase, of other azole antifungal drugs. CMS concludes that the technology does not meet the newness criterion.

Cost criterion In response to CMS' concerns discussed in the proposed rule, the applicant submitted additional information. After reviewing this additional information, CMS agrees with the applicant that the technology meets the cost criterion.

Substantial clinical improvement criterion CMS notes appreciation of the additional information the applicant submitted in response to CMS concerns discussed in the proposed rule, including the lack of data for comparative studies between CRESEMBA® and alternative therapies for the treatment of aspergillosis and invasive mucomycosis and safety in treating patients with renal impairment. CMS believes, that the outcomes of CRESEMBA® are similar to those using other azole antifungal drugs and that CRESEMBA® does not represent a substantial clinical improvement over existing technologies. CMS also acknowledges a commenter who also did not believe the technology represents substantial clinical improvement over existing technologies.

d. LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter, respectively. Both of these technologies are DCB PTA for patients with peripheral artery disease (PAD). Current treatments for PAD include angioplasty, stenting, atherectomy, and vascular bypass surgery. The applicants noted that the DCB catheter is a device-drug combination product comprised of a device component (an over-the-wire balloon catheter) and a drug component on the balloon. The device has two modes of action: the balloon mechanically dilates a de novo or restenotic lesion in the vessel and application

of the drug (paclitaxel) to the vessel wall to inhibit the restenosis that is normally associated with a proliferative response to the PTA. Predilatation with a nondrug-coated PTA balloon occurs prior to using the DCB PTA catheter. CMS evaluated both technologies as one application.

CMS finalizes that the LUTONIX® and IN.PACT™ Admiral™ technologies meet all three criteria for new technology add-on payments and are approved for add-on payments in FY 2016. Cases involving these technologies will be identified by one of the ICD-10-PCS procedure codes identified in the table in the final rule. New technology add-on payments for cases involving these technologies will be based on the weighted average cost of the two technologies described by the ICD-10-PCS procedure codes, which are not manufacturer specific. CMS projected that 25 percent of the cases would use the LUTONIX® technology with a cost of $662.41 per case and 75 percent of the cases would use the IN.PACT™ Admiral™ technology at $1,890 per case. This resulted in a case-weighted average cost of $2,071.45. The maximum new technology add-on payment for these technologies is $1,035.72 for FY2016. CMS estimates the FY 2016 add-on payments for these technologies are approximately $36 million.

Newness criterion The FDA approved LUTONIX® on October 9, 2014 and commercial sales in the US market began on October 10, 2014. IN.PACT™ Admiral™ received FDA approval on December 30, 2014 and commercial sales in the US market began on January 29, 2015. CMS concludes these technology meet the newness criterion and indicates the newness period began on October 10, 2014.

Cost criterion In response to CMS' concerns that both applicants excluded cases of patients that received stent implantations from their analysis, both applicants submitted additional information. After reviewing this additional information, CMS agrees with the applicants that these technologies meet the cost criterion.

Substantial clinical improvement criterion CMS acknowledges the additional information provided by both applicants, including data on the specific unmet need that may be met by the use LUTONIX® and IN.PACT™ Admiral™ technologies. After reviewing all the information, CMS agrees with the applicants that these technologies meet the substantial clinical improvement criterion.

e. VERASENSE™ Knee Balancer System (VKS)

OrthoSensor submitted an application for the VERASENSE™ Knee Balancer System (VKS), a sterile, single patient intraoperative used device to dynamically balance the patient's knee during total knee arthroplasty (TKA) surgery. The applicant noted that the VKS device combines dual sensor elements, coupled with micro-processing technology, to accurately depict intra-articular kinetics and contact point locations within the knee.

CMS finalizes that the VKS device is not eligible for new technology add-on payments for FY 2016 because it does not meet the newness and substantial clinical improvement criteria for new technology add-on payments.

Newness criterion In response to additional comments provided by the applicant, CMS continues to believe that the advancements made to the VKS that resulted in additional FDA approval clearances in 2013 are not significant enough to distinguish the current version of the technology from the first version of the VKS, which received FDA approval in 2009. After reviewing all the information, CMS concludes that the VKS device does not meet the three established criteria for the newness criterion.

Cost criterion In response to CMS' concerns about the three separate analyses discussed in the proposed rule, the applicant submitted additional information based on the FY 2013 MedPAR file. After reviewing this additional information, CMS agrees with the applicant that the technology meets the cost criterion.

Substantial clinical improvement criterion In response to comments, including comments provided by the applicant, CMS still has several concerns including the fact that most of the clinical evidence is based on patient satisfaction surveys and the use of historical literature controls. CMS also notes that the applicant did not present clinical data to distinguish between the first and advanced version of VKS. CMS concludes that this technology does not meet the substantial clinical improvement criterion.

f. WATCHMAN® Left Atrial Appendage Closure Technology

Boston Scientific Corporation submitted an application for the WATCHMAN® Left Atrial Appendage (LAA) Closure Device, an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli (that may result when a patient has atrial fibrillation (AF)) from entering into the arterial circulation from the LAA, and reduces the risk of stroke and potentially eliminate the need for Warfarin therapy in patients diagnosed with nonvalvular AF and are candidates for Warfarin therapy. CMS notes that the applicant submitted an application last year but withdrew its application after the FY 2015 IPPS proposed rule was issued.

CMS finalizes that the WATCHMAN® system is not eligible for new technology add-on payments for FY 2016 because it does not meet the substantial clinical improvement criterion for new technology add-on payments.

Newness criterion. The applicant received FDA approval of the WATCHMAN® system on March 15, 2015. CMS concludes that the WATCHMAN® system meets the newness criterion.

CMS notes they received a formal National Coverage Decision (NCD) request to cover percutaneous, transcatheter intraluminal LAA closure using an implanted device and expects to complete the National Coverage Analysis by February 16, 2015 (http://www.cms.gov/medicare-coverage-database/details/ncs-details.aspx?NCAId=281). CMS reminds the reader that the process for evaluation and determination of an NCD is independent of the process and approval of an application for new technology add-on payments.

Cost criterion After reviewing the comments, including additional analysis provided by the applicant, CMS concludes that the technology meets the cost criterion.

In the proposed rule, CMS discussed how their proposal to create two new MS-DRGs, MS-DRG 273 and MS-DRG 274, could impact the assignment of cases involving the WATCHMAN® system and discussed using supplemental threshold values (thresholds that are 75 percent of one standard deviation beyond the geometric mean standardized charge) as part of the cost criterion evaluation for this application. CMS posted supplemental threshold values on their website. CMS agrees with commenters that they should evaluate the cost threshold in effect at the time the new technology add-on payment application is submitted to determine if an applicant exceeds the cost threshold.

Substantial clinical improvement criterion CMS acknowledges the comments, including the additional information provided by the applicant, in support of the WATCHMAN® system for new technology add-on payment for FY 2016. CMS still remains concerned that the evidence presented by the applicant, including the continued follow-up of patients, is not sufficient to demonstrate the superiority of the WATCHMAN® system as compared to Warfarin therapy. After reviewing all the information, CMS concludes that the WATCHMAN® system does not meet the substantial clinical improvement criterion for new technology add-on payment for FY 2016. CMS "welcomes" the applicant to reapply next year as additional long term data become available.

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

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

CMS finalizes its proposal to continue using the same labor market areas in FY 2016 that it used for FY 2015 to calculate the area wage indexes and the transition periods. The current statistical areas (implemented beginning in FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13-01 based on the 2010 Census population data. A copy of this bulletin may be obtained at http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.

B. Verification of Worksheet S-3 Wage Data

CMS notes that the wage index values are based on data from FY 2012 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). As was done for FY 2015, 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), GME costs (teaching physicians and residents) and certified registered nurse anesthetists, hospital-based RHCs and FQHCs, and CAHs. CMS also notes this data is used to calculate wage indices for other providers of services as well as for prospective payments to IRFs, IPFs, LTCHs, and hospital outpatient services.

CMS calculates the FY 2016 wage index based on wage data of 3,362 hospitals from Worksheet S-3 of the cost report for cost reporting periods beginning on or after October 1,

2011, and before October 1, 2012. CMS initially excluded 93 providers due to excessively aberrant data but indicates that if the data could be corrected in time, it intends to include some of those providers in the final wage index for FY 2016. Since the issuance of the proposed rule, CMS has received corrected data or improved documentation for 34 hospitals, and therefore is including these 34 hospitals in the final FY 2016 wage index. CMS notes that the hospitals that are excluded from the wage index remain excluded for a variety of reasons, such as, but not limited to unresponsiveness to requests for documentation or insufficiently documented data, terminated hospitals' failed edits for reasonableness, or low Medicare utilization. CMS includes data from facilities that were IPPS hospitals in FY 2012 even if they terminated program participation as hospitals, but excludes data from CAHs and from IPPS hospitals that converted to CAH status. CMS removed 13 hospitals that converted to CAH status after February 13, 2014. For a multicampus hospital, CMS uses the same methodology as it did for the FY 2015 wage index to allot wages and hours data among the different labor market areas where the campuses are located. Table 2 includes separate wage data for the campuses of 8 multicampus hospitals, and is available from the CMS Web site: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html.

Commenters disagreed with the exclusion of certain hospital's data from the FY 2016 wage index public use files and requested that these hospitals be included in the FY 2016 final rule. Commenters asked for more transparency and disclosure of criteria for the reasons why hospitals are excluded from the wage index noting that deleting one hospital can significantly impact the entire Core-Based Statistical Areas's average hourly wage and that the number of hospitals excluded from the wage index has risen over past years. In addition, commenters asserted that CMS should prove that a hospital's costs are abnormal. Commenters also noted that CMS communication could be improved. Specifically, commenters asked that MACs notify hospitals in writing if the hospitals are excluded from the PUF, identify the criteria used to determine whether a hospital was excluded, and the procedures that a hospital may use to ask for reconsideration. Lastly, commenters also suggested that MACs be directed to notify State hospital associations when hospitals do not respond to desk reviews or when efforts are underway to correct hospitals' aberrant data.

In response, CMS disagrees with commenters that removing hospitals from the FY 2016 wage index PUFs was arbitrary. CMS notes that it never anticipated that the data of all 93 hospitals identified in the proposed rule would be corrected and that, unlike in the past, it had specified the total universe of deleted hospitals and not just the number of hospitals with aberrant data. CMS notes that the group of approximately 40 hospitals that were excluded during the development of the FY 2016 wage index and had the potential to improve their data is analogous to the 49 hospitals that were excluded from the FY 2015 proposed rule. The remaining hospitals were deleted for reasons that would make their data unresolvable, such as, but not limited to, termination (during or since the relevant past period), low/no Medicare utilization, being a CAH, or not reporting any wage data. CMS also notes that the current process worked, as only 5 hospitals of the approximately 40 whose data were potentially resolvable remain out of the final FY 2016 wage index.

Furthermore, CMS acknowledges the commenters' suggestions for increased transparency, disclosure of criteria for hospitals' exclusion, and improving awareness both at the State hospital association level and the hospital level. CMS notes that it has never been its policy to disclose audit protocol. However, CMS states that in the future, it may consider a limited proposal regarding criteria for excluding a hospital's data from the wage index due to its overall average hourly wage being either too high or too low, as well as utilizing additional methods of communicating with stakeholders regarding the adequacy of their wage data.

C. FY 2016 Unadjusted Wage Index

The FY 2016 national average hourly wage, unadjusted for occupational mix, is $40.2911 ($16.9153 for Puerto Rico). CMS uses the same methodology it applied for the FYs 2012, 2013, 2014, and 2015 wage index in computing the unadjusted wage index for FY 2016. CMS notes that it did not change the use of the employment cost index as its data source for wages, salaries and other price proxies in the IPPS market basket.

D. Occupational Mix Adjustment to the FY 2016 Wage Index

CMS finalizes its proposal to calculate the occupational mix adjustment factor using the same methodology it used for FYs 2012, 2013, 2014, and 2015. As a result of applying this methodology, the FY 2016 occupational mix adjusted national average hourly wage is $40.2555; the FY 2016 occupational mix adjusted Puerto Rico-specific average hourly wage is $16.8711. CMS finalizes its proposal to calculate the occupational mix adjustment using the 2013 occupational mix survey data of 3,135 hospitals for which CMS also had Worksheet S-3 data. CMS reports a response rate of 93.2 percent and notes it applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data; CMS requires those hospitals to explain their noncompliance and may consider penalties in the future.

Section 1886(d)(3)(E) of the Act requires the collection of data every 3 years on the occupational mix of employees for each Medicare participating short-term, acute care hospital to construct an occupational mix adjustment to the wage index. CMS finalizes its proposal to use data collected on the new 2013 Medicare Wage Index Occupational Mix Survey for the FY 2016 wage index. The 2013 Occupational Mix Survey Hospital Reporting Form CMS-10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html?DLPage=1&DLSort=1&DLSortDir=descending. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014, and preliminary, unaudited 2013 survey data were posted on the CMS Web site afterward, on July 11, 2014. CMS notes that certain surveys with aberrant data elements are excluded from the FY 2016 wage index.

As it did for FY 2015, CMS continues to apply the occupational mix adjustment to 100 percent of the FY 2016 wage index. The FY 2016 national average hourly wages for each occupational mix nursing subcategory are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$38.8239
National LPN and Surgical Technician	$22.7674
National Nurse Aide, Orderly, and Attendant	$15.9559
National Medical Assistant	$18.0062
National Nurse Category	$32.8760

CMS observes that, based on its analysis of the occupational mix data, the national percentage of hospital employees in the nurse category is again approximately 43 percent, and that the wage index values for FY 2016 would increase for a larger percentage of urban areas (53.8 percent) than would rural areas (51.1 percent).

E. Transitional Wage Indexes

In the FY 2015 IPPS/LTCH PPS final rule, CMS established transition methodologies to mitigate any negative payment impacts experienced by hospitals due to its adoption of the new OMB labor market area delineations. These transition periods were designed to address payment impacts for hospitals in urban areas that became rural, hospitals that qualified as urban under section 1886(d)(8)(B) of the Act ("Lugar hospitals") that became rural, and hospitals that experienced a decrease in wage index under the new OMB delineations.

1. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule, CMS adopted a policy for hospitals located in an urban county that became rural under the new OMB delineations (and had no form of wage index reclassification or redesignation in place for FY 2015) to assign them the urban wage index value of the Core-Based Statistical Area (CBSA) in which they are physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2016 will represent the second year of this transition policy, and CMS did not propose any changes to this policy.

CMS notes situations in which a hospital could not be assigned the wage index value of the CBSA in which it geographically was located in FY 2014. In these cases, CMS proposes to continue its approach to assign the wage index of the labor market area to which they are closest. CMS states that any such assignment made in FY 2015 will continue for FYs 2016 and 2017. CMS continues its policy that if a hospital seeks and is granted reclassification or redesignation for FYs 2016 or 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it.

CMS notes that these hospitals maintain their status as rural hospitals for other payment considerations and are included in the statewide rural area in which they are geographically located. CMS states that after the 3-year transition period (beginning in FY 2018), these formerly urban hospitals will receive their statewide rural wage index, absent any reclassification or redesignation. CMS did not receive any comments on these policies.

2. Transition for Hospitals Deemed Urban under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural

In the FY 2015 IPPS/LTCH PPS final rule, CMS finalizes a policy to apply a 3-year transition to hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural. Hospitals designated as urban under section 1886(d)(8)(B) of the Act are generally referred to as "Lugar" hospitals. For FY 2016, CMS is not proposing any changes to this policy and will continue with the second year of its implementation of this transition policy. If the hospital cannot be assigned the wage index value of the CBSA in which it geographically was located in FY 2014, CMS continues its approach to assign the wage index of the labor market area to which it is closest. CMS notes that the wage index assignment based on this transition policy will be forfeited if the hospital obtains any form of wage index reclassification or redesignation. CMS did not receive any comments on these policies.

3. Expiring Transition for Hospitals that Experience a Decrease in Wage Index under the New OMB Delineations

In the FY 2015 IPPS/LTCH PPS final rule, CMS established a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index. This 1-year blended wage index expires at the end of FY 2015, and CMS is not proposing any additional transitional adjustment for these hospitals. CMS notes its belief that a transition period longer than 1-year (other than those hospitals changing from urban to rural status) would reduce the accuracy of the overall labor market area wage index.

The majority of commenters expressed appreciation to CMS for providing a transitional wage index and supported CMS' plan to discontinue the 1-year transition in 2016. One commenter requested that the transition period be extended for one year with a suggested "75/25 percent" methodology. In response, CMS acknowledged the commenter's support, but did not believe an extension was warranted, and thus will allow the transition adjustment to expire at the end of FY 2015.

F. Rural, Imputed, and Frontier Floors

CMS notes that the rural floor will increase the final FY 2016 wage index for 346 hospitals. CMS projects that, in aggregate, rural hospitals will experience a 0.2 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) would experience 0.1 percent increase

in payments; and urban hospitals in the New England region can expect a 1.6 percent increase in payments, primarily due to the application of the rural floor in Massachusetts. CMS expects that 39 urban providers in Massachusetts will receive a rural floor wage index value and will receive approximately a 3.1 percent increase in IPPS payments due to the application of the rural floor. The application of the rural floor increases payments by $98 million to Massachusetts. CMS also expects that 203 urban hospitals in California will receive a 2.2 percent increase in IPPS payments due to the application of the rural floor or imputed floor, increasing payments to this state by $221 million.

CMS finalizes its proposal to extend for one additional year (through September 30, 2016) its temporary imputed floor program whereby CMS imputes a "floor" for States with no rural counties. Under the OMB's new labor market area delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. CMS finalizes its proposal to continue both the original imputed floor methodology (which benefits New Jersey and Delaware) and its alternative, temporary methodology for the benefit of Rhode Island, which has only one CBSA in contrast to New Jersey's 7 and Delaware's 3. Under this alternative, the lowest post-reclassified wage index assigned to a hospital in a State with one CBSA (viz. Rhode Island) is 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). Twenty-one hospitals in New Jersey and four hospitals in Rhode Island will receive an imputed floor. CMS estimates an aggregate increase in payments of roughly $27 million in FY 2016 for the New Jersey hospitals, and $4.5 million for the four hospitals in Rhode Island. No hospitals in Delaware will benefit from the imputed floor under either methodology because all hospitals in the affected labor market areas will receive a higher wage index value due to reclassification. CMS provides in the final rule a table showing the payment impact of the rural floor and imputed floor with budget neutrality at the State level (see pages 2044-2045 of display copy).

Forty-eight hospitals in Montana, North Dakota, South Dakota, and Wyoming will receive the frontier floor value of 1.0000 for FY 2016; though Nevada qualifies as a frontier State, its FY 2016 rural floor value is greater than the frontier floor. Overall, CMS estimates an increase of approximately $60 million (or 0.1 percent) in IPPS operating payments in FY 2016 by reason of the frontier floor.

G. FY 2016 Wage Index Tables

CMS finalizes its proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. The wage index tables have consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that are made available via the Internet on the CMS Web site. However, with the exception of Table 4E, CMS streamlined and consolidated these 11 tables into 2 tables. The tables can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html. CMS did not receive any public comments on its proposal for the tables.

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

CMS notes that at the time the final rule was constructed the Medicare Geographic Classification Review Board (MGCRB) had completed its review of FY 2016 reclassification requests. Based on these requests, 282 hospitals were approved for wage index reclassifications starting in FY 2016, and because such reclassifications are effective for 3 years, a total of 841 hospitals are in a reclassification status for FY 2016 (including those initially approved by the MGCRB for FYs 2014 and 2015). Applications for FY 2017 reclassifications are due to the MGCRB by September 1, 2015 which is also the deadline for canceling a previous wage index reclassification withdrawal or termination.

CMS continues its policy that an eligible hospital that waives its Lugar status (as established under Section 1886(d)(8)(B)(i) of the Act) to receive 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. CMS permits a Lugar hospital to submit a single 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 to return to its deemed urban status.

CMS received concerns from commenters that new hospitals are not able to obtain the same reclassified wage index as other hospitals in the countywide (group) reclassifications. In response, CMS states that it is not making any changes to these provisions at this time, but makes a clarification regarding hospitals that acquire other providers located in different labor market areas with current reclassifications. CMS elaborates that it believes that the acquiring hospital should be able to make determinations regarding the reclassification status of the subordinate campus located in a different labor market area if it accepted the provider agreement of that subordinate campus. CMS clarifies that if the acquired campus (that is, the hospital whose CCN will no longer be active) has remaining years left on a MGCRB reclassification, this reclassification status remains in effect for the subordinate campus located in a different market area. CMS also notes that the acquiring hospital is authorized to make timely requests to terminate, withdraw, or reinstate any reclassification for the subordinate campus for any remaining years of the reclassification.

I. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

Table 2 (formerly Table 4J and available from the CMS Web site) lists the out-migration wage index adjustments for FY 2016. The "out-migration" adjustment is an adjustment to the hospital wage index based on commuting patterns of hospital employees.[6] CMS continues to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment, and estimates increased payments of approximately $45 million in FY 2016 for 336 hospitals receiving the out-migration adjustment. This provision is not budget neutral.

[6] Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index.

To determine the new out-migration adjustments and applicable counties, CMS finalizes its proposal to calculate the FY 2016 out-migration adjustment based on the data derived from the custom tabulation of the American Community Survey (ACS). Specifically, CMS analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. CMS previously computed the out-migration adjustment from a special tabulation of the 2000 Census journey-to-work data for all industries. Seventy-five hospitals would be newly eligible for the out-migration adjustment in FY 2016 using the new data. CMS received several comments in support of its policies to update the out-migration adjustment for FY 2016.

CMS notes for FY 2016, hospitals that qualified in FY 2014 or FY 2015 to receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014 will continue to receive the same out-migration adjustment for the remainder of their 3-year qualification period (as required by Section 1886(d)(13)(F) of the Act). This is true regardless of whether the FY 2016 adjustment would be higher or lower than the adjustment based on FY 2014 data. If the hospital qualifies in FY 2017 (after the expiration of the 3-year qualifying period for the out-migration adjustment, which began in FY 2014) to receive the out-migration adjustment based on the new commuting data and OMB delineations in effect in FY 2017, it could receive the out-migration adjustment based on the new data for FYs 2017, 2018, and 2019.

J. Process for Requests for Wage Index Data Correction

CMS describes the process by which a hospital may submit to its Medicare Administrative Contractor (MAC) requests to change or revise wage index data, and indicates that April 15, 2015 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. The wage data files were provided in late May 2014 and the occupational mix data files were provided in mid-July. CMS notes that it posted the final wage index data public use files on May 1, 2015 at the following CMS Web site: (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2016-Wage-Index-Home-Page.html.) CMS notes that these files were made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data. If a hospital believed a potential error existed because of these reasons, the hospital was required to send its request and supporting documentation to CMS and to the MAC no later than June 1, 2015. Verified corrections were incorporated into the final wage index in the FY 2016 IPPS/LTCH PPS final rule.

CMS retains the right, however, (but not the obligation) in the event errors are identified by hospitals after the June 1, 2015 deadline, to make midyear changes to the wage index under limited circumstances as follows: 1) 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 1, 2015 deadline. If such a correction would change the wage

index value for an area, the revised wage index would be effective prospectively from the correction date.

Only under very limited circumstances would CMS make wage index value changes retroactive to the beginning of the fiscal year involved, as follows: 1) the MAC or CMS erred in tabulating data; 2) the hospital knew and requested a correction before June 1, 2015; and 3) CMS agreed that the error was made and should be corrected. However, this would not apply for a hospital that seeks to revise another hospital's data; nor can the correction be used to revise a prior fiscal year's wage index data. CMS notes that there would also be retroactive effect where a judicial decision reverses a CMS denial of a hospital's wage index revision request.

K. Labor-Related Share for the FY 2016 Wage Index

CMS finalizes its proposal to continue to use a labor-related share of 69.6 percent, based on the FY 2010-based IPPS market basket, for discharges occurring on or after October 1, 2015. CMS continues to apply the revised labor-related share in a budget neutral manner, but in doing so it assumes all hospitals receive the higher labor-related share of the standardized amount. CMS continues to apply the wage index to the labor-related share of 62 percent of the national standardized amount for hospitals with wage indices less than 1.0 and 69.6 percent of the national standardized amount for hospitals with wage indices greater than 1.0.

For Puerto Rico hospitals, CMS will also rebase and revise the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as the base year. For FY 2016, CMS continues to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2015. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 63.2 percent or 62 percent, whichever results in higher payments to the hospital.

One commenter believed that the current labor-related share percentage of 62 percent is too high for providers in Puerto Rico, and that data show that nonlabor costs are higher, such as utilities. CMS in response notes that current law requires that the labor-related share for the national standardized amount be set at 62 percent for hospital with a wage index less than or equal to 1.0000, and that the wage index for all Puerto Rico hospitals is less than 1.0000.

L. Changes to 3-Year Average for the FY 2017 Wage Index Pension Cost

CMS reconsidered the changes made to the FY 2017 wage index timeline in light of its experience to date with the administrative aspects of the 3-year average pension policy, and believes that changes are warranted, beginning with the FY 2017 wage index. CMS stated, in many cases, hospitals that participate in a systemwide pension plan or State-run retirement system have been unable to obtain timely documentation to support their allocated share of total plan contributions.

CMS finalizes its proposal that, for the FY 2017 wage index and all subsequent fiscal year wage indexes, the 3-year average would be based on pension contributions made during the

base cost reporting period plus the prior 2 cost reporting years. The change in the 3-year averaging period would produce a 1-year lag in reporting pension costs relative to reporting all other costs. For example, the FY 2017 wage index would reflect the average pension contributions made in hospitals' cost reporting periods beginning during FYs 2011, 2012, and 2013 (rather than FYs 2012, 2013, and 2014 under the current FY 2015 policy). For most hospitals, this would result in the same 3-year average pension costs being used for the FYs 2016 and 2017 wage index.

For FY 2017 only, CMS finalizes its proposal that all hospitals submit requests to revise their previously submitted pension data by early October to mid-October (instead of the first week of September, as stated in the FY 2015 IPPS/LTCH PPS final rule). For FY 2018 and subsequent fiscal years, CMS finalizes its proposal to require that all hospitals request revisions to the preliminary PUF for all wage index issues, including submission and/or revisions of pension data, by the first week of September.

Commenters were generally supportive of the proposed modifications to the wage index timetable. Some commenters were supportive of the single deadline for revisions to the preliminary wage index data, but preferred an October deadline, rather than September, to allow hospitals more time to review their data. In response, CMS is appreciative of the general support but believes that the deadline in early September is manageable for hospitals and provides the MACs with the most amount of time to complete their desk reviews. CMS adopts its proposed policies as final, without modification.

M. Changes to the Wage Index Timetable for FY 2017 and Subsequent Years

The chart below (reproduced from the final rule) shows the FY 2017 wage index timetable. The schedule is the same as published in the FY 2015 IPPS/LTCH PPS final rule, except for deadline for pension revisions. It includes the CMS change for FY 2017 for all hospitals to request revisions to their pension data by mid-October 2015. For FY 2018 and subsequent fiscal years, CMS will apply the same timetable as FY 2017, except all requests for revisions to the preliminary PUF, including pension data, will be required to be submitted by hospitals to MACs in the first week of September each year.

FY 2017 WAGE INDEX TIMETABLE WITH DEADLINE FOR PENSION REVISIONS

Actions	**Deadlines**
Posting of Preliminary PUF on CMS Web site	Mid-May 2015
Deadline for Hospitals to Request Revisions to Preliminary PUF	First week of September 2015
Deadline for Hospitals to Request Revisions to Pensi Data	Early October 2015 to Mid-October 2015

Actions	Deadlines
Deadline for MACs to Complete Desk Reviews	Mid-November 2015
Posting of January PUF on CMS Web site (formerly "February" PUF)	Late January 2016
Deadline Following Posting of January PUF for Hospitals to Request Revisions	Mid-February 2016
Completion of Appeals by MACs and Transmission Final Wage Data to CMS	Mid to Late March 2016
Deadline for Hospitals to Appeal in April	Early April 2016
Posting of Final Rule PUF	Late April 2016
Deadline for Hospitals to Appeal in May	Late May 2016
Expected Issuance of IPPS Final Rule	August 1, 2016

N. Clarification of Allocation of Pension Costs for the Wage Index

CMS notes that it has become aware of some confusion with respect to how hospitals are to compute the 3-year average when allocating their pension costs on the Medicare cost report if a hospital participates in a pension plan or retirement system that also covers other entities. CMS clarifies the participating hospital must report its respective 3-year average pension cost (or prefunding balance) reflecting only the hospital's allocated share of total plan contributions, and *not* including any share of pension costs of other entities. CMS notes that the allocated percentage to each entity can change due to mergers, changes in plan coverage, or other factors. CMS also states that if wage index reporting is required for two or more hospitals covered under the same pension plan or retirement system, those hospitals should ensure that the allocation of plan contributions for each reporting period is determined on a consistent basis to avoid duplicate reporting of costs. CMS did not receive any public comments on this clarification.

IV. Other Decisions and Changes to the IPPS for Operating Costs and Indirect Medical Education (IME) Costs

A. Changes in the Inpatient Hospital Update for FY 2016 (§§412.64(d), 412.211(c))

The inpatient hospital update for FY 2016 is calculated by determining the rate of increase in the hospital market basket for IPPS hospitals in all areas, subject to the following possible reductions (in the order presented):

1. For hospitals that fail to submit quality information, the FY 2016 inpatient hospital update will be reduced by one quarter of the applicable percentage increase.[7]
2. For a hospital that is not a meaningful electronic health record (EHR) user (and to which no exemption applies), the FY 2016 inpatient hospital update will be reduced by a 66 2/3 percent reduction to three quarters of the applicable percent increase in FY 2016 (i.e., one-half of the market basket update) [8]. This reduction will increase to three-fourths of the market basket update in FY 2017 and later fiscal years.
3. For all hospitals, the FY 2016 inpatient hospital update is subject to a 0.5 percentage point reduction for changes in economy-wide productivity (i.e., the multifactor productivity (MFP) adjustment)[9] which may result in an applicable percentage increase of less than zero.
4. For all hospitals, the statute calls for a 0.2 percentage point reduction for FY 2016[10] which may result in an applicable percentage increase of less than zero. For each of FYs 2017, 2018, and 2019, the statute imposes a 0.75 percentage point reduction.

CMS finalizes its proposals to continue to use the FY 2010-based IPPS operating and capital market baskets for FY 2016, and to continue to use a labor-related share of 69.6 percent (which is also based on the FY 2010-based IPPS market basket). Using more recent data (i.e., IHS Global Insight, Inc. (IGI) second quarter 2015 forecast (with historical data through the first quarter of 2015)) CMS estimates the FY 2016 market basket update used to determine the applicable percentage increase for the IPPS to be 2.4 percent and the MFP adjustment to be -0.5 percentage points.

With respect to the MFP adjustment, beginning with the FY 2016 rulemaking cycle, the adjustment will be calculated using a revised series of proxy variables developed by IGI to proxy the aggregate capital input. IGI replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs which it recently developed using a regression model. A complete description of the MFP projection is available at the CMS web site: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html. CMS also notes that future changes to the MFP methodology will only be announced on its web site rather than in annual rulemaking cycles.

[7] See section 1886(b)(3)(B)(viii) of the Act. This adjustment is calculated before the application of any payment adjustment under sections 1886(b)(3)(B)(ix) [failure to be a meaningful EHR user], 1886(b)(3)(B)(xi) [MFP adjustment], and 1886(b)(3)(B)(xii) [the statutory adjustment] of the Act.
[8] See section 1886(b)(3)(B)(ix) of the Act. This adjustment is calculated before the application of any payment adjustment under sections 1886(b)(3)(B)(viii) [failure to submit quality information], 1886(b)(3)(B)(xi) [MFP adjustment], and 1886(b)(3)(B)(xii) [the statutory adjustment] of the Act.
[9] See section 1886(b)(3)(B)(xi) of the Act.
[10] See section 1886(b)(3)(B)(xii)(IV) of the Act.

The different applicable percentage increases, depending on whether a hospital submits quality data and/or is a meaningful EHR user, are as follows:

FY 2016	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User	0.0	-1.2	0.0	-1.2
MFP Adjustment	-0.5	-0.5	-0.5	-0.5
Statutory Adjustment (Section 1886(b)(3)(B)(xii) of the Act)	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**1.7**	**0.5**	**1.1**	**-0.1**

For SCHs and MDHs, CMS finalizes the same four possible applicable percentage increases shown in the table above. The final rule reflects the extension of the MDH program enacted into law by MACRA.

For Puerto Rico hospitals, CMS finalizes an applicable percentage increase of 1.7 percent to the Puerto Rico-specific operating standardized amount for FY 2016. CMS explains that Puerto Rico hospitals are not subject to adjustments for failure to submit quality data or failure to be a meaningful EHR user. CMS used IGI's second quarter 2015 forecast (with historical data through the first quarter of 2015) to finalize the update for Puerto Rico hospitals.

Commenters expressed various concerns about the update. One noted that the Medicare program asks hospitals to invest in health information technology, report more data, change the way in which care is delivered etc., yet the increases in Medicare IPPS payments are inadequate to help hospitals (especially safety net hospitals) meet the burden of new requirements. Others indicated that the update doesn't take into account the impact of sequestration. CMS acknowledges the concerns but indicates that this situation is largely driven by statutory requirements.

B. Rural Referral Centers: Annual Updates to Case-Mix Index and Discharge Criteria (§412.96)

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

minimum national and regional numbers of discharges. These factors are among those used to determine whether a hospital qualifies for RRC status.

To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2015, CMS a rural hospital with fewer than 275 beds available for use must, among other things:

- Have a CMI value for FY 2014 that is at least—
  - 1.6082, or
  - The 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 cost reporting period that began during FY 2013 at least—
  - 5,000 (3,000 for an osteopathic hospital) or
  - The median number of discharges for urban hospitals in the census region in which the hospital is located.

The final median regional CMIs and median regional numbers of discharges are listed in the final rule and reflect the latest available data: for CMI values, CMS used FY 2014 bills received through March 2015, and for numbers of discharges, CMS used discharge data based on FY 2013 cost report data. CMS notes that the median number of discharges for hospitals in each census region is greater than the national average of 5,000 discharges.

C. Indirect Medicare Education (IME) Payment Adjustment Factor for FY 2016 (§412.105)

Pursuant to statute,[11] for discharges occurring in FY 2016 the final rule continues to apply the IME adjustment factor of 5.5 percent for every approximately 10-percent increase in a hospital's resident-to-bed ratio.

D. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

1. Background

This section of the final rule describes the additional Medicare payments to IPPS hospitals that serve a significantly disproportionate number of low-income patients under section 1886(d)(5)(F). CMS notes that references to "days" in the DSH formula apply only to hospital acute care inpatient days.

[11] See section 1886(d)(5)(B) of the Act which provides for an IME formula multiplier of 1.35 for discharges occurring on or after October 1, 2007.

2. Impact on Medicare DSH Payment Adjustment of Proposed Implementation of New OMB Labor Market Delineations

The final rule describes the effects of the new labor market areas on the DSH payment adjustment; no related policy changes are made. The DSH payment adjustment cannot exceed 12 percent for rural hospitals with less than 500 beds, unless they are classified as rural referral centers (RRCs). Hospitals with less than 500 beds that are currently in urban counties but which would become rural under the new OMB delineations, and that do not become RRCs, would become subject to this maximum DSH payment adjustment. Current regulations (42 CFR 412.102) provide an additional payment for two years after a hospital loses urban status as a transition to the lower payment. In the first year (FY 2015), the hospital receives an additional payment equal to two-thirds of the difference between the hospital's applicable disproportionate share payments before its redesignation from urban to rural and the disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation. In the second year (FY 2016), the additional payment is one-third of the difference. CMS received no comments on this provision.

3. Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) under Section 3133 of the Affordable Care Act (§412.106)

Section 3133 of the ACA added a new section 1886(r) to the Act changing the methodology for computing the Medicare DSH payment adjustment. Beginning with FY 2014 discharges, hospitals that qualify for Medicare DSH payments receive two separately calculated payments: 1) 25 percent of the amount they would have received under the statutory formula for Medicare DSH payments prior to the ACA amendments (referred to as the "empirically justified Medicare DSH payment;" and 2) "uncompensated care payments," paid from a pool comprised of the remaining amount, which equals the Secretary's estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured.

Eligibility for empirically justified Medicare DSH payments is unchanged by the ACA provision. Also, the new DSH policies established by the ACA only affect DSH payment under the operating IPPS. The ACA does not revise or replace the capital IPPS DSH payment under the regulations at 42 CFR Part 412, Subpart M.

For FY 2016, CMS continues these policies unchanged from the FY 2014 and FY 2015 final rules:

- The ACA DSH provisions apply to:
  - hospitals in Puerto Rico; and
  - sole community hospitals if they are paid based on the federal rate and not the hospital-specific rate.
- The ACA DSH provisions do not apply to:
  - sole community hospitals paid based on the hospital-specific rate (because add-on payments, such as outliers, DSH, and IME, do not apply to these hospitals);
  - the 23 hospitals participating in the Rural Community Hospital Demonstration (because these hospitals also do not receive DSH payments); or

  - hospitals in Maryland, which are not paid under Section 1886(d) of the Act because the state entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model.
- MDHs paid under the IPPS federal rate are eligible to receive Medicare DSH payments if their disproportionate patient percentage is at least 15 percent. CMS applies the same process to their determine eligibility for Medicare DSH and the uncompensated care payment as it does for all other IPPS hospitals.[12]

CMS makes interim DSH payments equal to 25 percent of what the DSH payment would have been absent the ACA changes. Final eligibility for Medicare DSH payments and the final amount of the payments for eligible hospitals is determined at cost report settlement, as occurred prior to the ACA changes.

Uncompensated Care Payments

For FY 2016 CMS finalizes these policies, unchanged from the FY 2014 and FY 2015 final rules, for the uncompensated care portion of the DSH payment:

- Per the statute, only hospitals that receive empirically justified Medicare DSH payments in FY 2016 are eligible to receive an additional Medicare uncompensated care payment for that year.
- Uncompensated care payments will be made on a per discharge basis through the IPPS PRICER program, as discussed below.[13]
- The statutory 12-percent cap on the Medicare DSH payment adjustment percentage for certain rural hospitals applies to the amount of the empirically justified DSH payment and to the determination of Factor 1 in the uncompensated care formula (discussed below), but does not limit the amount of DSH uncompensated care payments that a hospital can receive.

The statute provides that the uncompensated care portion of the DSH payment amount for each DSH hospital is the product of three factors:

- Factor 1 equals 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) without application of the DSH changes made by the ACA;
- Factor 2 reduces the amount determined by Factor 1 based on the ratio of the percent of the population who are insured in the most recent period following implementation of the ACA to the percent of the population who were insured in a base year prior to ACA implementation; and

[12] The MDH program was extended by MACRA through September 30, 2017. MDHs are paid based on the IPPS federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate.

[13] For SCHs, the MAC determines whether the federal or hospital-specific rate is projected to yield the highest aggregate payment prior to the beginning of the federal fiscal year and automatically makes interim payments at the higher rate using the best data available. DSH uncompensated care payments are considered in determining whether the federal or the hospital-specific rate is higher. If the federal rate is higher, SCHs that receive interim empirically justified DSH payments also will receive interim uncompensated care payments. The MAC will make a final adjustment of all payments, including eligibility for DSH payments and the amount of uncompensated care payments, at cost report settlement.

- Factor 3 equals a hospital's share of uncompensated care for a given time period relative to the uncompensated care for that same time period for all hospitals that receive Medicare DSH payments in that fiscal year, expressed as a percent.

Proposed FY 2016 Factor 1

Factor 1 is the difference between CMS' estimates of: (1) the amount that would have been paid in Medicare DSH payments for FY 2016 in the absence of the ACA payment provision and (2) the amount of empirically justified Medicare DSH payments that are estimated to be made for FY 2016 taking into account the requirement to reduce Medicare DSH payments by 75 percent.

Prior to each fiscal year, CMS develops final estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1). These amounts are estimated based on the most recent data available and are not adjusted based on actual data.

CMS uses the most recently available projections of Medicare DSH payments for a year, as calculated by CMS' Office of the Actuary (OACT), to determine Factor 1. OACT projects Medicare DSH payments on a biannual basis, usually in February of each year as part of the President's Budget, and in July as part of the Midsession Review (for this FY 2016 final rule, it is based on the March 2015 update of the 2012 cost report data in HCRIS and the FY 2015 IPPS/LTCH final rule impact file). Starting with these data sources, OACT applies inflation updates and assumptions regarding future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

The February 2015 OACT estimate for Medicare DSH payments for FY 2016, before application of the ACA reduction, was $13.338 billion. Based on this, the estimate for empirically justified Medicare DSH payments for FY 2016 after the ACA reduction was proposed to be $3.335 billion (25 percent of the total amount estimated). Thus, CMS set Factor 1 in the FY 2015 proposed rule at $10.003 billion ($13.338 billion minus $3.335 billion).

Comments on FY 2016 Factor 1

CMS received numerous comments questioning the calculation of Factor 1 and requesting greater transparency around the methodology used by OACT to estimate aggregate DSH payments. Commenters stated they lacked sufficient information to understand or replicate the relevant projections and estimates for Factor 1. They focused on the assumption labeled as "Other" as having a substantial negative effect on the Factor 1 estimate, and requested more information about the assumption as well as a reassessment of it; the "Other" factor changed from 1.0355 in the FY 2015 IPPS/ LTCH PPS final rule to 0.9993 in the FY 2016 IPPS/LTCH PPS proposed rule. Commenters posed numerous technical questions including issues such as the changes

in Medicaid and CHIP enrollment, actuarial assumption that the new enrollees are healthier than the average Medicaid recipient, completion factor, among others.

CMS responded that this final rule included additional information of data sources, methods, and assumptions used to estimate Factor 1. OACT's estimate included these assumptions:

- per capita spending for Medicaid beneficiaries who enrolled due to the expansion is 50 percent of the average per capita cost of the pre-expansion Medicaid beneficiary due to the better health of these beneficiaries; CMS reports this assumption to be consistent with internal estimates of Medicaid per capita spending pre-expansion and post-expansion;
- a discharge completion factor of 99 percent for FY 2013 and 98 percent for FY 2014; and
- that case-mix was stabilized at the time of the estimate and no additional completion factor adjustment was needed.

CMS again rejected commenters' request to reconcile Factor 1 with actual data in conjunction with final settlement of cost reports, noting that the aggregate Medicare DSH payment amount for each federal fiscal year is not known until the time of cost report settlements, which occur several years after the end of the fiscal year.

CMS finalizes its methodology for calculating Factor 1 as proposed.

Final FY 2016 Factor 1

OACT's estimates for the FY 2016 final rule began with a baseline of $11.637 billion in Medicare DSH expenditures for FY 2012. The table below shows the factors applied to update this baseline to the current estimate for FY 2016:

Factors Applied for FY 2013 through FY 2016 to Estimate Medicare DSH Expenditures Using FY 2012 Baseline

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payments (in billion)
2013	1.028	0.9844	1.014	1.0137	1.040189	$12.105
2014	1.009	0.9634	1.015	0.9993	0.985961	$11.935
2015	1.014	0.9893	1.005	1.0512	1.059784	$12.648
2016	1.009	1.0006	1.005	1.045	1.060313	$13.411

- The discharge factor shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FYs 2013 and 2014 were based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2015 was based on preliminary data for 2015. The discharge figure for

FY 2016 was based on the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare FFS and also MA plans.

- The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2013 and 2014 were based on actual data adjusted by a completion factor. The FY 2015 and FY 2016 increases were based on the recommendation of the 2010-2011 Medicare Technical Review Panel.
- The "Other" column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the increase in rates for the Cape Cod litigation and the reduction in rates for the 2-midnight stay policy). In addition, the "Other" column includes a factor for the Medicaid expansion due to the Affordable Care Act.

The table below shows the factors that were included in the "update" column of the table above.

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding Percentage Adjustment	Total Update Percentage
2013	2.6	-0.1	-0.7	+1.0	2.8
2014	2.5	-0.3	-0.5	-0.8	0.9
2015	2.9	-0.2	-0.5	-0.8	1.4
2016	2.4	-0.2	-0.5	-0.8	0.9

Note: All numbers are based on the Midsession Review of FY 2016 Budget projections.

The February 2015 OACT estimate for Medicare DSH payments for FY 2016, before application of the ACA reduction, was $13.338 billion. Based on this, the estimate for empirically justified Medicare DSH payments for FY 2016 after the ACA reduction was proposed to be $3.335 billion (25 percent of the total amount estimated). Thus, CMS set Factor 1 in the FY 2015 proposed rule at $10.003 billion ($13.338 billion minus $3.335 billion).

The July 2015 OACT estimate for Medicare DSH payments for FY 2016, before application of the ACA reduction, is $13.411 billion. Based on this estimate, the estimate for empirically justified Medicare DSH payments for FY 2016 after the ACA reduction is $3.353 billion (25 percent of the total amount estimated). Factor 1 is the difference between these two estimates. Thus, **CMS establishes FY 2016 final rule Factor 1 to be $10.058 billion**, a level that is $55 million higher than in the proposed rule.

Proposed FY 2016 Factor 2

Factor 2 is based on the percent change, essentially since implementation of the ACA, in the percent of individuals under the age of 65 who are uninsured.

For FYs 2014 through 2017, the statute defines Factor 2 as 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing (i) the percent of such individuals who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the director of the Congressional Budget Office before a vote in either house on the Health Care and Education Reconciliation Act of 2010), to the percent of such individuals who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017. [14]

For FY 2016, CMS finalizes its proposal to continue these policies, which are unchanged from the FY 2014 and FY 2015 final rules:

- CMS uses CBO's estimate that includes all residents, including unauthorized immigrants, to establish the 2013 baseline regarding the percent who are uninsured.
- For FYs 2014-2017, CMS' estimate of the uninsurance percentage for baseline year 2013 is 18 percent (calculated from the CBO March 20, 2010 letter reporting an estimate of the "Insured Share of the Nonelderly Population Including All Residents" as 82 percent).[15]
- CMS uses the same data source, CBO estimates, to determine the percent of individuals without insurance for the post-implementation years beginning with 2014.
- CMS uses the most recent estimates available from CBO in order to take into account changes in the environment that can impact insurance rates, such as more recent economic conditions and the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, regarding Medicaid expansions authorized by the ACA, and the effectiveness of the state exchanges.
- CMS does not adjust Factor 2 retroactively to account for more recent estimates that become available after its determination for the final rule.
- CMS normalizes the CBO estimates, which are for calendar years, to correspond with the appropriate fiscal years. CMS normalizes the estimate of uninsurance for FY 2016 by calculating a weighted average of the CBO estimates for CY 2015 and CY 2016, respectively.[16]

[14] For FY 2018 and subsequent years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals "who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS)", and "who are uninsured in the most recent period for which data is available (as so estimated and certified) minus 0.2 percentage points for FYs 2018 and 2019." Thus, for FY 2018 and subsequent years, the statute provides greater flexibility in the choice of the data sources to be used in the estimate of the change in the percent of the uninsured.

[15] The CBO estimate excludes Puerto Rico, which is encompassed by the ACA provision on DSH. CMS concludes that the impact of excluding Puerto Rico from the insurance estimate is negligible.

[16] The estimate for baseline year 2013 is the same whether it is normalized to FY 2013 or not because the CBO estimates indicate a rate of uninsurance of 18 percent for both CY 2012 and CY 2013, the calendar years involved in normalizing the estimate for FY 2013.

For the FY 2016 proposed rule, CMS used CBO's January 2015 estimates of the effects of the ACA on health insurance coverage (available at http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf). CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2015 is 87 percent. Therefore, CBO's most recent estimate of the rate of uninsurance in CY 2014 is 13 percent (i.e., 100 percent minus 87 percent.) Similarly, CBO's January 2015 estimate of individuals under the age of 65 with insurance in CY 2016 was 89 percent, implying that the rate of uninsurance in CY 2015 is 11 percent.

Using these CBO estimates, CMS calculated the proposed Factor 2 for the FY 2016 proposed rule to be 0.6369, or 63.69 percent, and the proposed uncompensated care amount for FY 2016 to be $10.003 billion "times" 0.6369 = $6.3712 billion.

Comments on FY 2016 Factor 2

Commenters questioned the accuracy of CBO's estimates and requested additional information on how the CBO calculates its insurance estimates, including the assumptions used in its estimates. Some questioned the accuracy of the CBO's assumptions regarding "unauthorized immigrants" and provided information from other data sources, such as the Census Bureau, Department of Homeland Security Office of Immigration Statistics, and the Pew Research Center, to suggest that the total uninsured percentage in FY 2016 should be 13 percent rather than 11 percent as proposed. Commenters also questioned whether the CBO insurance estimates take into account States that have not expanded their Medicaid programs, or whether CBO accounted for factors that affect the insured population, such as individuals who will disenroll from coverage due to their inability to pay premiums or insured individuals who are unable to pay for hospital services they receive due to high deductibles and coinsurance in employer-sponsored and exchange-sponsored plans.

CMS responded that based on statutory provisions and regulations adopted in FY 2014, it uses the most recently available CBO estimates to calculate Factor 2. The agency believes that CBO projections of insurance coverage are the most reliable and consistent basis on which to calculate Factor 2. CBO estimates take into account uncertainties and risks under the ACA, including the probabilities of different outcomes of Medicaid expansions and changes in insurance coverage status over time. For more information on CBO's methodology and assumptions, CMS refers readers to the CBO Web site and particularly the Appendix of the March 2015 Updated Budget Projections: 2015-2025 (which are available at http://www.cbo.gov/sites/default/files/cbofiles/attachments/49973-UpdatedBudgetProjections.pdf).

As with Factor 1, CMS rejected commenters' request to reconcile Factor 2 with actual data regarding the rate of uninsurance at the time of cost report settlements because this would impose an unacceptable delay in the final determination of uncompensated care payments.

Commenters expressed concerns and suggestions regarding a possible adverse decision in the *King v. Burwell* case pending before the Supreme Court as the comment period closed.

Finally, citing a lack of statutory authority, CMS rejected commenters' request to delay implementation of Factor 2, or to phase in reductions, or to use the percentage of uninsured which was applied for FY 2015.

CMS finalizes its methodology for calculating Factor 2 as proposed.

Final FY 2016 Factor 2

For the FY 2016 final rule, CMS used CBO's March 2015 estimates of the effects of the ACA on health insurance coverage (which are available at http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf). CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2015 is 87 percent and its estimate of this percentage in CY 2016 is 89 percent, implying that the rates of uninsurance are 13 percent and 11 percent, respectively. These rates are unchanged from CBO's January 2015 estimates used for the proposed rule.

Using these CBO estimates, CMS calculated final Factor 2 for FY 2016 as follows:

- CY 2015 rate of insurance coverage (March 2015 CBO estimate): 87 percent
- CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent
- FY 2016 rate of insurance coverage: (87 percent * .25) + (89 percent * .75) = 88.5 percent
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent
- Percent of individuals without insurance for FY 2016 (weighted average): 11.5 percent
- 1-|((0.115-0.18)/0.18)|= 1- 0.3611=0.6389 (63.89 percent)
- 0.6389 (63.89 percent) - .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.6369 or 63.69 percent
- 0.6369 = Factor 2

Thus, CMS calculated Factor 2 for the FY 2016 final rule to be 0.6369, or 63.69 percent, and the final uncompensated care amount for FY 2016 to be $10.058 billion "times" 0.6369 = $6.406 billion, which is about $1.24 billion less than the FY 2015 uncompensated care payment total of about $7.647 billion; the percentage reduction is 16.2 percent.

Proposed FY 2016 Factor 3

Factor 3 equals the proportion of hospitals' aggregate uncompensated care attributable to each IPPS hospital (including Puerto Rico PPS hospitals). The product of Factors 1 and 2 determines the total pool available for uncompensated care payments. This result multiplied

by Factor 3 determines the amount of the uncompensated care payment that each eligible hospital receives.

For Factor 3, the statute requires the Secretary to determine: (1) the definition of uncompensated care; (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the amount for each hospital estimated to receive DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period "based on appropriate data." In addition, it permits the Secretary to use alternative data if the Secretary determines that available alternative data are a better proxy for the costs of PPS hospitals for treating the uninsured.

For FY 2016 as in FY 2014 and FY 2015, CMS did not propose to use the S-10 data on uncompensated care because of concerns regarding variations in the data reported on the Worksheet S-10 and the completeness of these data and it again proposed to determine Factor 3 based on the utilization of insured low-income patients specified as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively. The proposed rule reiterated CMS' intention to initiate rulemaking in the future to use the Worksheet S-10 data to determine Factor 3 but did not give a timetable.

For FY 2016, CMS proposed to change the time period used to determine low-income patient days. The FY 2015 final rule policy used the most recently available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios for the Medicare SSI days. Since publication of that rule, CMS has learned from the hospital community that for several reasons (including getting timely eligibility data from state Medicaid agencies) hospitals may not be able to submit accurate data for Medicaid days within the allowed timeframes, generally 5 months after the close of the cost reporting period. CMS also was informed that there is variation in the ability of hospitals and MACs, respectively, to submit and accept amended cost report data in time for the computation of Factor 3.

To address these issues, for FY 2016 CMS proposed to hold constant the cost report years used to calculate Medicaid days and to again use data from the 12-month 2012 or 2011 cost reports and, in the case of IHS hospitals, the 2012 cost report data submitted to CMS by IHS hospitals. CMS did, however, propose to use cost report data for these years from the most recent HCRIS database available for FY 2016 rulemaking. For the FY 2015 final rule, CMS used the March 2014 HCRIS update and for the proposed rule it used the December 2014 update. CMS proposed that the final rule would use the March 2015 update. To codify this change, it proposed to amend the regulations at § 412.106(g)(1)(iii)(C).

To determine Medicare days for the FY 2016 final rule, CMS proposed to use the FY 2013 SSI ratios to be published on the following CMS Web site when they become available: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html. The proposed rule continues to use the FY 2012 SSI ratios.

Comments and Final FY 2016 Factor 3

a. Comments pertaining to use of Medicaid and Medicare days as proxy

Most commenters believed that the Worksheet S-10 data are not yet sufficiently consistent and reliable to be employed for purposes of determining each hospital's share of uncompensated care payments, and they supported CMS' proposal to continue employing Medicare SSI days and Medicaid days to determine Factor 3 for FY 2016. Commenters made several suggestions to change the Worksheet S-10 and instructions as well as the process to audit Worksheet S-10, and these are summarized in the final rule (See pages 816-820 of the display copy). Many commenters requested that CMS provide a tentative timeline and implementation process for when and how the Worksheet S-10 would be used for determining Medicare uncompensated care payments.

CMS responded that it appreciates commenters suggestions and will consider them as it continues to evaluate reporting on Worksheet S-10. CMS indicated that it expects reporting on Worksheet S-10 to improve over time, both in accuracy and consistency, particularly in the area of charity care, which is already being used and audited for payment determinations related to the EHR Incentive Program. CMS says it is considering a possible timeline for using Worksheet S-10 data to calculate Factor 3, and will discuss this further in the FY 2017 IPPS/LTCH proposed rule.

Several commenters, including MedPAC, objected to the proposal to calculate Factor 3 based on a hospital's share of total Medicaid days and Medicare SSI days. MedPAC cited its 2007 analysis of data from the Government Accountability Office (GAO) and data from the American Hospital Association (AHA) suggesting that Medicaid days and low-income Medicare days are not a good proxy for uncompensated care costs. MedPAC also reported an additional, recent analysis testing whether data from the Worksheet S-10 or Medicaid and Medicare SSI days are a better indicator of costs associated with caring for the uninsured. Comparing 2011 data from Worksheet S-10 and 2011 Medicaid and Medicare SSI days with 2009 audited data obtained from the Medicaid and CHIP Payment and Access Commission (MACPAC), the analysis found that the correlation between audited uncompensated care data and data from the Worksheet S-10 was over 0.80, while the correlation between audited uncompensated care data and Medicaid and Medicare SSI days was only about 0.50. It also found that the 2011 S-10 data explained over 60 percent of the variance in audited uncompensated care costs compared to about 25 percent of the variance explained by Medicaid days and Medicare SSI days.

CMS responded that it believes data on utilization for insured low-income patients continues to be a reasonable proxy for the treatment costs of uninsured patients, especially considering the numerous concerns that continue to be expressed by commenters about the accuracy and consistency of the data reported on the Worksheet S-10. CMS says it is encouraged by the MedPAC analysis and that it is refining its benchmarking analyses in order to compare available Worksheet S-10 data to other data sources on uncompensated care, such as uncompensated care costs reported to the Internal Revenue Service on Form 990 by not-for-profit hospitals. CMS acknowledges that states that choose to expand Medicaid may receive

higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid.

CMS rejects suggestions that it apply a wage and case mix adjustment to the Medicaid and Medicare SSI days. It also declines a suggestion to use a proxy for SSI days in the calculation of Factor 3 and for other purposes related to DSH for Puerto Rico. The commenter had noted that U.S. citizens residing in Puerto Rico are not entitled to SSI benefits. Finally, CMS disagrees with commenters who asserted that a decision in the *Allina v. Sebelius* would affect the Medicare DSH and uncompensated care formulas.

After considering the public comments, CMS finalizes its proposal to use low-income insured days as a proxy for uncompensated care costs.

b. Comments regarding proposal to change the time period used to determine low-income patient days

Commenters generally supported CMS' proposal to use the more recent of the full year 2012 or 2011 data from the March 2015 update of the hospital cost report data in the HCRIS database to obtain the Medicaid days and to use the FY 2013 SSI ratios to determine the final Factor 3 for FY 2016. CMS also received comments posing several questions and technical issues concerning how the policy would be implemented, including application to new hospitals.

After considering the public comments, CMS finalizes its proposal, with some clarifications, to calculate Factor 3 using SSI days from the FY 2013 SSI ratios and Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals and the more recent of hospital-specific full year 2012 cost reports (unless that cost report is unavailable or reflects less than a full 12-month year, in which case CMS will use the cost report from 2012 or 2011 that is closest to being a full 12-month cost report) from the March 2015 update of the hospital cost report data in the HCRIS database. CMS finalizes its proposed revisions to the regulation at § 412.106(g)(1)(iii)(C), which codifies the cost reporting periods selected for purposes of determining Factor 3 of the uncompensated care payment methodology for FY 2016.

CMS notes that the FY 2013 SSI ratios have become available on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee- for-Service-Payment/AcuteInpatientPPS/dsh.html. It also clarifies that the 12-month cost report does not need to coincide with the Federal fiscal year.

CMS recognizes the challenges for estimating Factor 3 presented by the situation where a hospital remains in operation in both federal fiscal years for which it analyzes cost report data but submits cost reports for both federal fiscal years that reflect substantially less than a full year of data. It did not make a proposal to annualize or combine cost reports to calculate Factor 3, as suggested in comments, but intends to consider the issue further and may address it in future rulemaking.

With respect to new hospitals, CMS will treat them as it treats hospitals that are not found to be eligible to receive empirically justified Medicare DSH payments based upon the most recent available cost report from 2012 or 2011, causing the hospital to not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the new hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2016 cost report, the hospital also will receive an uncompensated care payment based on the sum of Medicaid days and Medicare SSI days reported on its FY 2016 cost report.

CMS finalizes its proposal to continue these other policies and procedures in FY 2016 unchanged from the FY 2014 and FY 2015 final rules:

- Tables in the FY 2016 final rule list Factor 3 levels for all hospitals that CMS projects will receive empirically justified DSH payments in FY 2016 and thus are eligible to receive interim uncompensated care payments during the fiscal year. The table also includes Factor 3 levels for the remaining IPPS hospitals that have the potential of receiving a DSH payment in the event that they receive an empirically justified DSH payment for FY 2016 as determined at cost report settlement. Relating to publication of the final rule, hospitals have until August 31, 2015 to review and submit comments on the accuracy of the tables.[17]
- CMS continues to make interim uncompensated care payments in FY 2016 on a per-discharge basis. The estimated per-discharge amount, which is fixed for a particular hospital and does not vary by case mix, is based on the amount of the uncompensated care payment that CMS calculates for a hospital for a fiscal year divided by the average number of discharges, or claims, in the most recently available three fiscal years of the Medicare claims dataset.
- Cost report settlement will not include reconciliation of the values of Factors 1, 2, or 3 established in the final rule. Reconciliation will only include adjustments for changes in whether the hospital is actually eligible to receive empirically justified DSH payments. The fiscal intermediary/MAC will recoup payments from hospitals that received interim payments but were determined at cost report settlement not to be eligible. Similarly, for a hospital that does not receive interim payments for its empirically justified DSH payments and therefore no uncompensated care payments but at cost report settlement is determined to be eligible for DSH payments, the fiscal intermediary/MAC will calculate the uncompensated care payment for the hospital based on the Factor 3 value determined prospectively and published with the final rule.

[17] Hospitals had 60 days from the date of the proposed rule's public display to review the tables accompanying the proposed rule and to notify CMS in writing of a change in a hospital's subsection (d) hospital status, such as if a hospital has closed or converted to a CAH. The 60-day period ended June 16.

Hospital mergers

For FY 2016, CMS finalizes its proposal to continue its FY 2015 policies regarding the process and data to be employed in determining Factor 3 in the case of hospital mergers.[18] Specifically, CMS:

- identifies the hospitals that merged after the period from which data are being used to calculate Factor 3 but before the publication of the final rule;
- identifies mergers by querying the Medicare contractors since a copy of each final sales agreement/transaction indicating the effective date of the acquisition is generally submitted to the Medicare contractors once an acquisition is finalized; for this final rule, CMS updated its list of mergers based on information submitted by the MACs as of June 15; and
- treats hospitals that merge after the development of the final rule as new hospitals are treated. That is, the newly merged hospital's interim uncompensated care payments would be based only on the data of the surviving hospital's CCN available when the final rule for the applicable fiscal year is prepared. At cost report settlement, however, CMS would determine the newly merged hospital's final uncompensated care payments based on the Medicaid days and SSI days reported on the cost report used for the applicable fiscal year. Thus, it revises the numerator of Factor 3 for the newly merged hospital to reflect the Medicaid and SSI days reported on the cost report for the applicable fiscal year.

CMS publishes a table on the CMS Web site, accompanying each fiscal year's proposed and final IPPS/LTCH rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of each year's proposed rule to review the tables and notify CMS in writing of any inaccuracies. After the publication of the IPPS/LTCH PPS final rule, hospitals have until August 31 of that year to review and submit comments on the accuracy of these tables for the applicable fiscal year (for FY 2016, the deadline is August 31, 2015). Comments can be submitted to a CMS inbox at Section3133DSH@cms.hhs.gov through August 31, and any changes to Factor 3 will be posted on the CMS Web site prior to the start of the applicable fiscal year on October 1.

One commenter was concerned that this process may result in an extended delay before a hospital's uncompensated care payment is corrected because recalculation would be performed on the surviving hospital's Factor 3 at the end of the applicable fiscal year in which the merger has taken place in the case of a hospital that is not identified as having undergone a merger prior to the public display of the final rule. This situation also could result in understated interim uncompensated care payments. CMS responds that in future

[18] Note: In the FY 2015 IPPS/LTCH final rule, CMS defined a merger to be an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider. It does not consider an acquisition to be a merger in situations where the new owner voluntarily terminates the Medicare provider agreement of the hospital it purchased by rejecting assignment of the previous owner's provider agreement.

notice-and-comment rulemaking it may explore the possibility of an alternative approach in which recalculation occurs during the tentative settlement process.

E. Hospital Readmissions Reduction Program (HRRP)

Section 1886(q) of the Act, added by section 3025 of the ACA, reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level. The payment reductions are based on a formula that compares each hospital's payments for actual readmissions (risk-adjusted) to payments based on an estimate of that hospital's expected readmissions (also risk-adjusted).

In the final rule for FY 2016, CMS takes these actions with respect to the Hospital Readmissions Reduction Program:

- refines the pneumonia readmissions measure to expand the measure cohort, effective for the FY 2017 payment determination and subsequent years;
- specifies the adjustment factor floor, applicable period, and calculation of aggregate payments for excess readmissions for FY 2016; and
- adopts an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years.

Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization Measure Cohort for the FY 2017 Payment Determination and Subsequent Years

CMS proposed to expand the cohort of patients that are included in CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization measure (NQF #0506) endorsed by the National Quality Forum (NQF). The cohort is the set of hospitalizations, or "index admissions," that meet all of the inclusion and exclusion criteria. The measure currently includes hospitalizations for patients with a principal discharge diagnosis of pneumonia indicating viral or bacterial pneumonia. The proposed expansion would add hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia as well as hospitalizations for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. Data sources, exclusion criteria, and assessment of the outcome of readmission would not change.

CMS indicated that the broader cohort would better represent the complete population of a hospital's patients who are receiving clinical management and treatment for pneumonia. It also would ensure that the measure includes more complete and comparable populations across hospitals in part by reducing measurement bias resulting from different coding practices across hospitals. The revisions, it said, would improve the measure's assessment of avoidable readmissions and more accurately reflect quality and outcome for pneumonia patients.

The Measure Applications Partnership (MAP) reviewed the proposed refinement of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) and conditionally supported its use for the Hospital Readmissions Reduction Program pending NQF review.[19] CMS plans to submit the revised measure to NQF for re-endorsement when the appropriate project has its call for measures in 2015. Some members of the MAP Hospital Workgroup and MAP Coordinating Committee raised the benefit of a phased approach to allow public reporting of the refined measure before implementing it in a pay-for-performance program so that providers could gain experience with the measure refinement. The MAP supported use of the measure refinement without stipulating prior public reporting as a condition of support, but CMS noted this concern in delaying the proposed implementation date until FY 2017.

CMS did not change the methodology for risk adjustment, statistical modeling and measure calculation. CMS confirmed association of the current risk-adjustment variables with the outcome in the expanded measure cohort and also examined additional risk variables leading to the addition of a few additional risk variables in the measure. Full measure specifications are available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

CMS simulated the effect of the proposed measure cohort refinements using administrative claims data for FY 2015 readmissions measures (i.e., discharges between July 2010 and June 2013) as if these changes had been applied for the HRRP FY 2015 payment determination. The current pneumonia readmission measure cohort for the HRRP includes 976,471 patients and 3,137 hospitals for FY 2015. Effects under the proposed expanded cohort if applied for FY 2015 were reported as follows:

(1) The measure cohort would increase by 634,519 patients to a total of 1,610,990 patients (65 percent increase);
(2) 42 more hospitals (1.3 percent increase) would meet the minimum 25 patient cases volume threshold over the 3-year applicable period and would be publicly reported for the measure;
(3) 40 percent of the total expanded measure cohort would come from the new group of patients (i.e., patients with a principal discharge diagnosis of aspiration pneumonia and patients with a principal discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission);
(4) The national observed readmission rate would increase by 0.9 absolute percentage points; and
(5) The excess readmissions ratios for some hospitals would be affected – no additional detail was provided in the proposed rule.

The proposed rule noted that the set of hospitals for which the refined measure would be calculated for the HRRP differs from the one used in calculations for the Hospital IQR Program. HRRP includes only subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act (and, if not waived from participating, those hospitals paid under section 1814(b)(3)

[19] The Pre-Rulemaking 2015 MAP Recommendations Report is available at: https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

of the Act[20]), while the Hospital IQR Program calculations include non-IPPS hospitals, such as CAHs, cancer hospitals, and hospitals located in the Territories.

Comments on the proposed expansion of the pneumonia measure cohort and modified version of the measure adopted in the final rule

Many commenters expressed concern that patients with acute respiratory failure present higher acuity than average community acquired pneumonia patients, noting that they often arrive at the hospital intubated or in immediate need of ventilator support and frequently have pre-existing lung disease and pathology, severe influenza, or viral pneumonia. Several commenters also stated that the proposed inclusion of patients with respiratory failure may result in the double counting of cases in two different readmission measures – pneumonia and chronic obstructive pulmonary disease (COP).

In response to these comments and additional internal analyses, CMS finalizes a modified version of the expanded pneumonia cohort. The modified version includes patients with a principal discharge diagnosis of pneumonia or aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis with a secondary diagnosis of pneumonia coded as present on admission. The modified version does not, however, include patients with a principal discharge diagnosis of respiratory failure or patients with a principal discharge diagnosis of sepsis if they are coded as having severe sepsis as had been proposed. According to CMS, the finalized readmission measure cohort will be approximately 15 percent smaller than originally proposed in the FY 2016 IPPS/LTCH PPS proposed rule.

CMS reports that further analysis after publication of the final rule uncovered issues with the risk adjustment methodology with respect to patients with severe sepsis and respiratory failure, and revealed that the proposed cohort expansion would exacerbate the bias in the existing measure that it was intended to mitigate. Excluding patients with a principal discharge diagnosis of respiratory failure in the modified version of the cohort removes the opportunity for readmissions to be counted in both the pneumonia and COPD readmission measures.

CMS states that the modified version responds to potential bias in the current measure, and that risk adjustment is adequate. The revised cohort expansion produces a more clinically comprehensive measure that does not favor or disadvantage hospitals on the basis of their coding practices. CMS analysis indicated that under the revisions, hospital performance among hospitals with higher rates of patients with sepsis or aspiration pneumonia is similar to those with fewer such patients, suggesting that the finalized risk adjustment methodology adequately accounts for the differences in risk among the subgroups of patients.

Regarding concerns that patients with a diagnosis of sepsis and secondary diagnosis of pneumonia have a higher predicted mortality and readmission risk, CMS states that while some patients with aspiration pneumonia have a higher predicted mortality or readmission

[20] Previously hospital in Maryland were paid under section 1814(b)(3), but currently no hospitals are paid under that section.

risk, many of the associated comorbidities are captured in the finalized measure's risk adjustment methodology, including clinical history of stroke, neuromuscular disease, and dementia.

Several commenters stated that adding aspiration pneumonia to the current measure denominator would result in a 26.4 percent increase in the patient cohort for major teaching hospitals, compared to a 20.6 percent increase for nonteaching hospitals, raising concerns that expanding the cohort would adversely affect teaching hospital measure performance. CMS responds that in clinical practice it can be challenging for physicians to differentiate aspiration syndromes, including pneumonitis and pneumonia, from other types of pneumonia included in the measure, perhaps contributing to the substantial variation across hospitals in the use of aspiration pneumonia diagnosis codes. CMS believes this variation suggests that hospitals are not consistently distinguishing between these conditions as distinct subtypes. CMS states that its analyses of the measure found that an approximately equal numbers of hospitals, and, specifically, equal numbers of teaching hospitals, improved or worsened their categorical performance under the modified version of the measure. It did not see evidence that teaching hospitals will be differentially burdened or adversely affected on the basis of this modification to the measure, due in part to what CMS believes is the adequate risk-adjustment for aspiration pneumonia patients.

Many commenters were concerned that the revised measure received only conditional support from the MAP for use in the Hospital Readmissions Reduction Program pending NQF review of the measure update and appropriate consideration under the NQF sociodemographic status pilot. CMS responds that it will submit the modified version of the measure to the NQF for endorsement maintenance as part of the Pulmonary Project when the project has its call for measures later this year. In addition, the modified version of the measure will be included in the NQF SDS pilot as part of the endorsement maintenance process. CMS acknowledges that both of these processes will provide valuable input on the measure, but it does not want to delay the implementation, noting that one of the most important goals of the HRRP is to more completely cover the inpatient hospital patient population.

Finally, CMS rejected commenters' suggestion that is should postpone implementation of the expanded measure cohort, citing the importance it attaches to expanding the portion of the hospital inpatient population covered by the HRRP. With respect to concerns about the expansion being coincident with implementation of ICD-10, CMS responds that it is not aware of any stakeholder concerns about the potential impacts to hospital performance on quality measures when ICD-10 is implemented. It also says that its systems for quality programs have been tested and will continue to be tested as ICD-10 data are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD-10, potential coding variation, and impacts on measure performance and payment incentive programs.

Details on the rationale for the cohort expansion, the analyses supporting the re-specified cohort, and the full specification and results of the measure as adopted in this final rule are available in the measure methodology report for the finalized measure in the AMI, HF, PN,

COPD, and Stroke Readmission Updates zip file on the CMS website at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

Other HRRP Policies

CMS reminds readers that beginning in FY 2015, technical specifications for quality measures for the HRRP are provided along with non-substantive updates on the CMS website in the Measure Methodology Reports at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html. Additional resources about the HRRP and measure technical specifications are on the QualityNet Web site on the Resources page at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995.

The final rule designates the applicable period for FY 2016 to be the 3-year period from July 1, 2011 through June 30, 2014. That is, the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 are based on data from the 3-year time period of July 1, 2011 through June 30, 2014.

The proposed rule makes no changes in the floor adjustment factor. It remains at 0.97, meaning that a hospital subject to the HRRP will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

The final rule also does not change the definitions and methodology used in the HRRP, including "base operating DRG payment amount," "aggregate payments for excess readmissions," "aggregate payments for all discharges," and "excess readmissions ratio;" these remain as codified in § 412.152 and § 412.154. Similarly, CMS made no changes in the use of MedPAR claims data or the types of claims which are excluded, as established in the FY 2015 IPPS/LTCH final rule (79 FR 50048), including the exclusion of Medicare Advantage claims.

To calculate aggregate payments for excess readmissions as well as the excess readmissions ratio for FY 2016, CMS identifies each applicable condition using the ICD-9-CM codes listed in tables included in the proposed rule (pp. 884-888 of the display copy). The discharge diagnoses for each applicable condition also are posted on the QualityNet Web site at: http://www.QualityNet.org > Hospital-Inpatient > Claims-Based Measures >Readmission Measures > Measure Methodology. The final rule notes that the compliance date for the ICD-10-CM and ICD10-PCS code sets is October 1, 2015, which occurs after the time periods used for the HRRP in FY 2016.

CMS includes this summary of the calculation methodology in the final rule:

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2016

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI x (Excess Readmissions Ratio for AMI-1)] + [sum of base operating DRG payments for HF x (Excess Readmissions Ratio for HF-1)] + [sum of base operating DRG payments for PN x (Excess Readmissions Ratio for PN-1)] + [sum of base operating DRG payments for COPD) x (Excess Readmissions Ratio for COPD-1)] + [sum of base operating DRG payments for THA/TKA x (Excess Readmissions Ratio for THA/TKA-1)].

Note: If a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

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).

Proposed Readmissions Adjustment Factor for FY 2016 is the higher of the ratio or 0.9700.

Note: Based on claims data from July 1, 2011 to June 30, 2014 for FY 2016.

Other public comments on HRRP

Several commenters recommended changes to the methodology to calculate the readmission payment adjustment factors, many of these similar to comments received in prior rulemaking. MedPAC also reiterated several comments addressing the readmissions payment adjustment factor, including that the readmission penalty formula is flawed because aggregate penalties remain constant even as national readmission rates decline; the condition-specific penalty per excess readmission is higher for conditions with low readmission rates; and the penalty should roughly equal the cost of excess readmissions over a fixed target level of readmissions. Some commenters believed CMS could use its rulemaking authority to fix the perceived flaws in readmission penalty formula, but CMS responded that the statute is prescriptive on this matter and does not leave room for administrative discretion.

CMS considered several public comments out of the scope of the proposed rule because they were not related to specific HRRP proposals set out in the proposed rule. The comments

covered a wide range of subjects including risk adjustment for sociodemographic status (SDS) at the patient and hospital level. CMS does not typically respond to out-of-scope comments, but chooses to address risk-adjustment for SDS because of the volume of public comments and the importance of this topic for outcome measures in payment programs. The agency's response is discussed in the value-based payment section below (see section IV.F.3). CMS intends to consider other out-of-scope topics when developing policies and program requirements for future years.

Exceptions Process to Address Hospitals with Extraordinary Circumstances

Several commenters responding to the FY 2015 IPPS/LTCH proposed rule supported the idea of establishing an exceptions process in the HRRP to exempt hospitals experiencing extraordinary circumstances such as a natural disaster. In the FY 2016 IPPS/LTCH proposed rule, CMS proposed to establish an exceptions process for a hospital experiencing a period of time during which it is unable to submit all of its claims (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. CMS stated that it did not intend to allow a hospital to use the exceptions policy and the request process to seek exclusion from the HRRP in its entirety for a given fiscal year(s) solely because of experiencing an extraordinary circumstance.

CMS indicated that a hospital could request an HRRP extraordinary circumstance exception at the same time it might request a similar exception under the Hospital IQR, VBP Program, or the HAC Reduction programs. It proposed that the request process for an extraordinary circumstance exception begin with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. The application must be signed by the CEO and must include, among other information:

- the measure(s) and submission quarters affected by the extraordinary circumstance for which the hospital is seeking an exception, accompanied with the specific reasons why the exception is being sought;
- how the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought; and
- evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles.

Several commenters believed the exceptions policy was too narrow and failed to address the possibility that a hospital's performance could be seriously compromised by circumstances outside the hospital's control even though it was able to submit claims or other measure data. The extraordinary circumstances could, for example, disrupt community services and hospital programs needed to continue readmission prevention efforts during natural disasters, which may result in higher readmission rates. CMS declines to broaden the exceptions policy and finalizes it as proposed.

F. Hospital Value-Based Purchasing (VBP) Program

Several changes are made to the Hospital VBP Program including measure removals and one addition to the measure set for FY 2018, addition of a new measure beginning in FY 2021, and changes in the domain weighting beginning in FY 2018. A summary of measures and domains for selected years appears in Summary Table VBP-1 at the end of section F.

1. Background

FY 2013 was the first year of payment adjustments under the Hospital VBP Program established by the ACA. Under the program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score (TPS) for a specified performance period. A hospital's VBP incentive payment adjustment factor for a fiscal year combines a uniform contribution to the VBP incentive payment funding pool (a reduction to each hospital's base operating DRG payments), described next, and a hospital-specific incentive payment percentage that results from the hospital's TPS. A hospital's adjustment factor may be positive, negative or result in no change in the payment rate that would apply absent the Hospital VBP Program.

The total amount available for value-based incentive payments for a fiscal year is specified in statute and estimated by the Secretary. For FY 2013, the available funding pool for value-based incentive payments equaled 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary; the funding pool increased to 1.25 percent of base-operating DRG payments for FY 2014 and 1.5 percent for FY 2015. For FY 2016, the funding pool will be 1.75 percent, and it will increase to 2.0 percent for FY 2017 and successive fiscal years.

For each payment year, CMS specifies through rulemaking a VBP measure set. For each measure, a baseline period and a performance period are finalized. A hospital's performance on each measure during the performance period is assessed (resulting in achievement points), and compared to its performance during the baseline period (resulting in improvement points). Measures available for inclusion in the VBP are those that are included in the Inpatient Quality Reporting (IQR) Program and have been included on the *Hospital Compare* website for at least one year prior to the start of the relevant VBP Program performance period. CMS calculates 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, and adding together the weighted domain scores. CMS then converts each hospital's TPS into a value-based incentive payment percentage using a linear exchange function, under which the sum of all hospitals' payments will equal the amount of dollars contributed to the VBP funding pool.

2. VBP for FY 2013 through FY 2017

CMS published a final rule in April 2011 (76 FR 26490 through 26547) establishing the Hospital VBP Program and setting the specific program requirements for FY 2013. That final rule adopted a measure set with 12 clinical process of care measures and 8 dimensions from the

HCAHPS survey and categorized them into two domains: a clinical process of care domain with the 12 measures and a patient experience of care domain with the HCAHPS survey.

Since the FY 2013 implementation, the measure set and domains have been expanded and modified. For reference, Summary Table VBP-2 (located at the end of this section IV.F) shows the Hospital VBP Program measures adopted for FYs 2013 through 2016. The FY 2014 IPPS/LTCH rule adopted, beginning in FY 2017, a new structure for the Hospital VBP Program domains. Summary Table VBP-3 below provides a crosswalk between FY 2016 and 2017 measures and domains.

3. VBP Payment in FY 2016

Using the December 2014 update of the FY 2014 MedPAR file, CMS estimates that the total amount available for VBP Program payments in FY 2016 is just under $1.5 billion. This reflects the requirement that for FY 2016 VBP Program payments equal 1.75 percent of base operating DRG payments.

CMS has posted on the FY 2016 IPPS final rule web page Table 16A which includes proxy hospital-specific value-based incentive payment adjustment factors for FY 2016. (In the impact analysis included in Appendix A of the proposed rule, these proxy factors are used to present average FY 2016 VBP Program payments by hospital type.) However, the proxy factors are calculated using each hospital's TPS from the FY 2015 Hospital VBP Program and therefore reflect the performance periods, measures, and domain weights in effect for that year. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2016 (expected in October 2015), CMS will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2016 program year.

CMS responds to a number of comments on the VBP Program overall. Statutory constraints are noted in response to commenters suggesting that the VBP penalties need to be larger to drive quality improvement and cost containment or that improvement scores should be phased out for measures that have been in the program for several years. To commenters suggesting that measures be adjusted for sociodemographic status (SDS), CMS repeats its past concerns about the potential for such adjustment to mask disparities or minimize incentives to improve care for disadvantaged patients, and continues to observe that hospitals caring for patients of low sociodemographic status are capable of performing well, referring readers to the 2014 Medicare Hospital Quality Chartbook pages 48-57, 70-73, and 78, which is available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf). CMS will monitor the outcome of the NQF trial regarding use of SDS factors in risk adjustment, and also the results of research underway by the HHS Assistant Secretary for Planning and Evaluation (ASPE) to examine the impact of sociodemographic status on quality and performance measures as directed by the IMPACT Act of 2014. Regarding overlap in measures between the HAC Reduction and VBP programs, CMS believe this is warranted because the programs have separate purposes and policy goals.

CMS notes stakeholder concerns about the potential effects of the move to ICD-10 coding on the VBP Program measures. Interested parties are encouraged to subscribe to the CMS listserv titled "Hospital Inpatient Value-Based Purchasing (HVBP) and Improvement" to receive notification of relevant events. Stakeholders may join at https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register.
In response to questions regarding specification changes to claims based measures, in particular the AHRQ PSI-90 patient safety composite measure, CMS notes that updated ICD-10 codes are contained in the Measure Information Forms (MIFs) on the NQF Web site. AHRQ's changes for ICD–10–CM/PCS conversion of its quality indicators are available at: http://www.qualityindicators.ahrq.gov/icd10/default.aspx.

4. VBP Measures for FY 2018

FY 2018 payment, CMS finalizes a set of 12 measures for the VBP Program. Two measures are removed from the set of 14 measures previously adopted for FY 2017 payment, and a new dimension is added to the HCAHPS measure. (Unless proposed and finalized for removal, measures are retained from year to year.) Summary Table VBP-1 (at the end of this section IV.F) shows the final measures for FYs 2016, 2017 and 2018, along with the associated measure domains, which change in FY 2017 under a previously adopted domain structure.

Response to comments on existing measures. CMS responds to a variety of comments it received on existing VBP Program measures that will be continued into the FY 2018 payment determination. Many comments pertain to the AHRQ PSI-90 patient safety composite measure, including the current deliberations at NQF for possibly expanding the measure to include additional patient safety indicators (PSI-9, PSI-10, and PSI-11). CMS will take the ultimate NQF decision into consideration for future rulemaking. With respect to the current component PSI-15 involving accidental punctures and lacerations, CMS believes that American Hospital Association Coding Clinical Guidance is sufficient to distinguish the correct coding of accidental punctures and lacerations that are not intrinsic or inherent in a major procedure, and that hospitals should continue to provide education to their staff on correct coding of PSI-15. The AHRQ Quality Improvement Toolkit is also referenced as potentially helpful: http://www.ahrq.gov/professionals/systems/hospital/qitoolkit/b4_documentationcoding.pdf.

Regarding the suggested exclusion of exenterations from the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) measure, CMS notes that CDC is collecting additional SSI risk factors that will enable new risk modeling using the 2015 SSI data. However, CMS notes that not all SSI risk differences associated with procedural and patient differences can be included because of the data collection burden that would be imposed on NHSN users. This comment is addressed later in the rule and CMS suggests that issues regarding exclusions from NSHN measures be taken up with CDC at NHSN@cdc.gov.

Several comments pertain to the HCAHPS pain management dimension and over-prescription of pain medication. CMS acknowledges that there have been anecdotal reports suggesting a link and that many providers believe such a link exists. However,

CMS is not aware of any findings that failure to prescribe unneeded pain medication lowers a hospital's HCAHPS scores. CMS points to evidence that good physician and nurse communication are the strongest predictors of better HCAHPS scores

Measure and domain removal. Two measures are removed beginning with the FY 2018 payment determination. IMM-2, "Influenza Immunization," has been identified by CMS as meeting the statistical criteria for being "topped out," meaning that hospital scores are uniformly high and the measure no longer makes meaningful distinctions in hospital performance. (However, as discussed in section VIII below, CMS retains this measure for reporting under the Inpatient Quality Reporting Program.)

The second measure removed, AMI-7a "Fibrolynic Therapy Received within 30 Minutes of Hospital Arrival," is not topped out. In this case, many hospitals do not meet the minimum case threshold for reporting this measure because most heart attack patients receive percutaneous coronary intervention instead of fibrolynic therapy. For this reason CMS does not believe the measure will advance quality improvement goals, and also notes that data collection for this measure is burdensome.

CMS also finalizes the removal of the Clinical Care – Process domain. With the removal of the two measures, only the measure of elective delivery prior to 39 weeks gestation (PC-01) would remain in this domain. The PC-01 measure is moved to the Patient Safety domain and the Clinical Care – Process domain is removed. The Clinical Care – Outcomes is renamed the Clinical Care domain, and, as discussed below, domain weights are modified. In responding to comments, CMS states that it did not intend to signal that process of care measures would not be considered for the VBP Program in the future. It will consider appropriate process of care measures for the VBP Program in the future, and says that process measures could be added to the remaining domains as needed.

HCAHPS care transitions measure. The "3-Item Care Transition" (CTM-3) measure which added three questions[21] to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience survey is made part of the VBP Program beginning with the FY 2018 payment determination. CTM-3 is endorsed by the National Quality Forum (NQF #0228), was adopted for the IQR Program with reporting beginning in January 2013, and initial performance data were posted on the *Hospital Compare* website in December 2014. As described below, the initial VBP Program performance period for this measure begins in January 2016.

In responding to comments, CMS reports that HCAHPS response rates are essentially unchanged since the addition of the CTM-3 component. To commenters offering alternative suggestions for consistency points in the HCAHPS, CMS says that consistency points are not awarded for consistently poor performance, and that these points offer an additional incentive for hospitals to

[21] The three questions are: 1) 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; 2) when I left the hospital, I had a good understanding of the things I was responsible for in managing my health; and 3) when I left the hospital, I clearly understood the purpose for taking each of my medications.

improve on their lowest-performing dimension. CMS further cites studies indicating that web-based surveys currently have lower response rates and representativeness than the HCAHPS.

Scoring of hospital performance on HCAHPS is modified to account for the additional questions; the approach is described in item 9 below.

Updates to National Healthcare Safety Network Measure Standard Population Data.

Hospital performance on the NHSN measures is calculated by the CDC. In doing so, CDC compares the number of actual infections to the number of infections it has predicted for the hospital using a standard population data base, adjusted for several risk factors. For all measures, CDC will update the standard population data used for this purpose using data that CDC collects in 2015 and begin using these data in 2016. (The standard population data periods that CDC currently uses vary among the measures, ranging from a 2006-2008 period for the surgical site infection measures to the most recent 2010-2011 period used for the MRSA bacteremia and C. difficile infection measures.)

For the purposes of the VBP Program, CMS finalizes its proposal to update the standard population data used in calculating the program's NHSN measures for the 2019 payment year. To do so before that date would require calculating improvement points by comparing baseline and performance scores each calculated using different standard population data. For 2019, the new standard population data will be used to calculate performance in both the baseline and performance periods. (As indicated in sections IV.G and VIII of this summary, CMS does not delay use of the new standard population data for purposes of the Hospital-Acquired Condition Reduction Program or the IQR Program.)

5. Measures for FYs 2019, 2020 and 2021

No new measures are proposed for FYs 2019 or 2020, but CMS discusses comments it received on its intention to propose future changes in two of the NHSN measures. Specifically, CMS intends to propose in future rulemaking that the Central Line Associated Blood Stream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures, which have been based on data collection from adult, pediatric and neonatal ICUs, be expanded to include selected ward (non-ICU) locations beginning with the FY 2019 program year. CMS previously modified IQR Program requirements to include reporting on the expanded locations beginning January 1, 2015. The intention is to propose a baseline period of CY 2015 and a performance period of CY 2017 for the initial FY 2019 VBP Program year. Proposed and final performance standards will be included in the FY 2017 IPPS/LTCH rulemaking.

One new measure is adopted for addition to the VBP Program beginning with the FY 2021 payment determination: Hospital 30-Day All-Cause Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893). This measure was added to the IQR Program measure set beginning with FY 2016 payment, and performance data was first included on *Hospital Compare* in December 2014. (As discussed below, the first proposed performance period will begin on January 1, 2016.) CMS notes that the MAP

supported inclusion of this measure in its 2015 recommendations, and states its view that this measure address a high volume high cost condition and aligns with the CMS quality strategy.

6. Possible Measure Topics for Future Years

In the proposed rule, CMS requested comments on measures that it indicated could be used to expand the Efficiency and Cost Reduction domain in the future. These include existing IQR Program efficiency measures and additional efficiency measures proposed in this rule and discussed in section VIII of this summary. In responding to comments it received, CMS indicates that it does not believe that condition-specific episode of care payment measures are duplicative of the overall Medicare spending per beneficiary (MSPB) measure. It sees these measures as providing "a more complete picture of Medicare spending in order to allow hospitals to better understand and target their efficiency efforts."

7. Performance and Baseline Periods

The baseline and performance periods adopted for FY 2018 are shown in the following table. As noted, for some outcome measures the periods were previously finalized. The previously finalized baseline and performance periods for FY 2017 are also shown below for reference.

Domain/Measures	Baseline Period	Performance Period
FY 2018		
Safety AHRQ PSI-90* NHSN (CLABSI, CAUTI, SSI, C.Diff, MRSA) and PC-01	July 1, 2010 – June 30, 2012 Jan. 1, 2014– Dec. 31, 2014	July 1, 2014 – June 30, 2016 Jan. 1, 2016– Dec. 31, 2016
Clinical Care (Mortality—AMI, HF, PN)*	Oct. 1, 2009 – June 30, 2012	Oct. 1, 2013 – June 30, 2016
Efficiency MSPB	Jan. 1, 2014 – Dec. 31, 2014	Jan.1, 2016 – Dec. 31, 2016
Patient Experience of Care HCAHPS, CTM-3	Jan. 1, 2014 – Dec. 31, 2014	Jan.1, 2016 – Dec. 31, 2016
*Previously finalized.		

FY 2017 (Previously Finalized)		
Safety AHRQ PSI-90 NHSN (CLABSI, CAUTI, SSI, C.Diff, MRSA)	Oct. 1, 2010 – June 30, 2012 Jan. 1, 2013– Dec. 31, 2013	Oct. 1, 2013 – June 30, 2015 Jan. 1, 2015– Dec. 31, 2015
Clinical Care – Outcomes (Mortality—AMI, HF, PN)	Oct. 1, 2010 – June 30, 2012	Oct. 1, 2013 – June 30, 2015
Clinical Care – Process	Jan. 1, 2013 – Dec. 31, 2013	Jan.1, 2015 – Dec. 31, 2015
Efficiency MSPB	Jan. 1, 2013 – Dec. 31, 2013	Jan.1, 2015 – Dec. 31, 2015
Patient Experience of Care HCAHPS	Jan. 1, 2013 – Dec. 31, 2013	Jan.1, 2015 – Dec. 31, 2015

8. Performance and Baseline Periods for Certain Measures for FYs 2019 through 2021

The table below shows previously adopted and newly finalized baseline and performance periods for certain measures for FY 2019 through 2021. (Because performance standards must be published prior to the start of the performance period, certain measures must be adopted and performance standards finalized earlier than others.) Note that for 2021, the periods for the THA/TKA measure shift from a July-June timeframe to an April –March timeframe. CMS says that this will align the baseline and performance periods with those of the IQR Program and make reporting "more seamless" for hospitals.

Domain/Measures	Baseline Period	Performance Period
FY 2019		
Clinical Care Mortality* THA/TKA*	 July 1, 2009 – June 30, 2012 July 1, 2010- June 30, 2013	 July 1, 2014 - June 30, 2017 January 1, 2015 - June 30, 2017
Safety AHRQ PSI*	 July 1, 2011- June 30, 2013	 July 1, 2015 -June 30, 2017
FY 2020		
Clinical Care Mortality* THA/TKA*	July 1, 2010-June 30, 2013	July 1, 2015- June 30, 2018
Safety AHRQ PSI	 July 1, 2012-June 30, 2014	 July 1, 2016-June 30, 2018
FY 2021		
Clinical Care Mortality THA/TKA	 July 1, 2011-June 30, 2014 Apr 1, 2011- Mar 31, 2014	 July 1, 2016-June 30, 2019 Apr 1, 2016-March 31, 2019
* Previously finalized. Notes: The FY 2019 THA/TKA performance period begins January 1, 2015; in the proposed rule it was incorrectly shown as June 1. Mortality measures in all years include AMI, HF, PN. COPD is added beginning in FY 2021		

9. Performance Standards

CMS discusses regulations (adopted in prior rulemaking) providing for adoption of "nonsubstantive" technical updates to previously adopted performance standards outside the rulemaking process, and references the January 29, 2015 announcement of a technical update to the performance standards for the PSI-90 measure for the FY 2017 program year. The change was made to reflect availability of a more recent version of the software AHRQ uses to calculate the performance standards and hospital performance results. The announcement is available on the QualityNet website:
https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228774624610

Adjustments are made to scoring the HCAHPS measure to reflect the addition of the CTM-3 measure as a ninth dimension. Currently, the eight HCAHPS dimensions provide from 0 to 10

points each, and the consistency score provides up to 20 points in addition, summing to 100 points. With the addition of the ninth dimension beginning in FY 2018, CMS will score each dimension in the same way that the eight dimensions are scored currently (i.e., the higher of 0 to 10 achievement points and 0 to 9 improvement points summed across the dimensions) with the addition of a step of "normalizing," or multiplying the resulting total score (of up to 90 points) by 8/9 (0.88888) to obtain a total of 0 to 80 points before adding the total to the (up to 20) consistency points. (Consistency points will take into account scores across all nine dimensions.) Under this approach, the nine dimensions will be treated equally and continue to provide a total of 0 to 80 points.

Although not reproduced in this summary, the final rule includes tables showing the proposed numerical performance standards (achievement thresholds and benchmarks) for each measure in the FY 2018 measure set and previously adopted and newly finalized standards for certain safety and clinical care domain measures for FYs 2019, 2020 and 2021.

10. FY 2018 Scoring Methodology, including Domain Weighting

In general, CMS continues for FY 2018 the previously adopted Hospital VBP Program scoring methodology, but changes are made to the domain weights to reflect the elimination of the Clinical Care—Process domain. Specifically, for FY 2018 the weight for each of the four finalized domains is 25 percent. CMS believes that equal weighting is appropriate based on the distribution of measures within the domains. The table immediately below shows domain weights for FYs 2017 and 2018. For reference, domain weights for earlier years (before the domain structure was changed) are shown in a following separate table.

Comparison of Domain Weights for FY2017 with Proposed Weights for FY 2018		
Domain	**FY 2017**	**FY 2018**
Safety	20%	25%
Clinical Care	(30%)	25%
Clinical Care–Outcomes	25%	--
Clinical Care–Process	5%	--
Efficiency and Cost Reduction	25%	25%
Patient and Caregiver Centered Experience of Care/Care Coordination	25%	25%

Domains and Domains Weights for FYs 2013-2016				
	Process of Care	**Experience of Care**	**Outcome**	**Efficiency**
2013	70%	30%		
2014	45%	30%	25%	
2015	20%	30%	30%	20%
2016	10%	25%	40%	25%

Minimum Domains for Total Performance Score. In scoring hospital performance for the VBP Program payment years FYs 2013 and 2014, hospitals had to have a score for all the applicable domains. For example, for FY 2014, scores were required for the Process of Care, HCAHPS, and Outcome domains. A hospital that did not meet that requirement had no Total Performance

Score and was not part of the VBP Program for that fiscal year. For FY 2015, when the Efficiency domain was added, and continuing into FY 2016, the requirements were modified so that a hospital needed scores in only two of the four domains to receive a Total Performance Score. (For hospitals with two or three domain scores, the domain weights were proportionately reweighted to total 100 percent.) Beginning in FY 2017, however, hospitals must have scores on at least three domains in order to receive a Total Performance Score. (For that year, a score on either the Clinical Care- Process or Clinical Care- Outcome subdomain will count as one domain for this purpose.) Proportional reweighting will still be used when scores are not available for all domains.

11. Minimum Cases and Measures

No changes are made to the previously adopted minimum number of cases required to receive a measure score and for the number of measures required to receive a domain score. These are shown in the tables below. Note that for FY 2017, these same minimums apply, plus the clinical process of care domain minimum is 1 measure.

Case Minimums Retained for FY 2018	
Type of Measure	**Cases**
PC-01 measure	10 cases
HCAHPS	100 surveys
Mortality	25 cases
Medicare Spending per Beneficiary	25 cases
AHRQ PSI 90 composite measure	3 cases for any underlying indicator
NHSN measures	1 predicted infection

Measure Minimums for Domain Score FY 2018	
Domain	**Minimum Measures**
Safety (includes NSHN, AHRQ PSI 90, PC-01)	3
Clinical Care (mortality)	2
Efficiency and Cost Reduction	MSPB score
Patient and Caregiver Centered Experience of Care/Care Coordination	HCAHPS score

For reference, previously adopted minimums for the number of measures required for a domain score in FY 2015 and 2016 are shown in the following table.

Measure Minimums for Domain Score, FYs 2015 and 2016	
Domain	**Minimum Measures**
Clinical Process of Care	4
Outcomes (Mortality, NSHN, AHRQ PSI 90)	2
Patient Experience of Care	HCAHPS score
Efficiency	MSPB score

12. Impact Analysis

Appendix A of the final rule includes a table and discussion of the estimated impact of the VBP Program for FY 2016 by type of hospital. However, these calculations rely on the FY 2015 hospital performance scores (based on the measures, performance periods and performance standards in effect for that year) to estimate the effects of the 2016 VBP Program.

Summary Table VBP-1: Measures and Domains for selected years				
Measure	**2017**	**2018**	**2019***	**2021***
Clinical Care–Process (*removed beginning 2018)*				
AMI-7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	X	Removed		
IMM-2 Influenza Immunization	X	Removed		
Perinatal Care: elective delivery < 39 completed weeks gestation	X	Moved to Safety domain		
Clinical Care–Outcomes *(labeled as 'Clinical Care' beginning 2018)*				
Acute Myocardial Infarction (AMI) 30-day mortality rate	X	X	X	X
Heart Failure (HF) 30-day mortality rate	X	X	X	X
Pneumonia (PN) 30- day mortality rate	X	X	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty			X	X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate				**X**
Safety				
AHRQ PSI–90 patient safety composite	X	X	X	X
Central Line Associated Blood Stream Infection (CLABSI)	X	X	X	X
Catheter Associated Urinary Tract Infection (CAUTI)	X	X	X	X
Surgical Site Infection: Colon Abdominal hysterectomy	X	X	X	X
Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	X	X	X	X
Clostridium Difficile infection (CDI)	X	X	X	X
Perinatal Care: elective delivery < 39 completed weeks gestation	In Clinical Care – Process domain	Moved from Clinical Care – Process		

Summary Table VBP-1: Measures and Domains for selected years				
Measure	**2017**	**2018**	**2019***	**2021***
Patient and Caregiver Centered Experience of Care/Care Coordination				
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)				
8 dimensions: Communication with Nurses Communication with Doctors Responsiveness of Hospital Staff Pain Management Communication About Medicines Cleanliness and Quietness of Hospital Environment Discharge Information Overall Rating of Hospital	X	X	X	X
9th dimension: 3-Item Care Transition measure		X	X	X
Efficiency and Cost Reduction				
Medicare Spending per Beneficiary	X	X	X	X
*No new measures set to begin in FY 2020				

SUMMARY TABLE VBP-2. Final Hospital VBP Program Domains and Measures for FYs 2013-2016					
Measure ID	**Measure Description**	**2013**	**2014**	**2015**	**2016**
Process of Care Domain					
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	X	X	X	X
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	X	X	X	
IMM-2	Influenza Immunization				X
HF-1	Discharge Instructions	X	X	X	
PN-3b	Blood Cultures Performed in the ED Prior to Initial Antibiotic Received in Hospital	X	X	X	
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	X	X	X	X
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	X	X	X	
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	X	X	X	X
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	X	X	X	X
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	X	X	X	
SCIP-Inf-9	Urinary Catheter Removal on Post-Operative Day 1 or 2		X	X	X

SUMMARY TABLE VBP-2. Final Hospital VBP Program Domains and Measures for FYs 2013-2016					
Measure ID	**Measure Description**	**2013**	**2014**	**2015**	**2016**
SCIP–Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	X	X	X	X
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	X	X		
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	X	X	X	X
Patient Experience of Care Domain					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (8 dimensions)		X	X	X	X
Outcome Domain					
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate		X	X	X
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate		X	X	X
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate		X	X	X
AHRQ PSI 90	Complication/patient safety for selected indicators (composite)			X	X
CLABSI	Central Line-Associated Blood Stream Infection			X	X
CAUTI	Catheter-Associated Urinary Tract Infection				X
SSI	Surgical Site Infection Colon Abdominal Hysterectomy				X
Efficiency Domain					
MSPB-1	Medicare spending per beneficiary			X	X

SUMMARY TABLE VBP-3. Comparison of Final Hospital VBP Program Measures and Domains for FYs 2016 and 2017		
Measure	**2016 Domain**	**2017 Domain**
AMI-7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	Clinical Process of Care	Clinical Care–Process
IMM-2 Influenza Immunization	Clinical Process of Care	Clinical Care–Process
PN-6 Initial Antibiotic Selection for CAP in Immunocompetent Patient	Clinical Process of Care	Removed
SCIP-Inf-2 Prophylactic Antibiotic Selection for Surgical Patients.	Clinical Process of Care	Removed
SCIP-Inf-3 Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	Clinical Process of Care	Removed
SCIP Inf-9 Urinary Catheter Removal on Postoperative Day 1 or 2	Clinical Process of Care	Removed
SCIP-Card-2 Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	Clinical Process of Care	Removed
SCIP-VTE-2 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	Clinical Process of Care	Removed
Perinatal Care: elective delivery < 39 completed weeks gestation		Clinical Care–Process
Acute Myocardial Infarction (AMI) 30-day mortality rate	Outcome	Clinical Care–Outcomes

SUMMARY TABLE VBP-3. Comparison of Final Hospital VBP Program Measures and Domains for FYs 2016 and 2017		
Measure	**2016 Domain**	**2017 Domain**
Heart Failure (HF) 30-day mortality rate	Outcome	Clinical Care–Outcomes
Pneumonia (PN) 30- day mortality rate	Outcome	Clinical Care–Outcomes
AHRQ PSI – 90 patient safety composite	Outcome	Safety
Central Line Associated Blood Stream Infection (CLABSI)	Outcome	Safety
Catheter Associated Urinary Tract Infection (CAUTI)	Outcome	Safety
Surgical Site Infection: Colon, Abdominal hysterectomy	Outcome	Safety
Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia		Safety
Clostridium Difficile (C.Diff)		Safety
HCAHPS (8 dimensions)	Patient Experience of Care	Patient and Caregiver Centered Experience of Care/Care Coordination
Medicare Spending per Beneficiary	Efficiency	Efficiency and Cost Reduction

G. Hospital-Acquired Condition (HAC) Reduction Program

No changes to the HAC Reduction Program methods and scoring methodology were proposed for FY 2016; for FY 2017, CMS finalizes its proposals to modify the performance period, change the methodology used to calculate the Domain 2 score for certain non-reporting hospitals, and reduce the weight of Domain 1 in calculating to the Total HAC Score. An extraordinary circumstance exception policy is finalized to begin in FY 2016.

1. Background

Section 3008 of the ACA requires the Secretary to implement a HAC payment adjustment beginning in FY 2015 under which an adjustment is made to payments of "applicable hospitals" to account for HACs with respect to discharges occurring in FY 2015 and later. The payment adjustment will result in the applicable hospitals receiving 99 percent of the payment that would otherwise apply (i.e., a 1 percent payment reduction). In the FYs 2014 and 2015 IPPS/LTCH final rules, CMS established the measures and scoring methodology for FY 2015.

Eight measures were adopted for FY 2015, grouped into two domains as shown in the Summary Table HAC-1 below. Domain 1 consists of the AHRQ PSI-90 measure, a composite measure of 8 individual claims-based AHRQ Patient Safety Initiative measures. Domain 2 includes two CDC NHSN healthcare associated infection (HAI) measures. Additional CDC HAI measures have been adopted for inclusion in the measure sets for FY 2016 and FY 2017, also shown in the table below. The applicable time periods for collecting data to calculate the total HAC scores for FY 2015 and FY 2016 are the 24-month periods shown in Summary Table HAC-1.

Under the previously finalized scoring methodology each hospital is first scored on each individual measure, and the hospital's scores on the measures within a domain are summed to calculate a score for the domain. The domain score is multiplied by a weight, and the weighted domain scores are then summed to calculate the Total HAC Score. It is the Total HAC Score that is used to identify which hospitals fall in the top quartile and are therefore subject to the

payment adjustment. The previously adopted domain weights for FYs 2015 and 2016 are shown in Summary Table HAC-1.

For each measure, hospitals with a score are assigned to deciles – increments of 10 – with points assigned to each decile. (For example, a hospital in the eighth percentile for a measure (between the 70th and 80th percentile) receives 8 points on the measure.) When there is more than one measure in a domain, points on each measure are averaged. For the NSHN Surgical Site Infection measure, which is added beginning in FY 2016, data for the two types of procedures measured (abdominal hysterectomy and colon procedures) for each hospital will be pooled into a single standardized infection ratio (SIR). Tied scores are handled by assigning all hospitals with the same results the same number of points based on the lowest appropriate percentile. For this program, having more points indicates a poorer performance, which is the opposite of Hospital VBP Program scoring.

2. Implementation of the HAC Reduction Program for FY 2016

CMS proposed no changes to the previously adopted policies for the FY 2016 HAC Reduction Program. An update is provided on NQF proceedings regarding the three measures adopted for FY 2016. The PSI-90 measure is undergoing maintenance review and as part of that process, AHRQ is considering the addition of three PSI measures to the PSI 90 composite measure. These are PSI-9: Perioperative hemorrhage rate, PSI-10: Perioperative physiologic metabolic derangement rate, and PSI-11: Postoperative respiratory failure rate. CMS indicates that it would consider the addition of one or more of these measures to be a significant change, requiring notice and comment rulemaking prior to requiring reporting of the revised composite.

Responding to numerous comments raising concerns about PSI-90, CMS says that this measure remains endorsed as a valid measure by the NQF, that it is an important measure of patient safety and that "experts agree this measure is scientifically rigorous." Specific suggestions regarding AHRQ patient safety indicator measure revisions can be made directly to QIsupport@ahrq.hhs.gov.

The NHSN CLABSI or CAUTI measures have completed NQF maintenance review, and modified versions of the measures were re-endorsed by NQF in November 2014. CMS notes that the new versions include a new statistical option (Adjusted Ranking Metric, or ARM) for calculating the measure result. For FY 2016, the CLABSI and CAUTI measures will be calculated using previously adopted SIR methodology. CMS will work with CDC to determine whether the ARM option is appropriate for use in the HAC Reduction Program, and if so it will propose a change through notice and comment rulemaking.

Suggestions regarding inclusion and exclusion criteria for NHSN measures, such as a comment made with respect to the SSI measure regarding exenterations, and another regarding spinal cord injury patients and CAUTI, should be directed to NHSN@cdc.gov. CMS uses the NSHN measures as specified by CDC.

CMS responds to a number of other comments on the HAC Reduction Program. With respect to the disproportionate effect on teaching hospitals, CMS says it will continue to monitor the program and will take commenters' concerns into consideration. Regarding a suggestion that CMS use the administrative authority to limit application of the penalty to base operating DRG

payments only, CMS reiterates the statutory provisions that apply the penalty to total payments. To commenters suggesting that adjustments for sociodemographic status be instituted, CMS repeats previous concerns about the potential for such adjustment to mask disparities or minimize incentives to improve care for disadvantaged patients. It will monitor the outcome of the NQF trial regarding use of SDS factors in risk adjustment, and also the results of research underway by the HHS Assistant Secretary for Planning and Evaluation (ASPE) to examine the impact of sociodemographic status on quality and performance measures as directed by the IMPACT Act. The overlap in measures between the HAC Reduction and VBP programs is warranted in CMS' view because the programs have separate purposes and policy goals.

3. Changes for FY 2017

Applicable time periods of 24 months are continued for all measures for FY 2017. For the PSI-90 measure this period will be July 1, 2013 through June 30, 2015; for the NHSN measures it will be January 1, 2014 through December 1, 2015.

The treatment of the Domain 2 score is changed in the case of a hospital that does not submit data on a measure and no waiver has been provided. (Because the CLABSI and CAUTI Domain 2 measures currently include ICU patients only, a hospital that participates in the IQR Program but has no ICU beds can apply for an ICU waiver so that they are not penalized for not reporting on these measures.) Under the policy in effect for FYs 2015 and 2016, if a hospital reports data on one but not all Domain 2 measures, its score will be based solely on the measure(s) reported, and it will not be assigned a maximum score of 10 for the non-reported data. In the proposed rule CMS noted that the performance periods for these initial two years of the HAC Reduction Program pre-dated the August 2013 announcement of the HAC Reduction Program in the FY 2014 IPPS/LTCH final rule. Beginning in FY 2017, the performance periods are entirely after that announcement, and if a hospital does not submit data for a Domain 2 measure, and does not have a waiver to do so, they will receive a maximum score of 10 for that measure and that score will be averaged with the score(s) on other measures. In the final rule, CMS reminds readers that if a Domain 2 score cannot be calculated for a hospital because there is less than 1.0 predicted infection for each measure, the Total HAC Score will be based fully on the hospital's Domain 1 score.

A change made to the relative weights of Domains 1 and 2; they will shift from the FY 2016 amounts of 25%/75% respectively to 15%/85% for FY 2017. In responding to comments CMS emphasizes that this change is made because MedPAC and others recommended a higher weight for Domain 2, and because additional measures (MRSA and C.diff) are included beginning in FY 2017.

Responding to concerns about the potential effects of the transition to ICD-10 coding, CMS indicates that it has tested its systems for quality programs and will continue to do so once ICD-10 data are submitted in order to assess coding variation and impacts on measure performance and payment program scoring. CMS plans to continue to work with stakeholders during the transition to address any issues that may occur.

Summary Table HAC-1 Previously and Newly Adopted HAC Reduction Program Measures, Performance Periods, and Domain Weights			
	FY 2015	**FY 2016**	**FY 2017**
Domain 1: AHRQ Patient Safety Indicators			
PSI-90 (PSI-90 is a composite of eight PSI measures: PSI-3 (pressure ulcer rate), PSI-6 (iatrogenic pneumothorax), PSI-7 (Central venous catheter related blood stream infections rate), PSI-8 (Postoperative hip fracture rate), PSI-12 (postoperative VE or DVT rate, PSI-13 (Postoperative sepsis rate), PSI-14 (Wound dehiscence rate), and PSI-15 (accidental puncture or Laceration).	X	X	X
Applicable Time Period/(Performance Period)	7/1/11-6/30/13	7/1/12-6/30/14	7/1/13-6/30/15
Domain 1 weight	35%	25%	15%
Domain 2: CDC HAI Measures			
Central Line-associated Blood Stream Infection (CLABSI)	X	X	X
Catheter-associated Urinary Tract Infection (CAUTI)	X	X	X
Surgical Site Infection (SSI): ◦ SSI Following Colon Surgery ◦ SSI Following Abdominal Hysterectomy		X	X
Methicillin-resistant staphylococcus aureus (MRSA)			X
Clostridium difficile			X
Applicable Time Period/(Performance Period)	1/1/12-12/31/13	1/1/13-12/31/14	1/1/14-12/31/15
Domain 2 weight	65%	75%	85%

4. Refinements to FY 2018 Measures

CMS finalizes its proposal that, beginning in FY 2018, the NHSN CLABSI and CAUTI measures used in the HAC Reduction Program include select ward (non-ICU) locations. Under the IQR Program, these measures were modified to collect data on adult and pediatric patients in medical/surgical wards as well as ICU locations beginning January 1, 2015. Responding to suggestions that the timing be delayed until 2019 in order to align with the introduction of the expanded measure to the VBP Program, CMS reiterates that these are separate programs, and that the VBP Program alone has a specific statutory requirement regarding the timing of new measures.

Some commenters questioned how the SIRs for ICUs and select ward locations would be displayed for public reporting because the rates can vary by location. CMS says it will consider this for the future.

CMS discusses CDC's changes to the standard population data that are used to calculate the predicted infections for the NHSN measures. (These changes are discussed with respect to the Hospital VBP Program in item 4 of section IV.F above.) CMS anticipates that the new data will affect the HAC Reduction Program beginning in FY 2018, when the applicable time period for these measures is likely to be January 1, 2015 through December 31, 2016. In response to comments, CMS clarifies that all SIRs used for the FY 2018 program (data for 2015 and 2016) will reflect the 2015 standard population.

5. Extraordinary Circumstances Exception Policy

CMS adopts an extraordinary circumstances exception policy beginning in FY 2016. Beginning with circumstances occurring on or after October 1, 2015, a hospital may apply for relief if its ability to collect or report accurate quality measure data has been negatively affected as a direct result of experiencing a significant disaster or other extraordinary disaster or circumstance. This is the same length of time adopted for the Hospital VBP Program, and the hospital may request a HAC Program Reduction exception at the same time it requests a similar exception under the IQR Program, the Hospital VBP Program, and the Hospital Readmission Reduction Program.

6. Impact Analysis

The regulatory impact analysis presented in Appendix A of the final rule includes a discussion of the estimated effects of the HAC Reduction Program for FY 2016.These estimates have been updated from the proposed rule. CMS estimates that 807 hospitals, or 24.4 percent of the total of 3,272 hospitals, will be subject to the 1 percent payment reduction. The impact analysis does not include an estimate of aggregate program savings from this program. The rule includes a table showing the percent of hospitals, by type, estimated to be subject to the 1 percent payment reduction. An estimated 50.4 percent of teaching hospitals with 100 or more residents are subject to the reduction; this group is most affected. Large hospitals, those with a relatively high disproportionate share percentage, government hospitals, and hospitals with a relatively low Medicare utilization (24 percent or less) are also much more likely to receive the HAC Program penalty.

H. Elimination of the Simplified Cost Allocation Methodology for Hospitals (§412.302)

In the FY 1997 IPPS final rule, in response to complaints that cost-finding methodologies for the allocation of direct and indirect costs were costly, CMS permitted hospitals to elect to use an alternative methodology (the simplified cost allocation methodology) which reduced the number of statistical bases that a hospital must maintain.

In the proposed rule, citing advances in recordkeeping technologies, the small number of hospitals and CAHs using the simplified methodology (23 and 9, respectively in FY 2013), and the concern that simplified methodology results in lower payments to hospitals (e.g., costs of capital-related movable equipment under this methodology yields less precise CCRs), CMS proposed to eliminate the simplified cost allocation methodology option for cost reporting periods beginning on or after October 1, 2015.

Commenters disagreed with CMS's calculation of the number of hospitals that used the simplified cost allocation methodology; some commenters suggested the actual number was closer to 2,000. CMS reassessed the data reported in the FY 2013 HCRIS, and using a series of filters (e.g., for buildings and fixtures, moveable equipment, laundry and linen, dietary, and nursing administration cost centers) it revised its estimate to less than 100 hospitals. CMS clarified for stakeholders that for a hospital to be considered to use the simplified cost allocation methodology, the hospital must use the entire list of statistical bases; hospitals that

used one or more but not all of those statistical bases are not deemed to be using the simplified methodology and were excluded from the CMS estimate.

Notwithstanding the small number of hospitals using the simplified cost allocation methodology, and taking into account commenters' concerns that eliminating the simplified methodology would disrupt a large number of hospitals that do not use dollar value to allocate capital-related moveable equipment, CMS does not eliminate the simplified methodology. Rather, it permits the use of either dollar value or square footage as the statistical basis for capital-related moveable equipment for hospitals that use the simplified methodology. Thus a hospital that uses the simplified cost allocation methodology (i.e., that uses each and every statistical basis within the list of cost centers) may continue to do so with the additional flexibility to request to use the dollar value statistical basis for capital-related moveable equipment. The hospital may get approval from its MAC using the instructions in Section 2313 of CMS Pub. 15-1.

CMS believes that using the dollar value as a statistic for capital-related moveable equipment supports more precise CCRs which outweighs the additional reporting burden on hospitals and encourages all hospitals to use dollar value as a statistical basis for the cost center.

A hospital that is not currently using the simplified cost allocation methodology may do so upon approval from its MAC; CMS notes that the MAC will approve a request to use the simplified methodology if the hospital shows that maintenance of the new statistics is less costly and does not result in inappropriate cost shifting. Hospitals using the standard cost allocation methodology but that use one or more of the statistical bases from the cost center list under the simplified methodology with the approval of their MACs may seek permission from their MACs to continue to do so.

I. Rural Community Hospital Demonstration Program

Background on Budget Neutrality Calculation

For hospitals participating in the budget neutral, rural community hospital demonstration program, CMS has for the past few fiscal years used its 3-step methodology (adopted in the FY 2013 IPPS/LTCH PPS final rule) to calculate the budget neutrality offset amount that is applied across aggregate IPPS payments. CMS calculates the budget neutrality offset amount by subtracting the sum of the estimated aggregate amount of payments to all hospitals participating in the demonstration program for covered inpatient hospital services, including the costs of swing bed services (if any), 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 made to all such hospitals for those services estimated to be made under the demonstration (calculated under Step 1 of the methodology). CMS:

1. Identifies a general reasonable cost amount using hospital data for all participating hospitals from “as submitted” cost reports for the hospitals’ cost reporting periods for the most recently available fiscal year;
2. Updates the estimated reasonable cost amounts for all hospitals under the demonstration by the *IPPS market basket percentage increases* for the fiscal year

involved and the preceding two fiscal years, and multiplies that figure by a 3-percent annual volume adjustment for each fiscal year (Step 1); and

3. Updates the estimated payments that would otherwise be made to those hospitals absent the demonstration by the *applicable percentage increases* for the fiscal year involved and the preceding two fiscal years, and multiplies that figure by a 3-percent annual volume adjustment for each fiscal year (Step 2).

Additionally, CMS adds to the budget neutrality adjustment amount calculated above an amount equal to the difference between the actual costs of the demonstration for a fiscal year and the budget neutrality adjustment for that fiscal year. The sum of these two amounts comprises the budget neutrality offset amount to the IPPS for the fiscal year for which a particular rulemaking cycle applies.

FY 2016 Budget Neutrality Offset Amount

CMS proposed to follow the methodology described above to calculate the estimated FY 2016 budget neutrality offset amount; however, changes were required to the methodology to account for the termination of the demonstration by October 1, 2015. For example, the 7 original hospitals (those that began participating between 2005 and 2009) will end participation before October 1, 2015, leaving 15 hospitals in the demonstration with different end dates during CY 2016, meaning that some hospitals will participate for only a fraction of FY 2016. Specifically, 8 hospitals will end participation before September 30, 2016, 3 will end on that date, and the remaining 4 hospitals will end on December 31, 2016.

Under its proposal, for each of those 8 hospitals ending before September 30, 2016, CMS would prorate the FY 2016 estimated reasonable cost amounts (including for swing-bed services) and the estimated amounts that would otherwise be paid the hospitals (including for swing-bed services) but for the demonstration project based on the ratio of the number of months the hospital participated in the project to the 12-month period of FY 2016. CMS believed that this represents an appropriate refinement to the methodology since more than half of the remaining hospitals are affected. By contrast, CMS did not provide for this prorating in the FY 2015 IPPS final rule because, for that fiscal year, only 5 of 22 hospitals participated for less than the entire FY 2015. Further, the methodology would be unchanged for the 7 hospitals with end dates on or after September 30, 2016.

CMS proposed to use data from "as submitted" cost reports for cost reporting periods ending in CY 2013, and for the FY 2016 budget neutrality offset amount, to update the estimated reasonable cost amounts for all hospitals under the demonstration by the IPPS market basket percentage increases (under Step 1), the applicable percentage increases (under Step 2) and the 3-percent annual volume adjustment, for each of FYs 2014 through 2016.

CMS did not receive any comments on its proposals and the agency finalizes the proposed methodology with some changes due to the availability of more recent data as follows:

Under step 1 (described above), CMS uses the final FY 2016 market basket percentage and applicable percentage increase described in section IV. A. above. Thus the estimated cost of the demonstration for FY 2016 for the participating 15 hospitals equals $26,044,620.

Under step 2 (described above), CMS identified the actual cost of the demonstration for FY 2009 (per the finalized cost reports for that fiscal year) as $14,332,936. The budget neutrality offset for FY 2009 was $22,790,338; CMS includes the difference ($8,457,452) in the FY 2016 budget neutrality offset amount.

Under step 3 (described above), using finalized cost reports for cost reporting periods beginning in FY 2010 for the 9 hospitals involved, CMS includes the difference between the actual cost of the demonstration in FY 2010 and the budget neutrality offset amount finalized for FY 2010. Because the demonstration project was scheduled to terminate in FY 2010 but was extended under the ACA, CMS finalized an estimated cost for the demonstration project for FY 2010 under the final IPPS rules for FY 2010 and 2011. The total estimated costs were $21,569,472. CMS determines in this final rule that the actual cost for that fiscal year was $16,817,922 (a difference of $4,751,550 which CMS applies to the budget neutrality offset amount for FY 2016).

Thus, CMS the total budget neutrality offset amount to the national IPPS rates for the cost of the demonstration during FY 2016 equals $12,835,618 which includes the amount by which the budget neutrality offset amounts for FY 2009 and FY 2010, respectively, exceeded expenditures for the demonstration for those fiscal years [$26,044,620 - ($8,457,452 + $4,751,550)].

J. Changes to MS-DRGs Subject to the Postacute Care Transfer Policy (§412.4)

For a new or revised MS-DRG assignment, CMS evaluates whether the postacute care transfer policy applies to that assignment using the following criteria:

- Whether the MS-DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS-DRGs; and
- Whether the proportion of (i) short-stay discharges to postacute care to (ii) total discharges in the MS-DRG exceeds the 55th percentile for all MS-DRGs.

If the MS-DRG satisfies both criteria, CMS applies the postacute care transfer policy to that MS-DRG as well as to any other MS-DRG that shares the same base MS-DRG.

Additionally, CMS will evaluate whether an MS-DRG that is subject to the postacute care transfer policy is also eligible for the special payment methodology for exceptionally higher shares of costs very early in the hospital stay. For these MS-DRGs, hospitals receive for the first day of the stay an amount equal to the sum of (i) 50 percent of the full MS-DRG payment and (ii) the single per diem payment, and for subsequent days hospitals receive the per diem payment (up to the full MS-DRG payment amount). CMS evaluates whether the MS-DRG qualifies for the special payment methodology using the following criteria:

- The geometric mean length of stay must exceed 4 days; and
- The average charges of 1-day discharge cases in the MS-DRG must be at least 50 percent of the average charges for all cases within the MS-DRG.

If the MS-DRG satisfies both criteria, CMS applies the special payment methodology to that MS-DRG as well as to any other MS-DRGs that are part of the MS-DRG severity level group that share the same base MS-DRG.

With respect to changes to several MS-DRG assignments effective for certain cardiovascular procedures for FY 2016, CMS evaluates the changes for purposes of the postacute care transfer policy criteria using FY 2014 MedPAR data. If an MS-DRG qualifies under the criteria, CMS also evaluates the MS-DRG under the special payment methodology criteria at §412.4(f)(6).

CMS did not receive any comments on its proposals with respect to the postacute care transfer policy status and special payment status for MS-DRGs 273 and 274. CMS finalizes its proposals without change as shown in the table below. CMS includes a more detailed table in the final rule which includes information on MS-DRGs 246 through 251 as well as 268 through 272 which did not qualify for postacute care transfer policy status.

POSTACUTE CARE TRANSFER POLICY STATUS AND SPECIAL PAYME POLICY STATUS IN FY 2016 FOR CERTAIN MS-DRGS			
MS-DRG	**MS-DRG Title**	**Postacute Transfer Status**	**Special Payment Polic**
2	Percutaneous Intracardiac Procedures with MCC	YES	YES
2	Percutaneous Intracardiac Procedures without MC	YES*	YES*

*MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer and special payment methodology policies if any one of the MS-DRGs that share that same base MS-DRG qualifies.

K. Short Inpatient Hospital Stays

CMS notes that stakeholders have expressed concerns about its policies on short inpatient hospital stays, long outpatient stays that include observation services, and when Part A payment is appropriate for short stays. CMS refers readers to the 2016 OPPS/ASC proposed rule (80 FR 39348) for its discussion in that rule of issues related to short inpatient hospital stays, and reminds readers that comments on that proposed rule are due by August 31, 2015.

L. Interim Final Rule with Comment Period Implementing Legislative Extensions Relating to the Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent, Small Rural Hospital (MDH) Program

Section 204 of MACRA, enacted on April 16, 2015, extends enhancements to the payment adjustment for low-volume hospitals under the IPPS through FY 2017. Similarly, section 205 of MACRA extends the Medicare-dependent, small rural hospital (MDH) program through FY 2017. The FY 2016 IPPS/LTCH final rule includes an interim final rule implementing these changes. The provisions of the interim final rule are applicable for discharges on or after April

1, 2015 and on or before September 30, 2017. **Comments on the interim final rule must be received by CMS by no later than 5 p.m. EST on September 29, 2015**. CMS does not note any specific issues for comment.

1. Extension of the Payment Adjustment for Low-Volume Hospitals

Background

Section 1886(d)(12) of the Social Security Act (the SSA) provides for an additional payment to qualifying low-volume hospitals under the IPPS beginning in FY 2005. Sections 3125 and 10314 of the Affordable Care Act (ACA) provided for temporary enhancements in the low-volume hospital payment policy for FYs 2011 and 2012. These temporary enhancements were extended several times: through FY 2013 by the American Taxpayer Relief Act of 2012 (ATRA), through March 31, 2014 by the Pathway for SGR Reform Act, through March 31, 2015 by the Protecting Access to Medicare Act (PAMA), and as noted above, through FY 2017 by the MACRA.

Under the ACA enhancements, a hospital qualifies as a low-volume hospital if it is more than 15 road miles, rather than 25 road miles as under the original provision, from another IPPS hospital and has less than 1,600 discharges (originally 800 discharges) of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year. In addition, the ACA provided that the low-volume hospital payment adjustment (i.e., the percentage increase) is to be determined "using a continuous linear sliding scale ranging from 25 percent for low volume-hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year."

Implementation under the Interim Final Rule

The interim final rule implements the MACRA amendments following CMS' historical policies for this provision. CMS previously addressed the implementation of the extension for discharges occurring on or after April 1, 2015 through September 30, 2015 through instructions issued in Change Request 9197, Transmittals 3263 and 3281 (the latter transmittal corrected an erroneous date in Attachment 3 of Transmittal 3263). Generally, hospitals receiving the low-volume hospital payment adjustment for FY 2015 as of March 31, 2015 would retain low-volume hospital status for the remainder of FY 2015 as long as the hospital continues to meet the applicable qualifying criteria, determined using FY 2013 Medicare discharge data from the March 2014 update of the MedPAR files.

For purposes of FY 2016, CMS updates the discharge data source used to identify low-volume hospitals and calculate the payment adjustment (i.e., the percentage increase) using Medicare discharge data from the March 2015 update of the MedPAR files; Table 14 in the Addendum of the final rule lists subsection (d) hospitals with fewer than 1,600 discharges but does not indicate whether the hospital is eligible for the low-volume hospital payment adjustment since this is also dependent upon meeting the mileage criterion specified at §412.101(b)(2)(ii). A

hospital must be located more than 15 road miles from any other IPPS hospital in order to qualify for a low-volume hospital payment adjustment for FY 2016.

To receive the low-volume hospital payment adjustment for discharges occurring during FY 2016, using CMS' previously established procedure a hospital must notify and provide documentation to its MAC that it meets the mileage criterion. The request must be made in writing and must be received by the MAC no later than September 1, 2015. A hospital that qualified for the low-volume payment adjustment in FY 2015 may continue to receive a low-volume payment adjustment for FY 2016 without reapplying if it continues to meet the Medicare discharge criterion and the distance criterion; **however, the hospital must send written verification that is received by its MAC no later than September 1, 2015, that it continues to be more than 15 miles from any other IPPS hospital.** CMS notes that the written verification could be a brief letter to the MAC. For a hospital that misses the September 1, 2015 deadline, if the MAC involved subsequently approves low-volume hospital status for the hospital, the MAC will apply the low-volume hospital payment adjustment prospectively within 30 days of the low-volume hospital status determination date.

2. Extension of the Medicare-Dependent, Small Rural Hospital (MDH) Program

Implementation

As noted previously, section 205 of MACRA extends the MDH program through FY 2017. Similar to the implementation of the low-volume hospital payment adjustment described above, CMS previously addressed the implementation of the extension of the MDH program for discharges occurring on or after April 1, 2015 and on or before September 30, 2015 through instructions issued in Change Request 9197, Transmittals 3263 and 3281 (the latter corrected an erroneous date in Attachment 3 of Transmittal 3263). Generally, a hospital classified as an MDH as of March 31, 2015, was reinstated as an MDH effective April 1, 2015 without having to reapply. However, if the hospital classified as an SCH or cancelled its rural classification, the effective date of MDH status may not be retroactive to April 1, 2015.

3. Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

CMS notes that the requirement for publication in the Federal Register of a notice of proposed rulemaking for a substantive rule may be waived when an agency for good cause finds that the notice and public comment period as well as the delay in the effective date are impractical, unnecessary or contrary to the public interest. CMS states that notice and comment rulemaking is unnecessary because the interim final rule states the requirements for the extension of the low-volume hospital and MDH programs pursuant to statute, especially because those statutory changes have already taken effect.

4. Regulatory Impact Analysis

CMS states that the interim final rule does not impose any collection of information requirements and thus OMB review of the rule is not required. CMS projects that FY 2016

IPPS payments to hospitals affected by sections 204 and 205 of MACRA will increase as follows:

- The low-volume hospital payment adjustments for the approximately 593 hospitals that will qualify for those adjustments will result in an aggregate increase in payments of $322 million compared to the FY 2016 payments estimated for these hospitals without the adjustment.
- The MDH program for the 90 hospitals that CMS projects will receive the blended payment amount (the federal standardized amount plus 75 percent of the amount by which the hospital-specific rate exceeds the federal standardized amount) will result in an increase in payments of $96 million to these hospitals compared to the FY 2016 payments estimated for these hospitals if the MDH program had expired.

V. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2016. For FY 2015, CMS established a national capital federal rate of $434.97. In this final rule, CMS establishes an update factor to the national capital federal rate for FY 2016 equal to 1.3 percent based on the capital input price index (CIPI) of 1.3 percent adjusted for other factors, which net out to 0.0 as detailed in the table below.

CMS projects a 0.5 percent total increase in the case-mix index. It estimates that the real case-mix increase will equal 0.5 percent for FY 2016. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, as proposed, the net adjustment for case-mix change in FY 2016 is 0.0 percentage point.

CMS FY 2016 UPDATE FACTOR
TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.3
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2014 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

*The capital input price index is based on the FY 2010-based CIPI.

As a result of this update and the final budget neutrality factors discussed below, CMS sets a national capital federal rate of $438.65 for FY 2016.

The final FY 2016 budget neutrality adjustment factor which is applied to the capital federal rate for changes in the MS-DRG classifications and relative weights and changes in the geographic adjustment factors (GAFs) is 0.9973; this adjustment in FY 2015 was 0.9993.

The final FY 2016 outlier adjustment factor is 0.9365, compared to 0.9382 in FY 2015. Outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital federal rate. The final FY 2016 outlier adjustment of 0.9365 would yield a net change in the outlier adjustment to the capital federal rate for FY 2016 compared to FY 2015 of 0.9973 (0.9365/0.9382), which is a -0.18 percent change. Thus, the outlier adjustment decreases the final FY 2016 capital federal rate by 0.18 percent.

Considering all adjustments, CMS sets a national capital federal rate for FY 2016 equal to $438.65, representing a 0.85 percent increase over the FY 2015 rate of $434.97. The final rule includes the following chart to show how each of the factors and adjustments for FY 2016 affects the computation of the FY 2016 national capital Federal rate in comparison to the FY 2015 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2015 Capital Federal Rate and FY 2016 Capital Federal Rate

	FY 2015	FY 2016	Change	Percent Change
Update Factor[1]	1.0150	1.0130	1.0130	1.3
GAF/DRG Adjustment Factor[1]	0.9993	0.9973	0.9973	-0.27
Outlier Adjustment Factor[2]	0.9382	0.9365	0.9982	-0.18
Capital Federal Rate	$434.97	$438.65	1.0085	0.85

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 2015 to FY 2016 resulting from the application of the 0.9973 GAF/DRG budget neutrality adjustment factor for FY 2016 is a net change of 0.9973 (or -0.27 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 2016 outlier adjustment factor is 0.9365/0.9382, or 0.9982 (or -0.18 percent).

For FY 2015, the special capital rate for hospitals located in Puerto Rico was $209.45. The final FY 2016 special capital rate for hospitals in Puerto Rico is $212.56.

Exception Payments. The final rule continues the policy under which 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

Rate-of-Increase in Payments to Excluded Hospitals for FY 2016

Based on IHS Global Insight Inc.'s 2015 second quarter forecast (which is the most recent data available) of the IPPS operating market basket, CMS sets a 2.4 rate-of-increase percentage for FY 2016 to the target amount for cancer hospitals, children's hospitals, religious nonmedical health care institutions (RNHCIs), and for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. These hospitals and institutions are not subject to the ACA-mandated percentage point reductions for multi-factor productivity or the statutory 0.2 percentage point reduction applicable to IPPS hospitals for FY 2016.

Section 4419(b) of Pub. L. 105-33 requires the Secretary to publish annually in the *Federal Register* a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year. The table below includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2014; these adjustments pertain to cost reporting periods ending in years prior to FY 2013.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Children's	1	$1,140,682	$829,567
Cancer	-	-	
Religious Nonmedical Health Care Institution (RNHCI)	2	$729,557	$685,537
Total	3	$1,870,239	$1,515,104

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2016

A. Background of the LTCH PPS

CMS finalizes several key changes to the LTCH PPS for FY 2016.

- Implements Section 1206 of Pub. L. 113-67 which requires the establishment of an alternate "site neutral" payment rate for Medicare inpatient discharges from an LTCH that fail to meet certain statutorily defined criteria. This results in a dual-rate LTCH PPS

payment structure: one for LTCH PPS standard Federal payment rate cases and one for site-neutral payment rate cases.

- Implements the statutory criteria for excluding cases from the site neutral payment rate, such as the criterion for a principal diagnosis related to a psychiatric diagnosis or rehabilitation, as well as establishes the requirements for determining the site neutral payment rate for a given LTCH discharge.
- Establishes two separate high-cost outlier fixed-loss amounts—one for LTCH site neutral payment rate cases that is equivalent to the IPPS and one for LTCH PPS standard Federal payment rate cases (computed using a similar approach as before, but now only includes data from the LTCH PPS standard Federal payment rate cases).
- Establishes a transitional blended payment rate methodology for site neutral payment rate cases for FYs 2016 and 2017, a 50/50 blend of the applicable site neutral payment rate and the LTCH PPS standard Federal payment rate.
- Provides technical clarifications on the statutory moratorium for establishing new LTCHs and satellite facilities and bed increases.

Summary of Changes to LTCH PPS for FY 2016*	
Standard Federal Rate, FY 2015	$41,043.71
Update factors	
Market basket change	+2.4%
Multi-factor productivity adjustment	-0.5%
Additional adjustment required by statute	-0.2%
Penalty for hospitals not reporting quality data	-2.0%
Net update, LTCHs reporting quality data	+1.7% (1.017)
Net update LTCHs not reporting quality data	-0.3% (0.997)
Adjustments	
Average wage index budget neutrality adjustment**	1.000513
Standard Federal Rate, FY 2016	
LTCHs reporting quality data ($41,043.71∗1.017∗1.000513)	$41,762.85
LTCHs not reporting quality data ($41,043.71∗0.997∗1.000513)	$40,941.55
Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard Federal payment rate cases	$16,423
Site neutral payment rate case (same as the IPPS fixed-loss amount)	$22,544
Impact of Policy Changes on LTCH Payments	
Total estimated impact	-4.6% (-$250 million)
LTCH standard Federal payment rate cases (54% of LTCH cases)	+1.5% (+50 million)
Site neutral payment rate cases (46 % of LTCH cases)***	-14.8% (-$300 million)
*More detail is available in Table IV, “Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2016” (see page 2106 in display copy). Table IV does not include the impact of site neutral payment rate cases. ** The computed total varies slightly from published amount. Based on exchange with CMS staff, the budget neutrality factor of 1.000513 is a typo and off by a small amount and will be corrected. ***LTCH site neutral payment rate cases are paid a rate that is based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case.	

B. Application of the Site Neutral Payment Rate (New §412.522)

Section 1206 of Pub. L. 113-67 mandates significant changes to the payment system for LTCHs beginning in FY 2016. Section 1206 requires the establishment of an alternate "site neutral" payment rate for Medicare inpatient discharges from an LTCH that fails to meet certain statutorily defined criteria. The statute defines "site neutral payment rate" as the lower of the IPPS comparable amount or 100 percent of the estimated cost of the case. LTCH discharges that do not meet the clinical criteria would be made at the applicable site neutral payment rate. The patient-level criteria (as defined in Section 1886(m)(6)(A)(ii) of the Act) that must be met in order for a standard LTCH PPS payment to be made under this guidance is the following:

- The stay in the LTCH is immediately preceded by a discharge (1) from an acute care hospital that included at least 3 days in an intensive care unit (ICU), or (2) from an acute care hospital and the patient's LTCH stay was assigned to an MS-LTC-DRG based on the receipt of ventilator services of at least 96 hours; and

- The LTCH discharge *does not* have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation.

In this final rule, CMS finalizes policies to implement the statutory criteria for excluding cases from the site neutral payment rate as well as establish the requirements for determining the site neutral payment rate for a given LTCH discharge. In addition, CMS finalizes conforming changes to the regulations to include the new site neutral payment rate as a method of payment under the LTCH PPS. CMS also finalizes a technical change to the regulatory language by changing the term from "Federal payment rate" to "standard Federal payment rate" in order to provide consistent terminology.

Many commenters objected to the application of the site-neutral payment rate expressing concerns that wound care is not categorically excluded from the application of the site-neutral payment rate and that payment for site neutral payment rate cases in rural LTCHs would not be sufficient and should be paid on a cost basis. In addition, commenters were concerned that the exclusion from the lower site neutral payment rates is dependent upon events outside of the LTCHs control, specifically the actions of subsection (d) hospitals. Other commenters were appreciative of the information added to the publically available FY 2014 MedPAR file for the proposed rule, but requested information be added, such as encrypted patient identifiers, admission and discharge dates, along with the number of days the patient spent in the ICU in the immediately preceding IPPS hospital stay prior to admission to the LTCHs. In response, CMS states that it does not have the statutory authority to establish regulatory payment policy provisions to exclude the application of the site neutral payment rate to wound care or to pay rural LTCHs any other rate than what is provided under the new dual-rate LTCH payment structure. With respect to LTCHs lack of control, CMS notes that it expects referring hospitals and LTCHs to be closely engaged in the coordination of care efforts with regards to their referred patients and believes the claims processing system change will appropriately identify all LTCH discharges. CMS also notes that LTCHs can contact their MACs in situations where an obvious error has occurred. With respect to the request to

include additional information to the MedPAR file, CMS cited privacy and security concerns for reasons not to add most of the information requested, but did agree to add information on the number of days the patient spent in the ICU in the immediately preceding IPPS hospital stay prior to admission to the LTCHs.

C. Criteria for Exclusion from the Site Neutral Payment Rate

In the final rule, CMS implements the statutory criteria for exclusion from the site neutral payment rate:

- Criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation
- Definition of a "Subsection (d) Hospital"
- Interpretation of "Immediately Preceded" by a Subsection (d) Hospital discharge
- Implementation of the ICU criterion
- Implementation of the Ventilator criterion

1. Implementation of the Criterion for a Principal Diagnosis Relating to a Psychiatric Diagnosis or to Rehabilitation

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that in order for an LTCH discharge to be excluded from payment under the site neutral payment rate, the LTCH discharge cannot have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation. In other words, if a LTCH discharge is assigned one of these principal diagnosis, payment would be a site neutral payment rate.

For FY 2016, CMS finalizes its proposal that an LTCH discharge assigned to one of the following ICD-10 MS-LTC-DRGs (Version 33) would identify a case with a principal diagnosis relating to a psychiatric diagnosis:

- MS-LTC-DRG 876 (O.R. Procedure with Principal Diagnosis of Mental Illness);
- MS-LTC-DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction);
- MS-LTC-DRG 881 (Depressive Neuroses);
- MS-LTC-DRG 882 (Neuroses except Depressive);
- MS-LTC-DRG 883 (Disorders of Personality & Impulse Control);
- MS-LTC-DRG 884 (Organic Disturbances & Mental Retardation);
- MS-LTC-DRG 885 (Psychoses);
- MS-LTC-DRG 886 (Behavioral & Developmental Disorders);
- MS-LTC-DRG 887 (Other Mental Disorder Diagnoses);
- MS-LTC-DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama);
- MS-LTC-DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy);
- MS-LTC-DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); and
- MS-LTC-DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC).

CMS also finalizes its proposal that, for FY 2016, an LTCH discharge assigned to one of the following ICD-10 MS-LTC-DRGs would identify an LTCH discharge with a principal diagnosis relating to rehabilitation:

- MS-LTC-DRG 945 (Rehabilitation with CC/MCC); and
- MS-LTC-DRG 946 (Rehabilitation without CC/MCC).

CMS received support from several commenters on its proposed list of specific MS-LTC-DRGs related to a psychiatric or to rehabilitation. In its response, CMS acknowledges the support and finalizes its proposal without modification.

2. Addition of Definition of a "Subsection (d) Hospital" to LTCH Regulations

The site neutral payment rate established in section 1206(a) of Pub. L. 113-67 includes several references to "subsection (d) hospitals". The term "subsection (d) hospital" generally refers to a hospital located in 1 of the 50 States or the District of Columbia and is subject to IPPS payment (does not include psychiatric hospitals, rehabilitation hospitals, children's hospitals, LTCHs, or cancer hospitals). CMS finalizes its proposal to define a "subsection (d) hospital" under §412.503, for purposes of new §412.522, as a hospital defined in section 1886(d)(1)(B) of the Act, and includes any hospital that is located in Puerto Rico that would be defined as a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act if it were located in 1 of the 50 States. CMS believes that this definition is consistent with definitions used in the statute, and would provide additional clarity in the regulations presented in this rule to implement the site neutral payment rate policies. CMS received favorable comments on this proposed change and finalized this proposal without change.

3. Interpretation of "Immediately Preceded" by a Subsection (d) Hospital Discharge

Section 1886(m)(6)(A)(ii)(II) of the Act specifies that, in order to be excluded from payment under the site neutral payment rate, the LTCH discharge must meet the ICU criterion of the Act,
Both the ICU criterion and the ventilator criterion require that the LTCH admission be immediately preceded by a discharge from a subsection (d) hospital. For purposes of the ICU criterion and the ventilator criterion, CMS finalizes its proposal that the phrase "immediately preceded" by a discharge from a hospital means a Medicare patient discharge from the hospital occurs immediately prior to the patient's admission to an LTCH. A Medicare patient discharge from the hospital to any other setting, including home, an IRF, an IPF, or a SNF would not be considered to be "immediately preceded" by a discharge from a hospital, nor fulfill the ICU criterion or the ventilator criterion in order to qualify for exclusion from the site neutral payment rate.

CMS finalizes its proposal to determine an applicable Medicare patient discharge from a hospital's discharge date on the Medicare claim and the LTCH admission date on the Medicare claim for the LTCH's discharge. CMS did not finalize its proposal that for the LTCH's discharge to be eligible for exclusion from the site neutral payment rate the discharge from the hospital on

the claims submitted must use Patient Discharge Status Code 63, which signifies a patient was discharged or transferred to an LTCH, or Patient Discharge Status Code 91, which signifies a patient was discharged/transferred to a Medicare-certified LTCH with a planned acute care hospital inpatient readmission. Thus, CMS finalizes its proposal that a Medicare patient discharge that occurred on the same date as the LTCH admission (or, in certain rare circumstances, that occurred the date before the date of the LTCH admission) would fulfill the immediately preceded portion of the requirements to be excluded from the site neutral payment rate.

CMS notes that this interpretation of "immediately preceded" would work in tandem with its existing interrupted stay policy.[22] Any interruption of stay would not invalidate the immediately preceded status for the LTCH admission because CMS states that it has historically treated interrupted stays as one stay.

Some commenters generally supported the CMS proposal related to the interpretation of "immediately preceded" by a subsection (d) hospital discharge. However, many commenters expressed concerns about the CMS proposal to require specific patient discharge status codes on the subsection (d) hospital claim. These commenters believed that reliance on these codes was unnecessary as a high percentage of LTCH admissions occur on the same day as the preceding subsection (d) hospital discharge and that there is inconsistency in how subsection (d) hospitals use these codes.

In response, CMS agrees with the commenters regarding the requirement of discharge status codes on subsection (d) hospital claims and thus is not finalizing this requirement. CMS is finalizing its proposal (at new §412.522(b)(1)(ii) that an LTCH discharge will be considered to have been immediately preceded by a discharge from a subsection (d) hospital if there was a direct admission from such a hospital, as evidenced by the dates of discharge and admission, to the LTCH.

4. Implementation of the ICU Criterion

Section 1886(m)(6)(A)(iii)(I) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ICU criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital that included at least 3 days in an ICU, as determined by the Secretary. The statute further specifies that the Secretary shall use data from revenue center codes 020X or 021X (or such successor codes as the Secretary may establish), which correspond to intensive care and coronary care revenue codes, respectively.

CMS finalizes its proposal, without modification, that at least 3 days must be reported on the hospital claim submitted by the subsection (d) hospital using revenue center codes 020X or 021X, the use of which must be consistent with the definition of an ICU under §413.53(d) in order to fulfill the ICU criterion to be excluded from the site neutral payment rate. CMS notes

[22] An interruption of stay occurs, for example, when during the course of an LTCH hospitalization, the patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment or service that is not available at the LTCH for a specified period followed by readmittance to the same LTCH.

that although it does not anticipate a change in general hospital coding practice regarding these revenue center code categories, CMS will monitor the use of these codes, and propose revisions to the ICU criterion regulations in the future, as necessary.

Commenters generally supported the CMS proposal related to the implementation of the ICU criterion. Some commenters believe that CMS lacked the authority to exclude certain subsets of these codes. Other commenters disagreed with the proposal to rely on subsection (d) hospitals' reporting of these revenue center codes because doing so would increase administrative burden, and preferred that CMS rely on information an LTCH submitted on its claim. In response, CMS disagreed with the commenters that it lacked the authority to exclude certain subsets of revenue center codes and disagreed with commenters that it should rely on ICU criterion based solely on data obtained from an LTCH's claim. CMS believes that the best source of data for what happened in a subsection (d) hospital is what is available on that hospital's claim. CMS finalizes its proposal related to the ICU criterion, without modification.

5. Implementation of the Ventilator Criterion

Section 1886(m)(6)(A)(vi) of the Act specifies that in order to be excluded from payment under the site neutral payment rate under the ventilator criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital and the LTCH discharge must be assigned to an MS-LTC-DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH.

CMS finalizes its proposal, without modification, to require LTCHs to report ICD-10-PCS procedure code 5A1955Z on their claims indicating that the beneficiary received at least 96 hours of ventilator services during the LTCH stay as a condition of that discharge being eligible for exclusion from the site neutral payment rate based on the ventilator criterion.[23] LTCH discharges that do not report this procedure code on the claim submitted for payment would not meet the ventilator criterion. CMS states that it recognized that many of the discharges reporting this procedure code are grouped into one of six MS-LTC-DRGs, but notes that these DRGs are not necessarily limited to beneficiaries who have received at least 96 hours of mechanical ventilation services.

Commenters general supported the CMS proposal with respect to the implementation of the ventilator criterion. Some commenters expressed concern that CMS' proposal failed to identify and include cases that receive exactly 96 hours of ventilator services, as ICD-10-PCS procedure code 5A1955Z consist of services greater than 96 consecutive hours and offered an alternative option. CMS agrees that the procedure code 5A1955Z does have that limitation, but did not believe the commenters' alternative suggestions was a viable option. CMS notes that if this rare instance occurs (exactly 96 hours of ventilator services), the LTCH should contact its MAC to have the appropriate LTCH PPS payment amount determined. After consideration of comments, CMS finalizes its proposal, without modification.

[23]Currently, under the ICD-9-CM coding system, procedure code 9672 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) is used to describe long-term mechanical ventilator services.

D. Determination of the Site Neutral Payment Rate

Beginning in FY 2016, CMS finalizes its proposal that LTCH discharges paid at the site neutral payment rate would be based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case. The sections below describe how CMS plans to calculate these amounts and a discussion of the transition period for these rates.

1. Calculation of the IPPS Comparable Per Diem Amount

Based on the policies finalized, CMS states that its calculation of the IPPS comparable per diem amount would be calculated using the same method used to determine an amount comparable to the hospital IPPS per diem amount (based on existing regulations at §412.529(d)(4)). That is, CMS will determine the IPPS comparable per diem amount based on the standardized amount determined adjusted by the applicable DRG weighting factors. CMS will further adjust this amount to account for differences in area wage levels based on geographic location (including additional adjustments for LTCHs in Alaska and Hawaii). This calculation will include a DSH payment adjustment (including a proxy adjustment for the uncompensated care payment), and an IME payment adjustment for LTCHs that are teaching hospitals. The IPPS comparable per diem amount would also include payment for inpatient capital-related costs adjusted for area wage levels, DSH, and IME. Finally, CMS will determine the IPPS comparable per diem amount by dividing the IPPS comparable payment amount by the geometric average length of stay of the specific MS-DRG under the IPPS and multiplying that amount by the covered days of the LTCH stay.

The IPPS comparable per-diem amount does not include additional payments for extraordinarily high-cost cases under the IPPS outlier policy. CMS proposes that site neutral payment rate cases receive an additional payment for a high-cost outlier (HCO) that would be equal to 80 percent of the difference between the estimated cost of the case and the HCO threshold, which CMS proposes would be the sum of site neutral payment rate for the case and the IPPS fixed-loss amount policy.

Commenters expressed concern that LTCHs would receive a lower payment than an IPPS hospital for treating the same type of case and recommended that CMS pay LTCH site-neutral payment rate cases the exact amount that would have been paid under IPPS. CMS states in its response that it does not have the statutory authority to make any further adjustments to the payment rate and finalizes, without modification, its proposal.

2. Calculation of 100 Percent of the Estimated Cost of the Case

CMS finalizes its proposal to calculate 100 percent of the estimated cost of a case by multiplying the LTCH's hospital-specific CCR by the Medicare allowable charges for the LTCH case, which is the same method CMS uses to determine short-stay outlier (SSO) payments and HCO payments. Under this policy, the CCR applied at the time a claim is processed would generally be based on either the most recent settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. CMS may specify an alternative to the

CCR otherwise applicable if it believes that the CCR being applied is inaccurate, or an LTCH may request an alternate (higher or lower) CCR based on its presentation of substantial evidence in support of that alternate. CMS did not receive any comments on this proposal, and adopted the proposal, without modification.

CMS did not finalize its proposal to reconcile site neutral payment rate payments based on the CCR calculated using the settled cost report that coincides with the discharge. CMS had proposed that such payments be adjusted to account for the time value of any underpayments or overpayments and any adjustment be based upon the monthly rate of return that the Medicare Trust Fund earns.

Several commenters disagreed with the CMS proposal to apply its existing reconciliation policy to payments made for site neutral payment rate cases stating that such a policy is unprecedented and contrary to the predictability of a PPS. CMS disagrees with the commenters and notes that payments for site neutral payment rate cases would be subject to reconciliation only when certain criteria are met. Nevertheless, CMS understood the commenters' concerns regarding the need for predictability and stability in LTCH PPS payments and it would be appropriate to postpone the implementation of a reconciliation policy. Thus, CMS is not finalizing the proposal to apply, under new §412.522(c)(4), a reconciliation policy to payments made for site neutral payment rate cases. However, CMS is finalizing the proposal to include any HCO payments made for site neutral payment rate cases under the existing reconciliation policy at §412.525(a)(4)(iv)(D).

3. Blended Payment Rate for FYs 2016 and 2017

Section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that will be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FYs 2016 or FY 2017. CMS finalizes its proposal that for LTCH discharges during FYs 2016 and 2017, the payment amount for site neutral payment rate cases would be a blended payment rate, which would be calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate. The payment amounts determined for the site neutral payment rate and the LTCH PPS standard Federal rate would include any applicable adjustments, such as HCO payments.

Some commenters requested that CMS establish a longer transitional period for LTCHs to receive blended payments given the potential negative impact of the new payment structure. CMS acknowledges the commenter's concerns, but notes the statute limits a longer transitional period. Thus, CMS finalizes its proposal, without modification.

4. LTCH Standard Federal Payment Rate

CMS finalizes its proposal that LTCH discharges that meet the criteria for exclusion from site neutral payment rate will be paid based on the LTCH PPS standard Federal payment rate. CMS also notes that all of the existing payment adjustments, such as the adjustments for interrupted stays and HCO, would still apply under this proposal, as appropriate. CMS did not receive any public comments on this proposal, and adopted this policy without modification.

E. Application of Certain Existing LTCH PPS Payment Adjustments to Payments Made Under the Site Neutral Payment Rate

CMS finalizes its proposal to apply payment adjustments for the interrupted stay policy and the 25-percent threshold policy to payments made under the site neutral payment rate.[24] CMS states that it is appropriate to apply these adjustments as the site neutral payment rate establishes an alternative payment amount rather than creating an exception from the LTCH PPS. CMS further states its belief that the interrupted stay policy has been effective in protecting the Medicare Trust Fund from significant and inappropriate expenditures and believes that, as such, the interrupted stay policy should be applied to site neutral payment rate cases. CMS also noted its recognition there is a current statutory moratorium on the full implementation of the 25-percent threshold. The statutory moratorium provides relief until cost reporting periods beginning on or after July 1, or October 1, 2016, as applicable.

CMS also finalizes its proposal not to apply the SSO payment adjustment to the site neutral payment rate, as applying the SSO payment adjustment to the site neutral payment rate cases would not affect the resulting LTCH PPS payment amount.

One commenter requested clarification about the CMS application of the 25-percent threshold policy to site neutral payment rate cases. Several commenters were supportive of the CMS proposal not to apply the SSO policy to site neutral payment rate cases, while others believed the SSO policy should be modified in consideration of site neutral payment rate cases. In response, CMS clarifies that the 25-percent threshold policy would apply to all LTCH discharges (site neutral payment rate cases or LTCH PPS standard Federal payment rate cases) that are beyond an LTCH's applicable threshold from a single referring hospital. CMS states that it would consider the commenters' suggestions to revise the SSO policy and may consider additional policy proposals in future rulemaking. CMS finalizes its proposals, without modification.

F. Policies Related to the LTCH Discharge Payment Percentage

Section 1886(m)(6)(C) of the Act, as added by section 1206 of Pub. L. 113-67, imposes several requirements related to an LTCH's discharge payment percentage. Consistent with the statute, CMS finalizes its proposal to define an LTCH's discharge payment percentage as a ratio, expressed as a percentage, of Medicare discharges excluded from the site neutral payment rate to total Medicare discharges paid under the LTCH PPS during the cost reporting period. The statute also requires that CMS provide notice to each LTCH of the LTCH's discharge percentage. CMS also finalizes its proposal, beginning in FY 2016, to inform each LTCH of their discharge

[24] Under the interrupted stay policy, patients who are treated and readmitted to the same LTCH within a certain number of consecutive days from an acute care hospital, IRF or a SNF setting—between 4-9 days for acute care hospital, 4-27 days for an IRF, and 4-45 days from a SNF—are treated as one episode of care and a single discharge payment is made to the LTCH. The 25-percent threshold payment adjustment, with some exceptions, adjusts payments if more than 25 percent of the discharges from an LTCH that is either a "hospital within a hospital" or a satellite that is co-located with a host hospital are admitted from that host hospital. Payment for discharges in excess of that 25-percent threshold would be the lesser of the payment for the MS-LTC-DRG or the amount that Medicare would have paid under the IPPS.

payment percentage. CMS states that it would develop a notification process through subbregulatory guidance.

CMS also notes that beginning in FY 2020, the statute requires that LTCHs failing to meet the "at least 50 percent" threshold would be paid an IPPS equivalent amount. CMS is also required to provide notice to LTCHs with a "discharge payment percentage" that does not meet the threshold. CMS also has the authority, under the statute, to establish a "reinstatement" process through which an LTCH can be "reinstated" and resume receiving standard LTCH payments or "site neutral" payments, as applicable. Because this statutory requirement is not effective until FY 2020, CMS notes that it did not make any proposal related to the limitation requirement or the process for reinstatement, but did invite public comment.

One commenter requested clarification about whether the definition of the discharge payment percentage included Medicare Advantage beneficiaries. Several commenters requested that CMS develop internal procedures and instructional mechanisms that explain how LTCHs will be notified of their discharge patient percentage through rulemaking. In response, CMS clarifies that the LTCH's discharge payment percentage under new §412.522(d)(1) would not include Medicare Advantage patients in either the numerator or denominator of that ratio. CMS also states that it would take into consideration the comments it receives regarding how to notify LTCHs of their discharge payment percentage and notes that the development of operational guidance does not require rulemaking, but that it would continue to engage stakeholders on this issue.

G. Additional LTCH PPS Policy Considerations Related to the Implementation of the Site Neutral Payment Rate

1. MS-LTC-DRG Relative Payment Weights

CMS finalizes its proposal that beginning with FY 2016, the annual recalibration of the MS-LTC-DRG relative payment weighting factors will be determined using only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases), or that would have met the criteria had the new dual rate LTCH PPS payment structure been in effect at the time of discharge. CMS will continue to apply the existing budget neutrality requirement for the annual changes to the MS-LTC-DRG classifications and relative payment weights. CMS believes that this approach would result in the most appropriate payments under the new statutory structure and is consistent with the stakeholder input CMS received on this issue in the FY 2015 rulemaking cycle.

Several commenters, including MedPAC, were generally supportive of computing the MS-LTC-DRG relative payment weights using only data from LTCH PPS standard Federal payment rate cases. Other commenters believed that the calculation of MS-LTC-DRG weights should be based on all LTCH cases in FY 2016, and then transition to using only data from LTCH PPS standard Federal payment rate cases. Some commenters believed that the budget neutrality requirement should not be included until the new payment system is in place for a few years. In response, CMS appreciates the support, but did not agree that it was necessary to use all LTCH cases in FY 2016 to set relative payment weights for payment stability. CMS also disagrees with

commenters' suggestion to delay the budget neutrality requirement as was done when LTCHs moved from cost-based payments to prospective payments. CMS finalizes its proposals without modification.

2. High-Cost Outliers

CMS historically set the HCO threshold before the beginning of the year so that total estimated HCO payments are projected to equal 8 percent of estimated total payments under the LTCH PPS. CMS solicited comments and performed its own evaluation to determine how to structure its HCO policy under the dual-rate LTCH PPS payment structure required by statute. Specifically, this included examining whether to continue having a single fixed-loss amount or whether it would be more appropriate to have two separate HCO targets (one for LTCH PPS standard Federal payment rate cases and one for site-neutral payment rate cases). CMS actuaries and commenters note that the type of site neutral payment rate cases may change in cost and severity over time in response to the new statutory payment structure because the payment for those cases would generally be lower than the current payment made under the LTCH PPS for these types of cases.

CMS believes that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. Thus, for FY 2016, CMS finalizes its proposal to set fixed-loss amount for site neutral payment rate cases the same as the IPPS fixed-loss amount for that year – in 2016 this equals $22,544. CMS also finalizes its proposal that site neutral payment rate cases would receive an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the site neutral payment rate HCO threshold, which would be the sum of site neutral payment rate for the case and the fixed-loss amount for such cases. CMS also finalizes its proposal that HCO payments to site neutral payment rate cases would be budget neutral, consistent with the current LTCH PPS HCO policy and proposes to apply a budget neutrality factor to these cases. The budget neutrality adjustment for estimated HCO payments to site neutral payment rate cases will only be applied to the site neutral payment rate portion of the transitional blended rate payment.

CMS did not propose any modifications to the HCO methodology as it applies to the LTCH PPS standard Federal payment rate cases other than determining a fixed-loss amount using only data from LTCH PPS standard Federal payment rate cases. CMS establishes a fixed-loss amount of $16,423 for LTCH PPS standard Federal payment rate cases for FY 2016.

Several commenters disagreed with the CMS proposed approach of adjusting all payments for site neutral payment rate cases in FY 2016 (that is, both the site neutral payment rate and the LTCH PPS standard Federal payment rate portions of the transitional blended rate payment) by a budget neutrality factor for estimated HCO payments payable to the site neutral payment rate cases. These commenters stated that the budget neutrality adjustment for estimated HCO payments to site neutral payment rate cases should only be applied to the site neutral payment rate portion of the transitional blended rate payment (and not applied to the LTCH PPS standard Federal payment rate portion of the transitional blended rate payment). In addition, commenters believed that the calculation of the HCO payments to site neutral payment rate cases includes a technical error. That is, the commenters stated that the calculation of the percentage of estimated

site neutral payment rate case HCO payments for FY 2016 of 2.3 percent appears to be based on estimated HCO payments for site neutral payment rate cases *before* applying the transitional blended rate payment.

In response, CMS agrees with the commenters with respect to the application of the budget neutrality factor and modifies its proposal to apply the budget neutrality adjustment for estimated HCO payments for site neutral payment rate cases only to the site neutral payment rate portion of the transitional blended rate payment. As a result of this modification CMS made conforming changes to its proposed codification of this policy under new §412.522(c)(2)(i) to specify that the site neutral payment rate HCO budget neutrality adjustment does not include the portion of the blended payment rate described in new §412.522(c)(3)(ii). In addition, CMS agrees that its calculation of HCO payments to site neutral payment rate cases includes a technical error and has included the necessary correction (calculated as 5.1 percent) in the calculation of its estimate of HCO payments for site neutral payment rate cases in the final rule.

3. Limitation on Charges to Beneficiaries

CMS finalizes its proposal to revise §412.507 to limit allowable charges to Medicare beneficiaries whose discharge from the LTCH is paid under the site neutral payment rate. CMS notes that, in general, the LTCH PPS payment an LTCH receives at the site neutral payment rate represents a full payment for purposes of determining allowable beneficiary charges for covered services. CMS finalizes revisions under §412.507 to limit allowable charges to beneficiaries and revise the terminology to differentiate between cases paid under the site neutral payment rate and those paid under the LTCH PPS standard Federal payment rate.

Specifically, CMS specifies that if Medicare has paid the full site neutral payment rate for a discharge, an LTCH may only charge the beneficiary applicable deductibles and copay amounts until the high-cost threshold is met. LTCHs may charge the beneficiary for noncovered services in the same manner as if the case were paid under the LTCH PPS standard Federal payment rate. CMS did not receive any comments on proposed changes to its limits on charges to beneficiaries and adopts its policies, without modification.

H. Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2016

1. Patient Classification into MS-LTC-DRGs

CMS continues to use the same MS-DRG classification system used for the IPPS payments for the LTCH PPS (MS-LTC-DRG). CMS notes, however, under the dual-rate LTCH PPS payment structure required by statute, that the annual recalibration of the MS-LTC-DRG relative payment weighting factors would be determined using only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate. As noted elsewhere in this summary, CMS increases the number of MS-DRGs from the current 753 to 758. 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. This includes that providers will being using the code sets under the ICD-10 coding system to report diagnoses (ICD-10-CM codes) and

procedures (ICD-10-PCS-codes) for Medicare hospital inpatient services under the MS-DRG system (and the MS-LTC-DRG system) beginning October 1, 2015. CMS did not receive any comments on the LTCH data used to determine the relative weights for MS-LTC-DRGs for FY 2016, and adopted those proposals as final without change.

2. Volume-related adjustments

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

- If a MS-LTC-DRG has at least 25 cases, it is assigned its own relative weight (CMS finds that there are 140 such MS-LTC-DRGs).
- If a MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges (CMS finds that there are 251 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 those weights to each MS-LTC-DRG assigned to the quintile. (See Table 13A at the Table link provided below for these low-volume MS-LTC-DRGs.)
- If a MS-LTC-DRG has zero cases (CMS finds that there are 342 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. This total excludes the 8 transplant, 2 "error" and 15 "psychiatric or rehabilitation" MS-LTC-DRGs. (See Table 13B at the Table link provided below for these zero-volume MS-LTC-DRGs.)

CMS 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. CMS also will assign a 0.0 relative weight for the 2 "error" MS-LTC-DRGs (998 and 999) because these cannot be properly assigned to a MS-LTC-DRG group. CMS notes it will not calculate a weight for the 15 "psychiatric and rehabilitation" MS-LTC-DRGs because these MS-LTC-DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. To determine a transitional payment for FY 2016, CMS finalizes its proposal to use the FY 2015 relative weight for these MS-LTC-DRGs.

Commenters generally supported the CMS proposal to adopt the FY 2015 relative weights for the "psychiatric or rehabilitation" MS-LTC-DRGs. However, commenters noted that the proposed FY 2016 weights for these MS-LTC-DRGs listed in the proposed rule were not the FY 2015 relative weights. CMS in response acknowledges the support and notes that the commenters were correct that Table 11 in the proposed rule contained technical errors for the MS-LTC-DRGs and that it has corrected this error in Table 11 of the final rule. CMS finalizes its policy.

3. Determining relative weights in the MS-LTC-DRGs

In computing the relative weights, CMS continues its prior policy to exclude data on 10 all-inclusive rate providers, one LTCH that is paid under demonstration projects, and all Medicare

Advantage claims that would have met the criteria for exclusion from the site neutral payment rate.

CMS continues two long-standing policies for setting the relative weights of the MS-LTC-DRGs in a manner different from the IPPS.

- CMS calculates 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. The relative weights will be based on only data from LTCH discharges that meet the criteria for exclusion from the site neutral payment rate.
- CMS continues to set the relative weights based on a hospital-specific relative-value (HSRV) methodology, because CMS finds that LTC facilities often specialize in certain services that have the potential to distort charge differences among facilities.

CMS continues its policy of calculating the relative weights by first removing cases with a length of stay of 7 days or less and then removing statistical outliers (charges outside of 3.0 standard deviations from the mean). CMS notes in this final rule that, based on comments received, it found an inadvertent error in the order in which it had been presenting steps 1 and 2 of the methodology.- Previously it had presented the order as removing the statistical outliers first in the process. CMS notes in its calculations it had completed the steps correctly, and that this was merely a presentation error.

CMS continues to adjust for the effect of SSO cases (cases with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) 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 continues to adjust in cases where it finds that relative weights within an MS-LTC-DRG decrease as severity increases within the DRG (a "nonmonotonic" relative weight). CMS, in such cases, combines severity levels within such a base MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained.

4. Budget Neutrality Factor

Consistent with prior policy, CMS continues a two-step budget neutrality adjuster for the annual update to the MS-LTC-DRG classifications and relative weights. That adjuster first includes a normalization adjustment (1.27929) that CMS applies to the recalculated relative weights to ensure that the recalibration does not change the average case mix index. CMS then applies a budget neutrality adjustment of 1.0033952. CMS did not receive any comments on this issue and adopts this policy as final without modification.

I. LTCH PPS Standard Federal Payment Rates for FY 2016

1. Annual Market Basket Update

Using the FY 2009-based LTCH-specific market basket, CMS finalizes a market basket update of 2.4 percent for FY 2016 based on IGI's second quarter 2015 forecast. This is lower than the 2.7 percent projected in the proposed rule, which was based on IGI's first quarter 2015 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.

CMS finalizes a full market basket update of 2.4 percent, with several adjustments.

- CMS finalizes a 0.5 percentage point decrease for the multi-factor productivity adjustment called for under the ACA.
- CMS finalizes an additional downward adjustment of 0.2 percentage points as called for under sections 1886(m)(3)(A)(ii) and 1866(m)(4)(E).

That yields an update of 1.7 percent for FY 2016.

2. Adjustment for LTCHs not reporting quality data

CMS finalizes its proposal to implement the 2 percentage point reduction for LTCHs not reporting required quality data.

- Hospitals reporting the required quality data would receive the 1.7 percent update noted above;
- Hospitals not reporting the required quality data would receive a -0.3 percent update (1.7 percent minus 2.0 percentage points).

CMS indicates that it does not have sufficient information to determine the precise number of LTCHs that would not be able to report the quality data for FY 2016. CMS notes that at the time its analysis was prepared 47 of the 442 Medicare LTCHs (approximately 10 percent) did not receive the full annual percentage increase for FY 2015.

3. Area wage levels and wage index

CMS finalizes a labor-related share of 62.0 percent based on the most recent IGI's second quarter 2015 projection for the FY 2009-based LTCH market basket. The components of the labor-related share are as follows:

FY 2016 Labor-Related Share Relative Importance	
Wages and Salaries	44.6
Employee Benefits	8.1
Professional Fees: Labor-Related	2.2
Administrative and Business Support Services	0.5
All Other: Labor-Related Services	2.5
Subtotal	57.9
Labor-Related Portion of Capital Costs (46%)	4.1
Total Labor-Related Share	**62.0**

CMS specifies the labor-related share to one decimal place, which is consistent with its approach for the IPPS labor-related share and the LTCH market basket update.

CMS continues to compute the wage index in a manner consistent with prior years, applicable to the LTCH PPS standard Federal payment rate cases. Further, CMS calculates a budget neutrality adjustment, computed as in prior years but using data only from LTCH PPS standard Federal payment rate cases, of 1.000513 for FY 2016.

CMS also continues to use the CBSA-labor market area delineations adopted in FY 2015 to determine the appropriate area wage index to use based on the geographic classification (labor market area) in which the LTCH is located. These labor market areas are based on the most recent OMB labor market area delineations that use the 2010 Census data. The 1-year blended wage index that CMS used to mitigate the potential negative impacts from adopting the new labor market areas expires at the end of FY 2015.

4. LTCH PPS Standard Federal Payment Rate

Based on the market basket update, budget neutrality adjustment, and quality reporting requirement, CMS finalizes the following LTCH PPS standard federal payment rates for FY 2016:

- Hospitals reporting the required quality data would receive an LTCH PPS standard Federal payment rate of $41,762.85 (calculated as $41,043.71*1.017*1.000513).
- Hospitals not reporting the required quality data would receive an LTCH PPS standard Federal payment rate of $40,941.55 (calculated as $41,043.71*0.997*1.000513).

5. COLA Updates for Alaska and Hawaii

For FY 2016, CMS continues to use the COLA factors for Alaska and Hawaii that were established in the FY 2014 final rule. CMS notes that it updates COLA factors for LTCHs in Alaska and Hawaii every 4 years 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 continues to use the statutorily mandated cap of 25 percent on the adjustments.

Cost-of-Living Adjustment Factors for Alaska and Hawaii Hospitals for the LTCH PPS for FY 2016	
Alaska	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

6. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the new statutory dual-rate LTCH PPS payment structure, CMS establishes two separate HCO targets—one for LTCH PPS standard Federal payment cases and one for site neutral payment rate cases. For standard Federal payment rate cases, CMS establishes a fixed-loss amount and target for LTCH PPS standard Federal payment rate cases using the current LTCH PPS HCO policy, but limits the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges. CMS finalizes its proposal to continue payments for high cost outlier (HCO) cases if the estimated cost of a case exceeds a threshold amount, which is the adjusted LTCH PPS payment for the MS-LTC-DRG plus a fixed-loss amount. In such cases, CMS makes a payment that is 80 percent of the difference between the estimated cost of the case and the outlier threshold amount.

CMS computes the fixed-loss amount so that projected outlier payments are 8 percent of projected total LTCH PPS payments. CMS establishes a fixed loss amount of $16,423 for FY 2016. CMS notes that the proposed fixed-loss amount is higher than the $14,972 fixed loss amount for FY 2015, and is largely attributable to the implementation of the new statutory dual-rate LTCH PPS payment structure. CMS also states that the increase was necessary to maintain the existing requirement that estimated outlier payments equal 8 percent of total LTCH PPS payments.

CMS continues to calculate the estimated cost of the case by multiplying the Medicare allowable covered charge by the hospital's overall cost-to-charge ratio (CCR). The CCR methodology is also used in determining payments for SSO cases. In general, CMS uses the hospital's CCR, but if the hospital's CCR is in excess of a CCR ceiling, CMS uses the statewide average CCR instead. For FY 2016, CMS establishes a CCR ceiling of 1.335. The statewide average is also used if CMS is unable to determine a CCR for a hospital (for example, new LTCHs or hospitals with missing or faulty data). Table 8C in the final rule (see Table link provided below) shows the statewide average CCRs for urban and rural hospitals for FY 2016.

Commenters supported the CMS proposals to apply the existing HCO policy to LTCH PPS standard Federal payment rate cases, including the 8 percent HCO payment percentage target. However, some commenters requested a different approach to calculating the fixed-loss amount for these cases – stating that CMS include all of the cases in the historical data that would have been paid had the FY 2016 LTCH PPS been in effect at the time of the discharge. In response, CMS appreciates the commenters' support of its proposal, but disagreed with the commenters' suggestion about an alternative approach to computing the fixed-loss amount. CMS believes the commenters' approach would lead to less stability in the fixed-loss amounts between FY 2016 and FY 2017. CMS finalizes its proposal.

7. Update to the IPPS Comparable/Equivalent Amounts to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

Under the LTCH PPS and consistent with its historical practice, CMS establishes that the calculation of the "IPPS comparable amount" under §412.529 and the "IPPS equivalent amount" under §412.534 and §412.536 will include an applicable operating Medicare DSH payment amount that will be equal to 72.77 percent of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act. CMS believes that this approach results in appropriate payments under the LTCH PPS and is consistent with its intention that the "IPPS comparable amount" and the "IPPS equivalent amount" under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care.

J. Moratorium on the Establishment of LTCHs and LTCH Satellite Facilities and on the Increase in the Number of Beds in Existing LTCHs or LTCH Satellite Facilities

The Protecting Access to Medicare Act of 2014 (PAMA) amended section 114(d) of the MMSEA by adding a "new" statutory moratorium on the classification and establishment of new LTCHs and LTCH satellite facilities, and on the increase in the number of hospital beds in existing LTCHs and LTCH satellite facilities. The new moratorium, established under section 114(d)(7) of the MMSEA, runs for the period beginning April 1, 2014, and ending September 30, 2017.

Under the new PAMA moratorium, there are no exceptions provided for increases in the number of hospital beds in existing LTCHs and LTCH satellite facilities; thus as of April 1, 2014, an existing LTCH may not increase its number of hospital beds through September 30, 2017. The only exception to the new PAMA moratorium is for the establishment and classification of new LTCHs and LTCH satellite facilities, and that exception is subject to meeting the following criteria:

Before April 1, 2014, a hospital or entity must:

1. Have begun its qualifying period for payment as an LTCH under §412.23(e);
2. Have a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for an LTCH, and must have expended before April 1, 2014, at least 10 percent of the estimated cost of the project or, if less, $2,500,000; and
3. Have obtained an approved certificate of need in a State where one is required.

CMS clarified in the proposed rule that the existing regulation text regarding the moratorium on the establishment and classification of new LTCHs and LTCH satellite facilities only requires that one of the three exceptions had to be met in order to qualify for an exception to the moratorium. CMS stated that the existing regulation text could be misread as requiring all three conditions to qualify for an exception and to minimize any confusion CMS revised the regulations under §412.23(e)(6)(ii) to more accurately convey the established policy that only one of the statutory conditions, as applicable, needs to be met in order to qualify for the

exception to the new moratorium on the establishment of new LTCH and LTCH satellite facilities.

CMS states that it has also become aware of confusion concerning what constitutes the "estimated cost of the project" with regard to the second exception. CMS states that the "cost of the project" includes the enumerated activities specified in the second prong of the exception: "actual construction, renovation, lease, or demolition for a long-term hospital." CMS clarifies in that in using "or" in this list of activities, CMS intended to acknowledge that any one project may or may not include every element listed (for example, new construction may not include any demolition), but if it does include an element, CMS' policy is that the cost of that element and the costs of any other of the listed elements in the project are to be summed to determine the total cost of the project.

CMS also provides additional clarification on its policy concerning the moratorium on increases in the number of beds in existing LTCH and LTCH satellite facilities. CMS states if an existing LTCH meets one of the statutory exceptions and opens a new LTCH satellite facility during the moratorium, that new LTCH satellite facility's beds must come from the movement of beds in existence prior to April 1, 2014, from other locations of the existing LTCH to the new LTCH satellite facility. The total number of beds cannot exceed number that existed prior to April 1, 2014. CMS notes that this requirement also applies to any remote locations that may be established by an existing LTCH during the moratorium on new beds.

Several commenters expressed concern with how CMS articulated the existing policy and believes that CMS was proposing to change policy rather than clarify existing policy. CMS disagrees with any assertion that the clarification in the proposed rule represents a change in policy. CMS seeks to reiterate its existing policy stating that without exception, an LTCH may not increase the total number of Medicare certified beds beyond the number that existed prior to April 1, 2014. The number of Medicare certified beds in an LTCH includes beds in all locations, including, as applicable, satellite facilities.

K. Changes to Average Length of Stay Criterion

CMS finalizes its proposal to revise §412.23 to implement the statutory changes to the calculation of the average length of stay for an LTCH under section 1206(a)(3) of Pub. L. 113-67. As required by statute, in order for a hospital to be classified as an LTCH, it must maintain an average length of stay of greater than 25 days, which is calculated by dividing the total number of covered and noncovered Medicare inpatient days by the total number of Medicare discharges. This calculation currently includes Medicare inpatient days and discharges that are paid under an MA plan.

CMS finalizes its proposal to revise §412.23 by adding a new paragraph (e)(3)(vi) to specify that Medicare inpatient days and discharges paid at the site neutral payment rate or under an MA plan will not be included in the calculation of an LTCH's average length of stay. Furthermore, CMS adds a new paragraph (e)(3)(vii) to §412.23 to specify that the provisions only apply to a hospital that is classified as of December 10, 2013, as a long-term care hospital.

CMS did not receive any public comments on this proposal. However, CMS, upon further consideration, realized that section 112(c)(2) of Pub. L. 113-93 altered the "subsection (d) hospital" language established by section 1206(a)(3)(B) of Pub. L.113-67 to "long-term care hospital." CMS waived notice-and-comment rulemaking for this change (replacing "subsection (d) hospital" with "long-term care hospital") in the proposed rule's text, finalizing that change, and otherwise finalizing the remaining proposed regulation text changes in §412.23 without modification.

L. Impact of Payment Rate and Policy Changes to LTCH PPS Payments for FY 2016

1. CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2015 to FY 2016, would result in a decrease of 4.6 percent or $250 million in aggregate payments (decrease in aggregate payments from $5.40 billion to $5.15 billion). This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $50 million and the projected decrease in payments to site neutral payment rate cases of approximately $300 million under the new dual-rate LTCH PPS payment rate structure required by the statute beginning in FY 2016. CMS modeling assumes that approximately 54 percent of LTCH cases would meet the criteria for exclusion from the site neutral payment rate (that is, those cases would be paid the LTCH PPS standard Federal payment rate) and approximately 46 percent of LTCH cases would be paid the site neutral payment rate (calculated using FY 2013 LTCH claims data).

CMS states it was unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail. Thus, Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2016" in the final rule shows the detail impact by location, participation date, ownership type, region, and bed size (see page 2106 of the display copy) for only LTCH PPS standard Federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases.

The overall impact of LTCH PPS standard Federal payment rate cases results in an increase in aggregate LTCH payments in FY 2016 relative to FY 2015 of approximately $50 million ($684 payment per discharge increase*73,745 discharges). LTCHs located in the New England region would have the largest positive increases (2.6 percent), largely attributable to changes in the area wage level adjustment.

Summary of Impact of Changes to LTCH PPS for Standard Federal Payment Rate Cases for FY 2016 *		
LTCH Classification	Number of LTCHs	Estimated percent change in payments per discharge
All LTCH providers	419	+1.5%
By Location:		
Rural	21	+0.9
Urban	398	+1.5%
By Ownership Type:		
Voluntary	78	+1.6%
Proprietary	326	+1.5%
Government	15	+1.8%
By Region		
New England	13	+2.6%
Middle Atlantic	29	+0.8%
South Atlantic	61	+1.3%
East North Central	69	+1.4%
East South Central	34	+1.2%
West North Central	25	+1.4%
West South Central	130	+1.7%
Mountain	33	+1.4%
Pacific	25	+1.8%
*More detail is available in Table IV, "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Federal Payment Rate Cases, FY 2016", (see page 2106 of display copy).		

2. Tables

The complete set of tables providing detail on the LTCH PPS for FY 2016 is at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Regulations-and-Notices-Items/LTCH-PPS-CMS-1632-F.html

The information at that link provides:

- Table 8C: Statewide average cost-to-charge ratios (CCRs) for LTCHs (Urban/Rural)
- Table 11: MS-LTC-DRGs, relative weights, geometric average length of stay, SSO threshold, and IPPS comparable threshold for FY 2016
- Tables 12A: LTCH PPS Wage Index for Urban Areas for FY 2016
- Tables 12B: LTCH PPS Wage Index for Rural Areas for FY 2016
- Table 13A: Composition of low-volume quintiles for MS-LTC-DRGs for FY 2016
- Table 13B: No volume MS-LTC-DRG crosswalk for FY 2016 LTCH PPS FY 2016 Impact File

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, changes are made to quality reporting programs for acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. In addition, changes are adopted, with modifications from the proposed rule, to align hospital quality reporting requirements with the meaningful use requirements under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

A. Hospital Inpatient Quality Reporting (IQR) Program

CMS adopts a number of changes to the Hospital IQR Program, including a measure set for the FY 2018 payment determination that includes 43 measures which are specifically required, plus a requirement for reporting of 4 out of 28 electronically-specified measures. For FY 2019 payment, three additional measures will be required. Table VIII at the end of this section shows these final measure sets, and for reference the IQR Program measure sets for the FY 2016 and FY 2017 payment determinations are also included.

1. Criteria for Removal and Suspension of Hospital IQR Program Measures

In general, once a measure is adopted for the IQR Program it is retained for future years. In past rulemaking CMS has identified a series of factors it considers in determining when to propose a measure for removal. While these are factors to be taken into account, CMS notes they are not firm requirements. In this rule, CMS finalizes changes to the factors it will consider in determining whether a measure should be removed or retained. The criteria are summarized below, and an asterisk indicates newly finalized factors. One previously identified factor ("Availability of alternative measures with a stronger relationship to patient outcomes") was removed because it is duplicative.

Measure Removal Factors:
* = newly finalized

1. Meaningful distinctions and improvements in performance can no longer be made (''topped-out" measures)
2. Measure does not align with current clinical guidelines or practice
3. Availability of a more broadly applicable measure
4. Measure performance or improvement does not result in better patient outcomes
5. Availability of a measure more strongly associated with desired patient outcomes 6. Collection or public reporting leads to negative unintended consequences other than patient harm
7. It is not feasible to implement the measure specifications*

Measure Retention Factors:

1. Measure aligns with other CMS and HHS policy goals*
2. Measure aligns with other CMS programs, including other quality reporting programs or the EHR Incentive Program
3. Measure supports efforts to move facilities towards reporting electronic measures

2. Removal of Measures for the FY 2018 Payment Determination and Subsequent Years

CMS finalizes the proposed removal of nine measures from the IQR Program beginning with the FY 2018 payment determination. These are shown in the table below. Six of the measures were identified by CMS as meeting the statistical test as "topped out." Data collection had previously suspended on two of the three removed measures: The pneumococcal immunization measure was suspended because as specified it is no longer in compliance with clinical guidelines issued by the Advisory Committee on Immunization Practices, while numerous stakeholders expressed concern about the clinical specifications for SCIP-Inf-4, Cardiac Surgery Patients with Controlled Postoperative Blood Glucose, which led to its suspension in July 2014. The final measure removed (AMI -7a regarding fibrinolytic therapy) is infrequently reported by hospitals because most acute myocardial infarction patients receive percutaneous coronary intervention instead of fibrinolytic therapy.

For six newly removed chart-abstracted measures (STK-06, STK-08, VTE-1, VTE-2, VTE-3, and AMI-7a) CMS will retain the electronic clinical quality measures (eCQM) version. CMS notes that the electronically specified versions of these measures are reported with non-zero values by as many as 2,864 hospitals attesting under the 2014 meaningful use program and that hospitals report on the full range of available eCQMs. Retaining the measures will align the Hospital IQR Program with the Medicare EHR Incentive Program, allow CMS to monitor the effectiveness of measure reported by EHRs, and help hospitals gain experience with reporting electronically specified measures. In response to various concerns raised regarding electronically specified measures, CMS indicates that it will consider removing electronic measures from IQR Program reporting in future rulemaking, possibly including the following: VTE-3; VTE-4; VTE-5; VTE-6; PN-6; Healthy Term Newborn; AMI-7a; SCIP-INF-9; CAC-3; AMI-2; AMI-10; SCIP-INF-1a; SCIP-INF-2. (As discussed in item 7 below, CMS modified its proposal regarding mandatory electronic reporting to require that only four of the 28 eCQMs be reported instead of the proposed requirement for 16 measures.)

Measures Removed for the FY 2018 Payment Determination and Beyond
Topped Out Measures
STK-01: Venous Thromboembolism (VTE) Prophylaxis (NQF #0434)
STK-06 Discharged on Statin Medication (NQF #0439) – eCQM retained
STK-08 Stroke Education – eCQM retained
VTE-1 Venous Thromboembolism Prophylaxis (NQF #0371) – eCQM retained
VTE-2 Intensive Care Unit VTE Prophylaxis (NQF #0372) – eCQM retained
VTE-3 VTE Patients with Anticoagulation Overlap Therapy (NQF #0373) – eCQM retained
Measures Removed for Other Reasons
IMM-1 Pneumococcal Immunization (NQF #1653) – previously suspended
AMI-7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival* (NQF #0164) – eCQM retained
SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300) – previously suspended

In the proposed rule CMS noted that an additional measure (IMM-2: Influenza Immunization) has been found to be topped out, but it did not propose to remove this measure from the IQR Program because it is the only IQR Program measure to address the "Best Practices to Enable Healthy Living" National Quality Strategy (NQS) priority/CMS quality strategy goal, and it supports other NQS priorities and CMS quality strategy goals. Responding to comments opposing its retention, CMS says that it believes that the value of retaining this measure outweighs the burden associated with collection.

3. NHSN Measures Standard Population Data

CMS included in the proposed rule discussion of the CDC's plans to update the standard population data used to estimate predicted infections in calculating the Standardized Infection Ratios (SIRs) for various NHSN healthcare-associated infection measures that are included in the IQR Program. Specifically, beginning in CY 2016, CDC will use data collected for infection events that occurred in 2015 as the new standard population. As noted in section IV.F above, CMS proposes to wait until FY 2019 to reflect the new standard population in the NHSN measures included in the Hospital VBP Program. No parallel proposal is made to delay use of these updated data in the IQR Program. CMS invited public comment although the CDC update was not a Hospital IQR Program proposal.

CMS responds to comments it received noting that due to changes in measure definitions, 2015 CAUTI data may not be reflective of actual infection rates. CMS believes that the CDC's new CAUTI definition, which was developed by a subject matter expert working group, is simplified and less subjective than previous iterations.

CDC has informed CMS that its technical infrastructure includes built-in controls on data entry that serve as safeguards against the reporting of events that do not meet the new CAUTI definition, and that it is confident that the CAUTI data reported in 2015 will be reflective of actual infection rates and appropriate to use for a new standard population.

4. Refinements to Existing Measures

CMS finalizes with significant modification its proposal to modify the two pneumonia-related claims-based measures: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization; and Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization. As finalized, in each case the cohort of patients included in the measure, currently defined to include patients with a principal discharge diagnosis of viral or bacterial pneumonia, will be expanded to also include patients with a principal discharge diagnosis of aspiration pneumonia, and patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia that was POA. CMS had also proposed, but does not finalize, the inclusion of patients with a principal discharge diagnosis of severe sepsis (including septic shock) if pneumonia was POA; and principal discharge diagnosis of respiratory failure if pneumonia was POA. The finalized measures, with the modified expanded cohort, also do not include additional risk variables for the presence of sepsis or respiratory failure in index admission as part of the measures' risk-

adjustment because patients with respiratory failure or severe sepsis will not be included in the finalized measures.

The changes to the proposed rule measure cohort were made in response to public comment and further analysis. Many commenters opposed the proposed changes because the scope of the change was so great and because the expansion group of patients would be more severely ill. Analyses conducted after publication of the proposed suggested that the proposed cohort expansion could exacerbate the bias in the existing measure that it was intended to mitigate. CMS found that differences in coding frequency were associated with measure performance. Specifically, hospitals with the greatest proportion of patients receiving a principal diagnosis of sepsis or respiratory failure had the lowest risk-adjusted mortality and were more likely to be 'better-performing' outliers.

CMS says that for the finalized measures risk-standardization adequately accounted for case-mix differences across hospitals, without being confounded by hospital coding patterns. Furthermore, it believes that the re-specification better reflects clinical patterns of care, because patients with principal discharge diagnosis of severe sepsis or respiratory failure often require care in an ICU and other specialized interventions (such as ventilator support) that make them clinically distinct from the care provided to patients with less severe forms of pneumonia. For the revised measure methodology, CMS refers readers to the AMI, HF, PN, COPD, and Stroke Readmission Updates zip file on its Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

In responding to comments received regarding clinical differences among patients with aspirational pneumonia, CMS says that the variation in use of aspiration pneumonia diagnosis codes reflects the challenges to physicians in differentiating types of pneumonia included in the measure, and that treatment of patients hospitalized for pneumonia, aspiration pneumonia, or sepsis due to pneumonia is very similar. Moreover, it believes the risk adjustment methodology captures associated comorbidities for patients with aspiration pneumonia that have a higher predicted mortality or readmission risk. CMS does not believe that stratification of the measures is needed because hospitals will not be unfairly penalized for treating sicker patients. Its analyses (described in the methodology report available at the link above) found that hospitals with higher rates of patients with sepsis or aspiration pneumonia have similar performance to those with fewer of these patients.

The finalized measures will not expand the population by as much or change the national rate as much as the proposed versions: the modified mortality measure cohort will be approximately 18 percent smaller than what was proposed and the modified readmission measure cohort will be approximately 15 percent smaller than what was proposed. (In the proposed rule CMS estimated that the refinements would expand the cohort of included patients by 70 percent for the mortality measure and 61 percent for the readmission measure.)

Responding to a comment, CMS clarifies the status of the Sepsis Management Bundle measure (NQF #0500), which was suspended from IQR Program data collection in August 2014. On March 26, 2015 CMS issued a notification announcing that hospitals are required to submit data on the Sepsis Bundle measure for the Hospital IQR Program beginning with October 1, 2015

discharges for the FY 2017 payment determination and subsequent years based on updates to the measure and subsequent NQF re-endorsement. Changes to the specifications have been made centering on the measure's composite "Element F," permitting reassessment of volume and perfusion through a physical exam.

5. New Measures for the FY 2018 Payment Determination and Subsequent Years

Seven of eight proposed new measures are finalized for addition to the IQR Program, four beginning with the FY 2018 payment determination, and three episode-based payment measures delayed until the FY 2019 payment. The seven measures include six claims-based measures relating to Medicare payments or utilization for specific clinical conditions, and one structural measure. A proposed claims-based measure relating to lumbar spine fusion/refusion is not finalized. None of the newly adopted measures is NQF-endorsed. CMS reiterates its authority to adopt non-endorsed measures and its view that consensus among affected parties also can be achieved during the measure development process, through broad acceptance and use of measures, and through public comment. A link to information on the measure methodologies is provided: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

Hospital Survey on Patient Safety Culture. This measure will be reported annually by hospitals through a web-based survey tool on the QualityNet website. Questions cover whether (and how frequently) the facility administers a detailed assessment of patient safety culture using a standardized collection protocol and structured instrument; the name of the survey; whether results are reported to a central location; the number of staff who were requested to complete the survey and response rates. The MAP supported inclusion of this measure in the IQR Program. The initial data collection period (for the FY 2018 payment determination) is CY 2016, with data submission occurring in CY 2017.

In responding to comments, CMS agrees that this measure does not itself assess the safety cultures of hospitals, it says that it will assess whether and which patient safety culture surveys are being used by hospitals and how frequently, which is a necessary first step in determining whether a specific survey indicating hospital scores could be implemented in the future.

With respect to the proposed spinal fusion/re-fusion clinical episode measure that is not finalized in this rule, CMS agrees with commenters that additional refinements are needed to account for the variety of patient clinical presentations and ensure appropriate measurement across hospitals. Procedure codes do not adequately account for the heterogeneity among beneficiaries who experience episodes for the measure. Refinements might include stratification to address differences in reasons for surgery (for example, elective vs. emergency). CMS plans to continue development of this measure and discussion with clinical experts and may propose it again in future rulemaking.

As noted above, the three clinical based episode payment measures are finalized for the FY 2019 payment determination, a year later than proposed. Responding to comments, CMS will provide hospitals with confidential hospital-specific feedback reports and supplemental files containing performance data for CY 2016 on the three new clinical episode-based payment measures similar

to the report provided on the MSPB measure. In addition, CMS indicates that it will post a measure reliability analysis and that prior to public reporting of these measures it will propose in future rulemaking a minimum number of cases to ensure reliability of publicly-reported data.

CMS disagrees with comments regarding the ability of hospitals to affect performance on these measures. As with the MSPB measure, CMS believes that all hospitals, regardless of the degree of integration, can achieve efficiencies by providing quality inpatient care, appropriate discharge planning and working with other providers on follow-up care. It also notes that these measures respond to concerns about the MSPB measure in that the services included are only those clinically related to the reason for the hospital admission. They are viewed by CMS as companions to the MSPB that allow patients and payers to make more fully informed comparisons of hospitals' performance and provide hospitals with actionable feedback with which to target improvements. Further, data on physician performance on these measures are reported in the confidential feedback reports that CMS provides physicians and group practices.

Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA. This measure uses three years of data to assess hospital risk-standardized payments associated with THA/TKA over 90 days beginning with the date of an index admission. An episode includes all payments for the initial 30 days of the episode, and all payments for a predefined set of care settings and services for days 31 through 90. Payments include those made by CMS, patients, and other insurers. The existing THA/TKA complication measure captures specific complications up to 90 days after admission, and the measure cohort generally aligns with that measure. CMS intends to report hospital performance on this new measure on *Hospital Compare* along with THA/TKA complication measure performance.

Responding to comments questioning validity, reliability and feasibility of the measure, CMS discusses the validity of Medicare claims data, the role of the technical expert panel it convened regarding this measure, the similarities to NQF-endorsed episode payment measures for AMI, heart failure and pneumonia and the MSPB measure.

CMS believes the measure provides actionable information to hospitals and to consumers. Because it includes only elective procedures, providers have an opportunity to plan for care during the episode such as follow-up visits and choice of postacute providers. Moreover, CMS believes that quality of care during the hospital stay affects the need for post-discharge services. For beneficiaries, CMS believes transparency in episode payments provides information about variation in costs of care that can inform patient decisions, especially when paired with performance on the corresponding THA/TKA complications measure.

Two new measures of excess days in acute care (EDAC) after a hospital stay. Two new measures will each use three years of data to assess outcomes (for AMI and heart failure, respectively) that account for the full range of acute care use that patients may experience post-discharge: hospital readmissions, observation stays, and ED visits. Specifically, each measure compares the number of days that patients with that condition (AMI or heart failure) are predicted to spend in acute care (including unplanned hospital readmissions, observation stays, and ED visits) within 30 days after discharge from a hospital, compared to the acute care days expected based on their degree of illness.

The measures are calculated as a rate of "excess days" per 100 discharges. Observation stays are counted by hours in observation rounded up to the nearest half day, and an ED visit (with release on the same day) would be counted as a half day. The cohort of patients for each measure will be almost the same as that used for the related AMI or heart failure readmissions measure, except that patients admitted to Veterans Administration hospitals are excluded. Inclusions and exclusions, calculation of excess acute care days, risk adjustment, and other details are discussed in the rule. The MAP supported these measures conditioned on NQF endorsement, and noted that the appropriateness of an adjustment for sociodemographic status should be considered; CMS intends to submit the measure to NQF, with appropriate consideration of SDS, once an appropriate endorsement project has a call for measures.

Noting comments regarding the interaction between the "2-midnight" policy and the EDAC measures, CMS says that because the measures aim to capture all post-discharge acute care days, regardless of whether they are considered outpatient or inpatient, the 2-midnight policy or related changes have no effect on measure performance.

Responding to numerous other comments objecting to the EDAC measures, CMS states that the measured acute care utilization (that is, return to the ED, observation stay, and readmission) is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. It believes that efforts by hospitals and physicians to engage appropriate care transition processes can reduce use of these services. It emphasizes that the IQR Program is not pay-for-performance, and that the measures are not intended to penalize hospitals or prevent them from keeping patients in the ED or observation units but instead to inform hospitals, physicians and beneficiaries as to the variation in post-discharge use of acute services for these conditions. The measures provide a broader perspective than readmissions alone and are intended to incentivize improvements in care transitions. Accordingly, CMS indicates its intention to publicly report performance on these measures in a straightforward easy-to-understand manner. CMS also states that as part of its regular measure reevaluation, it evaluates whether certain hospitals are negatively affected by the measure.

Regarding risk-adjusting IQR Program measures for SDS, CMS repeats the response it makes elsewhere in the rule regarding its continued concern about the potential for such risk adjustment to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations, and noting its intention to monitor the NQF trial and ASPE research that is underway. (For more detail on this response see IV.F.3 above.)

6. Voluntary Reporting of Electronic Clinical Quality Measures for FY 2017

In the FY 2015 IPPS/LTCH final rule, CMS adopted requirements for voluntary reporting of electronic clinical quality measures under the IQR Program. For participation in IQR Program voluntary electronic reporting in FY 2017, providers must report any 16 of the 28 Hospital IQR Program measures that align with the Medicare EHR Incentive Program measures, as long as the 16 measures span at least three different NQS domains. A hospital that chooses to voluntarily report electronic measures must submit at least one quarter of electronic clinical quality measure data from Q1, Q2, or Q3 of CY 2015. Hospitals have until November 30, 2015 to submit data on

electronic clinical quality measures, regardless of which quarters' data is submitted. CMS will only publish the names of hospitals that successfully submit Q1, Q2 or Q3 electronic clinical quality measure data by November 30, 2015; actual data or performance rates for electronic clinical quality measures will not be posted on *Hospital Compare*.

CMS now clarifies that for the FY 2017 payment determination (CY 2015 data submission), the previously adopted policy will continue regarding the measure STK-01. That is, hospitals that chose to submit the STK-02, STK-03, STK-04, STK-05, STK-06, STK-08, and STK-10 as electronic clinical quality measures are not required to also chart-abstract and submit STK-01 in order to meet Hospital IQR Program requirements for the FY 2017 payment determination. However, hospitals that do not submit the specified electronic clinical quality measures must continue to chart-abstract and submit STK-01 as previously required. (As discussed above, STK-01 is removed from the measure set beginning with the FY 2018 payment determination.)

Responding to comments, CMS acknowledges that the measure Stroke Education (STK-08) is no longer NQF endorsed and that The Joint Commission (the measure steward) is not planning to resubmit it for re-endorsement. However, CMS believes that this measure should remain in the IQR Program to promote alignment with the EHR Incentive Program.

7. Required Reporting of Electronic Clinical Quality Measures for FY 2018

CMS finalizes with significant modifications its proposal regarding mandatory reporting of electronic clinical quality measures under the IQR Program beginning with the 2018 payment determination. Specifically, hospitals will be required to select and submit 4 electronic clinical measures from the 28 available measures for 1 quarter (either Q3 or Q4) of CY 2016 for the FY 2018 payment determination, with a submission deadline of February 28, 2017. CMS had proposed that hospitals submit 16 electronic clinical quality measures covering three NQS domains; data would have been reported for both calendar quarters Q3 and Q4 with deadlines of November 30, 2016 and February 28, 2017, respectively. Note that with respect to the 4 measures required under the final rule, no domain coverage requirement applies.

CMS does not finalize its proposal to allow hospitals to elect to report six measures either by chart abstraction or as electronic clinical quality measures for purposes of the IRQ Program 2018 payment determination. The measures that could be reported either way are ED-1, ED-2, STK-04, VTE-5, VTE-6, and PC-01. Reporting of these measures by chart abstraction will continue to be required for purposes of the IQR Program, and performance on these measures will continue to be publicly reported. However, hospitals may choose to also report the electronic version of any of these measures to meet the 4-measure minimum requirement for electronic reporting that is finalized in this rule.

CMS is expanding the Extraordinary Circumstances Extensions/Exemptions policy to allow hospitals to request an exemption from the Hospital IQR Program's electronic clinical quality measure reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting. Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen

circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification). Hospitals newly participating in the IQR Program may also be considered undergoing hardship and can apply for an exemption. In addition to this modification to the extraordinary circumstances policy, CMS notes that the existing zero denominator and case threshold exceptions to electronic reporting will continue to apply.

CMS does not finalize its proposal to indicate in a footnote on *Hospital Compare* that the hospital submitted data via EHR. With respect to public reporting, CMS intends to assess results of the validation pilot test of electronically specified measures, which is expected to be completed later in 2015, and to propose its plans regarding public display of electronic data in next year's rulemaking. Therefore, any public display details would be finalized prior to the February 28, 2017 deadline for electronic clinical quality measure data submission.

Responding to comments, CMS believes that finalizing mandatory electronic reporting is appropriate for the FY 2018 payment determination because 95 percent of hospitals currently attest to successful electronic clinical quality measure reporting under the EHR Incentive Program, and the IQR Program has included 2 years of pilot reporting and 2 years of voluntary reporting of electronic measures. CMS believes its decision to reduce the number of required eCQMs from the proposed 16 to 4 will address concerns of commenters, particularly with respect to resources needed to map the necessary data elements from the EHR to a QRDA format. However, CMS anticipates increasing the number of required measures in future years.

Regarding engagement with stakeholders on the transition to electronic reporting, CMS plans to identify a website where the public will be able to access information on various events it has conducted, referring in particular to annual eCQM kaizen event where experts gather to apply Lean principles to further the development of eCQMs.

8. Future Considerations for Electronically Specified Measures: Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements

Looking forward, CMS is considering the use of core clinical data elements derived from EHRs in future quality measures and in the proposed rule sought comments on these issues. Among other reasons, this approach is considered in response to comments from the clinical community regarding the benefits of using data gathered directly from patients and clinicians for risk adjusting outcome measures.

CMS describes its work in this area, which has involved a Technical Expert Panel and led to identification of a set of 21 core clinical data elements. These are routinely collected on hospitalized adults and CMS states they can be feasibly extracted from hospital EHRs. (The 21 elements are listed in the rule and include age and gender, seven first-captured vital signs, and the results of a complete blood count and basic chemistry panel.) Many potential uses for this approach are envisioned, but CMS has focused first on using them for risk adjustment of outcome measures. CMS has tested these variables by developing two hybrid measures, one a 30-day AMI mortality measure eMeasure, which uses five of the core elements and has received NQF endorsement (NQF #2473), and the other a "hybrid" hospital wide 30-day readmission

measure which uses 14 of the 21 clinical data elements as well as claims data . CMS sought public comment in July 2014 on the hospital-wide readmission measure. In addition to risk adjusting claims-based measures, CMS is considering using core clinical data elements for quality measures that apply to an all-payer population of adults. Any requirement for reporting core clinical data elements would be in the context of specific measures proposed through rulemaking.

CMS is interested in receiving public comments on the potential use of core clinical data elements derived from EHRs in future quality measures. In particular, comments were sought with respect to 1) the use of core clinical data elements derived from EHRs in risk adjustment of outcome measures and other types of measures; 2) the collection of additional administrative variables to enable linkage of EHR data on a patient to claims data for an episode of care (e.g., admission and discharge dates, CMS certification number, date of birth); and 3) use of content exchange standards. With respect to the latter, CMS particularly seeks input on a possible requirement that hospitals use QRDA Category 1 as the standard for transmitting clinical data elements to CMS.

CMS describes a wide variety of comments it received in response to this request, which it will take into consideration in developing future policy. Responding to commenters suggesting that CMS first focus efforts toward ascertaining reliable, consistent, and valid methods of reporting electronic data, so that reporting core clinical data elements could be implemented successfully, CMS notes that interoperability and adoption of updated standards is one of the main tenets of the 2015 Edition Standards and Certification Criteria proposed rule. It describes its work with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data and proposed standards for certified health IT to improve the reliability and consistency of reporting. Any data element requirements for hospital risk-adjusted hybrid measures would be formally proposed in future rulemaking with opportunity for public comment. CMS desires ongoing input from stakeholders and notes that comments and responses from earlier comment requests outside of rulemaking are posted on its website under the download section in the "archived public comment files" folder at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.

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

CMS did not propose any changes to the procedural requirements for the IQR Program previously adopted (and codified at 42 CFR 412.140) or the previously adopted data submission requirements for chart-abstracted measures, HCAHPS, structural measures or measures reported through the CDC NHSN.

With respect to electronically-specified measures, CMS finalizes several changes, with some important modifications from the proposed rule. See item VIII.A.7 above for discussion of the electronic reporting requirement, including expansion of the Extraordinary Circumstances Exceptions policy to include hardships affecting electronic reporting.

- Hospitals may report using either the 2014 or 2015 edition of CEHRT for the CY 2016 reporting period/FY 2018 payment determination. CMS had proposed to continue to require that hospitals use CEHRT 2014 Edition. The change is made in response to a suggestion from commenters.
- Hospitals must adopt the most recent annual electronic measure specifications update prior to data submission. For the 2016 data submission (FY 2018 payment determination), hospitals must submit data using the 2015 Annual Update, regardless of whether 2014 or 2015 CEHRT is used. CMS notes that the later reporting deadline February 28, 2017 for either Q3 or Q4 data gives hospitals more time to update to the 2015 measure specifications.
- Hospitals must report data via QRDA I for 4 of 28 available eCQMs for one quarter (either CY 2016 Q3 or Q4) by the submission deadline of February 28, 2017. While no QRDA version requirement was proposed, CMS received comments suggesting that QRDA I be required or asking for clarification on the QRDA requirement. CMS believes this requirement is consistent with prior policies. QRDA I reporting has been a requirement of 2014 Edition CEHRT under the EHR Incentive Program and for hospitals that chose to voluntarily submit electronic clinical quality under the IQR program. To comply with this requirement, hospitals may use a third party to submit QRDA I files on their behalf, or may pull the data from non-certified sources and then input these data into CEHRT for capture and reporting.

CMS encourages hospitals to work closely with their vendors to ensure that a contract is in place which supports the hospital's quality reporting requirements and the annual update of those measures. Similarly, CMS further encourages hospitals to work with their vendors to ensure support for technical mapping. CMS believes that the minimum requirements for reporting 4 measures for one quarter by February 28, 2017 established in the final rule provide time for hospitals to address these mapping and testing issues with vendors. Readers are referred to https://ecqi.healthit.gov/ecqm for further details on technical requirements and to the HITPC recommendations at http://healthit.gov/FACAS/sites/faca/files/HITPC_QMTF_Presentation_2015-06-3.pdf for additional details regarding eCQM provisions in payment rules.

Section VIII.D below discusses related EHR Incentive Program requirements.

CMS finalizes changes to requirements regarding hospital submission of quarterly aggregate population and sample size data for chart-abstracted measures. Beginning with the 2018 payment determination, hospitals are required to submit these data only for measures that the hospital submits as chart-abstracted measures under the IQR Program. That is, population and sample size data are not required for measures submitted electronically or for any measure that becomes voluntary or is suspended.

10. Data Validation

CMS finalizes changes to data validation for IMM-2: Influenza Immunization measure, which as discussed in section IV.F is removed from the hospital VBP Program. Consistent with that removal, CMS also removes the separate immunization validation stratum it instituted to ensure

that every hospital selected for validation would be validated on this VBP program measure. The Influenza Immunization measure will be included in the clinical process of care measure validation stratum. No changes are made to the overall validation sample size. Eight charts will continue to be required for validation; all of them drawn from the clinical process of care measures, which include STK, VTE, ED, Sepsis, and Immunization. In addition, the validation topic area weights are modified to reflect the removal of the separate immunization stratum. The healthcare associated infection topic area weight remains 66.7 percent; the weight for other/clinical process of care measures increases from 11.1 percent to 33.3 percent.

11. Impact Analysis

When discussing the impact of the IQR Program requirements in the proposed rule, CMS reported that historically an average of 100 hospitals that participate in the IQR Program do not receive the full annual percentage increase in any fiscal year for failure to meet program requirements. The highest number of hospitals failing to meet program requirements was approximately 200 after the introduction of new NHSN reporting requirements. Notably, in the final rule impact analysis, CMS indicates that only 26 hospitals are estimated to not receive the full update factor for FY 2015 either because they failed the quality data submission process or did not choose to participate. Because of the new reporting requirements finalized for the FY 2018 payment determination, CMS anticipates that the number of hospitals not receiving the full annual percentage increase may be higher than average. If so, that number would be expected to reduce over time as hospitals gain experience with the new requirements.

Table VIII. Final IQR Program Measures for Payment Determination in FYs 2016 – 2019
X= required measure *=electronic clinical quality measure

	2016	2017	2018	2019
Chart-Abstracted/Electronic Measures				
AMI-2 Aspirin prescribed at discharge for AMI*	Removed			
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival*	X	X	Removed	
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) *	X	Removed		
AMI-10 Statin at discharge*	Removed			
HF-2 Evaluation of left ventricular systolic function	X	Removed		
PN-6 Appropriate initial antibiotic selection*	X	Removed		
STK-1 VTE prophylaxis	X	X	Removed	
STK-2 Antithrombotic therapy for ischemic stroke*	X	Removed		
STK-3 Anticoagulation therapy for Afib/flutter*	X	Removed		
STK-4 Thrombolytic therapy for acute ischemic stroke*	X	X	X	X
STK-5 Antithrombotic therapy by end of hospital day 2*	X	Removed		
STK-6 Discharged on statin*`	X	X	Removed	
STK-8 Stroke education*	X	X	Removed	
STK-10 Assessed for rehabilitation services*	X	Removed		
VTE-1 VTE prophylaxis*	X	X	Removed	
VTE-2 ICU VTE prophylaxis*	X	X	Removed	
VTE-3 VTE patients with anticoagulation overlap therapy*	X	X	Removed	
VTE-4 VTE patients receiving un-fractionated Heparin with doses/labs monitored by protocol*	X	Removed		
VTE-5 VTE discharge instructions*	X	X	X	X

Table VIII. Final IQR Program Measures for Payment Determination in FYs 2016 – 2019 X= required measure *=electronic clinical quality measure				
	2016	**2017**	**2018**	**2019**
VTE-6 Incidence of potentially preventable VTE*	X	X	X	X
Severe sepsis and septic shock: management bundle		X	X	X
SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision*	X	Removed		
SCIP-INF-2 Prophylactic antibiotic selection for surgical patients*	X	Removed		
SCIP-INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hrs for cardiac surgery)	X	Removed		
SCIP-INF-4 Cardiac surgery patients with controlled 6AM postoperative serum glucose	Suspended July 2014		Removed	
SCIP–INF-9 Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero*	X	Removed		
SCIP-Cardiovascular-2 Surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period	X	Removed		
SCIP-VTE-2 Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery	X	Removed		
ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital*	X	X	X	X
ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status*	X	X	X	X
IMM-1 Immunization for pneumonia	Suspended		Removed	
IMM-2 Immunization for influenza	X	X	X	X
PC-01 Elective delivery < 39 completed weeks gestation*	X	X	X	X
Exclusive breast milk feeding considering mother's choice*				
Healthy term newborn*				
Hearing screening prior to hospital discharge*				
Children's asthma care – 3 home management plan of care document given to patient/caregiver*				
NHSN Measures				
Central Line Associated Bloodstream Infection (CLABSI)	X	X	X	X
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	X	X	X
Catheter-Associated Urinary Tract Infection (CAUTI)	X	X	X	X
MRSA Bacteremia	X	X	X	X
Clostridium Difficile (C.Diff)	X	X	X	X
Healthcare Personnel Influenza Vaccination	X	X	X	X
Claims-Based Measures				
Mortality				
AMI 30-day mortality rate	X	X	X	X
Heart Failure (HF) 30-day mortality rate	X	X	X	X
Pneumonia 30-day mortality rate	X	X	X	X
Stroke 30-day mortality rate	X	X	X	X
COPD 30-day mortality rate	X	X	X	X
CABG 30-day mortality rate		X	X	X
Readmission				
AMI 30-day risk standardized readmission	X	X	X	X
Heart Failure 30-day risk standardized readmission	X	X	X	X
Pneumonia 30-day risk standardized readmission	X	X	X	X
Total Hip/Total Knee Arthroplasty (TKA/THA) 30-day risk standardized readmission	X	X	X	X
Hospital-wide all-cause unplanned readmission	X	X	X	X
Stroke 30-day risk standardized readmission	X	X	X	X

Table VIII. Final IQR Program Measures for Payment Determination in FYs 2016 – 2019 X= required measure *=electronic clinical quality measure				
	2016	**2017**	**2018**	**2019**
COPD 30-day risk standardized readmission	X	X	X	X
CABG 30-day risk standardized readmission		X	X	X
Patient Safety				
PSI-90 Patient safety composite	X	X	X	X
PSI-04 Death among surgical inpatients with serious, treatable complications	X	X	X	X
Surgical Complications				
THA/TKA complications	X	X	X	X
Efficiency				
Medicare Spending per Beneficiary	X	X	X	X
AMI payment per episode of care	X	X	X	X
Heart Failure payment per episode of care		X	X	X
Pneumonia payment per episode of care		X	X	X
THA/TKA payment per episode of care			X	X
Excess days in acute care after hospitalization for AMI			X	X
Excess days in acute care after hospitalization for HF			X	X
Kidney/UTI clinical episode-based payment				X
Cellulitis clinical episode-based payment				X
Gastrointestinal hemorrhage clinical episode-based payment				X
Patient Survey				
HCAHPS survey + 3-item Care Transition Measure	X	X	X	X
Structural Measures				
Participation in a Systematic Database for Cardiac Surgery	X	Removed		
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	X	X	X	X
Participation in a Systematic Clinical Database Registry for General Surgery	X	X	X	X
Safe Surgery Checklist Use	X	X	X	X
Hospital Survey on Patient Safety Culture			X	X
Note that electronic reporting is voluntary for FY 2016 and 2017 (16 of 28 measures across three NQS domains) and mandatory for FY 2018 payment determination (at least 4 of the 28 measures, with no domain requirements).				

B. PPS Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In the FY 2013 IPPS/LTCH final rule, CMS established a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals (PCHs), as required under section 1866(k) of the Act, as added by 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 was adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS indicated its intention to address the issue in future rulemaking. Five initial measures were adopted for FY 2014, and subsequent rulemaking has added measures. A total of 19 measures were adopted for FY 2017.

CMS finalizes its proposal for a set of 16 measures beginning with the FY 2018 PCHQR Program, shown in the table below. Six previously adopted Surgical Care Improvement Project (SCIP) measures are removed beginning with the fourth quarter 2015 discharges. These

measures were found to be topped out in the IQR Program. Because they have been removed from the IQR Program, CMS states that data collection is no longer feasible for the PCHQR Program because the infrastructure for collection of these measures will be removed from the IT data warehouse. Three NHSN measures are added to the PCHQR Program, specifically those relating to *Clostridium difficile* infection (CDI) (NQF #1717), MRSA (NQF #1716), and influenza vaccine coverage among healthcare personnel (NQF #0431). These measures have previously been adopted for the IQR Program. Reporting for the CDI and MRSA measures will be quarterly, following the approach used for the other NSHN measures previously adopted for the PCHQR Program. For the influenza vaccine measure, PCHs will submit annual data by May 15 of the following year.

Responding to comments regarding comparison of cancer hospitals to others, CMS notes that performance of cancer hospitals is displayed separately from other hospitals. With respect to MRSA, it notes that until there are sufficient data with which to risk adjust MRSA bacteremia in the cancer hospital population, CDC plans to submit unadjusted, facility-specific healthcare facility-onset, incidence rates without comparison to a national benchmark. CMS further clarifies that it has not provided any guidance surrounding the definition of a benchmark for any of the PCHQR Program measures.

Six previously adopted measures will be added for public display on *Hospital Compare* beginning in 2016. This is in addition to the public display of five measures adopted in prior rulemaking. These measures, with date of initial public reporting are noted on the table below. Responding to comments regarding reporting of measure data with short performance periods, CMS indicates that it will address criteria for data suppression from public reporting in future rulemaking.

PCHQR Program Measures for 2018	
Measure	**Public Display**
Safety and Healthcare Associated Infection	
NHSN CLABSI (NQF #0139)	2017
NHSN CAUTI (NQF #0138)	2017
NHSN SSI (NQF #0753)	
NHSN CDI (NQF #1717)	
NSHN MRSA bacteremia (NQF #1716)	
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	
Clinical Process/Cancer-Specific Treatments	
Adjuvant chemotherapy is considered or administered within 4 months of surgery for certain colon cancer patients (NQF #0223)	2014
Combination chemotherapy is considered or administered within 4 mos. of diagnosis to certain breast cancer patients (NQF #0559)	2014
Adjuvant hormonal therapy for certain breast cancer patients (NQF #0220)	2015
Clinical Process/Oncology Care	
Oncology-Radiation Dose Limits to Normal Tissues (NQF #0382)	2016
Oncology: Plan of Care for Pain (NQF #0383)	2016
Oncology: Pain Intensity Quantified (NQF #0384)	2016
Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients (NQF #0389)	2016
Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)	2016
Patient Experience of Care	

PCHQR Program Measures for 2018	
HCAHPS	2016
Clinical Effectiveness	
External Beam Radiotherapy for Bone Metastases (NQF#1822)	

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

In the FY 2012 IPPS/LTCH final rule, CMS established a quality reporting program beginning in FY 2014 for LTCHs, as required under section 1886(m) of the Act as added by section 3004 of the ACA. Further developed in subsequent rulemaking, the LTCHQR Program follows many of the policies established for the IQR Program, including the principles for selecting measures and the procedures for hospital participation in the program. An LTCH that does not meet the requirements of participation in the LTCHQR Program for a rate year is subject to a 2.0 percentage point reduction in the update factor for that year. In the impact analysis presented in Appendix A to the final rule, CMS reports that 47 out of 442 active LTCHs did not receive the full update factor for the FY 2015 payment determination.

The Improving Medicare Postacute Care Transformation (IMPACT) Act of 2014, enacted on October 6, 2014, requires the Secretary to implement quality measures for five specified quality measure domains using standardized data elements to be nested within the assessment instruments currently required for submission by LTCHs and other postacute providers (IRFs, SNFs, and HHAs). Other measures are to address resource use, hospitalization, and discharge to the community. The intent of the Act is to enable interoperability and access to longitudinal information among postacute providers to facilitate coordinated care, improve outcomes, and provide for quality comparisons across providers. In total, the IMPACT Act measure domains are:

- Skin integrity and changes in skin integrity;
- Functional status, cognitive function, and changes in function and cognitive function;
- Medication reconciliation;
- Incidence of major falls;
- Transfer of health information and care preferences when an individual transitions;
- Resource use measures, including total estimated Medicare spending per beneficiary;
- Discharge to community; and
- All-condition risk-adjusted potentially preventable hospital readmissions rates.

For LTCHs, the Secretary must specify quality measures by October 1, 2018. For IRFs and SNFs the deadline is October 1, 2016, and for HHAs is January 1, 2019.

1. LTCHQR Program Measures

The previously adopted LTCHQR Program measure set for the FY 2018 payment determination includes 12 measures. These are shown in the table below along with measures for earlier years, which are included for reference.

No new measures were proposed for addition to the LTCHQR Program; the status of four measures is modified. One previously adopted measure is modified to reflect NQF endorsement status and three others are addressed in the context of IMPACT Act requirements. The claims-based measure "All-cause Unplanned Readmission Measure for 30-days Post Discharge from LTCHs," which was adopted to begin with the FY 2017 payment determination, is now NQF endorsed (NQF #2512), and CMS finalizes adoption of the NQF-endorsed version for the LTCHQR Program and changes the data period used for the initial calculations to CYs 2013 and 2014 instead of FYs 2013 and 2014 as previously finalized.

Three previously adopted LTCHQR Program measures are adopted as cross-cutting quality measures that satisfy IMPACT Act clinical quality domains. In each case, CMS refers to input from a Technical Expert Panel in reviewing the technical specifications and assessing applicability of the measure as a cross-cutting measure across postacute settings. CMS refers readers to its LTCH Quality Reporting Measures Information web page for details on the standardization of patent assessment data and the cross cutting measures specifications: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html. (CMS notes that the specifications it posts there are more detailed than those on the NQF website, as CMS works to more clearly explain certain aspects of the measure and make language consistent with the various PAC data sets.) The three cross-cutting measures are:

- Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) addresses the domain of skin integrity and changes in skin integrity clinical domain. CMS notes that this measure has been implemented in two other PAC settings in addition to LTCHs (IRFs and SNFs), and states that the MAP supports its use as a cross-cutting measure. No changes are made to the data collection, measure calculation, or risk adjustment for this measure.
- Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (Application of NQF #0674) is proposed to address the incidence of major falls clinical domain. This measure is also part of the Nursing Home Quality Initiative. CMS states that the MAP conditionally supports its use as a cross cutting measure.
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) addresses the domain of functional status, cognitive function, and changes in function and cognitive function. (This is an application of a previously adopted measure that was developed by CMS and at the time of the proposed rule was undergoing NQF review. NQF endorsement was obtained on July 23, 2015.) The items in the cross-cutting application of this measure are a subset of those included in the version of this measure that was finalized in last year's rulemaking for the LTCHQR Program FY 2018 payment determination. To clarify which items are included in each function measure for each quality reporting program, CMS directs readers to the table in Appendix B of a document "LTCH QRP Measure Specifications," which is available for download on its LTCH Quality Reporting Measures Information web page. For example, the cross cutting measure does not include the Confusion Assessment Method items which are part of the measure adopted for the LTCHQR Program. Consistent with the schedule previously adopted for

the LTCHQR Program, data collection for this measure will begin April 1, 2016 for the FY 2018 payment determination.

CMS responds to numerous comments regarding each of the three measures and the implementation of the IMPACT Act more generally. Among points made by CMS is that while standardization of measures and data collection across PAC settings is important, there may be instances where some providers types may need more or fewer standardized items than others. With respect to the pressure ulcer measure, CMS says that although the timing of when data are obtained differs across PAC settings, for each setting the measure calculates the total number of new or worsened pressure between admission and discharge. Finally, with respect to concerns regarding the lack of risk adjustment for SDS factors among LTCH patients, CMS repeats the response it made to similar comments elsewhere in the rule. See, for example, section IV.F.3 above.

LTCHQR Program Measures X= required measure, I= IMPACT Act cross-cutting measure, P= 2016 public display				
Measure Title	**FYs 2014 and 2015**	**FY 2016**	**FY 2017**	**FY 2018**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X	X, P
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	X	X	X, P
Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678)		X	X	X, I, P
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)		X	X	X
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)		X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)			X	X
NHSN Facility-Wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)			X	X
All-Cause Unplanned Readmissions for 30 Days Post Discharge from LTCHs (NQF #2512)			X	X, P
Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (Application of NQF #0674)				X, I
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)				X, I
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)				X
NHSN Ventilator Associated Event Outcome Measure				X

2. Possible Future LTCHQR Program Measures

CMS discusses comments it received on 11 measures it listed in the proposed rule as under consideration for inclusion in the LTCHQR Program in future years. Five of these are cross-setting measure domains included in the IMPACT ACT. The full list involves ventilator weaning; ventilator process elements; VTE prophylaxis; medication reconciliation; transfer of health and care preferences during patient transitions; preventable readmissions; discharge to community; patient experience of care; percent of patients with moderate to severe pain; advance care plan; and Medicare spending per beneficiary. CMS indicates that its contractor, RTI International continues to engage a Technical Expert Panel for advice on measure development, which it describes as being in the early stages.

3. Data Submission by New LTCHs

CMS finalizes its proposal that beginning with the FY 2017 payment determination, a new LTCH must begin reporting data under the LTCHQR Program by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number notification letter. (For example, reporting would begin July 1 if the letter was dated March 15). This requirement is codified in a new §413.560(a).

4. Revised Data Reporting Deadlines

CMS finalizes, with one exception, revised data submission and correction deadlines for the LTCHQR Program; the changes are intended to align the deadlines with those of the IQR Program for public display purposes and to meet requirements of the IMPACT Act. The new deadlines allow 4.5 months (approximately 135 days) after the end of each calendar year quarter for submission, review, and correction of quality data for that quarter. The new deadlines will begin with Q4 of 2015. The exception is the measure Influenza Vaccination Coverage among Healthcare Personnel, which has a one-time annual reporting requirement for coverage in the period from October 1-March 31. The reporting deadline for this measure will remain unchanged. The final rule includes tables that detail the data submission method, data collection period, and data submission deadline for the FY 2017 and FY 2018 payment determinations. For the three IMPACT Act measures, the data collection and data submission timelines align with the data collection and data submission timelines adopted for each respective measure starting with April 1, 2016.

5. Data Validation

CMS did not propose any data validation policies, but continues to explore potential validation methods and threshold policies that address the accuracy of LTCHQR Program data while limiting burden and cost to LTCHs.

6. Public Display of LTCHQR Program Data

CMS finalizes its proposal to begin to display performance on LTCHQR Program quality measures on *Hospital Compare* or another CMS website by the fall of 2016. Providers will have

a 30-day preview opportunity prior to public display; additional information about preview reports will be announced on the LTCHQR Program website. At some point in the future, CMS anticipates developing a 5-star rating methodology. Decisions about this type of rating system and implementation timeline will be announced during CMS listening sessions on LTCHs, email notification, open door forums and web postings.

The public display will contain data on four measures: CLABSI, CAUTI, percent of patients with new or worsened pressure ulcers, and all-cause unplanned readmissions 30 days post LTCH discharge. With one exception, data will be displayed on the basis of four rolling quarters beginning with CY 2015; the readmission measure rates will be displayed on a calendar year basis, beginning with data for CYs 2013 and 2014. The NHSN measures will display standardized infection ratios; the pressure ulcer and readmissions measures will be risk adjusted.

Providers will have an opportunity to review and correct data submitted to the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system and to NHSN using reports that will be created and refreshed at least once a month. The reports will contain information on the provider's performance on each measure. (Eventually but not initially, reports will include claims-based measures as well as those for which LTCHs submitted data.) These reports will serve as the opportunity for providers to review and correct quarterly data. Patient-level correction to the data submitted by the hospital will not be permitted after the quarterly submission deadline. In addition, providers will be given a 30-day period for review of data in the system prior to public display.

CMS will also publish a list of LTCHs that successfully meet reporting requirements for each payment determination. This will be posted on the LTCHQR Program website. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/. The list will be updated after the reconsideration period. This proposal is codified at §412.500(d)(3).

7. Reconsideration/Appeals and Other Procedures

CMS clarifies the previously finalized process under which an LTCH may seek reconsideration of an initial noncompliance decision that would subject the LTCH to a 2 percentage point update factor reduction. Specifically, CMS clarifies that an LTCH seeking reconsideration must do so by emailing LTCHQRPReconsiderations@cms.hhs.gov; requests received through any other channel, including the U.S. Postal Service or telephone, will not be considered as a valid reconsideration request.

A change is finalized to the reconsideration process with respect to notification of noncompliant LTCHs. Beginning with the FY 2016 payment determination; the QIES will be used to communicate with LTCHs regarding their compliance with reporting requirements. Medicare-certified LTCH compliance letters will be uploaded to QIES for each LTCH to access. (Currently, only non-compliant LTCHs are notified through a certified letter.)

The LTCHQR Program exception and extension requirements are codified at new §412.560(c) and (d).

D. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals Participating in EHR Incentive Programs in 2016

A hospital that is not identified as a meaningful EHR user under the Medicare EHR Incentive Program is subject to a reduction of 0.5 percentage points in the update factor for FY 2016. In the impact analysis section of the final rule, CMS estimates that 153 hospitals will be subject to this update reduction for FY 2016.

CMS aims to align requirements of the IQR Program with those of the Medicare EHR Incentive Program, and in keeping with this goal makes changes in the 2016 reporting requirements for electronically submitted clinical quality measures (CQMs) for the 2016 reporting period. Because this final rule modifies the proposed IQR Program requirements for mandatory electronic reporting (see item VIII.A.7 above), parallel changes are finalized for hospitals that choose to electronically report CQMs for the Medicare EHR Incentive Program. Specifically, hospitals that submit CQMs electronically for the Medicare EHR Incentive Program in 2016 must report on a minimum of 4 CQMs with no NQS distribution requirement. CMS' proposal would have maintained the existing requirement under which eligible hospitals and CAHs must electronically report on 16 CQMs covering at least 3 NQS domains. Eligible hospitals and CAHs in any year of participating in the Medicare EHR Incentive Program may choose to report CQMs in 2016 either by attestation or electronically. No changes are made with respect to requirements for attestation. That is, hospitals that choose to report CQMs by attestation in 2016 are required to continue to report on a minimum of 16 CQMs covering at least 3 NQS domains.

Reporting period and data submission deadlines for CY 2016. CMS also finalizes data submission deadlines that differ from those in the proposed rule. Noting that the EHR Incentive Program Stage 3 proposed rule would shift the EHR reporting period to a calendar year basis, CMS had proposed to adopt a calendar-year based reporting for CQMs in 2016. In addition, reporting and data submission dates were proposed that would serve to align the EHR Incentive Program with the Hospital IQR Program electronic quality measure data submission requirements for 2016 (FY 2018 payment determination). However, consistent with the finalized requirements for the IQR Program, for electronic quality measure data submission in 2016, CMS finalizes that hospitals must report only one full quarter of data (Q3 or Q4 of CY 2016) by February 28, 2017. CMS believes this longer timeline and reduced burden will encourage more hospitals to report electronically for 2016. CMS intends to increase the number of required measures to 16 in future rules.

For eligible hospitals and CAHs reporting CQMs by attestation, reporting for CY 2016 would be required by February 28, 2017, except that for those demonstrating meaningful use for the first time in 2016, attestation could alternatively be made for any continuous 90-day reporting period within 2016. These reporting periods would apply for Medicaid, but states determine data submission methods and deadlines.

Certified EHR Technology (CEHRT) for EHR Incentive Programs in 2016. Eligible hospitals and CAHs must use CEHRT when capturing, calculating, and reporting CQM data. Following prior policy, CMS will continue to require for 2016 reporting that hospitals and CAHs must use the most recent release of the CQM version for each CQM to which the EHR is certified. For

2016, this is the Spring 2015 release of the CQMs available at the CMS eCQM Library. CMS notes that an EHR certified under the 2014 Edition criteria need not be recertified each time it updates to a more recent version of the CQMs. However, developers are encouraged to test updates on an annual basis.

Some commenters requested clarification of the requirements regarding Quality Reporting Data Architecture (QRDA) standards, and CMS finalizes in this rule a related proposal included in the EHR Incentive Program Stage 3 proposed rule (80 FR 16771). Under the 2014 standard, CEHRT must enable a user to electronically create a data file for transmission of CQM data using QRDA Category I and Category III standards and which can be accepted by CMS. In the Stage 3 proposed rule, CMS proposed to remove the QRDA-III option, requiring use of QRDA-I data. That proposal is finalized here. Specifically, beginning in 2016, QRDA-I is required for CQM electronic submissions to the Medicare EHR Incentive Program. CMS says that QRDA-I data are essential for data verification for the VBP Program, and are protected by CMS privacy standards. With respect to the Medicaid EHR Incentive Program, states would continue to have the option to allow QRDA-III for CQM reporting, subject to prior approval by CMS.

CMS defers a decision regarding the "CQMs-report" clarification criterion proposed by the ONC in the FY 2016 IPPS/LTCH proposed rule. ONC proposed a new 170.315(c)(3) which would require that technology certified to the 2015 Edition must enable a user to electronically create a file for transmitting eCQMs that at a minimum meets the requirements of 170.205(h) and 170.205(k) and optionally, can be electronically accepted by CMS. The references are to versions adopted by the ONC in its 2014 Edition (77 FR 55232): 170.205(h) is the HL7 Implementation Guide (IG) for CDA Release 2: Quality Reporting Document Architecture – Category I, Draft Standard for Trial Use (DSTU) Release 2 (July 2012); §170.205(k) is the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 2 (November 2012). CMS says that it will finalize the certification criterion and the versions of the standards adopted for this criterion in a final rule later this year, and at that time will address public comments received on these provisions.

CMS intends to publish a request for information on the establishment of an ongoing cycle for the introduction and certification of new measures, testing of updated measures, and testing and certification of submission capabilities.

IX. MedPAC Recommendations

CMS reports that it reviewed MedPAC's March 2015 "Report to the Congress: Medicare Payment Policy" and considered the report's recommendations in developing the policies included in this final rule. CMS addresses MedPAC's recommendations for the IPPS for FY 2016 in Appendix B to the final rule.

MedPAC recommended an update to the hospital inpatient rates equal to 3.25 percent concurrent with changes to the outpatient prospective payment system and with initiating changes to the LTCH PPS. As it did in the preceding year, MedPAC's analysis finds that efficient hospitals can maintain positive Medicare margins while maintaining a relatively high quality of care.

CMS responds that section 1886(b)(3)(B) of the Act, as amended by the sections 3401(a) and 10319(a) of the ACA, sets the requirements for the FY 2016 applicable percentage increase. Therefore, CMS set an applicable percentage increase for FY 2016 of 1.7 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with these statutory requirements. CMS notes that, because the operating and capital prospective payment systems remain separate, it is continuing to use separate updates for operating and capital payments.

X. Other Required Information

This section describes the various data sets which are available to the public and also presents information on the data collection burden associated with policies in the final rule, as required by the Paperwork Reduction Act of 1995.

Appendix: Regulatory Impact Analysis Table

TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2016

	Number of Hospitals (1) [1]	Hospital Rate Update and Documentation and Coding Adjustment (2) [2]	FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3) [3]	FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4) [4]	FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5) [5]	FY 2016 MGCRB Reclassifications (6) [6]	Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7) [7]	Application of the Frontier Wage Index and Out-Migration Adjustment (8) [8]	All FY 2016 Changes (9) [9]
All Hospitals	3,369	0.9	0	0	0	0	0	0.1	0.4
By Geographic Location:									
Urban hospitals	2,533	0.9	0	0	0.1	-0.1	0	0.1	0.4
Large urban areas	1,393	0.9	0.1	0.1	0.2	-0.3	0	0.1	0.4
Other urban areas	1,140	0.9	0	-0.1	-0.2	0.1	0.1	0.2	0.4
Rural hospitals	836	1.3	-0.2	-0.3	-0.5	1.4	-0.2	0.1	0.2
Bed Size (Urban):									
0-99 beds	668	0.9	-0.3	-0.2	-0.4	-0.6	0.1	0.3	0.2
100-199 beds	778	0.9	-0.1	0.1	0.1	0	0.3	0.2	0.4
200-299 beds	445	0.9	0	0	0	0.1	0	0.1	0.4
300-499 beds	428	0.9	0	0	0	-0.2	0.1	0.2	0.4
500 or more beds	214	0.9	0.1	0.1	0.2	-0.2	-0.2	0.1	0.4
Bed Size (Rural):									
0-49 beds	329	1.3	-0.2	-0.3	-0.5	0.3	-0.2	0.3	-0.1
50-99 beds	297	1.4	-0.3	-0.2	-0.5	0.7	-0.2	0.1	0.2
100-149 beds	121	1.4	-0.2	-0.2	-0.5	1.7	-0.3	0.2	0.4
150-199 beds	48	1.2	-0.2	-0.4	-0.5	1.9	-0.3	0.1	0.3
200 or more beds	41	1.1	-0.1	-0.5	-0.5	2.5	-0.2	-0.1	0.1
Urban by Region:									
New England	120	0.9	0	0.7	0.7	1.3	1.6	0	-0.1
Middle Atlantic	318	0.9	0.1	0.2	0.3	0.8	-0.4	0.2	1
South Atlantic	407	0.9	0	0.1	0.1	-0.5	-0.4	0.1	0.2
East North Central	396	0.9	0	0	0.1	-0.3	-0.5	0	0.5
East South Central	150	0.9	0	-0.4	-0.4	-0.7	-0.4	0	-0.4
West North Central	166	0.9	0	-0.6	-0.5	-0.8	-0.4	0.8	0.3
West South Central	384	0.9	0	-0.5	-0.4	-0.6	-0.5	0	-0.4
Mountain	161	1	-0.1	-0.3	-0.3	0	-0.1	0.2	0.2
Pacific	380	0.9	0	0.4	0.3	-0.3	1.7	0.1	1

	Number of Hospitals (1) [1]	Hospital Rate Update and Documentation and Coding Adjustment (2) [2]	FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3) [3]	FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4) [4]	FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5) [5]	FY 2016 MGC RB Reclassifications (6) [6]	Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7) [7]	Application of the Frontier Wage Index and Out-Migration Adjustment (8) [8]	All FY 2016 Changes (9) [9]
Puerto Rico	51	1	0.1	-0.9	-0.7	-1	0.1	0.1	-2.4
Rural by Region:									
New England	22	1.2	-0.1	-0.6	-0.7	1.7	-0.4	0	-0.1
Middle Atlantic	55	1.4	-0.1	0.2	0	0.8	-0.2	0.2	0.2
South Atlantic	128	1.2	-0.2	-0.1	-0.3	2.4	-0.2	0	0.6
East North Central	116	1.4	-0.2	-0.1	-0.4	1	-0.2	0.1	0.9
East South Central	164	0.9	0	-0.7	-0.7	2.5	-0.4	0.1	-1
West North Central	101	1.7	-0.4	-0.2	-0.5	0.2	0	0.3	0.8
West South Central	165	1.2	-0.1	-0.9	-0.9	1.5	-0.3	0.1	-0.8
Mountain	61	1.4	-0.3	-0.1	-0.4	0.2	-0.1	0.2	0.7
Pacific	24	1.4	-0.4	0.1	-0.3	0.6	-0.2	0	1.5
By Payment Classification:									
Urban hospitals	2,476	0.9	0	0	0.1	-0.1	0	0.1	0.4
Large urban areas	1,386	0.9	0.1	0.1	0.2	-0.3	0	0.1	0.4
Other urban areas	1,090	0.9	0	-0.1	-0.1	0.1	0.1	0.2	0.4
Rural areas	893	1.3	-0.2	-0.3	-0.4	1.1	-0.2	0.3	0.3
Teaching Status:									
Nonteaching	2,326	1	-0.1	-0.1	-0.1	0.1	0.2	0.1	0.3
Fewer than 100 residents	794	0.9	0	-0.1	-0.1	-0.1	0	0.2	0.4
100 or more residents	249	0.9	0.2	0.1	0.3	0	-0.2	0.1	0.4
Urban DSH:									
Non-DSH	653	0.9	-0.2	0.1	-0.1	0.1	-0.1	0.1	1.1
100 or more beds	1,593	0.9	0.1	0	0.1	-0.1	0	0.1	0.3
Less than 100 beds	328	0.9	-0.1	0	-0.1	-0.7	0	0.3	0.2
Rural DSH:									
SCH	260	1.6	-0.3	0	-0.4	0	0	0	0.7
RRC	347	1.3	-0.2	-0.3	-0.4	1.5	-0.2	0.4	0.4
100 or more beds	31	0.7	0.1	-0.6	-0.5	2.4	-0.5	0.1	-0.9
Less than 100 beds	157	0.8	0	-0.7	-0.6	1.7	-0.5	0.6	-1.2

	Number of Hospitals (1) [1]	Hospital Rate Update and Documentation and Coding Adjustment (2) [2]	FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3) [3]	FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4) [4]	FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5) [5]	FY 2016 MGCRB Reclassifications (6) [6]	Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7) [7]	Application of the Frontier Wage Index and Out-Migration Adjustment (8) [8]	All FY 2016 Changes (9) [9]
Urban teaching and DSH									
Both teaching and DSH	855	0.9	0.1	0	0.1	-0.2	-0.1	0.1	0.3
Teaching and no DSH	122	0.9	-0.1	0	-0.1	0.8	0.1	0.1	1.3
No teaching and DSH	1,066	0.9	0	0	-0.1	-0.1	0.4	0.1	0.2
No teaching and no DSH	433	0.9	-0.2	0.1	-0.1	-0.4	-0.2	0.1	1
Special Hospital Types:									
RRC	189	0.9	-0.1	-0.6	-0.6	2.1	-0.3	0.6	-0.4
SCH	327	1.6	-0.3	-0.1	-0.3	-0.1	-0.1	0	0.8
MDH	150	1.3	-0.3	-0.2	-0.4	0.2	-0.2	0.2	0.6
SCH and RRC	126	1.6	-0.3	-0.1	-0.4	0.4	0	0	0.9
MDH and RRC	13	1.5	-0.3	0	-0.4	0.1	-0.2	0	0.6
Type of Ownership:									
Voluntary	1,934	0.9	0	0	0	0	0	0.1	0.5
Proprietary	879	0.9	0	-0.1	-0.1	0	0.1	0.1	-0.1
Government	529	0.9	0.1	-0.1	0	-0.2	0.1	0.1	0
Medicare Utilization as a Percent of Inpatient Days:									
0-25	533	0.9	0.1	-0.1	0	-0.4	0.2	0	-0.6
25-50	2,134	0.9	0	0	0	0	0	0.1	0.5
50-65	571	1	-0.1	0.1	0	0.6	0	0.1	0.8
Over 65	97	1.1	-0.1	-0.2	-0.4	-0.4	0.3	0.1	0.4

	Number of Hospitals (1) [1]	Hospital Rate Update and Documentation and Coding Adjustment (2) [2]	FY 2016 Weights and DRG Changes with Application of Recalibration Budget Neutrality (3) [3]	FY 2016 Wage Data under New CBSA Designations with Application of Wage Budget Neutrality (4) [4]	FY 2016 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality (5) [5]	FY 2016 MGCRB Reclassifications (6) [6]	Rural and Imputed Floor with Application of National Rural and Imputed Floor Budget Neutrality (7) [7]	Application of the Frontier Wage Index and Out-Migration Adjustment (8) [8]	All FY 2016 Changes (9) [9]
FY 2016 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	830	1	0	-0.1	-0.1	2.2	0.1	0	0.7
Non-Reclassified Hospitals	2,539	0.9	0	0	0.1	-0.9	0	0.2	0.2
Urban Hospitals Reclassified	551	0.9	0	-0.1	0	2.2	0.1	0	0.8
Urban Non-reclassified Hospitals	1,925	0.9	0	0.1	0.1	-0.9	0	0.1	0.2
Rural Hospitals Reclassified Full Year	279	1.2	-0.2	-0.3	-0.5	2.3	-0.2	0	0.4
Rural Non-reclassified Hospitals Full Year	504	1.4	-0.3	-0.3	-0.5	-0.3	-0.2	0.3	0
All Section 401 Reclassified Hospitals:	64	1.4	-0.3	0	-0.2	-0.4	0	1.4	0.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	53	1	-0.1	-0.5	-0.6	3.4	-0.4	0	-0.3
Specialty Hospitals									
Cardiac specialty Hospitals	14	0.9	0.2	-0.9	-0.6	-1.1	0	0.9	0.7

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 2014, and hospital cost report data are from reporting periods beginning in FY 2013 and FY 2012.

2 This column displays the payment impact of the hospital rate update and the documentation and coding adjustment including the 1.7 percent adjustment to the national standardized amount and hospital-specific rate (the estimated 2.4 percent market basket update reduced by the 0.5 percentage point for the multifactor productivity adjustment and the 0.2 percentage point reduction under the Affordable Care Act) and the -0.8 percent

documentation and coding adjustment to the national standardized amount.

3 This column displays the payment impact of the changes to the Version 33 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2014 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 0.998399 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 2012 cost report data an d the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 0.998749.

5 This column displays the combined payment impact of the changes in Columns 2 through 3 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 0.997150 is the product of the wage 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) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the FY 2016 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2016. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.987905.

7 This column displays the effects of the rural floor and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor (which includes the imputed floor) applied to the wage index is 0.990298. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a budget neutrality factor of 0.999996.

8 This column shows the combined 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 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are non-budget-neutral policies.

9 This column shows the changes in payments from FY 2015 to FY 2016. It reflects the impact of the FY 2016 hospital update and the adjustment for documentation and coding. It also reflects changes in hospitals' reclassification status in FY 2016 compared to FY 2015. It incorporates all of the changes displayed in Columns 1, 4, 5, 6, and 7, (the changes displayed in Columns 2 and 3 are included in Column 4). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.