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# FINAL RULE SUMMARY
## Fiscal Year 2021 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule

On September 3, 2020, the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2021 policies and rates for Medicare's prospective payment systems for acute care inpatient hospitals (IPPS) and the long-term care hospital prospective payment system (LTCH PPS). The final rule will be published in the *Federal Register* on September 18, 2020.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1735-F) 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 final 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.

CMS makes many data files available to support analysis of the final rule. These data files are generally available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page. Numbered tables that were historically included in the IPPS rule are now only available on the CMS website can be found at the above hyperlink.

CMS ordinarily provides a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act. The Administrative Procedure Act ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the *Federal Register*. These requirements can be waived for good cause. CMS is waiving both of these requirements because of the COVID-19 public health emergency (PHE) and the strain it has put on CMS resources and is providing 28-day delay between the time the FY 2020 IPPS final rule goes on public display and its effective date.

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## I. IPPS Rate Updates and Impact of the Rule; Outliers

CMS estimates that policies and rates in the final rule would increase combined operating and capital payments to approximately 3,201 acute care hospitals paid under the IPPS by about $3.5 billion in FY 2021 compared to FY 2020. The rule indicates that the increase results from an

additional $3.0 billion in IPPS operating and uncompensated care payments and $506 million in IPPS capital and new technology add-on payments. While combined IPPS operating and uncompensated care payments are increasing $3.0 billion, uncompensated care payments are declining 0.7 percent or approximately $60.5 million.

### A. Inpatient Hospital Operating Update

The final rule would increase IPPS operating payment *rates* by 2.9 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.9 percent rate increase is the net result of a market basket update of 2.4 percent and an adjustment of +0.5 percentage points required under section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA). The payment rate update factors are summarized in the table below. As explained below, there is no adjustment to the FY 2020 update for multifactor productivity (MFP).

The IPPS payment increase will apply to the national operating standardized amounts and also to the hospital-specific rates on which some sole community hospitals (SCHs) and Medicare Dependent Hospitals (MDHs) are paid. However, the documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 2.4 percent increase rather than a 2.9 percent increase.

| Factor | Percent Change |
|---|---|
| FY 2021 Market Basket | 2.4 |
| MACRA Documentation and Coding Adjustment | +0.5 |
| Net increase before application of budget neutrality factors | 2.9 |

For FY 2021, hospitals that choose not to participate in the Inpatient Quality Reporting (IQR) Program or do not successfully submit the required quality data are subject to a one-quarter reduction of the full market basket of 2.4 percent or -0.6 percentage points. The statute additionally requires that the update for any hospital that is not a meaningful EHR user be reduced by three-quarters of the market basket update or 1.8 percentage points.

CMS estimates that 37 hospitals will not receive the full market basket rate-of-increase because they failed the quality data submission process or chose not to participate in IQR; 153 hospitals because they are not meaningful EHR users; and 30 hospitals are estimated to be subject to both reductions.

The update for hospitals that have not successfully submitted quality data will be 1.8 percent for FY 2021. The reduction to the update is applied before application of the MACRA documentation and coding adjustment and equals the 2.4 percent market basket less 0.6 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of 0.6 percent for FY 2021. This update is also applied before application of the MACRA documentation and coding adjustment and equals the 2.4 percent market basket net of MFP less 1.8 percentage points.

Hospitals that have neither successfully submitted quality data nor qualified as meaningful EHR users will receive an update of 0.0 percent or the 2.4 percent market basket net of MFP less 2.4 percentage points (the entire market basket).

## B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2021 payments increasing 2.5 percent. Not all policy changes are reflected in this total. For example, the total does not include the $60.5 million decrease in uncompensated care payments or any increases in new technology add-on payments. The factors that are included in this total are:

| Contributing Factor | National Percentage Change |
|---|---|
| FY 2021 increase in payment rates | +2.8[1] |
| Outliers | -0.2[2] |
| Residual | -0.1[3] |
| Total | +2.5[4] |

[1]Weighted average of hospital-specific rate update of 2.4 and 2.9 percent for all other hospitals inclusive of the +0.5 percentage points for documentation and coding.
[2] Based on FY 2019 MedPAR data, CMS estimates outliers at 5.3 percent of total payments. As it is anticipating paying 5.1 percent of total payments as outliers, CMS estimates a 0.2 percentage point reduction in outlier payments.
[3]CMS explains the residual and the total may be explained by "interactive effects among various factors" that CMS cannot isolate.

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 summarizes the impact by selected hospital categories.

| Hospital Type | All Proposed Rule Changes |
|---|---|
| All Hospitals | 2.5% |
| Urban | 2.5% |
| Rural | 2.2% |
| Major Teaching | 2.7% |

To the extent a given hospital category impact deviates from the national average of 2.5 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with the average for all hospitals. Typically, the impact would be redistributive from a policy that is budget neutral. The redistributive payment changes are reasonably modest. Nearly all of the changes are within a few tenths of a percentage point from the national average.

Other provisions having an impact include:

Rural Floor: The rural floor raises the wage index of 285 urban hospitals such that an urban wage index may not be below the wage index for the rural area of its state. CMS calculates a national rural floor budget neutrality adjustment factor of 0.993433 (-0.66 percent) applied to

hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.2 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no change in payments; and urban hospitals in the New England region can expect a 2.3 percent increase in payments, primarily due to the application of the rural floor in Massachusetts. Fifty-two urban providers in Massachusetts are expected to receive the rural floor wage index value increasing payments by an estimated $158 million or 4.1 percent. Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the rural floor for FY 2021.

Frontier Wage Index and Outmigration. In the IPPS impact table, CMS includes a column for the frontier hospital wage index floor that increases payment by about $69 million to 44 hospitals and the out-migration adjustment that increases payments about $51 million to 212 providers. These increases are not budget neutral.

New Technology Add-On Payments (NTAP).

CMS is discontinuing NTAP payments for 9 new technologies, continuing NTAP payments for 8 new technologies and approving NTAP payments for an additional 14 new technologies. Of these 14 new technologies, eight are automatically deemed to have met the substantial clinical improvement criterion as a breakthrough technology or qualified infectious disease product (QIDP). One of these products has a conditional QIDP approval pending its actual approval by the Food and Drug Administration (FDA) with this designation. CMS estimates that costs for new technologies receiving NTAP for the first time in FY 2021 will be $665.756 million. This increase in payments is not budget neutral.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 0.7 percent or about $60.5 million. More detail on these calculations is in section IV. G.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2021 payments to an estimated 2,545 hospitals or 85 percent of all hospitals. This reduction in payment is not budget neutral. The readmissions penalty is estimated to affect 0.68 percent of payments to the hospitals that are being penalized for excess readmissions. CMS includes an unnumbered table that illustrates the average net percentage payment adjustment by category of hospital (e.g. Large Urban, Other Urban, Rural, etc.) in FY 2021.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute about $1.9 billion (2 percent of base operating MS-DRG payments) based on hospitals' performance scores. CMS includes an unnumbered table that illustrates the average net percentage payment adjustment by category of hospital (e.g. Large Urban, Other Urban, Rural, etc.) in FY 2021.

Hospital Acquired Conditions (HAC) Reduction Program. CMS provides an analysis by hospital category of how hospitals are affected by the HAC reduction program. By law, the penalty

applies to 25 percent of all hospitals or 777 of 3,111 non-Maryland hospitals with a HAC score. The reductions in payment is not budget neutral.

Rural Community Hospital Demonstration Program. CMS is applying a budget neutrality adjustment for the Rural Community Hospital Demonstration Program based on $39.8 million in costs for FY 2021 for 22 hospitals.

Allogeneic Hematopoietic Stem Cell Acquisition Costs. For cost reporting periods beginning on or after October 1, 2020, Medicare statute requires allogeneic stem cell acquisition costs be paid on the basis of reasonable costs rather than the IPPS. The statute requires this change to be budget neutral so it will not have any cost or savings but is accounted for by -0.02 percent budget neutrality adjustment.

### C. IPPS Standardized Amounts

The following four rate categories continue in FY 2021:

- Hospital Submitted Quality Data and is a Meaningful EHR User (applicable percentage increase [i.e., before adjustments] = 2.4 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.8 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.6 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.0 percent)

The applicable percentage changes listed above are prior to budget neutrality factors applied to the standardized amount and the documentation and coding adjustment. The updated standardized amounts for the final rule were calculated applying the additional MACRA mandated documentation and coding adjustment of +0.5 percentage points for FY 2021. Additional budget neutrality adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 0.99798 (a decrease of 0.2 percent);
- Wage index, 1.000426 (an increase of 0.04 percent);
- Geographic reclassification, 0.986583 (a reduction of 1.34 percent);
- Increase in wage indexes below the 25$^{th}$ percentile budget neutrality of 0.998835 or -0.12 percent;
- Budget neutrality for a 5 percent cap on reductions to wage indexes of 0.99015 or -0.20 percent;
- The outlier offset factor is 0.949 or -5.1 percent;
- The rural community hospital demonstration program adjustment is 0.999626 or -0.04 percent;
- The adjustment for paying allogeneic hematopoietic stem cell acquisition cost on the basis of reasonable costs rather than under the IPPS is 0.999848 or -0.02 percent.

Of the adjustments above, MS-DRG recalibration and wage index is maintained on the standardized amount from year-to-year. The prior year adjustments for geographic reclassification, wage indexes below the 25th percentile, the 5 percent cap on reductions to the wage index, the outlier adjustment and rural community hospital demonstration project are removed from the FY 2020 standardized amount before the FY 2021 adjustment is applied. The net increase in the standardized amount results as follows:

| Factor | Net Change |
|---|---|
| Update | 2.4% |
| DRG Recalibration | -0.202% |
| Wage index | +0.043% |
| Geographic Reclassification | +0.115% |
| 25th Percentile | +0.094% |
| 5% Cap | -0.082% |
| Outlier | 0.000% |
| Rural Community Hospital | -0.015% |
| Allogeneic Hematopoietic Stem Cell | -0.015% |
| Doc and Coding | +0.500% |
| Net Change | 2.848% |

The capital rate increases by 0.84 percent from $462.33 to $466.22. The combined increase in the operating standardized amount and the capital rate will be 2.7 percent for FY 2021.

Note that the standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 2028 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.

## FY 2021 RULE TABLES 1A-1D

| TABLE 1A. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2021 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.4 Percent)** | | **Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.6 Percent)** | | **Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.8 Percent)** | | **Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = 0.0 Percent)** | |
| **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** |
| $4,071.49 | $1,889.70 | $3,999.92 | $1,856.48 | $4,047.63 | $1,878.63 | $3,976.06 | $1,845.41 |

| 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)—FY 2021 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.4 Percent)** | | **Hospital Submitted Quality Data and is a NOT a Meaningful EHR User (Update = 0.6 Percent)** | | **Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update =1.8 Percent)** | | **Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = 0.0 Percent)** | |
| **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** |
| $3,695.94 | $2,265.25 | $3,630.97 | $2,225.43 | $3,674.28 | $2,251.98 | $3,609.31 | $2,212.16 |

| TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE | |
|---|---|
| | **Rate** |
| National | $466.22 |

## 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 MS-DRG, plus IME, DSH, uncompensated care and new technology add-on payments, plus the "outlier threshold" or "fixed-loss" amount, which is $26,552 in FY 2020. 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 (90 percent for patients in the burn DRGs).

FY 2021 outlier threshold. CMS is adopting an outlier threshold for FY 2021 of $29,051. CMS projects that the outlier threshold for FY 2021 will result in outlier payments equal to 5.11 percent of operating DRG payments and 5.363 percent of capital payments. After accounting for outlier reconciliation (explained below), CMS is applying adjustments of 0.949 (5.11 percent less 0.01 for operating outlier reconciliation) to the operating standardized amounts and 0.94657 (5.363 percent less 0.02 percent for capital outlier reconciliation) to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2021 outlier threshold methodology. CMS is following past practice targeting total outlier payments at 5.1 percent of total operating DRG payments (including outlier and uncompensated care payments but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program before accounting for reconciliation payments). To calculate the final FY 2021 outlier threshold, CMS simulated payments by applying FY 2021 payment rates and policies using cases from the FY 2019 Medicare Provider Analysis and Review File (MedPAR) with the hospital charges on the MedPAR claims adjusted for 2 years of inflation; from FY 2019 to FY 2021.

*Charge Inflation*. For the FY 2021 final rule, CMS is using publicly available MedPAR files from March 2020 for the FY 2019 charge data compared to the same data from one year earlier. CMS determined the 1-year average annualized rate-of-change in charges per case for FY 2021 by comparing the average covered charge per case of:

FY 2018: $61,578.82 ($584,618,863,834 / 9,493,830 cases)
FY 2019: $65,522.10 ($604,209,834,207 / 9,221,466 cases)[1]
Annual Rate of Increase: 6.4 percent (1.06404)

[1] In the final rule, CMS states that the denominator is 9,519,120. CMS has indicated that this figure is erroneous and should be $9,221,466.

wo Year Rate of Increase: 13.2 percent (1.13218).

*CCRs.* CMS is using hospital CCRs from the March 2020 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 compares the national average case-weighted operating and capital CCRs from the most recent (March 2020) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (March 2019) update of the PSF. The methodology uses total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison.

Operating:
March 2019: 0.254027
March 2020: 0.247548
% Change: -2.55 percent or 0.974495.

Capital:
March 2019: 0.02073
March 2020: 0.19935.
% Change: -3.84 percent or 0.96165.

For estimating the outlier threshold for FY 2021, CMS's calculation will reflect application of the floor on the wage index of eligible hospitals in frontier states and adjustments to the wage index for outmigration as well as continuing policies to: 1) increase the wage index for hospitals with a wage index below the 25th percentile wage index value across all hospitals, and (2) apply a 5 percent cap for FY 2021 on any decrease in a hospital's final rule wage index from its FY 2020 wage index.

*Reconciliation.* Over the course of the year, Medicare makes outlier payments based on hospital data from a prior year. Outlier reconciliation occurs when the hospital's actual CCR for the period changes from the CCR used to make outlier payments by more than 10 percentage points or the hospital receives more than $0.5 million in outlier payments. Continuing a practice began in FY 2020, CMS will reflect the potential for reconciliation in the determination of the FY 2021 outlier threshold.

For the FY 2021 outlier threshold, CMS proposed to use the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a beginning date on or after October 1, 2014, and on or before September 30, 2015). CMS indicated these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC for the FY 2021 proposed and final rule. For the FY 2021 proposed rule, CMS used the December 2019 extract of the Hospital Cost Report Information System (HCRIS). For the FY 2021 final rule, CMS is using the March, 2020 extract of HCRIS.

CMS is using the same methodology for FY 2021 advanced by one year as it used for FY 2020 to determine a reconciliation adjustment for calculating the outlier threshold. Reconciled outlier payments are a percentage of total outlier payments for the year under analysis (FY 2015 for FY

2021). This amount (expressed as percentage points) is then subtracted from the 5.1 percent of total operating IPPS payments that CMS is targeting as outlier payments for the payment year. For the proposed rule, CMS estimated that reconciliation in FY 2015 resulted in hospitals being owed $2.5 million or less than 0.01 percent of total operating IPPS payments. As this figure rounds to 0.0 percent, CMS proposed to not make any adjustment for reconciled operating outlier payments in setting the FY 2021 outlier threshold. One commenter was able to replicate CMS' proposed calculations given the logic described and agreed no adjustment was needed to the FY 2021 outlier threshold for reconciliation.

CMS is finalizing its outlier reconciliation methodology but uses more recent data available for the final rule. Based on the March 2020 HCRIS, a total of 19 hospitals were refunded $8,650,344 in reconciled outlier payments on total Federal operating payments of $90,321,677,004. The ratio of these two amounts is -0.009577 percent rounded to - 0.01 percent. CMS, therefore targeted the outlier threshold to pay 5.11 percent [5.1 percent - (- 0.01 percent)] of total IPPS operating payments as outliers.

There is not a separate capital outlier threshold. CMS establishes a single unified outlier threshold based on the operating outlier threshold. Accordingly, CMS adjusts the capital rate to reflect the percentage of total payments estimated to be paid as capital outliers. CMS proposed to include reconciled capital outlier payments in the adjustment in the same way as the percentage was calculated for operating payments. There were no public comments and CMS is finalizing its capital outlier reconciliation methodology as proposed. For capital, CMS estimates $1,901,335 in reconciled capital outlier payments owed to 19 hospitals in FY 2015 on total Federal capital payments of $8,114,957,508. The ratio of these two amounts is -0.023430 percent rounded to -0.02 percent. For FY 2021, CMS will decrease the estimated percentage of FY 2021 aggregate capital outlier payments by -0.02 percent (or increase it by 0.02 percent).

As hospitals were owed money due to reconciliation, the reconciliation adjustment has the effect of slightly increasing the percentage of operating and capital payments targeted as outlier payments and lowering the outlier threshold. CMS estimates the outlier threshold absent reconciliation would be $29,108 or $57 higher.

FY 2019 Outlier Payments. CMS' current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.43 percent of actual total MS-DRG payments. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2019 are equal to the projected 5.1 percent of total MS-DRG payments.

FY 2020 Outlier Payments. While CMS says in this section that FY 2020 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2020, the impact section says that 2020 outliers are approximately 5.3 percent of total payments based on FY 2019 data.

## II. Medicare Severity (MS) Diagnosis-Related Groups (DRGs)

### A. Documentation and Coding Adjustment

CMS provides an abbreviated history of the MS-DRGs and documentation and coding adjustment going back to adoption of the MS-DRGs in FY 2008. In summary, CMS adopted a preemptive negative rate adjustment for FY 2008 to offset increases in IPPS spending due to improvements in documentation and coding. Subsequent statutory amendments required different adjustments over the years since that time. The most recent statutory provisions require CMS to make a series of annual positive adjustments to offset prior negative ones through FY 2023. For FY 2021, consistent with section 414 of MACRA, CMS is implementing a positive 0.5 percentage point adjustment to the standardized amounts to end prior year recoupments of increased spending due to documentation and coding.

Public commenters continue to request that CMS restore an additional 0.7 percentage point adjustment made to the rates for FY 2017 that resulted from CMS changing its estimate of the amount needed to fully recoup past documentation and coding spending. This adjustment was made after Congress enacted legislation to require CMS to restore 3.0 percentage points of the previously estimated 3.2 percent reduction that was needed to recoup excess spending over six years in 0.5 percentage point increments annually. With Congress' enactment, CMS planned to restore only 3.0 percentage points of a 3.9 percent reduction made to recoup documentation and coding spending. Congress has since reduced the first-year adjustment from 0.5 percentage points to 0.4588 percentage points but remained silent on the additional 0.7 percentage point adjustment.

Public commenters continue to maintain that CMS is required by law to restore this 0.7 percentage point adjustment. CMS responds that it sees no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher than expected final documentation and coding adjustment made in FY 2017.

### B. Changes to Specific MS-DRG Classifications

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

In the FY 2018 IPPS final rule, CMS changed the deadline to request updates to the MS-DRGs to November 1 of each year. CMS has found that with the ICD-10 coding system, some requests for changes to the MS-DRG classification require more time to identify and analyze all the data to evaluate the potential change. As a result, some of the topics discussed below require more analysis and CMS will continue to consider these topics in future rulemaking. In addition, to provide more time to evaluate requests, CMS proposed to change the deadline to request changes to the MS-DRGs to October 20$^{th}$ of each year.

A commenter opposed CMS' proposal to change the deadline to submit requested changes to the MS-DRGs from November 1$^{st}$ to October 20$^{th}$ because hospitals need more time to evaluate

finalized MS-DRG changes. Other commenters urged CMS to consider the impact of COVID-19 PHE on the FY 2020 MedPAR data in evaluating potential MS-DRG changes for FY 2022. Because of the PHE, CMS is maintaining November 1, 2020 as the deadline for submitting FY 2022 MS-DRG classification change requests. CMS expects to reconsider a change to the deadline for FY 2023. In response to comments about the impact of the PHE on the FY 2020 MedPAR data, CMS will consider these concerns in developing FY 2022 proposals. **To be considered for any updates or changes in FY 2022, comments should be submitted by November 1, 2020** to the CMS MS-DRG Classification Change Request Mailbox at: MSDRGClassificationChange@cms.hhs.gov.

For the FY 2021 final rule, CMS generally did not perform any further MS-DRG claims data. Therefore, the MS-DRG analysis is based on ICD-10 claims data from the September 2019 update of the FY 2019 MedPAR file, which contains hospital bills received through September 30, 2010 for discharges occurring through September 30, 2019.

In deciding on modifications to the MS-DRGs for particular circumstances, CMS 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' clinical advisors 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 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. 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 following criteria:

- 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; and
- There is a $2,000 difference in average costs between subgroups.

CMS proposed to expand these criteria to include the NonCC subgroup. CMS believes that this will better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the NonCC level MS-DRGs.

The table below, reproduced from the rule, illustrates all five criteria and how they are applied to each CC.

| Criteria Number | Three-Way Split<br>123<br>(MCC vs CC vs NonCC) | Two-Way Split<br>1_23<br>MCC vs (CC+NonCC) | Two-Way Split<br>12_3 (MCC+CC) vs NonCC |
|---|---|---|---|
| 1. At least 500 cases in the MCC/CC/NonCC group | 500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group | 500+ cases for MCC group; and 500+ cases for (CC+NonCC) group | 500+ cases for (MCC+CC) group; and 500+ cases for NonCC group |
| 2. At least 5% of the patients are in the MCC/CC/NonCC Group | 5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group | 5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group | 5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group |
| 3. There is at least a 20% difference in average cost between subgroups | 20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group | 20%+ difference in average cost between MCC group and (CC+NonCC) group | 20%+ difference in average cost between (MCC+ CC) group and NonCC group |
| 4. There is at least a $2,000 difference in average cost between subgroups | $2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group | $2,000+ difference in average cost between MCC group and (CC+ NonCC) group | $2,000+ difference in average cost between (MCC+ CC) group and NonCC group |
| 5. The R2 of the split groups is greater than or equal to 3 | R2 > 3.0 for the three-way split within the base MS-DRG | R2 > 3.0 for the two way 1_23 split within the base MS-DRG | R2 > 3.0 for the two way 12_3 split within the base MS-DRG |

For analysis of requests to create a new MS-DRG, CMS evaluates the most recent year available of MedPAR claims data. For evaluation of requests to split an existing base MS-DRG into severity levels, CMS analyzes the most recent 2 years of data. Using 2 years of data reduces changes related to an isolated year's data fluctuation. CMS first evaluates if the creation of a new CC subgroup is warranted to determine if all criteria are satisfied in a three-way split. If the criterial fail, CMS will determine if criteria are satisfied for a two-way split. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for the base MS-DRG. CMS notes that in a response to a request to specifically split an existing base MS-DRG into a two-way split, it will evaluate the criteria for both of the two-way splits, but it will not also evaluate the criteria for a three-way split.

A commenter questioned the appropriateness of CMS applying its proposal for FY 2021 before this change was finalized. The commenter also requested clarification about how CMS will apply the proposal and noted that if CMS were to apply the NonCC criteria retroactively in future rulemaking this would result in changes in the MS-DR groupings and relative weights. In response, CMS states it applied the proposed criteria to the analysis of the MS-DRG classification requests for FY 2021 but that the expansion of these criteria to the NonCC subgroup were finalized through rulemaking and it is appropriate to apply these finalized expanded criteria to the MS-DRG classification requests. CMS notes that for the MS-DRG related proposals for FY2021 the results are similar using the established criteria and the expanded proposed criteria. CMS also notes that the expansion of the criteria to include the

NonCC subgroup, is only applicable for a three-way split because the NonCC subgroup already existed in the options for a two-way split.

**CMS finalizes its proposal to expand the criteria to include the NonCC subgroup**. CMS clarifies there are no plans to apply the expansion of the criteria to the NonCC subgroup retroactively in future rulemaking. CMS agrees with the commenter that this would result in modifications to certain MS-DRGs. Any proposed modifications to the MS-DRGs would be addressed in future rulemaking and reflected in Table 5 (Proposed List of MS-DRGs, Relative Weighting Factors, and Geometric Arithmetic Mean Length of Stay for the applicable fiscal year).

The FY 2021 ICD-10 MS-DRG GROUPER and Medicare Code Editor (MCE) Software Version 38, the ICD-10 MS-DRG Definitions Manual files Version 38 and the Definitions of Medicare Code Edits Manual Version 38 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

2. Pre-MDC

*a. Bone Marrow Transplants*

CMS received a request to redesignate MS-DRG 014 (Allogeneic Bone Marrow Transplant), MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy), and MS-DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) from surgical to medical MS-DRGs. CMS agreed with the requestor that the majority of the procedures currently assigned to these MS-DRGs are designated as non-operating room (non-O.R.) procedures. CMS' clinical advisors agreed with the requestor that bone marrow transplant procedures are similar to blood transfusion procedures, do not utilize the resources of an operating room, and are not surgical procedures. CMS **finalizes its proposal** to redesignate MS-DRGs 014, 016 and 017 as medical MS-DRGs.

During the review of the logic for MS-DRGs 016 and 017, CMS identified 8 procedures that were designated as O.R. procedures and it **finalizes its proposal** to redesignate these procedure codes from O.R. to non O.R. procedures.

CMS also received a request to split MS-DRG 014 into two severity levels based on the presence of an MCC.[2] CMS conducted analysis of MS-DRG 014 to determine if the criteria to create subgroups were met and found that the claims data did not support a two-way severity level split.

CMS **finalizes its proposal** to maintain the current structure of MS-DRG 014.

[2]In FY 2020, CMS did not agree with the requestor's request to split MS-DRG 014 into two new MS-DRGs according to donor source.

*b. Chimeric Antigen Receptor (CAR) T-Cell Therapy*

CMS received several requests to create a new MS-DRG for procedures involving CAR T-cell therapies. Some requestors provided recommendations including how to treat cases where the CAR T-cell product was provided without cost as part of a clinical trial.

CMS evaluated creating a new MS-DRG specifically for cases involving CAR T-cell therapies. CMS examined claims data for cases reported with the two ICD-10-PCS procedure codes for CAR T-cell therapies, XW033C3 and XW043C3. CMS identified clinical trial claims as claims with ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) which is reported only for clinical trial cases, or with standardized drug charges of less than $373,000, which is the average sales price of the two approved CAR T-cell therapies (KYMRIAH and YESCARTA). CMS agreed with requestors who indicated that given the high cost of the CAR T-cell product, it was appropriate to distinguish cases where the CAR T- cell therapy was provided without cost as part of a clinical trial so that the analysis reflected the resources to provide CAR T-cell therapy outside of a clinical trial. CMS also included 18 cases that would have been identified as statistical outliers of MS-DRG 016 because these cases would not have been identified as statistical outliers when examining only CAR T-cell therapy claims. CMS' findings are shown in the table (reproduced from the proposed rule).

| MS-DRG | Description | | Number of Cases | Average Length of Stay | Average Costs |
|---|---|---|---|---|---|
| 016 | All Cases | | 2,212 | 18.2 | $55,001 |
| | ICD-10-PCS codes XW033C3 or XW043C3 | All cases | 262 | 16.3 | $127,408 |
| | | Non-clinical trial cases | 94 | 17.2 | $274,952 |
| | | Clinical trial cases | 168 | 15.8 | $44,853 |

The data indicated that the average costs for the non-clinical trial cases involving CAR T- cell therapies are almost five times higher than the average costs for all cases in MS-DRG 016. CMS' clinical advisors also believed that cases involving CAR T-cell therapies can be clinically differentiated form other cases grouping to MS-DRG 016. Although CMS generally prefers not to create a new MS-DRG with a small number of cases, its clinical advisors believed that the vast discrepancy in resource consumption and the clinical differences warranted the creation of a new MS-DRG. CMS proposed to assign cases reporting ICD-10-PCS procedure codes XW033C3 and XW043C3 to a proposed new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy. CMS proposed to revise the title for MS-DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC".

The vast majority of commenters supported this proposal; a few did not support the proposal and recommended CMS consider other options such as maintain the new technology add-on payment for CAR T-cell therapies and delay creating a new MS-DRG. CMS believes it has sufficient data to establish a new MS-DRG and not continue the new technology add-on payment.

CMS clarifies that as additional procedure codes describing CAR T-cell therapies are approved and finalized it will use its established process to assign these procedure codes to the most appropriate MS-DRG. Assigning new procedure codes involves review of the predecessor procedure code's MS-DRG assignment but this process does not automatically result in the new procedure code being assigned to the same MS-DRG as the predecessor code (84 FR 42061). CMS notes that if additional cellular therapies become available, it would use this process to assign the most appropriate MS-DRG.

In response to requests that CMS consider subdividing MS-DRG 018 into separate MS-DRG subgroups to account for the higher costs involved in treating patients who develop Cytokine Release Syndrome(CRS), CMS noted that it identified 262 total cases in MS-DRG reporting ICD-10 procedure codes XW033C3 or XW043C3 and will consider this in future rulemaking once additional data is available. CMS will also consider requests for the creation of new costs centers for revenue codes 891 and 892 in future rulemaking.

CMS acknowledges comments about outpatient billing instructions and payment issues for TEFRA hospitals but it considers these comments outside of the scope of the proposals in the proposed rule and will consider these for future years.

CMS **finalizes its proposal** to assign cases reporting ICD-10 PCS procedure codes XW033C3 or XW043C3 to MS-DRG 018 (CAR T-cell Immunotherapy) and to revise the title for MS- DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC".

3. MDC 1 (Diseases and Disorders of the Nervous System)

*a. Carotid Artery Stent Procedures*

In the FY 2020 IPPS final rule, CMS reassigned 96 ICD-10-PCS procedure codes describing dilation of carotid artery with an intraluminal device(s) from MS-DRGs 036, 038, and 039 (Extracranial Procedures) to MS-DRGs 034, 035, and 036 (Carotid Artery Stent Procedures). CMS received a request to review six ICD-10-PCS procedure codes describing dilation of a carotid artery with drug eluting intraluminal device using an open approach that are currently assigned to the logic for case assignment to MS-DRGs 037, 038, and 039 and not included in the list of codes finalized for reassignment to MS-DRGs o34, 035, and 036. Based on its analysis, CMS proposed to reassign these six ICD-10-procedure codes that describe procedures involving dilation of the carotid artery with an intraluminal device to MS-DRGs 034, 035, and 036. **CMS finalizes this proposal**.

During the review of claims data for these six codes, CMS reviewed the logic list for MS-DRGs 252, 253, and 254 (Other Vascular Procedures) and identified 36 ICD-10-PCS codes for procedures that describe dilation of the carotid artery with an intraluminal device with an open

approach that are not currently assigned to MDC 01. CMS' clinical advisors supported adding these codes to MS-DRGs 034, 035, and 036 in MDC 01. For FY 2021, CMS proposed to reassign the identified 36 ICD-10-PCS codes (listed in the final rule) that describe procedures involving dilation of the carotid artery with an intraluminal device through an open approach to the GROUPER logic for MS-DRGs 034, 035, and 036. **CMS finalizes this proposal**.
In response to a comment suggesting reassignment of additional codes, CMS states that recommendations regarding changes to the MS-DRG classification should be submitted no later than November 1, 2020 for possible inclusion in the FY 2022 proposed rule to MSDRGClassificationChange@cms.hhs.gov.

*b. Epilepsy with Neurostimulator*

CMS received a request to modify the MS-DRG assignment for cases involving the use of the RNS© neurostimulator, a cranially implanted neurostimulator used as a treatment option for individuals diagnosed with medically intractable epilepsy. Cases involving the RNS© neurostimulator are captured within four ICD-10-PCS codes (0NH00NZ, 00H00MZ, 00H03MZ, and 00H04MZ) and are assigned to MS-DRG 023. The requestor asked CMS to reassign these cases to MS-DRG 021 or to reassign these cases to another MS-DRG 021 for more appropriate payment. The requestor stated that MS-DRG is a better fit for the RNS© neurostimulator in terms of average cost and clinical coherence.

Based on its analysis of MS-DRG 023, CMS determined that the number of cases involving the RNS© neurostimulator (81 cases) is too small to warrant creating a new MS-DRG for these cases. CMS also examined the reassignment of these cases to MS-DRGs 020, 021, and 022 (Intracranial Vascular Procedures with PDX Hemorrhage). CMS' clinical advisors reviewed the claims data and the clinical issues and did not support reassigning these cases. CMS explored alternative options, including examining if these cases had at least one other procedure designated as an O.R. procedure and found that of the 81 cases, 19 reported at least one other procedure which had higher costs compared to the average costs of the other cases. CMS also reviewed the secondary diagnosis conditions reported for these 81 cases and found that these patients typically have multiple MCC and CC conditions which contribute to the increased cost for these patients. CMS concluded there is insufficient data to reassign these cases to another MS-DRG and anticipates that in the future, additional data based on an increased number of cases could be used to evaluate these cases. **CMS finalizes its proposal to maintain the assignment of RNS© neurostimulator cases**.

Commenters agreed with CMS' proposal not to reassign cases involving the RNS© neurostimulator. Several commenters expressed concerns that the costs for the insertion of this device is not recouped and suggested potential changes to the current MS-DRG assignments. CMS will continue to explore mechanisms to ensure appropriate assignment of cases with RNS© neurostimulators.

4. MDC 3 (Diseases and Disorders of Ear, Nose and Throat): Temporomandibular Joint Replacements

CMS received a request to consider reassignment of two ICD-10-procedure codes for replacement of the temporomandibular joint (TMJ), 0RRC0JZ and 0RRD0JZ from MS-DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures) to MS-DRGs 131 and 132 (Cranial and Facial Procedures). As an alternative, the requestor suggested CMS analyze if there is any other higher weighted MS-DRG that could more appropriately reimburse for a TMJ replacement with a prosthesis procedure. The requestor also recommended that CMS analyze all procedures involving the mandible and maxilla and consider reassigning these codes from MS-DRGs 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and 130 (Major Head and Neck Procedures without CC/MCC) to MS-DRGs 131 and 132 because the codes describe procedures performed on facial and cranial structures. The requestor also suggested another option that included modifying the surgical hierarchy for MDC 03 by sequencing MS-DRGs 131 and 132 above MS-DRGs 129 and 130 which would provide more appropriate payment for the performance of multiple fascial procedures. CMS performed multiple data analyses to evaluate this request that are summarized in the final rule.

As a result of its extensive review, CMS proposed the deletion of MS-DRGs 129 through 134 and the creation of six new MS-DRGs. CMS proposed to create two base MS-DRGS, each divided into 3 levels according to the presence of a CC or MCC. Specifically, CMS proposed MS-DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and proposed new MS-DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC respectively). Tables 6P.2a and Tables 6P.2b contain the list of procedure codes CMS proposed to assign to the new MS-DRGs. CMS also proposed the removal of procedure codes 00J00ZZ and 0WJ10ZZ and the 338 procedure codes listed in Table 6P.2c from the logic for MDC 03.

Commenters generally agreed with CMS' proposal. Several commenters recommended CMS review the list of proposed procedure codes for assignment to the proposed new MS-DRG. One commenter noted the procedure codes describing reposition of the left temporal bone and the procedure codes describing reposition of the right temporal bone were assigned to different MS-DRGs. Another commenter believed that CMS should classify all repositions of occipital, temporal, frontal and other bones of the skull as major surgery and assign them to proposed new MS-DRGs 140, 141, and 142.

CMS notes that the assignment of repositions of the temporal bones was an inadvertent error. CMS disagrees that all repositions of the occipital, temporal, frontal and other bones of the skull should be reassigned to the proposed MS-DRGs 140, 141, and 142.

**CMS finalizes its proposal for FY 2021 to**:

- Create two new base MS-DRGs, 140 and 143, with a three-way severity level split for new MS-DRGs 140, 141, and 143;
- Create new MS-DRGs 143, 144, and 145; and
- Delete MS-DRGs 129 – 134.

The finalized list of procedure codes that define the logic for the finalized MS-DRGs are available at https://www.cms.gov/MEdicar/Medicare-Fee-for-Service-PAyment/AcuteInpatientPPS/index

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

*a. Left Atrial Appendage Closure (LAAC)*

CMS received two separate but related requests involving the procedure codes describing the technology utilized in the performance of LAAC procedures. The first request was to reassign ICD-10-PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) from MS-DRG 274 (Percutaneous Intracardiac Procedures without MCC) to MS-DRG 273 (Percutaneous Intracardiac Procedures with MCC); ICD-10-PCS 02L73DK identifies the WATCHMAN LAAC device. The second request was to create a new MS-DRG specific to all LAAC procedures or to map all LAAC procedures to a different cardiovascular MS-DRG that have payment rates appropriate for the procedural costs. Cases involving LAAC procedures with a percutaneous or percutaneous endoscopic approach are assigned to MS-DRGs 273 and 274 (Percutaneous Intracardiac Procedures).

(1) Reassign ICD-10-PCS procedure code for WATCHMAN LAAC from MS-DRG 274 to MS-DRG 273. According to the requestor, within MS-DRG 274, cases with a LAAC procedure code (02L73DK) are more clinically similar and their costs are more closely aligned to cases with MS-DRG 273. CMS' data analysis demonstrated that the average costs of cases reporting procedure code 02L73DK in MS-DRG 274 have slightly higher costs than the average costs of all cases in MD-DRG 274 but the average length of stay for these cases is shorter compared to all the cases in MS-DRG 274. CMS noted that if it reassigned these cases with an average length of stay of 1.2 days to MS-DRG 273, it would be reassigning these cases to an MS-DRG with an average length of stay of 6.1 days. CMS' clinical advisors did not support this reassignment. The clinical advisors were also concerned about making MS-DRG changes based on a specific, single technology identified by only one procedure code (the WATCHMAN LAAC device) instead of considering proposed changes based on a group of related procedure codes that report similar technology. **CMS finalizes its proposal to maintain the assignment of cases reporting ICD-10-PCS procedure code 02L73DK to MS-DRG 273 and to maintain the current title for MS-DRG 273**.

Several commenters supported CMS' proposal. One commenter noted that MS-DRG categories are not intended to benefit a single technology or to be narrowly constructed to include a single device implant when there are other techniques and technologies that address a similar disease and do not require an implant. The commenter also stated that it was premature to modify MS-DRG 273 because there are a number of new technologies, including non-implanted devices, that are being studies in IDE approved clinical trials and should be considered in any MS-DRG reclassification. CMS appreciates this information and agrees that the new technologies should be considered in any potential future MS-DRG reclassification.

The requestor provided additional information and analysis. CMS' clinical advisors still continue to support the current structure of MS-DRGs 273 and 274 which includes all LAAC procedures, with or without an implant.

(2) All LAAC procedures. The MS-DRG assignments for the 9 ICD-10 PCS procedure codes that describe LAAC procedures are based on the surgical approach: open approach (MS-DRGs 250 and 251), percutaneous approach (MS-DRGs 273 and 274) , or percutaneous approach (MS-DRGs 273 and 274) (see table in the proposed rule for more details). CMS performed multiple data analyses to evaluate this request that are summarized in the proposed rule.

CMS' clinical advisors did not support creating a new MS-DRG for all LAAC procedures. The clinical advisors believed that procedure codes that describe a LAAC procedure with an open approach are more suitably grouped to MS-DRGs 273 and 274. **CMS finalizes its proposal to reassign the open approach ICD-10-PCS codes 02L70CK, 02L70DK, and 02L70ZK from MS-DRGs 250 and 251 to MS-DRGs 273 and 274.** CMS also finalizes a revision to the titles for MS-DRG 273 and 274 to "Percutaneous and Other Intracardiac Procedures" with and without MCC, respectively.

Several commenters supported this proposal; one commenter suggested CMS revise the titles of MS-DRGs 273 and 274 to include percutaneous and other intracardiac procedures. A commenter did not support the proposal because it would result in inappropriate procedures included under the title of "percutaneous" procedures. The commenter asserted that open atrial appendage closures are rarely performed as standalone procedures and, in those situations, they would be more appropriate assigned to MS-DRGs 228 and 229. In response, CMS considers the reassignment of open LAAC procedures outside the scope of the proposal discussed and will consider additional claims data analysis for these procedures in future rulemaking.

*b. Endovascular Cardiac Valve Replacement and Supplement Procedures*

CMS received a request to revise MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively) by removing the current two-way severity level split and create a base MS-DRG without any severity level split. CMS' analysis of the claims data supports the criteria for the current two-way split. CMS' clinical advisors also did not agree with the requestor that a single, base MS-DRG would assist in calculating costs for these cases more reliably. **CMS finalizes its proposal to maintain the current structure of MS-DRGs 266 and 237**.

In response to a commenter who suggested a modification of the logic for all the acute heart failure codes, CMS notes this suggestion is outside the scope of the proposed rule and should submitted to CMS by November 1, 2020 as an MS-DRG classification request.

*c. Insertion of Cardiac Contractility Modulation Device*

CMS received a request to review the MS-DRG assignment for cases that identify patient who receive a cardiac contractility modulation (CCM) device system for congestive heart failure. CCM utilizes electrical signals which are intended to enhance the strength of the heart and

overall cardiac performance. The requestor stated that MS-DRGs 222 through 227 (Cardiac Defibrillator Implant DRGs) include code combinations describing the insertion of the CCM device but the MS-DRG GROUPER logic needs to be revised to group cases reporting the use of the CCM device appropriately. The requestor noted that to date the procedure has been performed on an outpatient basis, but it is expected that some Medicare patients will receive CCM devices as hospital inpatients.

CMS agreed that the MS-DRG GROUPER logic needs to be revised and **finalizes its proposal to delete 12 clinically invalid code combinations for CCM devices and to add 24 ICD-10-PSC combinations for CCM devices (listed in the final rule) to MS-DRGs 222 through 227**. CMS will also monitor claims data for unintended consequences as a result of the deletion of the 12 clinically invalid code combinations from the GROUPER logic.
In response to a commenter's question about the assignment of CCM devices and cardiac resynchronization therapy pacemakers to different MS-DRGs, CMS acknowledges that clinical practice might have changed since the creation of codes for CCM and its clinical advisors believe additional analyses are needed in MDC 05, specifically for cases reporting both CCM device systems and pacemakers.

6. MDC 6 (Diseases and Disorders of the Digestive System): Acute Appendicitis

CMS received a request to add ICD-10-CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) to the list of complicated principal diagnoses that group to MS-DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis). This request grouped all the ruptured/perforated appendicitis codes in MD 06 to group to the same DRGs. ICD-10-CM diagnosis code K35.20 currently groups to MS-DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis). The requestor stated that K35.20 was the only ruptured appendicitis code not included in the complicated principal diagnosis list in MS-DRGs 338, 339, and 340.

Based on analysis of the claims data and input from its clinical advisors, CMS proposed to (1) maintain the current assignment of K35.20 to MS-DRGs 341, 342, and 342; (2) reassign diagnosis code K35.32 from MS-DRGs 338, 339, and 340 to MS-DRGs 341, 342, and 342; and (3) remove K35.32 from the complicated principal diagnosis list in MS-DRGs 338, 339, and 340. Commenters did not support the proposal to reassign diagnosis code K35.32 because this diagnosis represents a complicated diagnosis and requested CMS to maintain the current diagnosis classification. Another commenter analyzed data from their facility and found that the average LOS (4.18 days) and average charges ($60,000) supporting the current MS-DRG assignments for these cases. CMS' clinical advisors continue to believe that the degree and severity of peritonitis varies greatly in a patient with acute appendicitis but they also are aware that the National Center for Health Statistics (NCHS) is reviewing diagnosis codes K35.2 and K35.3. CMS decides not to finalize the related proposals for K35.32 and will continue to analyze this issue in future rulemaking.

**CMS finalizes its proposal that diagnosis code K35.20 will maintain its current assignment to MS-DRGs 341, 342, and 342. CMS is not finalizing its proposal to reassign diagnosis**

**code K35.32 from MS-DRGs 338, 339 and 340 and to continue to list K35.32 as a complicated principal diagnosis for these MS-DRGs**.

7. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

*a.* Cervical Radiculopathy

CMS received a request to reassign two ICD-10-CM diagnosis codes for radiculopathy (M54.11 and M54.13) from MDC 01(Nervous System) to MDC 08. The requestor stated when these diagnosis codes are reported as a principal diagnosis in combination with a cervical spinal fusion procedure, the cases currently group to MDC 01 in MS-DRGs 028,029, and 030 (Spinal Procedures) and they should group with other cervical spinal fusion procedures to MDC 08 in MS-DRGs 471, 472, and 473 (Cervical Spinal Fusion).

Based on claims data for cases reporting a principal diagnosis of cervical radiculopathy with a spinal cord fusion, CMS found the average costs of the cases are consistent with the average costs of all the cases in MS-DRGs 028, 029, and 030 and also consistent with the average costs of all the cases in MS-DRGs 471, 472, and 473. CMS' clinical advisors did not support reassigning the diagnosis codes that describe radiculopathy in the cervical/cervicothoracic area of the spine until it performs additional analysis of the appropriate assignment of these codes and other diagnosis codes describing radiculopathy. **CMS finalizes its proposal to maintain the diagnosis codes in MDC 01 at this time**. CMS will do further analysis of all diagnosis codes describing radiculopathy of a specified or unspecified site to determine if they should be assigned to the same MDC, and if so, whether those codes should be assigned to MDC 01 or MDC 08.

*b. Hip and Knee Joint Replacements*

CMS received a request to restructure the MS-DRGs for total joint arthroplasty that utilizes an oxidized zirconium bearing surface implant for total hip replacement and total knee replacement procedures. The requestor provided three options for consideration; two options involved creating a new MS-DRG for joint replacements utilizing an oxidized zirconium bearing surface implant and the third option was to reassign all the cases reporting a total hip replacement using an oxidized zirconium bearing implant with a principal diagnosis of hip fracture from MS-DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) to MS-DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement). The requestor also welcomed CMS analysis of the claims data that might better align patient severity, clinical value, and payment.

Based on claims data analysis and input from its clinical advisors, CMS did not agree with the first and second option suggested by the requestor. For option three, the clinical advisors recommended CMS conduct further review of cases reporting a hip replacement procedure with a principal diagnosis of hip fracture, with or without an oxidized zirconium bearing surface implant. CMS performed additional analysis of cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture for both MS-DRGs 469 and 470. Based on this analysis, the clinical advisors supported differentiating the cases reporting a total hip

replacement procedure with a principal diagnosis of hip fracture from those cases without a hip fracture by assigning them to a new MS-DRG. CMS applied the criteria to create subgroups in a base MS-DRG and found the criteria for a two-way split for the "with MCC" and "without MCC' met all five criteria.

**CMS finalizes its proposal to create two new MS-DRGs**: MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and MS-DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC). Table 6p.1d has the list of procedure codes describing hip replacement procedures and Table 6P.1e has the list of diagnosis codes describing hip fracture diagnoses that CMS proposes for these new MS-DRGs.

Several commenters supported this proposal; a few supported the proposal but thought CMS should not finalize until further analysis could be conducted. CMS provides additional analysis in the final rules supporting the proposal.

A commenter expressed appreciation for CMS' proposal but believed that CMS should adopt a specific MS-DRG for patients with a principal diagnosis of hip fracture receiving an oxidized zirconium bearing surface implant in a hip replacement procedure. The commenter indicated CMS has broad statutory authority and did not need to limit its MS-DRG subgroups exclusively to co-morbidities or complications. The commenter also though CMS should utilize the substantial clinical improvement criterion as part of its DRG assignment. The commenter thought that if CMS did not agree with the need for a specific MS-DRG for oxidized zirconium implant it supported CMS' proposal. CMS does not believe it is appropriate or necessary to create a separate MS-DRG subgroup for patients that receive an oxidized zirconium bearing surface implant and will consider the commenter's suggestion in future rulemaking.

In the proposed rule, CMS noted that the Comprehensive Care for Joint Replacement (CJR) model includes episodes for hip fracture triggered by MS-DRGs 469 and MS-DRG 470 and invited comments on the effect of the proposal to create new MS-DRGs 521 and 522 would have on the CJR model. CMS notes that the comment period for the CJR proposed rule closed on June 23, 2020 and it intends to address all comments received in the Comprehensive Care for Joint Replacement Model Three-Year Extension final rule. CMS also notes that it has extended the duration of the CJR model through March 31, 2021 to ensure continuity of CJR models during the COVID-19 PHE. It plans to adopt a policy in the CJR final rule that incorporates MS-DRG 521 and MS-DRG 522 into the CJR model as of the effective date of these new MS-DRGs.

8. MDC 11 (Diseases and Disorder of the Kidney and Urinary Tract)

*a. Kidney Transplants*

CMS received two requests to review the MS-DRG assignment for procedures describing kidney transplantations. The first request was to designate kidney transplants as a Pre-MDC MS-DRG in the same manner as other organ transplants. The requestor stated it did not appear appropriate that a kidney transplant would group to MS-DRG 981 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) when diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease) was a

legitimate principle diagnosis for this procedure. The requestor also suggested a severity level split for the MS-DRG for kidney transplants. The second request was to create a new MS-DRG for kidney transplant cases where the patient received dialysis during the inpatient stay and after the date of the transplant.

CMS noted that in the FY 2020 IPPS rules,[3] it proposed to add procedure codes for transplantation of allogeneic kidneys (ICD-10-PCS 0TY00Z0 and 0TY10Z0) to MS-DRG 264 in MDC 05. (Disease and Disorders of the Circulatory System). Cases reporting a principal diagnosis in MDC 05 with a procedure describing a kidney transplantation would group to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05. Commenters opposed CMS' proposal and raised concerns that the proposal would reduce the reimbursement for kidney transplantation of recipients with serious cardiac conditions by 33 percent. Commenters stated that cases involving both chronic kidney disease and heart failure should not be paid less that cases involving patients without serious comorbid conditions. After consideration of comments, CMS did not finalize its proposal and stated it would continue to examine this issue. Cases reporting a principal diagnosis in MDC 05 with a procedure describing kidney transplantation continue to group to MS-DRGs 981 through 983.

(1) Designate kidney transplants as a Pre-MDC MS-DRG. CMS did several data analyses, including analyzing clinical data for cases reporting a circulatory O.R. procedure and MDC 05 ICD-10-CM diagnosis code I13.2. The results showed that if CMS moved diagnosis code I13.2 to MDC 11, 4,366 cases would be assigned to the surgical class referred to as "unrelated operating room procedures". As an alternative option, CMS proposed to modify the grouper language for MS-DRG 652 (Kidney Transplant) to allow the presence of a procedure code describing kidney transplantation to determine the MS-DRG assignment independent of the MDC of the principal diagnosis except the logic for MDC 24 (Multiple Significant Trauma) and MDC 25 (Human Immunodeficiency Virus Infections) will remain unchanged. Diagram 1 in the proposed rule illustrates how the logic for the MS-DRG would work. **CMS finalizes its proposal to modify the grouper language for MS-DRG 652 (Kidney Transplant)**.

CMS also examined whether MS-DRG 652 met the criteria for a severity level split and did not find a two-way split meeting the five criteria. **CMS finalizes its proposal not to subdivide MS-DRG 652 into severity levels.**

(2). Create a new MS-DRG for kidney transplant cases where the patient receives dialysis. CMS acknowledged that MS-DRG 652 is one of the only transplant MS-DRGs not currently defined as a Pre-MDC. For Pre-MDC DRGs, the initial step in DRG assignment is based on the high costs of certain surgical procedures instead of the principal diagnosis. Pre-MDC DRGs were added to Version 8 of the DRGs for services that were considered as very resource intensive. CMS stated the current proposed refinements to MS-DRG 652 represent how it may further consider the concept of allowing certain procedures to affect MS-DRG assignment regardless of the MDC from which the diagnosis is reported. This might allow removing the Pre-MDC category and allow resource intensive procedures currently assigned to Pre-MDC MS-DRGs to be assigned to MS-DRGs within the clinically appropriate MDC.

[3]The proposal was discussed in the FY 2020 IPPS PPS final rule, 84 FR 42128 through 42129.

CMS' examined the impact of dialysis in cases in MS-DRG and found that the average length of stay and average cost of cases in MS-DRG 652 where the patient received hemodialysis and a kidney transplant were higher than for all cases in the MS-DRG. CMS did a similar analysis with patients that require a simultaneous pancreas/kidney transplant procedure and found similar findings for cases in Pre-MDC MS-DRG 008 (Simultaneous Pancreas/Kidney Transplant). CMS' clinical advisors believed that hemodialysis procedures performed either before or after kidney transplant or a simultaneous pancreas/kidney transplant contributed to increased resource consumption for these patients. Although the data only had a few cases describing a simultaneous pancreas/kidney transplant with hemodialysis procedures, CMS believed creating a separate MS-DRG for these cases would be consistent with the President's Executive Order on Advancing American Kidney Health.[4] CMS also examined if the criteria were met for severity level subgroups.

**CMS finalizes its proposals to**:

- Create a new-Pre-MDCMS-DRG for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant, Pre-MDC MS-DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis)
- Create two new MS-DRGs with a two-way severity level split for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11, MS-DRG 650 (Kidney Transplant with Hemodialysis with MCC) and MS-DRG 651 (Kidney Transplant with Hemodialysis without MCC).

CMS finalizes its proposal to add the procedure codes from the current Pre-MDC MS-DRG 008 to the proposed new MS-DRG 019 with the procedure codes describing a hemodialysis procedure. Similarly, CMS finalizes its proposal to add the procedure codes from MS-DRG 652 to the proposed MS-DRGs 650 and 651 with the procedure codes describing a hemodialysis procedure. For the logic for the new MS-DRGs, CMS also finalizes its proposal to designate these codes as non-O.R. procedures affecting the MS-DRG. Diagram 1 in the final rule illustrates how the MS-DRG logic for kidney transplants will work.

Many commenters supported this proposal. A few commenters opposed this proposal because of concerns that it would decrease Medicare payment for all kidney transplants not requiring post-transplant dialysis. CMS continues to believe the new MS-DRG would improve clinical coherence and address the differential in resource consumption is cases requiring hemodialysis.
*b. Proposed Addition of Diagnosis to Other Kidney and Urinary Tract Procedures Logic*
*CMS received* a request to add 29 ICD-10-CM diagnosis codes to the list of principal diagnoses assigned to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures) in MDC 11 when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices.

[4] https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/

| ICD-10-CM Code | Code Description | MDC |
|---|---|---|
| T86.11 | Kidney transplant rejection | 11 |
| T86.12 | Kidney transplant failure | 11 |
| T86.13 | Kidney transplant infection | 11 |
| T86.19 | Other complication of kidney transplant | 11 |
| E10.21 | Type 1 diabetes mellitus with diabetic nephropathy | 11 |
| E10.22 | Type 1 diabetes mellitus with diabetic chronic kidney disease | 11 |
| E10.29 | Type 1 diabetes mellitus with other diabetic kidney complication | 11 |
| E11.21 | Type 2 diabetes mellitus with diabetic nephropathy | 11 |
| E11.22 | Type 2 diabetes mellitus with diabetic chronic kidney disease | 11 |
| E11.29 | Type 2 diabetes mellitus with other diabetic kidney complication | 11 |
| E13.21 | Other specified diabetes mellitus with diabetic nephropathy | 11 |
| E13.22 | Other specified diabetes mellitus with diabetic chronic kidney disease | 11 |
| E13.29 | Other specified diabetes mellitus with other diabetic kidney complication | 11 |
| I13.2 | Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease | 05 |
| T80.211A | Bloodstream infection due to central venous catheter, initial encounter | 05 |
| T80.212A | Local infection due to central venous catheter, initial encounter | 05 |
| T80.218A | Other infection due to central venous catheter, initial encounter | 05 |
| T82.41XA | Breakdown (mechanical) of vascular dialysis catheter | 05 |
| T82.42XA | Displacement of vascular dialysis catheter | 05 |
| T82.43XA | Leakage of vascular dialysis catheter | 05 |
| T82.49XA | Other complication of vascular dialysis catheter | 05 |
| T82.7XXA | Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter | 05 |
| T82.818A | Embolism due to vascular prosthetic devices, implants and grafts, initial encounter | 05 |
| T82.828A | Fibrosis due to vascular prosthetic devices, implants and grafts, initial encounter | 05 |
| T82.838A | Hemorrhage due to vascular prosthetic devices, implants and grafts, initial encounter | 05 |
| T82.848A | Pain due to vascular prosthetic devices, implants and grafts, initial encounter | 05 |
| T82.858A | Stenosis of other vascular prosthetic devices, implants and grafts, initial encounter | 05 |
| T82.868A | Thrombosis due to vascular prosthetic devices, implants and grafts, initial encounter | 05 |

Based on a review of the data and input from its clinical advisors, CMS made the following proposals:

- Not to add the following 18 ICD-10-CM codes to the list of principal diagnosis codes for MS-DRGs 673, 674, and 675 when reported with a procedures code describing the insertion of a TIVAD or a tunneled vascular access device: E10.21, E10.29, E11.21, E11.29, E13.21, E13.29, I13.2, T80.211A, T80.212A, T80.218A, T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A.
- Add ICD-10-CM codes E09.22, E10.22, E11.22, and E13.22, when reported with a secondary diagnosis of N18.5 or N18.6, to the list of principal diagnosis codes in the subset of GROUPER logic in MS-DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis. Add ICD-10-CM codes T86.11, T86.12, T86.13, and T86.19 to the list of principal diagnosis codes in this subset of GROUPER logic in MS-DRGs 673, 674, and 675.
- Remove ICD-10-CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 from the subset of GROUPER logic in MS-DRGs 673, 674, and 675 that recognizes the

insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

Commenters supported these proposals and **CMS finalizes these proposals**.

9. MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms: Inferior Vena Cava Filter Procedures

CMS received a request to review the GROUPER logic in MDC 17 for chemotherapy diagnoses reported with procedures describing the placement of an inferior vena cava (IVC) filter. CMS' clinical advisors reviewed the data and indicated that ICD-10-procedure codes describing the insertion of an intraluminal device into the IVC (06H00DZ, 06H03DZ, and 06H04DXZ) do not require the resources of an operating room and that these codes should be designated as Non-O.R. procedures. CMS proposed to remove these three ICD-10-PCS procedure codes from the MS-DRG Version 38 Definitions Manual Appendix E as O.R. procedures. Under this proposal, these procedures would no longer impact MD-DRG assignments.

CMS' clinical advisors agree with comments that insertion of an IVC filter is not surgical in nature, and procedures describing the insertion of an intraluminal device into the IVC performed via an open or a percutaneous endoscopic approach could require greater resources than a procedure describing insertion of an intraluminal device into the IVC performed via a percutaneous approach.

**CMS finalizes its proposal to change the designation of ICD-10 PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure. CMS maintains the designation of procedure codes 06H00DZ and 06H04DZ and these procedure codes will continue to impact MS-DRG assignment**.

10. Review of Procedure Codes in MS-DRGs 981 through 983 and 987 through 989

*a. Adding Procedure and Diagnosis Codes*

CMS annually reviews procedures grouping to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) or MS-DGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) on the basis of volume and by procedure to see if it would be appropriate to move these procedure codes into one of the surgical MS-DRGs for the MDC related to the principal diagnosis. CMS looks at both the frequency count of each major operative procedure code and compares procedures across MDCs by the volume of procedure codes within each MDC.

CMS **finalized its proposals** to move the cases reporting the procedures and/or principal diagnosis codes described below from MS-DRGs 981 through 983 and 987 through 989 into one of the surgical MS-DRGs for the MDC which the principal diagnosis or procedure is assigned. The reader is referred to the final rule for a discussion of the following diagnoses:

- Horseshoe Abscess with Drainage
- Chest wall Deformity with Supplementation
- Hepatic Malignancy with Hepatic Artery Embolization
- Hemoptysis with Percutaneous Artery Embolization
- Acquired Coagulation Factor Deficiency with Percutaneous Artery Embolization
- Epistaxis with Percutaneous Artery Embolization
- Revision or Removal of Synthetic Substitute in Peritoneal Cavity
- Revision of Totally Implantable Vascular Access Devices
- Multiple Trauma with Internal Fixation of Joint

*b. Reassignment of Procedures*.

CMS **finalizes its proposals** for the following reassignments:

- Reassign three procedure codes from MS-DRGs 981, 982, and 983 to MS-DRGs 987, 988, and 989: ICD-10-PCS codes for 0W3G3ZZ and 0W3G4ZZ (control bleeding in peritoneal cavity) and 0WBC0ZX (Excision of mediastinum, open approach)
- Reassign three procedure codes from MS-DRGs 987, 988, and 989 to MS-DRGs 981, 982, and 983: ICD-10-PCS codes for 0DB90ZZ (Excision of duodenum), 0DBA0ZZ (Excision of jejunum), and 0DBB0ZZ (Excision of ileum).

11. Operating Room (O.R.) and Non-O.R. Issues

CMS has a list of procedures that are considered O.R. procedures. CMS discussed how historically this list was developed using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.)

CMS describes the current process used to determine whether and in what way each ICD-10-PCS procedure code on a claim impacts the MS-DRG assignment. First, each procedure code is either designated as an O.R. or non-O.R. procedure.[5] Second, each O.R. procedure is further classified as either extensive or non-extensive. Third, each non-O.R. procedure is further classified as either affecting or not affecting the MS-DRG assignment (CMS refers to these as "non-O.R. affecting the MS-DRG"). For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS-DRG, CMS' clinical advisors recommend the MS-DRG assignment which are listed in Table 6B (New Procedure

[5] CMS refers readers to the ICD-10 MS-DRG Version 36 Definitions Manual for detailed information regarding the designation of procedures as O.R. or non-O.R. affecting the MS-DRG. This is available at https://www.cms.gov/MEdicare/MEdicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Softwar.html.

Codes) and subject to public comment.[6] CMS notes these proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes.

In the FY 2020 IPPS proposed rule, CMS discussed its plans to conduct a multi-year comprehensive, systematic review of the O.R. and non-O.R. ICD-10-PCS procedure codes. CMS believes there may be other factors, such as resource utilization, besides whether or not a procedure is performed in an operating room for determining these designations.

Several commenters requested that CMS consider the complexity and resource consumption for the entire procedure and not only O.R. charges. The commenters discussed the differences between large hospitals with hybrid operating rooms or specialized procedure rooms (e.g., interventional radiology suites) and smaller communities hospitals with multi-purpose O.R.s where the same room may be used for invasive general surgeries as well as procedures, such as a cardiac catherization, that may be performed in catherization lab in larger hospitals. The commenters noted that the complexity and resource consumption for the procedure may be similar wherever the procedure was performed. Another commenter suggested CMS consider the definition of a "significant procedure" as defined in the Uniform Hospital Discharge Data Set (UHDDS) which is not dependent on whether an "O.R." is required. CMS agrees that there may be other factors to consider with resource consumption and it is exploring alternatives on how to restructure the current O.R. and non-O.R. designations for procedures.

Several commenters suggested that CMS create an advisory panel comprised of clinical, coding and financial stakeholders, physician specialty societies and experts to review methodologies for O.R. determination. Commenters thought CMS should also address procedures performed in all settings because there may be important variations based on factors such as geographic differences and hospital size. CMS notes it has already convened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts and looks forward to industry collaboration.

**CMS again requests comments on what factors or criteria should be considered in determining whether a procedure is designated as an O.R. procedure**. Commenters should submit their recommendations by October 20, 2020 to MSDRGClassificationChange@cms.hhs.gov. CMS will provide more information about this issue, including responding to comments, in future rulemaking.

For review of requests for FY 2021 consideration, CMS' clinical advisors considered the following for each procedure:

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or non-extensive procedure; and
- To which MS-DRG the procedure should be assigned.

[6] Table 6B is available at https://www.cms.gove/Medicare/Medicare-Fee-for-Service-PAyment/AcuteInpatientPPS/index.html.

In addition, cases that contain O.R. procedures will map to MS-DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) or MS-DRGs 987, 988, or 989 (Non-Extensive O.R, Procedure Unrelated to Principal Diagnosis) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. Thus, these procedures do not need to be assigned to MS-DRGs 981 through 989.
CMS received several requests to change the O.R. designation of specific ICD-10-PCS procedure codes. CMS will consider some of these requests as part of its comprehensive review of procedure codes. The reader is referred to the final rule a discussion of the **finalized proposals** for the following requests:

*a. O.R. Procedures to Non-O.R. Procedures*

- Endoscopic Revision of Feeding Tubes

*b. Non O.R. Procedures to O.R. Procedures*

- Percutaneous/Endoscopic Biopsy of Mediastinum
- Percutaneous Endoscopic Chemical Pleurodesis
- Percutaneous Endoscopic Excision of Stomach
- Percutaneous Endoscopic Drainage
- Control of Bleeding
- Inspection of Penis

12. Changes to the MS-DRG Diagnosis Codes for FY 2021

Under the IPPS MS-DRG classification, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule[7], CMS described its process for establishing three different levels of CC severity into which it would subdivide the diagnoses codes: MCC, a CC, or a non-CC.

In the FY 2020 IPPS proposed rule, CMS proposed changes to the severity level designations for 1,492 ICD-10-CM diagnosis codes. Many commenters expressed concern with CMS' proposal and recommended that CMS conduct further analysis. In the FY 2020 final rule, CMS postponed adoption of the proposed comprehensive changes in the severity level designations to allow further opportunity to provide additional information to the public on the methodology utilized and clinical rationale for its proposals.[8] CMS hosted a listening session on October 8, 2019[9] to provide CMS an opportunity to receive public input on its analysis and to address any questions to assist the public in formulating written comments for consideration in the FY 2021 rulemaking.

[7] 72 FR 47152 through 47171
[8] 84 FR 42150 through 42152
[9] A transcript and audio file of the listening session is available at https://www.cms.goc/Outreach-and-Education/Outreach/OpenDoorForums/PoscastAndTranscripts.html. The supplementary file containing the data for the proposed changes is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html.

Following the listening session, CMS considered the public comments received and reconvened an internal workgroup to identify guiding principles to apply in evaluating whether changes to the severity level of diagnosis are needed. The goal was to develop a set of guiding principle that could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resources in most instances. The workgroup identified the following nine principles as meaningful indicators of expected resource use by a secondary diagnosis:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and ability.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions,
- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

CMS plans to continue a comprehensive CC/MC analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles.

Many commenters supported the guiding principles and thought that using them instead of solely relying on a mathematical analysis of claims data was a good approach. Some commenters were concerned that the guiding principles are general and open to interpretation and do not provide a clear logic for decision-making. CMS clarifies that the guiding principles are not criteria but are intended to provide a framework for assessing relevant clinical factors. As part of an examination of the secondary diagnoses, CMS would consider what additional resources are required, beyond those that are already utilized to address the principal diagnosis and/or secondary diagnoses that might be present on the claim.

CMS states that the goal of its comprehensive analysis is to create stratification for reimbursing inpatient hospitalizations in the fewest categories with the most explanatory power in a clinically cohesive way. CMS intends to use the guiding principles in making an initial clinical assessment of the appropriate severity level diagnosis for each ICD-10-CM code as a secondary diagnosis. CMS will then use a mathematical analysis of claims data to determine if the presence of the ICD-10-CM code as a secondary diagnosis appears to increase hospital resource consumption. CMS notes there may be circumstances where it decides that the clinical analysis after application of the nine guiding principles weighs in favor of proposing to maintain or proposing changes to the severity designation of an ICD-10-CM code.

CMS disagrees with commenters that the guiding principles would be mostly applicable to MCC conditions. CMS notes that it does not intend to require a diagnosis code satisfy each guiding principle or a specific number of principles in assessing whether to designate a secondary

diagnosis code as a non-CC versus a CC versus an MCC. CMS refers readers to the FY 2008 IPPS final rule (72 FR 47159) for a complete discussion of its approach.

CMS appreciates suggestion of other available data sets to use for analysis of severity levels for diagnostic codes. CMS notes that the Medicare Grouper is for the Medicare population and does not account for all populations included in the APR-DRG GROUPER, so it does not generally use the APR-DRG GROUPER. CMS is considering the use of datasets other than MedPAR for codes, such as obstetrical codes, with limited use in the Medicare population.

The final rule discusses the comments CMS received for each guiding principle. CMS agrees with commenters' that the guiding principles include the term "post-procedure' to more broadly recognize that some procedures have associated complications that are severe and typically require additional resources.

**CMS finalizes, with modifications, the nine guiding principles**:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and ability.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions,
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

**CMS continues to solicit feedback regarding these guiding principles and other suggestions for incorporating meaningful indicators of clinical severity**. CMS requests that comments include a detailed explanation of how applying a suggested principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code. Commenters should submit their recommendations by November 1, 2020 to MSDRGClassificationChange@cms.hhs.gov.

*a. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2021*[10]

The following tables identify the proposed additions and deletions to the diagnosis code MCC and CC severity levels:

[10] The tables are available on the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

- Table 6I – Compete MCC List
- Table 6I.1 – Proposed Additions to the MCC List;
- Table 6I.2 – Proposed Deletions to the MCC List;
- Table 6J.1 – Proposed Additions to the CC List; and
- Table 6J.2 – Proposed Deletions to the CC List

*b. CC Exclusions List for FY 2021*

CMS created the CC Exclusions List to preclude coding of CCs for closely related conditions; to preclude duplicative or inconsistent coding from being treated as CC's; and to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. CMS received a request to consider removing diagnosis codes describing any type of stroke that is designated as an MCC in the code range I60.00 through I63.9 from the CC Exclusion List when a principal diagnosis of diabetes in the code range E08.00 through E13 is reported. CMS reviewed this request and proposed to accept this request as reflected in Tables GH.1 and GH.2 for the CC Exclusion List. **CMS finalizes this proposal**.

The following tables identify the final additions and deletions to the CC Exclusion list:

- Table 6G.1 - Secondary Disorders Order Additions to the CC Exclusion List;
- Table 6G.2 - Principal Disorders Order Additions to the CC Exclusion List;
- Table 6H.1 - Secondary Disorders Order Deletions to the CC Exclusion List;
- Table 6H.2 - Secondary Disorders Order Deletions to the CC Exclusion List; and
- Table 6K - Complete List of CC Exclusions

13. Changes to the ICD-10-CM and ICD-10-PCS Coding Systems

The following tables identify new, revised and deleted diagnosis and procedure codes for FY 2021:

- Table 6A - New Diagnosis Codes;
- Table 6B - New Procedure Codes;
- Table 6C - Invalid Diagnosis Codes; and
- Table 6D - Invalid Procedure Codes.

The tables are available on the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

CMS received many comments related to a subset of diagnosis codes for cases with Cytokine Release Syndrome (CRS) associated with COVID-19**. CMS finalizes its proposals with modifications** and summarizes the final decisions in the table below, reproduced from the final rule. CMS also finalizes modifications to the ICD-10 MS-DRG GROUPER logic V38 for MS-DRGs 814, 815 and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively).

| ICD-10-CM Code | Description | Proposed Severity Level | Finalized Severity Level |
|---|---|---|---|
| D89.831 | Cytokine Release Syndrome, grade 1 | NonCC | NonCC |
| D89.832 | Cytokine Release Syndrome, grade 2 | NonCC | NonCC |
| D89.833 | Cytokine Release Syndrome, grade 3 | NonCC | CC |
| D89.834 | Cytokine Release Syndrome, grade 4 | NonCC | CC |
| D89.835 | Cytokine Release Syndrome, grade 5 | NonCC | CC |
| D89.839 | Cytokine Release Syndrome, grade unspecified | NonCC | NonCC |

The final rule discusses additional comments CMS received for specific diagnosis and procedure codes. This includes a detailed discussion of the assignment of the procedure codes for Ultrasound accelerated thrombolysis procedures utilizing the EKOS device; CMS finalizes its proposal.

14. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedures, and demographic information are entered into the Medicare claims processing systems and 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. The link to the MCE Version 38 manual file, along with the link to the mainframe and compute software for the MCE Version 38 (and ICD-10 MS-DRGs) are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS discusses requests it received by November 1, 2019 to examine specific code edit lists in the final rule for the following edits:

- Age conflict;
- Sex conflict;
- Manifestation Code as Principal Diagnosis Edit; and
- Unacceptable Principal Diagnosis Edit.

CMS engaged a contractor to assist in the review of the limited coverage and noncovered procedure edits in the MCE that may also be in the claims processing systems utilized by the MACs. The review is designed to identify where duplicate edits may exist and to determine the impact if these edits were removed from the MCE. CMS is considering whether the inclusion of coverage edits in the MCE necessarily aligns with the MCE goals to ensure that errors and inconsistences in the coded data are recognized during claims processing.

CMS encourages **comments on whether there are additional concerns with the current edits**, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to MSDRGClassificationChange@cms.hhs.gov by November 1, 2020.

15. Changes to Surgical Hierarchies

The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive. It ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS-DRG by frequency to determine the weighted average resources for each surgical class.

Based on the finalized MS-DRG proposals for FY 2021, the following tables, reproduced form the final rule, summarize the changes for Appendix D MS-DRG Surgical Hierarchy by MDC and MS-DRG of the ICD-10 MS-DRG Definitions Manual Version 38. **CMS finalizes these proposals without any modifications**.

| **Surgical Hierarchy: Pre-MDC MS-DRGs** | |
|---|---|
| Proposed New MS-DRG 018 | Chimeric Antigen Receptor (CAR) T-cell Immunotherapy |
| MS-DRGs 001-002 | Heart Transplant or Implant of Heart Assist System |
| MS-DRGs 003-004 | ECMO or Tracheostomy with MV >96 Hours or PDX Except Face, Mouth and Neck |
| MS-DRGs 005-006 | Liver or Intestinal Transplant |
| MS-DRG 014 | Allogeneic Bone Marrow Transplant |
| MS-DRG 007 | Lung Transplant |
| Proposed New MS-DRG 019 | Simultaneous Pancreas/Kidney Transplant with Hemodialysis |
| MS-DRG 008 | Simultaneous Pancreas/Kidney Transplant |
| MS-DRGs 016-017 | Autologous Bone Marrow Transplant |
| MS-DRG 010 | Pancreas |
| MS-DRG 011-013 | Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy |

| **Surgical Hierarchy: MDC 03** | |
|---|---|
| Proposed New MS-DRGs 140-142 | Major Head and Neck Procedures |
| Proposed New MS-DRGs 143-145 | Other Ear, Nose, Mouth and Throat O.R. Procedures |
| MS-DRGs 135-136 | Sinus and Mastoid Procedures |

| **Surgical Hierarchy: MDC 08** | |
|---|---|
| MS-DRGs 453-455 | Combined Anterior/Posterior Spinal Fusion |
| MS-DRGs 456-458 | Spinal Fusion Except Cervical with Spinal Curvature / Malignancy / Infection or Extensive Fusions |
| MS-DRGs 459-460 | Spinal Fusion Except Cervical |
| MS-DRGs 461-462 | Bilateral or Multiple Major Joint Procedures of Lower Extremity |
| MS-DRGs 463-465 | Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders |
| MS-DRGs 466-468 | Revision of Hip or Knee Replacement |
| Proposed New MS-DRGs 521-522 | Hip Replacement with Principal Diagnosis of Hip Fracture |
| MS-DRGs 469-470 | Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity |

| Surgical Hierarchy: MDC 11 | |
|---|---|
| Proposed New MS-DRGs 650-651 | Kidney Transplant with Hemodialysis |
| MS-DRG 652 | Kidney Transplant |

16. Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems

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 NCHS has lead responsibility for the ICD-10-CM diagnosis codes and CMS has lead responsibility for the ICD-10-PCS 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, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments can also be sent to: nchsicd10cm@cdc.gov.
- For procedure codes send questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

The official list of ICD-10-CM and ICD-10-PCS codes can be found at https://www.cms.gov/Medicare/Coding/ICD10/index

CMS notes that Change Request (CR) 11623, Transmittal 10317, "Update to the ICD-10 Diagnosis Codes for Vaping Related Disorder and Diagnosis and Procedure Codes for the 2019 Novel Coronavirus (COVID-19) was issued on August 21, 2020 and is available at: https://www.cms.gov/files/document/r10317OTN.pdf. CMS also announced on July 30, 2020 the implementation of 12 new ICD-10-PCS procedure codes to identify the introduction or infusion of therapeutics for treating hospital inpatients with COVID-19. These codes are effective with discharges on and after August 1, 2020 and are designated as non-O.R. codes.

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[11], 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/LTCH final rule,[12] 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.

[11] 72 FR 47246 through 47251
[12] 76 *FR* 51556 and 51557

CMS generally maps new MS-DRGs onto the list when they are formed from procedures previously assigned to MS-DRGs that are already on the list. Since CMS finalized the applicable proposed MS-DRG changes, **CMS finalizes its proposal to add MS-DRGs 140, 141, 142, 521, and 552 to the list**. CMS also finalizes its proposal to continue to include the existing MS-DRGs current subject to the policy as displayed in the table reproduce below from the final rule.

| 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 | 141 | Major Head and Neck Procedures with MCC |
| MDC 03 | 142 | Major Head and Neck Procedures with CC |
| MDC 03 | 143 | Major Head and 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 5 | 218 | Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC |
| MDC 5 | 219 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC |
| MDC 5 | 220 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC |
| MDC 5 | 221 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC |
| MDC 5 | 222 | Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with 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 5 | 223 | Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC |
| MDC 5 | 224 | Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC |
| MDC 5 | 225 | Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC |
| MDC 5 | 226 | Cardiac Defibrillator Implant without Cardiac Catheterization with MCC |
| MDC 5 | 227 | Cardiac Defibrillator Implant without Cardiac Catheterization without MCC |
| MDC 5 | 242 | Permanent Cardiac Pacemaker Implant with MCC |
| MDC 5 | 243 | Permanent Cardiac Pacemaker Implant with CC |
| MDC 5 | 244 | Permanent Cardiac Pacemaker Implant without CC/MCC |
| MDC 5 | 245 | AICD Generator Procedures |
| MDC 5 | 258 | Cardiac Pacemaker Device Replacement with MCC |
| MDC 5 | 259 | Cardiac Pacemaker Device Replacement without MCC |
| MDC 5 | 260 | Cardiac Pacemaker Revision Except Device Replacement with MCC |
| MDC 5 | 261 | Cardiac Pacemaker Revision Except Device Replacement with CC |
| MDC 5 | 262 | Cardiac Pacemaker Revision Except Device Replacement without CC/MCC |
| MDC 5 | 265 | AICD Lead Procedures |
| MDC 5 | 266 | Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC |
| MDC 5 | 267 | Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC |
| MDC 5 | 268 | Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC |
| MDC 5 | 269 | Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC |
| MDC 5 | 270 | Other Major Cardiovascular Procedures with MCC |
| MDC 5 | 271 | Other Major Cardiovascular Procedures with CC |
| MDC 5 | 272 | Other Major Cardiovascular Procedures without CC/MCC |
| MDC 5 | 319 | Other Endovascular Cardiac Valve Procedures with MCC |
| MDC 5 | 320 | Other Endovascular Cardiac Valve Procedures without MCC |
| MDC 8 | 461 | Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC |
| MDC 8 | 462 | Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC |
| MDC 8 | 466 | Revision of Hip or Knee Replacement with MCC |
| MDC 8 | 467 | Revision of Hip or Knee Replacement with CC |
| MDC 8 | 468 | Revision of Hip or Knee Replacement without CC/MCC |
| MDC 8 | 469 | Major Joint Replacement or Reattachment of Lower Extremity with MCC |
| MDC 8 | 470 | Major Joint Replacement or Reattachment of Lower Extremity without MCC |
| MDC 8 | 521 | Hip Replacement with Principal Diagnosis of Hip Fracture with MCC |
| MDC 8 | 522 | Hip Replacement with Principal Diagnosis of Hip Fracture without MCC |

## C. Recalibration of the FY 2021 Relative 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 2021, CMS uses two data sources:

- FY 2019 MedPAR data: Bills received through March 31, 2020 from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage claims and claims from facilities currently classified as critical access hospitals (CAH) are excluded. CMS used data from approximately 9,218,950 million Medicare discharges regrouped using the FY 2021 MS-DRG classifications.
- FY 2018 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2018 cost reporting periods, using the March 31, 2020 update of the FY 2018 HCRIS.

CMS calculates the IPPS relative weights by reducing hospital charges to cost using CCRs for 19 distinct cost centers. For FY 2021, CMS did not propose changes to its methodology and is calculating the MS-DRG weights using national averages for the 19 CCRs. Accompanying the final rule, CMS posted the version of HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2021 on the CMS website. Go to the link at the beginning of the summary. Select file #4 under FY 2021 Final Rule Data files (HCRIS Data File FY 2021 Final Rule).

*Relative Weights with a Large Decline in Value*. For FY 2020, CMS adopted a temporary one-time measure that limited the decline in a relative weight. If the relative weight declined by more than 20 percent, the relative weight would be maintained at its prior year value. One MS-DRG would meet this criterion for FY 2021—MS-DRG 215 (Other Heart Assist System Implant). CMS requested comment on whether it should maintain the relative weight for MS-DRG 215 at its FY 2020 value or average the FY 2020 and FY 2021 relative weights.

*Comment/Response:* Commenters indicated that extensive coding changes have resulted in hospitals not correctly reporting their costs for procedures in MS-DRG 215. They supported either maintaining the FY 2021 relative weight equal to the FY 2020 relative weight for MS-DRG 215, or averaging the FY 2020 and FY 2021 relative weights. Even with these options, commenters indicated payment would still be below cost. These commenters indicated payment stability for the cases in MS-DRG 215 could be improved if they were assigned to MS-DRGs 216 through 2018. Other commenters asked CMS to adopt similar policies in any situation when the relative weight for an MS-DRG is drastically reduced in a given year, particularly when it follows a significant decline in prior years.

While CMS is reluctant to override the underlying data, it will set the 2021 relative weight for MS-DRG 215 equal to the average of the FY 2020 and FY 2021 relative weights. CMS did not propose reassigning cases in MS-DRG 215 to MS-DRGs 216 to 218 but will consider this suggestion in future years. Other MS-DRGs referenced by the commenters are low volume and may experience a greater degree of year-to-year variation (both increases and decreases). CMS will consider how to improve annual payment stability for low-volume MS-DRGs.

*Relative Weight Calculation for CAR-T cell Therapy*. CMS proposed to create MS-DRG 018 for CAR-T cell therapy cases. In some cases, the CAR-T cell therapy patients may be part of a clinical trial where the high cost therapy product is furnished to the hospital at no cost. CMS proposed a differential payment for these cases to recognize hospitals' lower costs. CMS also proposed to exclude CAR-T cases billed with a clinical trial indicator or less than $373,000 in drug costs—the average sales price of KYMRIAH and YESCARTA, the two CAR-T cell products approved to treat relapsed/refractory diffuse large B-cell lymphoma in drug costs—from the relative weight calculation.

In addition, CMS proposed to adjust the case count for CAR-T cell therapy to determine the national average standardized cost per case, budget neutrality and outlier threshold. Proposed rule data showed that that the average costs of CAR T-cell therapy clinical trial cases are 15 percent of the average costs of CAR T-cell therapy cases identified as non-clinical trial cases ($277,592). CMS proposed to use an adjusted case count of 0.15 for CAR-T clinical trial cases used in determining national average standardized cost per case, budget neutrality and outliers.

*Comment/Response:* Commenters raised complex issues with how hospitals bill for clinical trial cases and how they set their charges. CMS is finalizing its proposal but, in response to comments, will include clinical trial cases where the hospital incurs the full cost of the CAR T product and the clinical trial is for a different product. In addition, CMS will override its default policy of excluding charges from revenue center 891 in setting the MS-DRG relative weights for MS-DRG 018 only. For MS-DRG 018, CMS will include cases where charges equal or exceed $373,000 from revenue center 891 when calculating the relative weight.

*National Average CCRs*. The FY 2021 CCRs are shown in the following table.

| Group | FY 2020 CCR | FY 2021 CCR |
|---|---|---|
| Routine Days | 0.432 | 0.421 |
| Intensive Days | 0.358 | 0.344 |
| Drugs | 0.189 | 0.187 |
| Supplies & Equipment | 0.299 | 0.297 |
| Implantable Devices | 0.299 | 0.293 |
| Therapy Services | 0.297 | 0.288 |
| Laboratory | 0.109 | 0.107 |
| Operating Room | 0.173 | 0.167 |
| Cardiology | 0.098 | 0.094 |
| Cardiac Catheterization | 0.106 | 0.100 |
| Radiology | 0.140 | 0.136 |
| MRIs | 0.072 | 0.070 |
| CT Scans | 0.034 | 0.034 |
| Emergency Room | 0.152 | 0.147 |
| Blood and Blood Products | 0.283 | 0.271 |
| Other Services | 0.346 | 0.343 |
| Labor & Delivery | 0.373 | 0.359 |
| Inhalation Therapy | 0.150 | 0.147 |
| Anesthesia | 0.077 | 0.071 |

The final rule cost-based relative weights were normalized by an adjustment factor of 1.819227 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.

For very low volume MS-DRGs (less than 10 cases, generally those for newborns), CMS maintains the prior year relative weight and adjusts it by the average change in the relative weight for all MS-DRGs.

## D. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(K) and (L) of the Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the IPPS. 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. Under an alternative pathway, certain transformative new devices and Qualified Infectious Disease Products (QIDP) may qualify for a new technology add-on payment (§ 412.87 (c) and (d)). CMS notes that add-on payments for new medical services or technologies are not subject to budget neutrality.[13]

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 2022, 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 2022.

*a. New Technology Add-On Payment Criteria*

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. CMS uses three criteria for evaluating whether a new technology is substantially similar to an existing technology[14]:

[13] Section 503(d)(2) of Pub. L. 101-173 provides there will be no reduction or adjustments in aggregate payments under the IPPS due to add-on payments for new technologies.
[14] 74 FR 43813 and 43814

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

*(1) Newness Criterion*. If a technology meets all three of the criteria, CMS considers it substantially similar to an existing technology and for purposes of the new technology add-on payments, CMS would not consider the medical service or technology "new". CMS first determines whether a medical service or technology is new; if CMS determines the medical service or technology is considered new, then it will make a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

*(2) Cost Criterion*. For purposes of the cost criterion, for FY 2021, CMS included the applicable MS-DRG thresholds in the data files associated with the FY 2020 annual IPPS rules. The proposed MS-DRG thresholds applicable to FY 2022 are included in the data files associated with the FY 2021 final rule on the CMS website.[15]

In the FY 2016 IPPS final rule[16], CMS discussed whether the cost threshold value associated with a proposed new MS-DRG should be considered in determining whether the applicant meets the cost criterion. CMS invited public comments on this issue and after consideration of the comments, CMS agreed with the commenters and decided to use the cost threshold in effect at the time the new technology add-on application was submitted to determine if an applicant exceeded the cost threshold. CMS also agreed with commenters that this policy was most predictable for applicants. At the time of the FY 2106 final rule, however, CMS did not anticipate the onset of new, extremely high cost technologies, such as CAR T-cell therapy and the significant variance between the thresholds at the time of application and the thresholds based on the finalized MS-DRG assignment for the upcoming year. Based on the data file released with the FY 2020 final rule for FY 2021 applications, the threshold amount for the MS-DRG 016 (the current DRG assignment for CAR T-cell therapies) is $170,573 as compared to the threshold amount of $1,237,393 (in the data file released with the FY 2021 proposed rule) for the proposed new MS-DRG 018 for CAR T-cell therapies.

CMS continues to believe that predictability is important but, it also believes that payment accuracy is important and proposed to revise its policy in situations when the procedure code associated with a new technology application is proposed to be assigned to a proposed new MS-DRG. Specifically, CMS proposed that effective for FY 2022, for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for a proposed new MS-DRG for the upcoming fiscal year would be used to evaluate the cost criterion for technologies that would be assigned to a proposed new MS-DRG. CMS believes this policy would promote payment accuracy and also provide the applicant and the public adequate time to analyze whether the technology meets the cost criterion using the proposed thresholds and provide public comment.

[15] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[16] 80 FR 49481 and 49482

For FY 2021 new technology add-on payments, CMS proposed to evaluate the cost criterion for the CAR T-cell therapy technologies using the proposed threshold for the newly proposed MS-DRG (MS-DRG 018), including the CAR T-cell therapies previously approved for new technology add-on payments and the new FY 2021 CAR T-cell therapy applications, KTE-X19 and Liso-cel.

CMS believes this policy is consistent with section 1886(d)(5)(K)(ix) of the Act which requires that before establishing any add-on payment for a new medical service or technology, the Secretary seeks to identify one or more DRGs associated with the new technology (based on similar clinical or anatomical characteristics and the cost of the technology) and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. CMS notes this provision also states that no add-on payment will be made with respect to such new technology.

**Final Decision**: Beginning with FY 2022 new technology add-on payments for all applicants and previously approved technologies that may continue to receive new technology add-on payments, CMS will use the proposed threshold for a proposed new MS-DRG for the upcoming fiscal year to evaluate the cost criterion for technologies that would be assigned to a proposed new MS-DRG.

*(3) Substantial Clinical Improvement Criterion*. Under the third criterion, a medical service or technology must represent an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS final rule[17], CMS codified (§412.87(b)) the following aspects of how it evaluates substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of circumstances is considered when making a determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries.
- A determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries means the new service or technology offers:
    - A treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
    - The ability to diagnose a medical condition in a patient population where that condition is currently undetectable; the ability to diagnose a medical condition earlier than methods currently available and the evidence supports that making a diagnosis affects the management of the patient; or
    - Significant improvement in clinical outcomes relative to services or technologies previously available as demonstrated by one of the following:
        - Reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
        - Decreased rate of at least one subsequent diagnostic or therapeutic intervention;
        - Decreased number of future hospitalizations or physician visits;

        - More rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
        - Improvement in one or more activities of daily living;
        - Improved quality of life; or
        - Demonstrated greater medication adherence or compliance; or
        - The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following sources: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- The service or technology may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

CMS reiterates that although it is affiliated with the FDA, it does not use FDA criteria to determine what drugs, devices or technologies qualify for new technology add-on payments. CMS states its criteria do not depend on the standards of safety and efficacy used by the FDA but on the demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

*b. Alternative Inpatient New Technology Add-on Payment Pathway*

In the FY 2020 IPPS final rule[18], CMS finalized that beginning with FY 2021, certain transformative new devices and QIDPs may qualify for a new technology add-on payment under an alternative pathway. As discussed below (section F.8.), CMS finalizes its proposal to expand the alternative pathway for QIDPs to include products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway and to refer more broadly to "certain antimicrobial products" instead of referring to a particular FDA program for antimicrobial products.

CMS notes that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS will review the application under the alternative pathways specified by the applicant. To receive approval under the alternative pathway, the technology must have the applicable designation and meet all the other requirements.

[18] 84 FR 42292 through 42297

(1) Alternative Pathway for Certain Transformative New Devices. If a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization (has been approved or cleared by, or had a De Novo classification request granted by FDA), it will be considered new and not substantially similar to an existing technology and will not need to meet the substantial clinical improvement requirements. The new device will still need to meet the cost criterion. As discussed below (section F.7.), CMS clarifies that a new medical device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation.

(2) Alternative Pathway for QIDPs. If a new medical product is designated as a QDIP and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology and will not need to meet the substantial clinical improvement requirements. The new product will still need to meet the cost criterion. CMS clarifies that the QIDP must receive marketing authorization for the indication covered by the QDIP designation.

*c. Additional Payment for New Medical Service or Technology*

In the FY 2020 IPPS final rule[19], CMS finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology, other than a medical product designated as a QIDP, beginning with discharges on or after October 1, 2019, Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 65 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

For medical products designated as a QIDP, Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 75 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medical payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for a QDIP) of the estimated costs of the new technology or medical service.

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

On December 16, 2019, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications.[20] CMS live-streamed the meeting and also posted the town hall on the CMS YouTube web page.

[19] 84 FR 42297 through 42300

[20] Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-173 requires a mechanism for public input about whether a medical service or technology represents a substantial clinical improvement is required

In their evaluation of individual applications, CMS considered the presentations made at the town hall meeting and written comments received by January 3,2020. Where applicable, CMS summarized comments in the proposed rule

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

Section "X" codes are ICD-10-PCS codes used to identify new medical services and technologies. Information regarding "X" codes can be found on the CMS web site at https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html. 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 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.

4. FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments.

CMS' policy is that a medical service or technology may be considered new within 2 or 3 years after which data becomes available which reflects the inpatient hospital code assigned to the new service or technology. CMS' practice has been to begin and end new technology add-on payments on the basis of a fiscal year and it generally follows a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend an add-on payment for an additional fiscal year. In general, CMS extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the US market occurs in the latter half of the fiscal year.

For FY 2021, CMS **finalizes its proposal to discontinue eight new technology add-on payments** for KYMRIAH™ and YESCARTA®, VYXEOS™, VABOMERE™, the remedē® System, Giapreza™, the Sentinel® Cerebral Protection System, the AQUABEAM System, and ERLEADA™. CMS **finalizes its proposal to continue ten new technology add-on payments** for ZEMDRI™, AndexXa™, AZEDRA®, CABLIVI®, ELZONRIS™, Balversa™, SPRAVATO™, XOSPATA®, JAKAFI™, T2Bacteria® Panel.

CMS summarizes these decisions in a table in the final rule, which is reproduced in this summary at the end of this section. The table includes information about the newness start date, CMS' decision, relevant final rule citations, the proposed maximum new technology add-on payment for FY 2021, and HCPCS coding used to identify cases eligible for the add-on payment. A high-level discussion of comments and CMS' response is summarized below; readers are advised to review the final rule for more detailed information.

*a. KYMRIAH™ and YESCARTA®*

Several commenters supported CMS' proposal to discontinue the new technology add-on payments and others were not supportive of the proposal to discontinue the new technology add-on payments for FY2021. Commenters were concerned that reimbursement through the new proposed MS-DRG will not fully compensate providers and hinder access for Medicare beneficiaries. One commenter through CMS should not use the date the first FDA-approved CAR T-cell product was delivered for use to an approved facility (November 22, 2017) but

instead use the date when the market was fully formed for Medicare beneficiaries (October 1, 2018) or waive CMS' policy for determining the length of the add-on payment and extend the add-on payment for six months. Another commenter suggested that all CAR T-cell products approved by FDA automatically receive new technology add-on payments. CMS disagrees with comments and notes that § 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data becomes available and when CMS has recalibrated the DRG, based on available data, to reflect the costs of a new medical service or technology, the newness period ends. CMS also notes that CMS does not believe that case volume is a relevant consideration for making the determination when a product is "new" (70 FR 47349).

In response to comments, CMS acknowledges that it used the wrong value for the average case-weighted standardized charge when evaluating the cost threshold for these CAR T-cell therapies and when this error is corrected, the therapies exceed the proposed threshold for MS-DRG 018.

*b. VABOMERE™*

Several commenters did not support CMS' proposal to discontinue the new technology add-on payment for FY 2021. Commenters highlighted the ongoing concerns with antimicrobial resistance and the particular value of VABOMERE™ during the COVID-19 PHE. Commenters also urged CMS to consider the data limitations regarding the infrequent use of novel antibiotics across many DRGs as justification for continuing the add-on payment to obtain additional data. The applicant suggested CMS implement a DRG carve-out policy for QIDPs that would provide for payment of QIDPs at 100 percent of ASP under the IPPS. In response, CMS reiterates its policy about the timeframe for a new technology add-on payment (see discussion above for KYMRIAH™ and YESCARTA®).

*c. remedē® System*

A commenter did not support CMS' proposal to discontinue the new technology payment for FY 2021 and requested an additional year because of reduced access to the technology during the COVID-19 PHE. CMS appreciates the commenter's concerns with the COVID-19 PHE but again reiterates its policy about the timeframe for a new technology add-on payment (see discussion above for KYMRIAH™ and YESCARTA®).

| Summary Table of FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments (NTAP) | | | | | |
|---|---|---|---|---|---|
| **Technology** | **Newness Start Date** | **Propose to Continue or Discontinue NTAP for FY 2021** | **Previous Final Rule Citations** | **Proposed Maximum NTAP Amount for FY 2021** | **Coding Used to Identify Cases Eligible for NTAP** |
| KYMRIAH® and YESCARTA® | November 22, 2017 | Discontinue | (83 FR 41283 through 41299) and (84 FR 42185 through 42187) | None | XW033C3 or XW043C3 |
| VYXEOS™ | August 3, 2017 | Discontinue | (83 FR 41299 through 41305) and (84 FR 42187 through 42188) | None | XW033B3 or XW043B3 |
| VABOMERE™ | August 29, 2017 | Discontinue | (83 FR 41305 through 41311) and (84 FR 42188 through 42189) | None | XW033N5 or XW043N5 or National Drug Codes (NDC) 65293–0009–01 or 70842– 0120–01 |
| remedē® System | October 6, 2017 | Discontinue | (83 FR 41311 through 41320) and (84 FR 42189 through 42190) | None | 0JH60DZ and 05H03MZ in combination with 05H33MZ or 05H43MZ |
| ZEMDRI™ | June 25, 2018 | Continue | (83 FR 41326 through 41334) and (84 FR 42190 through 42191) | $4,083.75 | XW033G4 or XW043G4 |
| GIAPREZA™ | December 21, 2017 | Discontinue | (83 FR 41334 through 41342) and (84 FR 42191) | None | XW033H4 or XW043H4 |
| Sentinel® Cerebral Protection System | June 1, 2017 | Discontinue | (83 FR 41342 through 41348) and (84 FR 42191 through 42192) | None | X2A5312 |
| AQUABEAM System | December 21, 2017 | Discontinue | (83 FR 41348 through 41355) and (84 FR 42192 through 42193) | None | XV508A4 |
| AndexXa™ | May 3, 2018 | Continue | (83 FR 41355 through 41362) and (84 FR 42193 through 42194) | $18,281.25 | XW03372 or XW04372 |
| AZEDRA® | July 30, 2018 | Continue | (84 FR 42194 through 42201) | $98,150 | XW033S5 and XW043S5 |
| CABLIVI® | February 6, 2019 | Continue | (84 FR 42201 through 42208) | $33,215 | XW013W5, XW033W5 and XW043W5 |
| ELZONRIS™ | December 21, 2018 | Continue | (84 FR 42231 through 42237) | $125,448.05 | XW033Q5 and XW043Q5 |
| Balversa™ | April 12, 2019 | Continue | (84 FR 42237 through 42242) | $3,563.23 | XW0DXL5 |
| ERLEADA™ | February 14, 2018 | Discontinue | (84 FR 42242 through 42247) | None | XW0DXJ5 |
| SPRAVATO™ | March 5, 2019 | Continue | (84 FR 42247 through 42256) | $1,014.79 | XW097M5 |
| XOSPATA® | November 28, 2018 | Continue | (84 FR 42256 through 42260) | $7,312.50 | XW0DXV5 |
| JAKAFI™ | May 24, 2019 | Continue | (84 FR 42265 through 42273) | $3,977.06 | XW0DXT5 |
| T2Bacteria® Panel | May 24, 2018 | Continue | (84 FR 42278 through 42288) | $97.50 | XXE5XM5 |

5. FY 2021 Applications for New Technology Add-On Payments

CMS received 17 applications for new technology add-on payments for FY 2021. Two applicants withdrew their applications prior to the issuance of the proposed rule. Three applicants did not receive FDA approval for their technology by July 1, 2020 and are not eligible for consideration for new technology add-on payments for FY 2021: Accelerate Diagnostics (the applicant for Accelerate Pheno Test™ BC kit), Kite Parma (the applicant for KTE-X19) and Juno Therapeutics (the applicant for Liso-cel). In response to comments requesting that CMS extend the July 1 deadline for FDA approval for FY 2021 due to the COVID-19 PHE, CMS states the July 1 deadline for approval or clearance remains for new technology add-on payments for FY 2021.

The summary below provides a high-level discussion of the remaining 12 applications. **CMS approves seven of the applications for new technology add-on payments for FY 2021: ContaCT, Eluvia™ Drug-Eluting Vascular Stent System, Hemospray® Endoscopic Hemostat, IMFINZI® and TECENTRIC®, Soliris, and the SpineJack® System.**

*a. BioFire® FilmArray® Pneumonia Panel*

BioFire Diagnostics, LLC submitted an application for the BioFire® FilmArray® Pneumonia Panel, an in-vitro diagnostic devices used to identify bacterial and viral targets from sputum (including endotracheal aspirate) and bronchoalveolar lavage sample in about an hour. The device also provides semi-quantitative results, which may help determine whether an organism is a colonizer or a pathogen.

Newness. The BioFire® FilmArray® Pneumonia Panel received FDA clearance via 510(k) on November 9, 2018, based on a determination of substantial equivalence to a legally marketed predicate device (Curetis Unyvero™). The product was available in the U.S. market on December 11, 2018. A Proprietary Laboratory Analyses (PLA) code, PLA Code 0151U was assigned to the device and became effective January 1, 2020.

For the first criterion (same or similar mechanism of action), the applicant stated that the BioFire® FilmArray® Pneumonia Panel is the only sample-to-answer, rapid (about 1 hour), and comprehensive molecular panel for the diagnosis of the major causes of infectious pneumonia. In addition, the device is also the only semi-quantitative molecular solution available for diagnosis of infectious pneumonia. The applicant described the other methods for determining the bacterial organism and noted that the current best practice is the standard culture technique. The applicant stated that other comprehensive molecular technologies, including Curetis Unyvero™ are more complex, only have bacterial targets, and only provide qualitative results.

For the second criterion (same or different MS-DRG), the applicant stated that potential cases involving this technology would be assigned to the same MS-DRGs as cases representing patients using competing technologies. Similarly, for the third criterion (same or similar disease or patient population), the applicant stated that the BioFire® FilmArray® Pneumonia Panel is the only FDA cleared comprehensive molecular panel approved for use on both sputum and

bronchoalveolar lavage and is the only molecular panel that detects both bacterial and viral causes of lower respiratory infections and pneumonia.

CMS was concerned that it lacked sufficient information to determine whether the mechanism of action of The BioFire® FilmArray® Pneumonia Panel is different from existing polymerase chain reaction (PCR) tests. CMS noted that the FDA decision described the test as a multiplex nucleic acid test, or PCR, accompanied by the applicant's software. In addition, the product does not appear to treat a different disease or population compared to other products. CMS also did not believe the evidence provided by the applicant supports differentiation of the test from other products.

CMS did not receive any public comments and it concludes it is unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the newness criterion.
Cost. In the proposed rule, CMS raised several concerns about the applicant's analysis, including using proprietary data from one hospital. CMS did not receive any public comments and it concludes it is unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that data shows that the BioFire® FilmArray® Pneumonia Panel detects major causes of pneumonia with a high degree of sensitivity and specificity in a clinically relevant timeframe and has the potential to impact antibiotic usage, including possible cost savings. The applicant submitted four poster presentations and noted that the data is still new and has not yet been published in academic journals. CMS acknowledged the supporting information was limited to poster presentations and that information pertaining to full manuscripts with detailed methods and data tables were not provided. Based on the information provided, CMS was concerned that the studies did not appear to be designed or powered to show conclusive evidence of clinical impacts. CMS noted that only one study compared the BioFire® FilmArray® Pneumonia Panel to other PCR-based technology, and that a statistical difference was not reported.

CMS did not receive any public comments addressing its concerns and concludes it is unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the substantial clinical improvement criterion.

**CMS finalizes that BioFire® FilmArray® Pneumonia Panel does not meet the criteria for new technology add-on payments**.

*b. ContaCT*

Viz.ai submitted an application for ContaCT, a radiological computer-assisted triage and notification system used by hospitals and clinicians to identify patients with a suspected large vessel occlusion on computed tomography angiogram (CTA) images of the brain.[21] The system analyzes CTA images of the brain, sends notifications to a neurovascular specialist(s) that a

[21] ContaCT consists of three individual components that are currently marked as VizLVO (for the algorithm), Viz Hub (for text messaging and calling platform), and Viz View (for the mobile image viewer).

suspected large vein occlusion (LVO) has been identified, and recommends review of those images.

Newness. ContaCT received FDA marketing authorization on February 13, 2018 under the De Novo pathway as a Class II medical device; the device was not commercially available until October 2018.

CMS noted that FDA issued a memorandum describing ContaCT as "an artificial intelligence algorithm [used] to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation". In addition, the order specified that 'identification of suspected findings is not for diagnostic use beyond notification."

For the first criterion (same or similar mechanism of action), the applicant stated that no existing technology is comparable to ContaCT and that the ContaCT system can shorten the clinical workflow for patients presenting with signs or symptoms of LVO. The applicant stressed that shortening the time to identify an LVO is critical because the efficacy of thrombectomy decreases as the time from symptoms to treatment increases. For the second criterion (same or different MS-DRG), CMS believed that cases involving this technology would be assigned to the same MS-DRGs as without the technology. Similarly, for the third criterion (same or similar disease or patient population), CMS believed that the technology would treat the same or similar type of disease and patient population as patients without the use of the technology.

CMS was concerned that streamlining hospital workflow might not represents a unique mechanism of action; as per the FDA, ContaCT is not used for diagnostic purposes and still requires a clinician to review the scan and make the diagnosis. CMS noted that the mechanism of action for ContaCT might be the use of AI to analyze images and notify physicians instead of streamlining hospital workflow. CMS was concerned, however, that the use of AI, an algorithm, or software is not a unique mechanism of action and wondered how updates to AI, an algorithm or software would affect an already approved technology or a competing technology.

Specifically, CMS questioned if software changes for an already approved technology could be considered a new mechanism of action and if an improved algorithm by a competitor would represent a unique mechanism of action if the outcome is the same as the initial technology. The applicant noted that there was a brief delay in the availability of ContaCT and the first hospital installation was not completed until January 2019. In response to CMS' concerns, the applicated asserted that no existing technology is comparable to ContaCT. With regard to the first criterion, the applicant stated that ContraCT was reviewed through FDA's De Novo pathway which is only available to novel medical devices not previously classified by the FDA.

With regard to the second and third criteria, the applicant stated that ContaCT is used in cases of stroke and suspected stroke and cases will match to the same or similar cases that do not use the technology.

With respect to the first substantial similarity criterion, the applicant disagreed with CMS and stated the computer-assisted triage and notification is the mechanism of action for ContaCT and

that AI is a necessary component of the technology but AI is not sufficient to achieve the therapeutic effect. The applicant also noted that there are no requirements for a new technology to have a specific mechanism of action to be eligible for new technology add-on payments. The applicant also disagrees with CMS that AI, an algorithm or software may never be considered a unique mechanism of action because the technology may simulate human intelligence or existing human processes. The applicant also asserts that because human intelligence and human processes are not FDA approved or cleared technologies they should not be used by CMS as comparators to evaluate ContaCT, or any technology, for determining the newness criteria. Finally, the applicant urges CMS not to make aby broad determination about whether technologies that use AI, algorithm or software to achieve a therapeutic effect are ineligible for new technology add-on payments; CMS should evaluate each new technology individually to whether it meets the established criteria.

The applicant also addressed CMS' questions about whether software changes for an already approved technology should be considered a new mechanism of action. The applicant stated that an update to the ContaCT algorithm that does not alter the mechanism of action of the technology should be considered to have the same or similar mechanism of action. Similarly, the applicant stated that a different technology that notifies the stroke team more rapidly would likely have a mechanism of action that is the same or similar to ContaCT.

The applicant also discussed that the mechanism of action of the means by which a product achieves the therapeutic outcomes should be assessed and not the newness of the individual components. The applicant noted CMS' assessment of the new technology add-on application for MIRODERM (81 FR 56893) where CMS concluded that MIRODERM proteins were different from other acellular skin substitutes but the determination of newness was based on the mechanism of action for wound healing that CMS concluded was not unique to the technology. The applicant argued that technologies that utilize AI, an algorithm or software should be similarly evaluated.

Several commenters provided similar comments as the applicant.

After reviewing the comments, CMS agrees that ContaCT does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatments because there are no FDA approved or cleared technologies that use computer-assisted triage and notification to rapidly detect an LVO and shorten the time to notification. Without addition information, CMS continues to believe that the newness period for ContaCT begins on October 1, 2018; CMS may consider additional information regarding the date of availability in future rulemaking.

CMS will continue to consider the issues related to determining newness for technologies that use AI, an algorithm or software, including devices classified as radiological computer aided triage and notification systems. Related issues include how to identify a unique mechanism of action and how updates could be considered a new mechanism of action.

Cost. The applicant provided several analyses based on data from the FY 2018 MedPAR dataset. In the first analysis, the applicant used the admitting diagnoses codes to identify cases of stroke

due to LVO, stroke not due to LVO, no stroke, and using a multi-step approach identified 375,925 cases across 143 MS-DRGs, approximately 66 percent of cases mapped to seven MS-DRGs. The applicant did not remove any changes for a prior technology but based on published studies, the applicant reduced some charges related to a reduced LOS associated with a mechanical thrombectomy. The applicant standardized the charges and applied an inflation factor of 11.1% (the same inflation factor CMS used to update the outlier threshold in the FY 2020 IPPS PPS final rule). Because the technology is provided by a subscription, the applicant added the charges for the new technology by determining the cost per case across a hospital and then averaging the cost per case across all hospitals to determine the average cost per patient.

The applicant calculated a case-weighted threshold amount of $51,358 and a final inflated average case-weighted standardized charge per case of $62,006. The applicant submitted three additional cost analyses using the same methodology but with limited MS-DRGs. CMS believes that a case weight provides more accuracy in determining the average cost per case as compared to the applicant's average of costs per case across all hospitals. CMS repeated the applicant's analyses and in all the scenarios, the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold amount by an average of $2,961.

CMS was concerned that the applicant used a single list price of ContaCT per hospital with a cost per patient that can vary based on the utilization of the technology by the hospital. The cost per patient could be skewed by a small number of hospitals utilizing the technology with low case volumes. CMS described an alternative methodology for determining the cost per patient. In response to CMS' concerns, the applicant submitted two additional analyses that followed CMS' suggestions in the proposed rule and concluded that ContaCT would meet the cost criterion. The applicant stated that because the overall cost per unit of subscription technologies is determined by each customer's ratio of price to utilization, an analysis that requires an estimate of cost per unit should be limited to subscribers. The applicant did agree with CMS that yearly updates to the cost per unit analysis are reasonable to reflect changes in subscribers and thus the overall cost per unit.

After consideration of the applicant's updated cost analyses, CMS agrees that ContaCT meets the cost criterion for FY 2021. CMS notes it will continue to consider the issues related to calculating the cost per unity of technologies sold on a subscription basis.

Substantial Clinical Improvement. The applicant stated that ContaCT substantially improves the ability to diagnose LVO stroke earlier by automatically identifying suspected disease in CTA images and notify the neurovascular specialist to enter the care workflow earlier than the normal standard of care. The applicant presented several studies to support this statement. The applicant also discussed real world evidence, clinical guidelines, and published studies demonstrating that faster time to treatment for stoke improves clinical outcomes.

The applicant provided a total of 19 articles: four retrospective studies, nine randomized clinical trials (RCTs), three meta-analyses, one registry, one guideline, and one systematic review. CMS discussed specific concerns with the submitted information, including the FDA decision memorandum stating that ContaCT is limited to analysis of imaging data and should not be used in-lieu of patient evaluation or relied upon to make or confirm a diagnosis. In addition, CMS

noted that the RCTs evaluated outcomes from specific treatment for patients who suffered strokes and not the time of imaging to treatment. Based on the RCTs and meta-analyses, CMS was concerned the evidence did not indicate a substantial clinical improvement for shorter notification times of an LVO. CMS noted that the guidelines and systematic literature review support the urgency of stroke care but do not demonstrate how ContaCT supports the urgency of stroke care.

The applicant responded to CMS' concerns and provided additional information supporting substantial clinical improvement. With regard to CMS' concerns about sensitivity and specificity, the applicant stated that no harm is expected from false positives or false negatives; false positives will result in an earlier review of the CT angiogram image and false negatives are similar to the standard of care without ContaCT. Other commenters supported the clinical improvement associated with using this technology for stroke patients.

After reviewing the clinical information and additional analysis, CMS believes that ContaCT represents a substantial clinical improvement over existing technologies.

**CMS finalizes that ContaCT meets all three criteria for new technology add-on payments and approves add-on payments for FY 2021**. Cases involving the use of ContaCT will be identified by ICD-10-PCS code 4A03X5D. Using customer data, the applicant estimated an average cost of ContaCT of $1,600. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving ContaCT is $1,040. CMS estimates the overall FY 2021 add-on payments at approximately $20,637,500, based on 12,700 patients.

*c. Supersaturated Oxygen ($SSO_2$) Therapy (DownStream® System)*

TherOX, Inc. submitted an application for the DownStream® System, an adjunctive therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in patients receiving treatment for an acute myocardial infarction (AMI). According to the applicant, $SSO_2$ Therapy is used for patients receiving treatment for an ST-segment elevation myocardial infarction (STEMI). The applicant asserted that the net effect of $SSO_2$ Therapy is to reduce the infarct size and therefore preserve heart muscle.

The $SSO_2$ Therapy consists of three main components: The DownStream® System, the Downstream cartridge, and the $SSO_2$ delivery catheter. The System and cartridge function together to create an oxygen-enriched saline solution called $SSO_2$ from hospital-supplied oxygen and physiologic saline. Using a small amount of the patient's blood, oxygen enriched hyperoxemic blood is obtained and then delivered to the left main coronary artery via the delivery catheter. The duration of the $SSO_2$ Therapy is 60 minutes and the oxygen partial pressure of the infusion is elevated to approximately 1000mmHg, therefore providing oxygen locally to the myocardium at a hyperbaric level for 1 hour. Coronary angiography is performed as a final step before removing the delivery catheter.

The applicant previously submitted an application for new technology add-on payments for FY 2019, which was subsequently withdrawn before the FY 2019 final rule. The applicant

submitted an application for FY 2020; a new technology add-on payment was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over available therapies to treat STEMI patients.

Newness. $SSO_2$ Therapy received premarket approval from the FDA on April 4, 2019. The applicant states that the use of $SSO_2$ Therapy can be identified by the ICD-10-PCS procedure codes 5A0512C and 5A0522C.
In the FY 2020 IPPS final rule (84 FR 42275), CMS determined that $SSO_2$ Therapy has a unique mechanism of action and meets the newness criterion. CMS considered the beginning of the newness period as the date of FDA approval on April 2, 2019.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes that the $SSO_2$ Therapy meets the cost criterion.

Substantial Clinical Improvement. According to the applicant, as an adjunctive treatment, the $SSO_2$ Therapy has demonstrated superiority over percutaneous coronary intervention (PCI) with stenting alone in reducing the infarct size which improves mortality outcomes and improves heart failure outcomes; reduces infarct size; prevents left ventricular dilation; and reduces death and heart failure at 1 year. In the FY 2020 IPPS final rule, CMS did not determine the technology represented a substantial significant improvement because it was concerned the data did not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of $SSO_2$ Therapy.

In addition to the studies submitted with both its FY 2019 and FY 2020 applications, the applicant provided additional information to support that the technology provides a treatment option for a patient population unresponsive to current treatments. CMS summarized these studies and the additional information provided to address CMS' prior concerns. CMS reiterated its previous concern that standard of care for STEMI has evolved since two studies (AMIHOT I and AMIHOT II) were conducted and it is not clear whether the use of $SSO_2$ Therapy would demonstrate the same clinical improvement when compared to current standard of care. It also noted that the studies may be based on patients with all types of STEMI and are not specific to the FDA-approved indication for the treatment of anterior STEMI. After reviewing all the information, CMS continued to believe that the data presented does not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of $SSO_2$ Therapy.

The applicant responded to CMS' concerns and provided additional information supporting substantial clinical improvement. Other commenters asserted that $SSO_2$ Therapy filed an unmet need and was superior to the current standard of care, PCI with stenting.

CMS does not believe the additional data provides sufficient evidence that $SSO_2$ Therapy improves mortality and heart failure among anterior STEMI patients and that additional data is needed to demonstrate that treatment with $SSO_2$ Therapy improves outcomes when compared to currently available therapies. CMS notes that the FDA ordered a post-approval study to confirm the safety and effectiveness of $SSO_2$ Therapy; this study has not begun enrollment.

**CMS finalizes that $SSO_2$ Therapy does not meet the criteria for new technology add-on payments**.

*d. Eluvia™ Drug-Eluting Vascular Stent System*

Boston Scientific submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System which is comprised of an implantable endoprosthesis and a stent delivery system (SDS). The drug-eluting stent system is indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic De Novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. The Eluvia™ stent system was granted approval of 16 ICD-10-PCS procedure codes, effective October 1, 2019.
The applicant previously submitted an application for new technology add-on payments for FY 2020. The application was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over existing technologies (84 FR 42220 through 42231).

Newness. The Eluvia™ Drug-Eluting System received FDA approval (PMA) on September 18, 2018. In the FY 2020 IPPS final rule (84 FR 42275), CMS determined that the Eluvia™ stent system has a unique mechanism of action and meets the newness criterion.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes that the Eluvia™ stent system meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the Eluvia™ stent is a substantial clinical improvement because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmissions; reduces the rate of device-related complications; and achieves similar functional outcomes and EQ-5D index values while associated with half the rate of target lesion revascularization (TLRs).

In the FY 2020 IPPS PPS final rule, CMS discussed FDA's preliminary review of data that identified a potential concern of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices. Because the FDA believed alternative treatment options should generally be used for most patients while it continued to evaluate the increase long-mortality associated with paclitaxel-coated devices and the impact on the overall benefit-risk profile of these devices, CMS concluded it not have enough information to determine that the Eluvia™ stent represented a substantial clinical improvement over existing technologies.

The applicant resubmitted its application and included updated two-year primary patency results to demonstrate the device represents a substantial clinical improvement over existing technologies. The applicant also addressed the FDA concerns about paclitaxel and stated that the

Eluvia™ stent is not associated with increased all-cause mortality and that two-year all-cause mortality are consistent with FDA-published rates for uncoated angioplasty devices. In addition, the applicant reiterated that the Eluvia™ stent was not included in the FDA meta-analysis and highlighted flaws in the analysis. The applicant cited the FDA June 2019 advisory panel conclusion that the benefits of paclitaxel-coated devices should be considered in individual patients along with potential risks.

CMS summarized these studies and the additional information provided to address CMS' prior concerns. CMS reiterated its previous concerns with the studies and the FDA meta-analysis results. It remained concerned that there is an increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limb. CMS cited the FDA's statement in the August 2019 letter[22] that because of the uncertainty regarding the long-term benefit-risk profile of paclitaxel-coated devices, clinical studies should collect long-term safety and effectiveness data.

A commenter discussed the evidence presented by the applicant and concluded that the evidence did not support that the Eluvia™ stent system demonstrated substantial clinical improvement. Another commenter stated that CMS has not articulated why the clinical trial information presented by the applicant does not demonstrate substantial clinical improvement and that instead, CMS has relied on the potential safety signals in the meta-analysis and the FDA review of the data on paclitaxel-coated devices. This commenter stressed that since the FDA has not limited the use of paclitaxel devices and CMS has not limited coverage of paclitaxel devices then the clinical information presented in the application should be utilized to determine if the technology represents substantial clinical improvement.

The applicant also provided comments on the implications of the meta-analyses. The applicant does not believe the findings of limited generalizability suggested in the meta-analysis should inhibit CMS from determining substantial clinical improvement. In addition, given the differences between the Eluvia™ stent system and other peripheral paclitaxel coated devices, it would be more appropriate to examine safety considerations for Eluvia™ compared to other products with similar mechanisms of action and dose levels, such as the Taxus coronary stent which has been studied for more than 14 years. The applicant provided additional information about the long-term safety associated with the Taxus stent. The applicant also noted that it remains questionable and unproven that the root cause of the observed higher mortality in the meta-analysis has a direct relationship to the presence of paclitaxel in the evaluated devises and that the mortality calculations significantly decrease with longer follow-up time frames.

CMS responds that it always considers all available evidence when making a determination of substantial clinical improvement for a new technology. After consideration of the comments and the FDA August 7, 2019 update, CMS believes that the Eluvia™ stent system represents a substantial clinical improvement over existing technologies.

[22] https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.

**CMS finalizes that the Eluvia™ stent system meets all three criteria for new technology add-on payments and approves add-on payments for FY 2021**. Cases involving the use of the Eluvia™ stent system will be identified by 16 ICD-10-PCS codes (listed in the final rule). Using customer data, the applicant estimated an average cost of ContaCT of $1,600. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving the Eluvia™ stent system is $3,646.50. CMS estimates the overall FY 2021 add-on payments at approximately $8,944,865, based on 2,453 patients.

*e. GammaTile™*

GT Medical Technologies, Inc. submitted an application for GammaTile™, a brachytherapy technology for use in the treatment of patients diagnosed with brain tumors using cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is biocompatible and bioabsorbable and is in the body permanently without the need for future surgical removal. An application for GammaTile™ was submitted for a new technology add-on payment in FYs 2018 and 2019; both were withdrawn because the technology did not receive FDA approval or clearance in the time required. An application was submitted for FY 2020 and was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over existing technologies (84 FR 42260 through 42265).

Newness. The applicant received FDA clearance under section 510(k) as a medical device on July 6, 2018 and was not commercially available until January 2019. The FDA cleared GammaTile™ as a Class II medical device under the corporate name of GT Medical Technologies on March 13, 2019. In the FY 2020 IPPS final rule (84 FR 42261), CMS determined that GammaTile™ has a unique mechanism of action and meets the newness criterion.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes that GammaTile™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that GammaTile™ might provide the only radiation treatment option for patients diagnosed with tumors located close to sensitive vital brain sites and patients diagnosed with recurrent brain tumors that may not be eligible for additional treatment involving the use of external beam radiation therapy. The applicant cited several sources of data to support the substantial clinical improvement criterion.

CMS noted that the clinical data submitted with the FY 2021 application is essentially identical to what was submitted with the FY 2020 application. CMS was still concerned that the findings appear to be derived from relatively small case studies with limited clinical efficacy and safety data. In addition, the findings are not data from FDA approved clinical trials. CMS acknowledged the difficulty in establishing randomized control groups in studies involving recurrent brain tumors, but it remained concerned that the technology does not represent a substantial clinical improvement over existing therapies. CMS noted the applicant had stated its intention to provide additional clinical data in connection with its application for FY 2021, including an update on patient outcomes from the complete clinical trial and additional meta-analysis to address concerns raised in the FY 2020 IPPS final rule.

The applicant submitted additional clinical data and information to support a determination of substantial clinical improvement, including updated clinical data from the pivotal clinical trial and results from a systematic literature review and analyses of historic controls. The applicant also submitted new analyses for the treatment of recurrent high-grade gliomas, recurrent meningiomas, and recurrent metastatic brain tumors. CMS discusses its concerns with this additional information and concludes it is unable to determine that GammaTile™ represents a substantial clinical improvement over existing therapies.

**CMS finalizes that GammaTile™ does not meet the criteria for new technology add-on payments**.

*f. Hemospray® Endoscopic Hemostat*

Cook Medical submitted an application for the Hemospray® Endoscopic Hemostat, a carbon dioxide powdered delivery system inserted through an endoscope to deliver the inert powder, bentonite, which forms an adhesive barrier to tissue. Hemospray® is indicated for hemostasis of nonvariceal gastrointestinal (GI) bleeding.

Newness. Hemospray® received FDA De Novo approval on May 7, 2018 and was classified as a Class II device for intraluminal GI use. According to the applicant, FDA required revisions to the instructions for use of the system delayed the commercial availability of the system until July 1, 2018.

Cook Medical voluntarily recalled the Hemospray® because of complaints about the device handle breaking and, in some cases, causing the carbon dioxide cartridge to exit the handle. Cook Medical is investigating the issue and will determine appropriate corrective actions. It received one report of a superficial laceration to the user's hand requiring basic first aid but, no reports of laceration, infection, or permanent damage to users or patients due to the carbon dioxide cartridge existing the handle. Although the recall restricts availability of the device, Cook Medical wants to continue their application because they believe the use of the device significantly improves clinical outcomes for certain patient populations.

For the first criterion (same or similar mechanism of action), the applicant stated that Hemospray® is a novel device that differs from standard treatment options (thermal modalities, injection needles, and mechanical modalities) by creating a diffuse mechanical barrier over the bleeding site with a non-thermal, non-traumatic, noncontact modality. For the second criterion (same or different MS-DRG), the applicant stated that cases involving the device would span a variety of MS-DRGs but would most likely be used in MS-DRGs 377, 378, and 379 (GI Hemorrhage). CMS believed that cases involving this technology would be assigned to the same MS-DRGs as standard of care treatments. Similarly, for the third criterion (same or similar disease or patient population), CMS believed that the technology would treat the same or similar type of disease and patient population as patients as the current standard of care.

CMS was concerned that the mechanism of action of Hemospray® may be similar to existing endoscopic hemostatic treatments such as Ankakferd Bloodstopper and EndoClot Polysaccharide

Hemostatic System. In response, the applicant noted that both the Ankakferd Bloodstopper and the EndoClot Polysaccharide Hemostatic System are not cleared for use in the U.S. for hemostatic treatment; the EndoClot Polysaccharide Hemostatic System is only cleared as a delivery system for submucosal injection.

After reviewing the information submitted by the applicant, CMS believes that Hemospray meets the newness criterion. CMS considers the beginning of the newness period to be the first date Hemospray was commercially available, July 1, 2018.

Cost. The applicant clarified that in the cost analysis it did not remove the costs for other devices because some physicians may choose to use Hemospray in conjunction with endoscopic clips or thermal coagulation. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes that Hemospray meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for the management of endoscopic bleeding. It would provide a substantial clinical improvement as a primary treatment or as rescue treatment after the failure of a conventional method and in treating malignant lesions. The applicant provided eight articles – three systematic reviews, three prospective studies, and two retrospective studies. CMS summarized this information and discussed specific concerns with the submitted information. CMS noted that the majority of studies lack a comparator and may not provide strong evidence of substantial clinical improvement. It noted several issues with one randomized study including the small sample size of 20 patients. CMS was concerned that the samples in the studies may not represent the Medicare population as most of the samples are predominantly male and many of the studies were not done in the U.S. CMS was also concerned about the potential for adverse events from Hemospray® and noted that the evaluation of adverse events in the studies was limited.

The applicant provided additional information supporting the substantial clinical improvement of Hemospray and responded to CMS' concerns. In response to CMS' concerns about potential adverse events, the applicant stated they clearly label the device with the potential risk information, conduct physician training, and diligently monitor reported complains or complications related to the device. The applicant stated that as of June 10, 2020 the FDA cleared Hemospray to return to the market and the applicant anticipated return to the U.S. market in July 2020.

CMS acknowledges the limitations of some of the data but believes that Hemospray represents a substantial clinical improvement for the treatment of gastrointestinal bleeding, including the use of Hemospray as an alternative to invasive treatments. CMS will continue to monitor available data for the potential risk of adverse events associated with Hemospray.

**CMS finalizes that Hemospray meets all three criteria for new technology add-on payments and approves add-on payments for FY 2021**. Cases involving the use of Hemospray will be identified by ICD-10-PCS codes XW0G886 and XW0H886. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Hemospray

is $1,625. CMS estimates the overall FY 2021 add-on payments at approximately $20,637,500 based on 12,700 patients.

*g. IMFINZI® (durvlaumab) and TECENTRIC® (atezolizumab)*

AstraZeneca PLC and Genentech, Inc submitted separate applications for FY 2021 for IMFINZI® (durvlaumab) and TECENTRIC® (atezolizumab), respectively. Both of these technologies are programmed death-ligand (PD-L1) blocking antibodies used for the treatment of patients with extensive small cell lung cancer (ES-SCLC). These applications were discussed as two separate technologies in the proposed rule. CMS believes these technologies are substantially similar to each other and evaluates both technologies as one application for new technology add-on payments. A comparison of the indications and FDA approvals for IMFINZI® and TECENTRIC® are summarized in the table below, reproduced from the final rule.

| **Comparison of Indication and FDA Approvals for IMFINZI® and TECENTRIC®** | | |
|---|---|---|
| **FY 2021 Applicant Technology Name** | **Description of Indication for which New Technology Add-on Payments Are Being Requested** | **FDA Approval Status** |
| IMFINZI® (AstraZeneca PLC) | In combination with etoposide and either carboplatin or cisplatin, first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). | FDA approval received 3/27/2020 |
| TECENTRIQ® (Genentech, Inc.) | In combination with carboplatin and etoposide, first-line treatment of adult patients with ES- SCLC. | FDA approval received 3/18/2019 |
| **Technology Approved for Other Indications** | **Description of Other Indications** | **FDA Approval of Other Indication** |
| IMFINZI® (AstraZeneca PLC) | Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum- containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy.<br><br>Treatment of patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy | FDA approval received 5/1/2017<br><br>FDA approval received 2/16/2018 |

| Comparison of Indication and FDA Approvals for IMFINZI® and TECENTRIC® | | |
|---|---|---|
| TECENTRIQ® (Genentech, Inc.) | Treatment of patients with locally advanced or metastatic urothelial carcinoma, and subsequently for patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. | FDA approval received 5/18/2016 |
| | Treatment of patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. | FDA approval received 10/18/2016 |
| | First-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. | FDA approval received 12/6/2018 |
| | Metastatic triple negative breast cancer. | FDA approval received 3/8/2019 |

Newness. In the proposed rule, CMS stated that both IMFINZI® and TECENTRIC® and appeared to be intended for similar patient populations and would be used for treatment of the same conditions: locally advanced or metastatic urothelial carcinoma and ES-SCLC.

The applicants for TECENTRIC® and IMFINZI® provided comments supporting why these two technologies are not substantially similar to each other. The applicant for TECENTRIC® stated that the technology is a humanized PD-L1 blocking antibody which binds to PD-L1 and blocks the interactions with both PD-1 and B7.1 receptors and is used for the treatment of multiple oncology indications. Used in combination with carboplatin and etoposide, TECENTRIC® is a indicated for the first-line treatment of adult patients with ES-SCLC. The applicant for TECENTRIC® stated that IMFINZI® is a human PD-L1 blocking antibody that blocks the interaction of PD-L1 with both PD-1 and CD80 receptors and is used for several cancers, including ES-SCLC. The applicant stated that although there are slight molecular differences between the two technologies, they both fall into the same class of PD-L1 blocking antibodies.

The applicant for IMFINZI® asserted the technologies are unique molecular entities, with unique active ingredients and should be considered separately for the new technology add-on payment. The applicant discussed the difference between IMFINZI®, a selective high-affinity, human IgG1 monoclonal antibody and TECENTRIC®, a humanized monoclonal antibody. The applicant also stated that the distinct ICD-10 procedure codes for IMFINZI® and TECENTRIC® supports considering the applications separately.

CMS acknowledges the slight molecular difference, but believes that both technologies are PD-L1 blocking antibodies and is not convinced the molecular differences result in different mechanisms of action. In addition, both technologies are intended to treat the same or similar

disease in the same or similar patient population (patients with ES-SCLC) and are purposed to achieve the same therapeutic outcome. CMS believes that IMFINZI® and TECENTRIC® are not substantially similar to any other existing technologies and meet the newness criterion.

Cost. To identify cases that may be eligible for IMFINZI®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting C34 in combination with Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy). The applicant also included any cases within MS-DRGs 180, 181, and 182 with an ICD-10-CM diagnosis code from category C34. The applicant identified a total of 24,193 cases and found 23,933 cases which mapped to 12 unique MS-DRGs. Using these 23,933 cases. The applicant calculated the unstandardized average charge per case for each MS-DRG. The applicant determined it did not need to remove any charges and assumed that ES-SCLC patients will receive their initial dose of IMFINZI® as an inpatient. The applicant standardized the charges, inflated the charges by 11.10 percent (inflation factor used by CMS in FY 2020 IPPS final rule), and added charges for IMFINZI®. The final inflated average case-weighted standardized charge per case was $111,093 and the average case-weighted threshold amount was $53,209.

To identify cases that may be eligible for TECENTRIC®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting an ICD-10-CM code from C34 and only considered cases where the diagnosis codes were used to differentiate ES-SCLC from limited-stage SCLC. This resulted in 33,404 cases mapped to 264 MS-DRGs. The applicant calculated the unstandardized average charge per case for each MS-DRG. The applicant determined it did not need to remove any charges and added the charges for TECENTRIQ®. The final inflated average case-weighted standardized charge per case was $88,561 and the average case-weighted threshold amount was $65,738. The applicant did a sensitivity analysis using the same methodology but only used the MS-DRGs representing 1 percent of case volumes which represented 88.31 percent of cases, or 29,500 cases over 10 MS-DRGs. This analysis resulted in a final inflated average case-weighted standardized charge per case of $88,404 and the average case-weighted threshold amount of $56,987.

CMS noted that the ICD-10-CM diagnosis codes and MS-DRGs in the cost analysis for IMFINZI® differ from those used in the cost analysis for TECENTRIQ®; TECENTRIQ® only search claims with category C34. CMS was concerned why the diagnosis codes are different as one analysis may be more accurate.

The applicant for TECENTRIC® stated that although the cost analyses approaches are different, both independently concluded that the cost criterion were met and explained the approach it took for the cost analysis. The applicant for IMFINZI® also noted that both approaches met the cost criterion and explained the approach it took for the cost analysis.

CMS concludes that both IMFINZI® and TECENTRIC® meet the cost criterion.

Substantial Clinical Improvement. The applicant for IMFINZI® stated the technology represented a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to current treatments and reduces mortality, decreases disease progression, and improves quality of life. The applicant provided supporting information from

the CASPIAN clinical trial, a randomized, multicenter, active-control, open-label, phase 3 trial. The major efficacy outcome measure was overall survival (OS); the applicant stated the results showed a sustained OS benefit following treatment with IMFINZI® plus chemotherapy. The applicant also stated that other key endpoints demonstrated consistent and durable improvement for IMFINZI®, including progression free survival.

CMS was concerned that the CASPIAN study is ongoing, and the information is preliminary. CMS was interested in additional information about the trial results and information about adverse events.

The applicant for TECENTRIQ® stated the technology represented a substantial clinical improvement because it offers a treatment option for a patient population unresponsive or ineligible for current treatments and improves overall survival and quality of life. The applicant presented information from the phase III (efficacy) and phase I (safety) study (IMpower133) that was double-blind, placebo-controlled, multicenter and compared TECENTRIQ® vs. placebo in combination with carboplatin and etoposide in patients with ES-SCLC who had not received prior systemic therapy. The applicant notes that over 40 percent of the population in the trial were of Medicare age.

CMS was concerned that the survival benefit from the addition of TECENTRIQ® was a median duration of only 2 months over standard therapy and the improvement for median progression free survival was less than one month. In addition, CMS was concerned that there really wasn't a clinically significant improvement in the quality of life for patients because of the number of adverse events in the TECENTRIQ® treatment arm.

Multiple commenters, including the applicant for TECENTRIQ®, discussed the characteristics of ES-SCLC and the limitations in current treatment options. The applicant for IMFINZI® provided additional information about the CASPIAN trial.

After consideration of the comments, CMS agrees that both IMFINZI® and TECENTRIC® represent a substantial clinical improvement over existing technologies because the technologies significantly improve clinical outcomes.

**CMS finalizes that both IMFINZI® and TECENTRIC® meet all three criteria for new technology add-on payments and approves add-on payments for both technologies for FY 2021.** Cases involving the use of IMFINZI® will be identified by ICD-10-PCS codes XW03336 or XW04336. Cases involving the use of TECENTRIQ® will be identified by ICD-10-PCS codes XW033D6 or XW043D6. CMS calculated a case-weighted average cost of $10,578.53 for these technologies. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving IMFINZI® or TECENTRIC® is $6,875.90. CMS estimates the overall FY 2021 add-on payments for IMFINZI® and TECENTRIC® at approximately $29,538,866 based on 4,296 patients.

*h. Soliris*

Alexion Inc, submitted an application for Soliris, a complement inhibitor, approved by the FDA for the treatment of neuromyelitis optical spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. NMOSD is a rare, severe, autoimmune disease that attacks the central nervous system without warning. These attacks, also referred to as relapses, can cause progressive and irreversible damage to the brain, optic nerve and spinal cord, which may lead to long-term disability. Complement activation due to the anti-AQP4 antibodies is one of the primary underlying causes of the disease. Soliris is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) which requires prescribers to enroll in the program. Soliris has a boxed warning for risk of serious meningococcal infections which can be mitigated with a meningococcal vaccination; no cases of meningococcal infection have been reported.

Newness. The FDA approved Soliris for treatment of NMOSD patients who are AQP4 antibody positive on June 27, 2019. Soliris was first approved by the FDA on March 19, 2007 for the treatment of patients with paroxysmal nocturnal hemoglobinuria and has received subsequent approval for additional complement mediated diseases.

CMS believes Soliris is not substantially similar to existing treatment options and concludes it meets the newness criterion.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes that Soliris meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Soliris represents a substantial clinical improvement over existing technologies because it significantly improves clinical outcomes relative to technologies previously available, including the prevention of relapses in patients with NMOSD. The applicant provided a randomized, controlled trial (PREVENT) and a poster presentation of post hoc efficacy analyses in pre-specified subgroups from the PREVENT study. CMS was concerned that the supporting information is only one study and all additional supporting documents are all based on the same trial. CMS noted that the study compared Soliris to placebo but there was no comparison of Soliris to currently available treatments. CMS also was concerned about the dosage amounts used in the study and would be interested in more information about the dosage amounts in the PREVENT trial.

The applicant submitted comments, including additional data, addressing CMS' concerns. In addition, several commenters supported the results of the PREVENT trial and a few commenters cited their own clinical experience with treating NMOSD patients with Solaris. CMS determines that Soliris represents a substantial clinical improvement over existing technologies for preventing relapses and improving long-term outcomes in the treatment of NMOSD.

**CMS finalizes that Solaris meets all three criteria for new technology add-on payments and approves add-on payments for FY 2021**. Cases involving the use of Solaris will be identified by ICD-10-PCS codes XW033C6 and XW043C6. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Solaris is $32,615. CMS

estimates the overall FY 2021 add-on payments at approximately $29,538,866 based on 4,296 patients.

*i. SpineJack® System*

Stryker, Inc. submitted an application for SpineJack® System, an implantable fracture reduction system for use in reduction of painful osteoporotic vertebral compression fractures (VCFs). The SpineJack® System is used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement. The SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. Once in place, the implants are expanded to mechanically restore vertebral body height and maintain the restoration. The implants remain within the vertebral body and, together with the delivered polymethylmethacrylate (PMMA) bone cement, stabilize the restoration, provide pain relief, and improve patient mobility. The SpineJack® system further reduces the risk of future adjacent fractures (ALFs).

The applicant stated that treatment of osteoporotic VCF in older adults begins with conservative care; vertebral augmentation (VA) may be indicated in patients that continue to have significant pain. Vertebroplasty (VP) and balloon kyphoplasty procedures (BKF) are two common minimally invasive percutaneous VA procedures; BKP is the most commonly performed procedure and considered the gold standard for VA treatment. Other treatment options include the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

Newness. The applicant states the device received FDA 510(k) clearance on August 30, 2018 and was available on the U.S. market October 11, 2018.

For the first criterion (same or similar mechanism of action), the applicant compares the SpineJack® system with other BKP implants and describes how the SpineJack® system is different because its implant construction, mechanism of action, bilateral implant load support and >500 Newtons (N) of lift pressure. The applicant also explains differences between the SpineJack® system and the Kiva® system. The applicant summarizes the differences and similarities of the SpineJack®, BKP, and the PEEK coiled implant and concludes that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than both BKP and the PEEK coiled implant.

For the second criterion (same or different MS-DRG), CMS noted that for the cost analysis, the applicant used the same MS-DRGs to which cases involving BKP are typically assigned. For the third criterion (same or similar disease or patient population), CMS noted the applicant generally indicated the technology treats osteoporotic VCFs and described other treatment options for the same disease and patient population.

Several commenters supported approval for the SpineJack® system for new technology because the system provides a significant benefit beyond other vertebral augmentation technology. The applicant provided additional clarification and acknowledged that the SpineJack® system would be assigned to the same MS-DRGs as existing technology for vertebral augmentation and treats

the same or similar disease and the same or similar patient population as other vertebral augmentation systems.

Two commenters asserted that the applicant's description of the mechanism of action of the SpineJack® system relative to other implant devices contained important inaccuracies including claims that the system acts uniquely to achieve craniocaudal expansion, bilateral load support and lift pressure >500 Newtons. Commenters noted that the newest generation of BKP implants are capable of inflating to 700 psi and generating a lift force of 1200 Newtons. Another commenter asserted that both the Kiva system and SpineJack® system use a similar mechanism of action to achieve a therapeutic outcome.
CMS appreciates the technology comments and notes that some of the comments are based on conflicting factual assertions made by commenters and the applicant; statements that CMS cannot directly resolve. CMS concludes that the SpineJack® system is not substantially similar to existing treatments and meets the newness criterion.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes the SpineJack® system meets the cost criterion.

Substantial Clinical Improvement. The applicant stated the SpineJack® system represents a substantial clinical improvement over existing therapies because clinical research supports that it reduces future interventions, hospitalizations, and hospitalizations through a decrease in ALFs. The applicant also asserted the treatment greatly reduces pain scores and the use of pain medications as compared to BKP. The applicant submitted eight studies to support these statements.

The applicant noted that the system has been available for treatment of osteoporotic VCFs for over 10 years in Europe and as a result the SpineJack® system has been extensively studied. The applicant highlighted the results from a recent, large, prospective, randomized study that compared SpineJack® to kyphoplasty in osteoporotic patients (SAKOS) study. The SAKOS study was the pivotal trial supporting the FDA 510(k) clearance and although the SAKOS study was performed in Europe, the FDA determined the study demographics were very similar to what has been reported for U.S. based studies of BKP. In addition, over 82 percent of the patients in the study were 65 years of age or older.

CMS acknowledged the results of the SAKOS trial and noted the results do not appear to have been corroborated in any other randomized controlled study. In addition, since the PEEK coiled system was considered the predicate device for the SpineJack 510, CMS was interested in information comparing the SpineJack® system to the PEEK coiled implant. CMS was also interested in information comparing the SpineJack® system to conservative medical therapy and notes an active study on clinicaltrials.gov comparing the system to conservative therapy. CMS noted that two recent systematic reviews of vertebral compression fractures[23] for the American

[23]Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., "Percutaneous vertebroplasty for osteoporotic vertebral compression fracture," Cochrane Database Syst Rev. 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A. Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A.

Society for Bone and Mineral Research (ASBMR) do not support vertebral augmentation procedures due to lack of evidence comparing the treatment to conservative medical management. The ASBMR recommends more rigorous studies of treatment options that include placebo controls and more data on serious adverse events.

The applicant submitted comments, including clarifications, addressing CMS' concerns. The applicant noted that the latest clinical evidence and a policy statement from the International Society for the Advancement of Spine Surgery (ISASS) provides support for the use of vertebral augmentation over non-surgical management for the treatment of osteoporotic VCFs. The applicant also noted recent Local Coverage Determinations for percutaneous vertebral augmentation for osteoporotic VCF. In addition, several commenters supported the clinical benefits from using the SpineJack® system including evidence of increased vertebral body height restoration. A few commenters believed that conservative medical management is no longer an accepted standard of care.

One commenter, a manufacturer of BKP implants made several criticisms of the evidence presented, including additional criticisms of the SAKOS study. The commenter also disagreed with the applicant's assertion that vertebral augmentation treatment with vertebroplasty may alleviate pain but cannot restore vertebral body height or correct spinal deformity and referenced three published articles with empirical evidence regarding the impact of BKP on kyphotic angle and vertebral body height restoration. Another commenter offered several additional criticisms of the SAKOS study, including the fact that the trial did not use new generation balloon implants. After consideration of all the comments received, CMS believes that its concerns have been addressed. CMS states the information provided from commenters with clinical experience with vertebral augmentation procedures and the SpineJack® system supports reduction in pain, vertebral body height restoration and ALF outcomes for patients with osteoporotic VCDs when compared with existing treatments demonstrates substantial clinical improvement. CMS determines the SpineJack® system represents a substantial clinical improvement over existing technologies.

**CMS finalizes that the SpineJack® system meets all three criteria for new technology add-on payments and approves add-on payments for FY 2021**. Cases involving the use of the SpineJack® system will be identified by ICD-10-PCS codes XNU0356 and XNU4356. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving the SpineJack® system is $3,654.72. CMS estimates the overall FY 2021 add-on payments at approximately $5,745,220 based on 1,572 patients.

*j. WavelinQ™ (4F) ENDO AVF System*

Becton Dickinson submitted an application for the WavelinQ™ (4F) ENDO AVF System, an FDA approved device for the creation of an arteriovenous (AV) fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum

Bouxsein M.L., "The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report." J Bone Miner Res., 2019, vol. 34(1), pp. 3-21

artery and vein diameters of 2.0 mm at the fistula creation site in patients with chronic kidney disease needing hemodialysis. According to the applicant, the Endovascular AV fistula created by the WavelinQ™ EndoAVF System is achieved by using flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), venography (to fluoroscopically guide placement and alignment of the venous magnetic RF catheter, ultrasound and final fistulogram to document AV fistula creation. Newness. According to the applicant, the predicate device WavelinQ™ (6F) ENDO AVF System received FDA marketing on June 22, 2018 for creation of an arteriovenous (AV) fistula using concomitant ulnar artery and ulnar vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site in patients with chronic kidney disease needing hemodialysis. On February 6, 2019 the WavelinQ™ (4F) ENDO AVF System cleared the FDA via its 510(k) pathway for expanded access indication with a smaller 4F catheter. The applicant states the only difference between the two technologies and their respective FDA approvals is the size of the catheters (6F vs 4F) and the expanded indication to treat the radial arteries and veins for the WavelinQ™ (4F) ENDO AVF System.

CMS believes the WavelinQ™ uses a unique mechanism of action with its dual catheter access of both venous and arterial systems, magnetic linking of the vessels and additional fistula site and is not substantially similar to existing treatment options. CMS concludes the technology meets the newness criterion.

Cost. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes the WavelinQ™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the WavelinQ™ (4F) ENDO AVF System represented a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to or ineligible for current treatments. The applicant stated the WavelinQ™ (4F) ENDO AVF System improves clinical outcomes for patients requiring hemodialysis in comparison to AV surgical fistulas and the Ellipsys Vascular Access System. The applicant provided four studies and additional information supporting these statements. CMS was concerned that there is no study directly comparing the WavelinQ™ (4F) ENDO AVF System to surgical AVF or Ellipsys Vascular Access System as the submitted studies use historical data for surgical AVF. CMS was also concerned about the limited number of participants in the clinical trials and whether the results are generalizable to the entire Medicare population.

The applicant submitted comments and additional evidence from published clinical studies to address CMS' concerns. The applicant provided additional information why a randomized, controlled study comparing the WavelinQ™ (4F) ENDO AVF System to surgical AVFs. The applicant also provided a clinical comparison to the WavelinQ™ (4F) ENDO AVF System to the Ellipsys Vascular Access System and provided several reasons why a study comparing the two technologies was not conducted. In addition to the information provided by the applicant, CMS discusses a published study on the real-world usage of the WavelinQ™ (4F) ENDO AVF

System.[24] CMS states the study concludes that the WavelinQ™ (4F) ENDO AVF System has a high initial procedural success rate, although a significant portion of patients required subsequent endovascular procedures. CMS notes the study concludes further work is needed on determining factors predictive of the need for re-intervention for patients with fistulas using the WavelinQ™

(4F) ENDO AVF System.

CMS concludes that additional data is needed to demonstrate the WavelinQ™ (4F) ENDO AVF System represents a substantial clinical improvement over existing technologies.
**CMS finalizes the WavelinQ™ (4F) ENDO AVF System does not meet the criteria for new technology add-on payments**.

*k. Zulresso™*

Sage Therapeutics submitted an application for Zulresso™, a neuroactive steroid gamma-aminobutyric acid $(GABA)_A$ receptor positive modulator indicated for the treatment of postpartum depression (PPD). The applicant stated that PPD is one of the most common complications of pregnancy affecting more than 400,000 women in the U.S. The applicant noted that women diagnosed with PPD who are disabled may be eligible for Medicare. The applicant stated that Zulresso™ is the first FDA drug specifically indicated for PPD; standard treatment of patients with PPS have generally consisted of medications typically used for major depression or other mood disorders and non-pharmacological treatments.

Newness. Zulresso™ received Priority Review and Breakthrough Therapy designations and was granted FDA approval on March 19, 2019 for treatment of PPD. On June 17, 2019, the Drug Enforcement Administration placed Zulresso™ into Schedule IV of the Controlled Substances Act and it became commercially available.

For the first criterion (same or similar mechanism of action), the applicant stated that Zulresso™ does not use the same or similar mechanism of action when compared to existing treatments. Zulresso™ works differently that current antidepressants because it does not directly affect the monoaminergic system and instead the mechanism of action for Zulresso™ is believed to be positive modulation of $GABA_A$ receptors. For the second criterion (same or different MS-DRG), the applicant stated that cases representing patients receiving Zulresso™ would be assigned to the same MS-DRG as other patients with PPD. For the third criterion (same or similar disease or patient population), the applicant stated the Zulresso™ would be used for a similar patient population as other therapies but that Zulresso™ was the only treatment specifically indicated for PPD.

CMS disagrees with the applicant that the use of the technology would not involve the treatment of the same or similar type of disease and the same or similar patient population as existing technologies. However, CMS agrees with the applicant that Zulresso™ does not use the same or

[24] Zemela MS, Minami HR, Alvarez AC, Smeds MR. Real-World Usage of the Ellipsys Vascular Access System [published online ahead of print, 2020 May 15]. Ann Vasc Surg. 2020;S0890-5096(20)30376-9.

similar mechanism of action when compared to existing therapies. CMS concludes that Zulresso™ meets the newness criterion.

Cost. In response to CMS' concern about the low volume of cases for the cost analysis, the applicant noted that CMS has approved new technology add-on payment for other low volume procedures. Based on the applicant's cost analysis summarized in the proposed rule, CMS concludes Zulresso™ meets the cost criterion

Substantial Clinical Improvement. The applicant stated Zulresso™ is the first FDA drug specifically approved for PPD. The applicant submitted three studies to support its assertion that Zulresso™ improves depressive symptoms and patients' functioning.

CMS had several concerns about the clinical trials, including lack of follow-up after 30 days and lack of a comparison of Zulresso™ to current regimens used to treat PPD. In addition, CMS was concerned that results of studies of otherwise healthy women with PPD may not be generalizable to the Medicare population, because Medicare beneficiaries would likely have disabilities and comorbidities for which Zulresso™ would not be appropriate or effective. CMS also noted that because of side effects of excessive sedation or sudden loss of consciousness, Zulresso™ is only available through a REMS program, and it was concerned that these adverse events would be unsafe for women with PPD in the Medicare population.

The applicant submitted comments and additional information to address CMS' concerns. Other commenters stated that Zulresso™ alleviates symptoms of PPD within hours or days, rather than the weeks required to relieve symptoms using other treatments. CMS remains concerned that the studies and additional information do not provide sufficient evidence to determine that Zulresso™ provides a substantial clinical improvement over existing technologies. CMS remains concerned that study participants has time-limited PPD that might have resolved with the passage of time, independent of treatment with Zulresso™.

**CMS finalizes that Zulresso™ does not meet the criteria for new technology add-on payments**.

6. FY 2021 Applications for New Technology Add-On Payments (Alternative Pathways).

For FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program or a product is designated by the FDA as a QIDP, and received marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS. The medical technology would not need to meet the requirements that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under the alternative pathway, these technologies must still meet the cost criterion. All applications must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

CMS received ten applications for new technology add-on payments under the alternative pathway. One applicant withdrew its applications, three of the technologies received a

Breakthrough Device designation from the FDA and six have been designated as a QIDP. In the proposed rule, CMS provided background information on each application and proposed whether or not each technology would be eligible for new technology add-on payment for FY 2021 based on whether the technology met the cost criterion. For the Breakthrough Devices Program, the new technology add-on payment is the less of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. For QIDPs, the new the new technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case

*a. Alternative Pathway for Breakthrough Devices.*

(1) BAROSTIM NEO® System. CVRx submitted as application for the BAROSTIM NEO® System, a neuromodulation therapy that triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. The BAROSTIM NEO® System is designated a Breakthrough Device, received FDA approval on August 16, 2019, and was available on the market immediately upon FDA approval. CMS agreed with the applicant that the device meets the cost criterion.

**CMS finalizes its proposal to approve the BAROSTIM NEO® System for new technology add-on payments for FY 2021**. Cases involving the use of the BAROSTIM NEO® System will be identified by ICD-10-PCS codes 0JH60MZ in conjunction with 03HK0MZ or 03HK0MZ. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving the BAROSTIM NEO® System is $22,750. CMS estimates the overall FY 2021 add-on payments at $16,425,500 based on 722 patients.

(2) NanoKnife®. Angiodynamics submitted an application for the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer. The device consists of a dedicated generator and specialized electrode probes currently for ablation procedures for surgical treatment of soft tissue ablation. The NanoKnife® System received FDA Breakthrough Device designation on January 18, 2018 and an FDA investigational device exemption (IDE) on March 28, 2019. The FDA has not yet cleared or market approved the NanoKnife® System for use in the treatment of pancreatic cancer. CMS agreed with the applicant that the device meets the cost criterion.

Subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020, CMS proposed to approve the NanoKnife® System for this indication for new technology add-on payments for FY 2021. The applicant provided comments that disagreed with CMS decision to limit the new technology add-on payment explicitly to the indication covered under the FDA Breakthrough Devices Program, including the requirement for marketing authorization for the specific indication. The applicant believes that the NanoKnife® System has sufficient FDA market authorization under the broad regulatory provision because it has 510(k) clearance for surgical ablation of soft tissue. The applicant commented that since CMS has approved several Medicare reimbursement policies for the NanoKnife® System for pancreatic system, including coverage for treatment of pancreatic cancer under the IDE and reimbursement for the device and the routine costs of patient care, these reimbursement policies fulfill the marketing authorization requirement. The applicant also

asserts that CMS would be inconsistent if it covered a clinical trial but denied the new technology add-on payment.

CMS disagrees with the applicant. It does not believe that 510(k) clearance for soft tissue ablation and Breakthrough Designation for treatment of Stage III pancreatic cancer is sufficient for approval under the alternative pathway. CMS has a longstanding policy that recognizes that a technology can have multiple indications, each indication has its own newness period and must meet the new technology add-on payment criteria (66 FR 46915). CMS states it did not modify this policy when it adopted the alternative pathway for certain transformative new devices. CMS reiterates its statements in the proposed rule that earlier versions of the NanoKnife® System approved for soft tissue ablation have been available on the U.S. market in 2008 and 2015 and are not relevant for the review of the indication for the treatment of Stage III pancreatic cancer. CMS also disagrees that an IDE can qualify as marketing authorization and notes that national coverage determinations, payment and coding is separate from the determination that a technology meets the criteria for new technology add-on payment.

The NanoKnife® System did not receive FDA clearance or approval by July 1, 2020 for use in the treatment of Stage III pancreatic cancer, the indication it received FDA Breakthrough Device Designation and the basis for its new technology add-on payment application. **CMS finalizes that NanoKnife® System does not meet the criteria for new technology add-on payments for FY 2021**. CMS notes the applicant would remain eligible to apply for the new technology add-on payment under the alternative pathway for a future fiscal year.

(3) The Optimizer® System. Impulse Dynamics submitted an application for The Optimizer® System, used for treatment of chronic heart failure in patients with advanced symptoms that have normal QRS duration and are not candidates for cardiac resynchronization therapy. The Optimizer® System received Breakthrough Device designation on March 21, 2019 and FDA premarket approval for the two-lead Optimizer System on October 23, 2019. CMS agrees with the applicant that the device meets the cost criterion.

**CMS finalizes its proposal to approve The Optimizer® System for new technology add-on payments for FY 2021**. Cases involving the use of The Optimizer® System will be identified by ICD-10-PCS codes 0JH60AZ, 0JH63AZ, 0JH80AZ, or 0JH83AZ. For 2021, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving The Optimizer® System is $14,950. CMS estimates the overall FY 2021 add-on payments at $22,425,000 based on 1,500 patients.

*b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs).*

(1) Cefiderocol (Fetroja). Shionogi & Co. submitted an application for Cefiderocol, a ß-lactam antibiotic indication for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, caused by multi-resistant gram-negative pathogens. Cefiderocol is designated as a QIDP and received FDA approval on November 19, 2019. The drug was not commercially available until February 24, 2020. CMS agrees with the applicant that the drug meets the cost criterion.

**CMS finalizes its proposal to approve Cefiderocol for new technology add-on payments for FY 2021**. Cases involving the use of Cefiderocol will be identified by ICD-10-PCS codes XW03366 or XW04366. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving Cefiderocol is $7,919.86. CMS estimates the overall FY 2021 add-on payments at $50,330,710 based on 6,355 patients.

(2) CONTEPO™. Nabriva Therapeutics submitted an application for CONTEPO™, an epoxide antibiotic intended for treatment of cUTIs. CONTEPO™ is designated as a QDIP and anticipates FDA approval by July1, 2020. CMS agrees with the applicant that the drug meets the cost criterion.

**CMS finalizes its proposal to approve CONTEPO™ for new technology add-on payments for FY 2021**. Cases involving the use of CONTEPO™ will be identified by ICD-10-PCS codes XW033K5 or XW043K5. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving CONTEPO™ is $2,343.75. CMS estimates the overall FY 2021 add-on payments at $20,369,531 based on 8,691 patients.

(3) NUZYRA® for Injection. Paratek Pharmaceuticals submitted an application for NUZYRA® for Injection, a tetracycline class antibacterial indicated for the treatment of community-acquired bacterial pneumonia and acute bacterial skin infections caused by susceptible microorganisms. NUZYRA® for Injection was designated as a QIDP and received FDA approval on October 2, 2018. The drug became commercially available in February 2019. CMS agrees with the applicant that the drug meets the cost criterion.

**CMS finalizes its proposal to approve NUZYRA® for new technology add-on payments for FY 2021**. Cases involving the use of NUZYRA® will be identified by ICD-10-PCS codes XW033B6 or XW043B6. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving NUZYRA® is $1,552.50. CMS estimates the overall FY 2021 add-on payments at $26,235,698 based on 16,899 patients.

(4) RECARBRIO™. Merck submitted an application for RECARBRIO™, a fixed-dose combination of imipenem (a penem antibacterial), cilastatin (a renal dehydropeptidase inhibitor) and relebactam (a novel ß-lactam inhibitor for treatment of cUTIs and complicated intra-abdominal infections. RECARBRIO™ received FDA approval on July 16, 2019 and is designated as a QIDP. The drug became commercially available on the market on January 6, 2020. CMS agrees with the applicant that the drug meets the cost criterion.

The applicant notified CMS that RECARBRIO™ was approved by FDA on June 5, 2020 and granted QIDP status for the additional indications of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP). CMS appreciates this update but since the applicant did not apply for new technology add-on payments for the additional indications of HABP and VABP, it states it is not applicable to consider these additional indications for FY 2021.

**CMS finalizes its proposal to approve RECARBRIO™ for new technology add-on payments for FY 2021**. Cases involving the use of RECARBRIO™ will be identified by ICD-

10-PCS codes XW033U5 or XW043U5. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving RECARBRIO™ is $3,532.78. CMS estimates the overall FY 2021 add-on payments at $2,691,978 based on 762 patients.

(5) XENLETA. Nabriva Therapeutics submitted an application for XENLETA, a pleuomutilin antibacterial agent for community-acquired bacterial pneumonia. The drug is administered as a tablet or as an IV infusion. XENLETA was approved by the FDA under the QIDP designation and received FDA approval on August 19, 2019 for the treatment of community-acquired bacterial pneumonia. The drug was commercially available on September 10, 2019. CMS agrees with the applicant that the drug meets the cost criterion.

**CMS finalizes its proposal to approve XENLETA for new technology add-on payments for FY 2021**. Cases involving the use of XENLETA will be identified by ICD-10-PCS codes XW03366, XW0436, or XW0DX66. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving XENLETA is $1,275.75. CMS estimates the overall FY 2021 add-on payments at $55,324,327 based on 30,117 patients.

(6) ZERBAXA®. Merck submitted an application for ZERBAXA® a combination of cerolozane and tazobactam used for patients with complicated intra-abdominal infections (cIAI), cUTIs, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). ZERBAXA® was initially approved by the FDA on December 19, 2014 for treatment of cIAI and for cUTIs. ZERBAXA® was approved by the FDA on June 3, 2019 for HABP/VABP. ZERBAXA® was designated as a QIDP. CMS believes that only the indication approved in 2019 for treatment of HABP/VABP is eligible for new technology add-on payments. CMS agrees with the applicant that the drug meets the cost criterion.

**CMS finalizes its proposal to approve ZERBAXA® for new technology add-on payments for FY 2021**. Cases involving the use of ZERBAXA® will be identified by ICD-10-PCS codes XW03396 or XW0496. For 2021, using a maximum new technology add-on payment of 75 percent, the add-on payment for a case involving ZERBAXA® is $1,836.98.

7. Technical Clarification to the Alternative Pathway for Certain Transformative New Devices

To be eligible for approval under the alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization. In response to question about the requirement for marketing authorization, CMS clarifies that when a product has more than one indication, an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and the device the applicant is seeking to qualify for payment under the alternative pathway. CMS notes this is consistent with existing policies for determining newness for a product with more than one indication.

CMS makes the following conforming change to the regulations at §412.87(c)(1) to state that to be eligible for approval under this alternative pathway a new medical device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation.

Commenters were mostly supportive of this policy clarification. Two commenters thought the policy clarification constituted a new regulatory provision and although it was described as a technical clarification, the denial of a new technology add-on payment made the clarification a significant regulatory change. Angiodynamics also submitted comments which are summarized above in the alternative pathway discussion for NanoKnife. CMS disagrees that this technical clarification is a significant change in payment policy. CMS states this technical clarification, and the proposed change to the regulations, are consistent with CMS' longstanding policy to require marketing authorization for the specific indication for which the applicant is seeking new technology add-on payment (66 FR 46915). **CMS finalizes its proposed conforming changes.**

8. Proposed Revisions to New Technology Add-on Payments for Certain Antimicrobial Products.

CMS discusses recent information from the CDC[25] that continues to highlight the significant concerns and impacts related to antimicrobial resistance and the importance of this issue to the overall public health of the U.S., especially Medicare beneficiaries. To address these concerns, CMS proposed changes to the alternative pathway for certain antimicrobial products.

*a. Changes and Technical Clarification to the Alternative Pathway for Certain Antimicrobial Products*

The FDA has a Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) which encourages the development of safe and effective drugs for serious bacterial and fungal infections.[26] An antibacterial or antifungal drug approved under the LPAD is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs. CMS proposed to expand the alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD.[27] Specifically, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial drug is approved by the FDA under the LPAD program it will be considered new and not substantially similar to an existing technology and does not need to meet the requirement that it represents an substantial clinical improvement relative to existing technologies (§412.87(d)(ii)). An antimicrobial product that is approved by FDA under the LPAD pathway will need to meet the cost criterion (§412.87(b)(3)). CMS also proposed to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway from 65 to 75 percent.

The FDA may approve a drug under the LPAD pathway if it meets certain statutory standards for approval. Although the FDA may provide advice on potential LPAD eligibility, it makes the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. Thus, an applicant that has not received FDA approval and has requested

[25] https://www.cdc.gov/drugresistance/biggest-threats.html
[26] Section 506(h) of the FD&C Act, 21 U.S.C. 356(h)
[27] CMS proposes to revise the title of existing §412.87(d) to refer more broadly to "Certain antimicrobial products" rather that specifying in the title the particular FDA program for antimicrobial products subject to this alternative pathway.

approval under the LPAD pathway may not know when submitting an application to under the proposed expanded alternative pathway whether it will qualify for approval under the LPAD pathway. If an applicant's drug does receive FDA approval but does not receive approval under the LPAD pathway and is not designated as a QIDP, the technology would not be eligible for the alternative pathway for certain microbial products. To seek approval for a new technology add-on payment, the applicant would need to re-apply under the traditional pathway for the following fiscal year.

Several commenters supported this proposal. MedPAC did not support the use of FDA's LPAD qualifications for a new technology unless the drug meets the current substantial clinical improvement criterion. MedPAC also raised concerns about the safety or effectiveness in the Medicare population, paying more for technologies that have not proven better outcomes for beneficiaries, and concerns about off-label use. Other commenters did not believe the proposal would ensure patients have effective antimicrobial treatments; some commenters thought that drugs that qualify for LAPD will likely also have QIDP designation. Commenters suggested that the alternative new technology add-on payment should be expanded to include other eligible products such as biologics and other expedited FDA pathways (e.g., Fast Track, Regenerative Medicine Advance Therapy designation and devices granted an HDE).

In response to comments, CMS continues to believe that making this policy applicable to all drugs and biologicals would increase incentives for innovation without decreasing costs, a key priority of the Administration. CMS states it will continue to consider the suggestions for expanding the program for future rulemaking. CMS disagrees with MedPAC's suggestion that LPADs should meet the substantial clinical improvement criterion because it believes the benefits of providing early access to critical and life-saving new cures and technologies that improve health outcomes is important for beneficiaries. CMS notes that approval of a new technology add-on payment is based on the applicant's FDA indicated market authorization use and the add-on payment is limited to this indication. CMS also states that there may be instances when a drug only receives QIDP or LPAD designation and it wants to broaden access to antimicrobial products.

**CMS finalizes its proposal to expend the current alternative new technology add-on payment pathway to include products approved under the LPAD pathway**. CMS also finalizes its proposal to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway from 65 to 75 percent.

Similar to the clarification regarding marketing authorization for transformative new devices alternative pathway, CMS clarified that a new medical product seeking approval for a new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation (§41.87(d)(1)). **CMS did not receive any comments and finalizes this clarification.**

*b. Changes to Announcement of Determination and Deadline for Consideration of New Medical Service or Technology Applications for Certain Antimicrobial Products*

CMS requires that all applications for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered ((§41.87(e)). CMS believes July 1 of each year provides the agency sufficient time to review each application and provide notice and comment before publication of the IPPS final rule by August 1 of each year. CMS continues to believe this policy is appropriate for new technology add-on payments but because of the significant ongoing concerns about antimicrobial resistance, it believes that the new technology add-on payment for certain antimicrobial products may warrant additional flexibility. In addition, CMS notes that the review of products under the alternative pathway do not need to demonstrate significant clinical improvement which reduces the time required for CMS to review the application.

In order to allow eligible antimicrobial products to begin receiving the new technology add-on payment sooner, CMS proposed to provide for conditional approval for antimicrobial products that otherwise meet the new technology add-on payment alternative pathway but do not receive FDA approval by July 1. Antimicrobial products that would otherwise meet the applicable add-on payment criteria would begin receiving the new technology add-on payment, effective for discharges the quarter after the date of FDA marketing authorization instead of waiting to re-apply for the next fiscal year, provided FDA marketing authorization is received by July 1 of the year for which the applicant applied for new technology add-on payments. CMS considered July 1 to be the cut-off for conditional approval because if the FDA marketing authorization is received on or after July 1, the new technology add-on payment would not be effective for discharges until the beginning of the next quarter on October 1, which would be the start of the next fiscal year.

CMS provided the following example. An eligible antimicrobial product is conditionally approved for new technology add-on payment in the FY 2021 IPPS final rule but FDA marketing authorization is not granted until February 1, 2021. The new technology add-on payment for the product would be made for discharges on or after April 1, 2021 (the beginning of the quarter after the FDA marketing authorization was granted). If the FDA marketing authorization was granted on or after July 1, 2021, the product would not receive any add-on payments for FY 2021. To be eligible for new technology add-on payments for FY 2022, the applicant would need to re-apply for such payments for FY 2022 by the applicable deadline.

For an applicant drug that receives FDA approval but did not receive approval under the LPAD pathway and is not designated as a QIDP, the product would not be eligible for approval under the alternative pathway for certain antimicrobial products. In this situation, even if the product received conditional approval, no new technology add-on payments would be made for the fiscal year. The applicant would need to re-apply for new technology add-on payments under the traditional pathway for the following fiscal year.

Some commenters were supportive of this proposal; other commenters suggested alternatives for the proposal and other commenters suggested ways to expand the proposal. Commenters suggested establishing a subregulatory process instead of the conditional approval process.

Several commenters recommended a faster review process for medical devices that are part of FDA's Breakthrough Devices Program and that devices that are part of the Breakthrough Devices Program also receive conditional approval. Other commenters suggested expansion to include products outside of the QIDP designation.

CMS appreciates all the suggestions and will consider them for future rulemaking. It continues to believe it is important to increase access to treatments of serious or life-threatening infections and **finalizes its proposal for conditional approval for certain antimicrobial products**.

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

CMS adjusts a portion of IPPS payments for area differences in the cost of hospital labor. The adjustment is known as the wage index.

Legislative Authority. Section 1886(d)(3)(E) of the Act requires an annual update to the wage index based on a survey of wages and wage-related costs (fringe benefits) of short-term, acute care hospitals which the agency collects on Medicare cost reports (CMS Form 2552-10, Worksheet S-3, Parts II, III, and IV). Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program in order to construct an occupational mix adjustment to the wage index.

### A. Labor Market Areas

Hospitals are assigned to labor market areas, and the wage index reflects the weighted (by hours) average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) Core-Based Statistical Areas (CBSAs) delineations as labor market areas. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01 and 17-01. CMS proposed to update the labor market areas using the September 14, 2018 OMB Bulletin No. 18-04. While OMB bulletins issued between decennial censuses usually have only minor modifications, OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical.

*Comments/Responses:* MedPAC and other commenters supported using the revised delineations. Commenters opposed to using the revised delineations asked CMS to delay adoption of the revised delineations until after the 2020 decennial census. These commenters indicated:

- CMS should consider that the New York-Newark-Jersey City, NY-NJ MSA is the area most affected by the labor market area changes with wage indexes going down;
- This same MSA has also been disproportionately affected by the COVID-19 pandemic;
- CMS has not previously established a new CBSA (the New Brunswick-Lakewood, NJ CBSA) outside of a decennial census;
- OMB Bulletin 18-04 warns that comparing Metropolitan Divisions with entire MSAs is inappropriate (the New Brunswick-Lakewood, NY is a Metropolitan Division that has been created and separated from the New York-Newark-Jersey City, NY-NJ MSA);
- Neither CMS, nor OMB, has presented any evidence that the counties that constitute the New

Brunswick-Lakewood, NJ CBSA function as a distinct area within the larger New York-Newark-Jersey City, NY-NJ MSA;
- The New Brunswick-Lakewood Metropolitan Division was created because an OMB commuting threshold between Monmouth and Middlesex Counties was narrowly exceeded, but the underlying commuting data is flawed because of the effects of Hurricane Sandy and its impact on commuting patterns in the 2011-2015 American Community Survey (ACS) Commuting Flows dataset that was used as the basis of Bulletin No. 18-04; and
- Hospitals had insufficient notice of these changes.

CMS responds that it is important for the IPPS to use the updated labor market area delineations in order to maintain a more accurate and up-to-date payment system that reflects the reality of current labor market conditions. While the revised delineations do not reflect the results of a new decennial census, they do incorporate the results from updated commuting survey data—the 2011-2015 ACS. CMS notes that it is limiting wage index reductions in a single year to 5 percent to mitigate significant negative impacts of, and provide time for hospitals to adapt to, the revised OMB delineations and seek newly available reclassification options.

In response to the specific comments above, CMS indicates:

- Nothing about the COVID-19 public health emergency diminishes the importance of ensuring that payments are as accurate as possible;
- Even though OMB Bulletins between decennial censuses typically make minor changes to CBSA delineations, CMS has routinely adopted revised delineations issued by OMB between decennial censuses;
- CMS acknowledges OMB's concern that delineations should be evaluated by any agency before use in program funding formulas. Further, CMS indicates that CBSA-based delineations were not specifically designed to define labor market areas. However, CMS believes OMB's CBSA delineations serve as useful proxies for this purpose;
- Under the revised delineations in OMB Bulletin No. 18-04, the changes adopted in FY 2015 to the New York-Newark-Jersey City MSA have reverted back to the CBSA delineations in place from FY 2005 through FY 2014;
- While CMS acknowledges that relatively small deviations in commuting interchange statistics may cause some counties to move between CBSAs if they are close to a specific threshold definition, CMS believes adopting the changes would more accurately reflect variations in area wage levels;
- CMS rejects the argument that Hurricane Sandy affected the labor market areas as suggested by the commenter given the distinctive change in the average hourly wage that occurs when removing hospitals from the New York-Jersey City-White Plains, NY-NJ CBSA ($59.21 compared to $47.79); and
- Revised delineations from OMB have been public for nearly 2 years.

CMS is finalizing, without modification, revised labor market areas resulting from OMB Bulletin No. 18–04 effective beginning with the FY 2021 IPPS wage index.

*Urban Counties Becoming Rural*. In the proposed rule, CMS indicated that the new OMB delineations would result in 34 counties (and county equivalents) including 10 hospitals going from urban to rural classification. Under current policy, the wage data for all hospitals located in these counties will now go into calculating the state's rural wage index. For purposes of DSH, CMS will follow a pre-established policy that will transition the hospital's payments based on two-thirds of the urban formula and one-third of rural formula in FY 2021; one-third of the urban formula and two-thirds of the rural formula in FY 2022 and 100 percent of the rural formula in FY 2023. CMS did not receive any comments on the reassignment of hospitals from urban to rural counties and is finalizing these policies as proposed.

*Rural Counties Becoming Urban*. In the proposed rule, CMS indicated that a total of 47 counties (and county equivalents) and 17 hospitals or critical access hospitals (CAHs) will go from rural to urban. Under current policy, the wage data for all hospitals located in these counties will now go into calculating the urban wage index for the CBSA in which it is located. To be eligible for CAH status, a hospital must be treated as rural for IPPS purposes. For CAHs moving from rural to urban, CMS proposed they be allowed to retain CAH status for two years. This policy will allow sufficient time for CAHs to apply for an urban to rural reclassification under section 1886(d)(8)(E) of the Act and 42 CFR §412.103 to retain CAH status.

*Comment/Response:* A hospital in Harnett County, NC currently has an automatic Lugar reclassification to Raleigh based on commuting patterns between its county and Raleigh. However, based on commuting patterns under the revised OMB delineations, Harnett County would be considered part of the Fayetteville CBSA reducing the hospital's wage index. The hospital asked to retain its Lugar reclassification to Raleigh as it believes that is where it will return after the 2020 decennial census. Based on the updated delineations in OMB Bulletin No. 18-04, CMS believes that Harnett County is appropriately classified as part of Fayetteville, but it will consider changes based on future revisions to OMB CBSA delineations.

One commenter requested CMS consider a 2-year extension of rural status for Medicare Dependent Hospitals (MDH) and Sole Community Hospitals (SCH) located in counties that are gaining urban status. CMS considered this comment in 2015 and provided the same reply: the payment consequences for CAHs of losing rural status are greater than for SCHs and MDHs. Further MDHs and SCHs have the ability to reclassify as rural immediately in order to retain their special payment status.

*Urban Counties Moving to a Different CBSA*. CMS lists a number of counties where OMB is now listing the county in a different CBSA. No special policy considerations are applicable as a result of this movement.

Tables 2 and 3 as well as the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the assignment of counties to CBSAs. In some cases, the revised OMB delineations changed a CBSA's name or number only but not any of its constituent counties which is why it may be listed differently than in prior years.

*Transition Policy:* In FY 2015, CMS implemented new OMB delineations based on the 2010 decennial census data and allowed for the following transition policies:

- Urban hospitals that became rural under the new delineations maintained the wage index value of the CBSA in which they were physically located for FY 2014 for three years;
- For hospitals that experienced a decrease in wage index values due to the change in labor market area definitions, CMS calculated a 1-year blended wage index where hospitals received 50 percent of their wage index based on the new OMB delineations that went into effect in FY 2015, and 50 percent of their wage index based on their FY 2014 labor market area.

For FY 2020, CMS did not adopt any labor market area changes but did make a number of revisions to hospital wage indexes and capped wage index reductions at 5 percent. For FY 2021, CMS also proposed to cap wage index reductions at 5 percent to mitigate the impact of large decreases in wage index values from using new OMB CBSA delineations.

*Comment/Response*: Public comments suggested a variety of alternatives to the 5 percent cap such as a lower cap or adopting transition policies like those CMS established for FY 2015. CMS rejected allowing urban hospitals that become rural to maintain an urban wage index for 3 years because all the hospitals that would shift from urban to rural under the revised delineations are located in "Lugar" counties that would be deemed as reclassified to an urban area. CMS rejected establishing a 1-year blended wage index based on the old and new OMB CBSA delineations because it believes the 5 percent cap accomplishes the same policy goal.

Another commenter asked CMS to apply the 5 percent cap from the wage index the hospital is actually paid rather than the wage index that was assigned to the hospital in the FY 2020 final rule. In this case, hospitals may be receiving a different wage index than the one assigned in the IPPS final rule because the hospital did a mid-year urban to rural reclassification to receive a higher rural wage index. In a later section, CMS expresses concern about hospitals reclassifying from urban to rural after the "lock-in" date to calculate the rural wage index. CMS indicates that these reclassifications are a form of gaming for which it is considering future policy changes. While CMS does not respond to this particular comment expressing this concern, it seems clear that CMS is rejecting that comment because of that concern. CMS responded that it will use the FY 2020 IPPS final rule wage index to apply the 5 percent cap on reductions to facilitate transparency. A hospital can contact its Medicare Administrative Contractor (MAC) for assistance if it believes the incorrect wage index value was used as the basis for its transition and the MAC can make any appropriate correction.

CMS is finalizing its transition policy as proposed.

*Transition Budget Neutrality:* For FY 2021, CMS proposed to use its section 1886(d)(5)(I) of the Act "exceptions and adjustments" authority to apply a budget neutrality adjustment to the standardized amount so that its transition policy is budget neutral. CMS did not receive any comments on this proposal that is finalizing without change.

## B. Worksheet S-3 Wage Data

The final rule wage index values are based on data from FY 2017 cost reports. Categories of included and excluded costs from prior years are unchanged for FY 2021.

The proposed rule clarified how physician compensation is accounted for in the calculation of the wage index because of concerns about the number of wage index appeals on this issue. CMS did not receive any comments on its clarifications of physician compensation for the wage index and how to provide supporting documentation.

CMS calculates the FY 2021 wage index based on wage data of 3,222 hospitals. CMS states that the data file used to construct the final wage index includes FY 2017 data submitted to CMS as of June 30, 2020. General wage index policies are unchanged from prior years. However, CMS notes that it is excluding 56 providers from the wage index calculations due to aberrant wage data. Another 9 hospitals that converted to CAH status since FY 2017 were also excluded from the calculation of the wage index. CMS describes how it allots costs for 16 multi-campus hospitals that cross labor market areas.

## C. Unadjusted Wage Index and the Occupational Mix Adjusted Wage Index

For the FY 2021 wage index, CMS refers readers to the FY 2020 final rule (84 FR 42304 through 42307) where it restated the steps published in the FY 2012 methodology updated for current references and technical changes. It also repeats those steps in this year's proposed and final rules. CMS did not propose any changes to the steps for computing the unadjusted wage index for FY 2021.

Section 1886(d)(3)(E) of the Act requires CMS to collect 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. The current occupational mix survey data from 2016 is used for the occupational mix adjustment applied to the FY 2019 through FY 2021 IPPS wage indexes.

Hospitals were required to submit completed 2019 occupational mix surveys to their MACs (not directly to CMS), on the Excel hospital reporting form, by July 1, 2020 via email attachment or overnight delivery. CMS granted an extension until August 3, 2020 for hospitals that may be unable to meet the July 1, 2020 deadline due to the COVID-19 public health emergency. The deadline was later extended to September 3. Preliminary CY 2019 unaudited occupational mix survey data will be released on the CMS website no later than September 8, 2020. Hospitals will have until September 10 to submit corrections to their MACs.

CMS reports having occupational mix data for 97 percent of hospitals (3,140 of 3,223) used to determine the FY 2021 wage index. The FY 2021 national average hourly wage, unadjusted for occupational mix, is $45.27. The occupational mix adjusted national average hourly wage is $45.23.

The FY 2021 national average hourly wages for each occupational mix nursing subcategory changed only very marginally from FY 2020. The effect of the occupational mix adjustment by type of area is almost identical to prior years.

**D. Rural Floor, Frontier Floor and Low Wage Index Hospital Policy**

*Rural Floor*. The rural floor is a provision of statute that prevents an urban wage index from being lower than the wage index for the rural area of the same state. CMS estimates that the rural floor will increase the FY 2021 wage index for 285 hospitals requiring a budget neutrality adjustment factor of 0.993443 (-0.66 percent) applied to hospital wage indexes.

*Frontier Floor Wage Index*. The Affordable Care Act requires a wage index floor for hospitals in the low population density states of Montana, Nevada, North Dakota, South Dakota and Wyoming. CMS indicates that 44 hospitals will receive the frontier floor value of 1.0000 for FY 2021. This provision is not budget neutral, and CMS estimates an increase of approximately $69 million in IPPS operating payments due to the frontier floor. No hospitals in Nevada will receive the frontier floor because all hospitals in Nevada have a wage index of greater than 1.0000.

*Low Wage Index Hospital Policy*. CMS proposed to continue the following policies that it first adopted in FY 2020to mitigate wage index disparities:

- Increase the wage index by one-half the difference between the hospital's otherwise applicable wage index and the 25$^{th}$ percentile wage index value. CMS plans to continue this policy for FY 2021 through FY 2023. For FY 2021, the 25th percentile wage index value across all hospitals is 0.8465. The budget neutrality adjustment for this policy is -0.12 percent;
- Remove the wage data from urban hospitals reclassifying as rural from the calculation of the rural floor wage index;
- Not apply a floor on a county's wage index based on the rural area wage index that results from a hospital in that county reclassifying from urban to rural; and
- Limit reductions in a hospital's wage index for any reason to 5 percent in a single year. For FY 2021, the budget neutrality adjustment for this policy will be -0.020 percent.

*Comments/Responses:* Public comments were generally the same as on the FY 2020 rule:

- Supporters appreciated CMS' addressing circularity issues with the wage index by adopting this policy while opponents indicated that the policy fails to address legitimate differences in the average hourly wage between labor market areas;
- Opponents of the policy indicated there are no guarantees that low-wage index hospitals will use the higher payments to pay higher wages;
- The circularity issue and the four-year lag between wages paid and the calculation of the hospital wage index is not limited just to lowest quartile hospitals;
- CMS does not have the legal authority to adopt this policy as it is does not reflect the area differences in wages as required by the statute;
- Commenters asked CMS not to apply the low wage index policy in a budget neutral manner. Some commenters further stated that the budget neutrality adjustment will offset more than

the wage index increase for some hospitals below the 25th percentile; and
- Supporters of the policy to exclude urban to rural reclassifications from the calculation of the rural floor wage index requested that CMS not apply national budget neutrality for the rural floor.

CMS' general response is that the policy is the same as for FY 2020 and it did not propose anything different. Otherwise, it indicated:

- The low wage index policy preserves the rank order in wage index values and continues to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas;
- CMS intends to assess whether the low wage index hospital policy has been effective in allowing hospitals to make adjustments in employee compensation based on wage data collected on hospitals' cost reports for the years during which this policy is in effect;
- While CMS agrees that the circularity issue and the 4-year data lag is not limited to hospitals in the lowest quartile, it poses a particular problem for low wage hospitals;
- Because the low wage index hospital policy is based on the actual wages that CMS expects low wage hospitals to pay, it falls within the scope of the authority in section 1886(d)(3)(E) of the Act that requires CMS to recognize the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level;
- The wage index is a technical adjustment not a policy tool, so CMS believes that it should not be used to increase Medicare spending to hospitals;
- CMS believes it has broad authority under the section 1886(d)(5)(I) "exceptions and adjustments" authority to make the low wage index policy budget neutral;
- Even though the budget neutrality adjustment may produce a net reduction in payments for some hospitals with wage indexes below the 25th percentile, CMS believes it remains appropriate to apply a budget neutrality adjustment to the national standardized amount for all hospitals; and
- The statute requires national budget neutrality for the rural floor.

**E. Wage Index Tables & Hospital Reclassifications**

Final rule wage index tables 2, 3 and 4A and 4B can be found at the link at the beginning of this summary. Select #2 under FY 2021 Final Rule Tables.

Geographic reclassification describes a process where hospitals apply to use another area's wage index. To use another area's wage index, the applying hospital must be within a specified distance and have comparable wages to that area. The Medicare Geographic Classification Review Board (MGCRB) decides whether hospitals meet the criteria to receive the wage index of another hospital. CMS did not propose any changes to the geographic reclassification criteria.

By law, reclassification applications are due to the MGCRB by September 1, 2020 for FY 2022. However, this deadline has been extended for applications for FY 2022 reclassifications to 15 days after the public display date of the final rule at the Office of the Federal Register (September 17, 2020) due to the COVID-19 Public Health Emergency.

*Geographic Reclassifications*. There are 392 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021. There are 245 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2019 that will continue for FY 2021, and 269 hospitals approved for wage index reclassification in FY 2020 that will continue for FY 2021. Eight hundred and ninety-five hospitals are in an MGCRB reclassification status for FY 2021 (with 90 of these hospitals reclassified back to their home area).

The deadline for withdrawing or terminating a wage index reclassification for FY 2021 approved by the MGCRB was 45 days from publication of the FY 2021 proposed rule in the *Federal Register* (July 13, 2020). Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process are incorporated into the final FY 2021 wage index values. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, CMS refers readers to 42 CFR §412.273.

*Comments/Responses:* Several commenters requested additional time to revise decisions to withdraw an approved MGCRB reclassification based on whether CMS finalizes changes to the labor market areas or to accommodate the decisions of other hospitals which may affect their own wage index. CMS maintains that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions even though hospitals may not know the final decisions by CMS or other hospitals. If hospitals were to withdraw or terminate reclassification statuses after the publication of the final rule, any resulting changes in the wage index would not be taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement.

Other commenters indicated that average hourly wage information to support geographic reclassification applications will not be available by the September 1 deadline to apply for geographic reclassification applications for FY 2022 because of late publication of the IPPS final rule. To address late publication of the final rule and the September 1 deadline for geographic reclassification applications, CMS made the 3-year average hourly wage information available before publication of the final rule on August 5, 2020 at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Three-Year-MGCRB-Reclassification-Data. In addition, CMS is providing hospitals until September 17, 2020 to submit their reclassification applications.

Another commenter objected to CMS' policy that treats reclassified hospitals as a group when determining whether to include or exclude the wage data for these hospitals in the calculation of the rural wage index. This commenter stated that hospitals reclassified under section 1886(d)(8)(B) of the Act (Lugar hospitals) should be treated as a group but separately from other hospitals reclassified under section 1886(d)(10) of the Act (MGCRB reclassifications) because section 1886(d)(8)(C)(ii) uses "or" rather than "and" when evaluating whether to include or exclude reclassified hospitals from the rural wage index.

CMS did not agree with the legal analysis provided by the commenter that requested Lugar hospitals be treated as a group separately from MGCRB reclassifications when deciding whether or not to include reclassified hospital wage data in the calculation of the rural wage index.

According to CMS, use of the plural "hospitals" supports its long-standing policy. Further, both reclassification under sections 1886(d)(10) and 1886(d)(8)(B) of the Act serve the same essential wage index functions, that is, assigning a hospital a wage index value for a nearby labor market area.

*Hospitals with One or Two Years of Wage Data Seeking MGCRB Reclassification*. CMS proposed to modify 42 CFR §412.230(d)(2)(ii)(A) to clarify that a hospital may qualify for an individual wage index reclassification if the hospital only has 1 or 2 years of wage data. The regulations state that a 3-year average hourly wage is used to support the reclassification application. The proposed revision was intended to clarify that the hospital may use 1 or 2 years of data in such circumstances as when a hospital is new and does not have 3 years of data to support a geographic reclassification application. This policy also applies to a change of hospital ownership where the new owner does not accept the provider agreement of the prior owner. Public commenters supported this policy that CMS is finalizing without modification.

*Revised OMB Labor Market Area Delineations on Reclassified Hospitals*. Hospitals applied for reclassification based on the prior OMB delineations, not the revised delineations proposed for FY 2021. CMS encouraged hospitals with current reclassifications to verify they remain reclassified to an area with a higher wage index. If not, hospitals were informed that they may withdraw or terminate their FY 2021 reclassifications by July 13, 2020 using the procedure outlined in 42 CFR §412.273(c). Hospitals with an FY 2019 or FY 2020 reclassification that may continue into FY 2021 as well as new reclassification beginning with FY 2021 also were given the opportunity to withdraw the more recent reclassification in favor of a prior one.

Following past practice when there are revised OMB delineations that affect geographic reclassification and it is not possible for the reclassification to continue seamlessly, CMS proposed to determine the best alternative location to reassign current reclassifications for the remaining 3 years:

- For individual hospital reclassification, CMS proposed to assign affected reclassified hospitals to a CBSA that would contain the most proximate county that: (1) is located outside of the hospital's proposed FY 2021 geographic labor market area, and (2) is part of the original FY 2020 CBSA to which the hospital is reclassified.
- For county group reclassifications, CMS proposed to reassign hospitals to the CBSA under the revised OMB delineations that contains the county to which the majority of hospitals in the group reclassification are geographically closest.

Individual hospitals were furnished the opportunity to request and be granted an alternative reclassification assignment if the requested area contains at least one county from the CBSA to which they are reclassified for FY 2020 and for which they meet the applicable proximity criteria. For county groups, a hospital or group of hospitals could request and be granted reassignment to another CBSA that would contain a county that is part of the current FY 2020 CBSA to which it is reclassified if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules.

Reclassified hospitals may receive a lower wage index that results from these policies than if the original delineations and reclassifications were retained. CMS believes the 5 percent cap on wage index reductions will help to mitigate any adverse financial impacts that result from the revisions to a hospital's wage index from the revised OMB delineations and geographic reclassification policies.

CMS received three timely requests for a reassigned geographic reclassification. Two of these requests were approved and one was denied for insufficient documentation to determine that the hospital met the applicable proximity criteria.

*Comments/Responses:* A number of commenters representing hospitals reclassified to current CBSA 35614 (New York City-Jersey City-White Plains, NY-NJ) objected to being assigned to a different CBSA using CMS's proposed reclassification assignment policy. These commenters argued the statute made their reclassification to CBSA 35614 effective for 3-years. Further, these commenters argue that CMS' policy for assigning a reclassification violates regulations that prohibit a hospital from reclassifying to an area with a lower wage index.

CMS agrees that it is obligated by the statute to maintain reclassification status for a period of 3 years after approval. However, since the CBSA to which these hospitals were approved has been reconfigured, it believes the FY 2020 CBSA 35614 is not the same entity as the revised FY 2021 CBSA. Hospitals reclassified to CBSA 35614 no longer meet the proximity criteria under the regulation to be reclassified to the same area where they were previously reclassified. CMS indicates that a hospital may not seek reclassification to an area with a lower wage index at the time it reclassifies. This regulatory provision does not affect CMS' proposed reassignment policy. A hospital reclassified to an area with a lower wage index than its home area wage index was entitled to cancel its proposed rule reclassification reassignment.

Table 1 lists CBSAs where one or more counties would be relocated to a new or different urban CBSA. Table 2 lists all hospitals subject to CMS' final reclassification assignment policy.

*Home Area Reclassifications.* Under prior policy, a hospital reclassified to a CBSA that had one or more counties moved to a new or different urban CBSA was required to be assigned a new or revised CBSA that is different than its home CBSA. At the time CMS adopted this policy, hospitals were not allowed to reclassify as rural and then back to their home CBSA. CMS has since removed this reclassification restriction and is similarly accounting for the revised policy for the new OMB delineations by not requiring hospitals with a home area reclassification to be assigned to a different CBSA.

For the FY 2021 rule, CMS proposed to assign hospitals with a home area reclassification to the hospital's home CBSA. The assigned home area reclassification CBSA may be different from previous year's if the hospital is located in a county that was relocated to a new or different urban CBSA. Table 3 lists hospitals affected by this policy.

A hospital with a geographic reclassification is ineligible for an out-migration adjustment. As CMS will no longer automatically end a geographic reclassification to a home area where the hospital's geographic CBSA and its reclassified CBSA are the same, CMS advised a hospital

with a home area reclassification to consider terminating that reclassification to be eligible for an outmigration adjustment in the proposed rule. CMS received no comments on proposals related to home area hospitals. It is finalizing the proposed policy without modification.

*Lugar Hospitals and Counties*. A "Lugar" county is a rural county adjacent to one or more urban areas that is deemed to be part of the urban area where the highest number of its workers commute. A Lugar hospital is located in a Lugar county.

The out-migration adjustment is a positive adjustment to the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. A hospital can either be reclassified or receive the out-migration adjustment but not both. Lugar status is automatic and must be declined through an urban to rural reclassification application for the hospital to receive an out-migration adjustment to its home area wage index.

Of the 47 rural counties that will become urban under the new OMB delineations, 23 are currently deemed urban Lugar counties. These counties will no longer be deemed urban under the new OMB delineations and hospitals within these counties would no longer be Lugar hospitals. CMS includes an unnumbered table that lists the counties that would no longer be deemed urban.

CMS revises the list of Lugar counties once every ten years based on information on commuting patterns from the decennial census. In past years, CMS did not revise eligibility for Lugar status between decennial censuses. However, CMS proposed to revise the list of Lugar counties based on the revised OMB delineations for FY 2021 because the revised OMB delineations will make some hospitals rural that are currently urban. As an urban wage index is generally higher than a rural wage index, CMS believes revising the list of Lugar hospitals may benefit those hospitals with a status changing from urban to rural as a result of the new OMB delineations.

The rule indicates that all 34 counties including 10 hospitals that are becoming rural will qualify for Lugar status. An additional two counties in New York State would qualify for Lugar status but hospitals in these counties have existing geographic reclassifications that would supersede these Lugar reclassifications. CMS did not receive any comments on this proposal that it is finalizing without modification.

**F. Out-Migration Adjustment & Reclassification from Urban to Rural**

CMS proposed to use the same policies for the FY 2021 out-migration adjustment that it has been using since FY 2012. Estimates of increased payments are $51 million in FY 2021 to 212 hospitals. This provision is not budget neutral. CMS received no comments on this proposal that it is finalizing without modification.

A qualifying IPPS hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Not later than 60 days after the receipt of an application from an IPPS hospital that satisfies the statutory criteria, CMS must treat the hospital as being located in the rural area of the state in which the hospital is located.

*Lock-in Date*. CMS describes the "lock-in date," or the date by which CMS would need information that a hospital has reclassified from an urban to a rural area in order to include its wage data in the rural wage index calculations for the following year's IPPS rates. That date is the same as the closing date for the comment period on the annual IPPS proposed rule. The lock-in date only affects the calculation of the following year's wage index. It does not affect eligibility or timing for when a hospital can be eligible or approved for an urban to rural reclassification.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42322), CMS expressed concern about hospitals applying for an urban to rural reclassification after the ''lock-in date'' to avoid lowering the rural wage index but then receive the higher rural wage index when IPPS rates are set for the following year. Hospitals could then do this repeatedly from year-to-year as a way of manipulating the rural wage index to their own benefit at the expense of other hospitals through the budget neutrality adjustment.

CMS indicates that twenty-one hospitals in one state and five hospitals in another state obtained urban to rural reclassifications after the FY 2020 lock-in date, effectively receiving their state's rural wage index without having their wage data included, which would have lowered their state's rural wage index. These hospitals then requested to cancel their urban to rural reclassifications for FY 2021. CMS will continue to monitor this situation over the course of FY 2021 and may consider proposing a policy in future rulemaking that requires hospitals reclassifying from urban to rural to maintain rural status for a minimum period of time to prevent this type of gaming.

*Allowing Electronic Appeals of MGCRB Decisions.* Regulations require that appeals of MGCRB applications must be mailed to the Administrator in care of the Office of the Attorney Advisor with a hardcopy to CMS' Hospital and Ambulatory Policy Group. Appeals may be not submitted by facsimile or other electronic means. CMS proposed to revise the regulation to remove the prohibition on electronic or facsimile submissions. Copies to the Hospital and Ambulatory Policy Group would be required by electronic means. Commenters supported this proposal that CMS is finalizing without modification.

*Rural Referral Center (RRC) Criteria.* An urban hospital can reclassify as rural to become an RRC if has over 275 beds or meets specific case mix and discharge criteria announced in the annual IPPS rule. CMS is aware of confusion regarding qualification for urban to rural reclassification based on discharge and case mix criteria. The confusion is over whether the criteria must be met using (1) the criteria in effect on the filing date of the hospital's urban to rural application or (2) the criteria that would be in effect during the fiscal year that any RRC classification would become effective.

CMS is clarifying that the criteria that must be met for the hospital to reclassify as rural are those in effect as of the filing date for RRC status. However, for purposes of actually qualifying for RRC status, the hospital must meet the discharge and case mix criteria in effect at the start of the hospital's next cost reporting period when it becomes an RRC. CMS indicates that this differential policy for reclassifying as rural and qualifying for RRC status is appropriate because

an urban to rural reclassification can happen at any time while applications for RRC status must be submitted during the last quarter of a hospital's cost reporting period. CMS did not receive any comments on this proposal that it is finalizing without modification.

### G. Process for Wage Index Data Corrections; Labor-Related Share

1. Process Wage Index Correction

CMS has established a multistep, 15-month process for the review and correction of the hospital wage data used to create the IPPS wage index for the upcoming fiscal year. The rule describes this process in great detail including when data files were posted and deadlines for hospitals to request corrections or revisions to audit adjustments. A hospital that fails to meet the procedural deadlines does not have a later opportunity to submit wage index data corrections or to dispute CMS' decision on requested changes. The process for the FY 2022 wage index has already begun. CMS posts the wage index timetable on its website at: https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page. Select file #1. This website also includes all of the public use files that CMS has made available during the wage index development process. For FY 2022, only the preliminary wage index file is currently available. Hospitals had until September 3, 2020 to make changes to this file.

In response to an inquiry, CMS clarifies that all deadlines are eastern standard time.

2. Labor-Related Share

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national standardized amount that is attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. The proportion of the standardized amount attributable to wages and wage-related costs is the national labor-related share. The factor that adjusts for the relative differences in labor costs among geographic areas is the wage index. Section 1886(d)(3)(E) of the Act directs the Secretary to employ 62 percent as the labor-related share if that would result in higher payments to the hospital than using the national labor-related share.

The Secretary is required to update the labor-related share from time-to-time but no less often than every 3 years. CMS is currently using a national labor-related share of 68.3 percent. No changes were proposed for FY 2021. If a hospital has a wage index of less than 1.0, its IPPS payments will be higher with a labor-related share of 62 percent. If a hospital has a wage index that is higher than 1.0, its IPPS payments will be higher using the national labor-related share.

## IV. Other Changes to the IPPS

### A. Post-Acute Care Transfers

1. Background

A post-acute care transfer is a discharge from a hospital to a rehabilitation hospital or unit, a psychiatric hospital or unit, a skilled nursing facility, a hospice or the patient's home with a written plan for home health services from a home health agency and those services begin within 3 days of the date of discharge. If that transfer occurs prior to the geometric mean length of stay and the patient is grouped to an MS-DRG subject to the post-acute care transfer policy, CMS makes payment to the transferring hospital using one of two methodologies: 1) payment at twice the per diem amount for the first day with each subsequent day paid at the per diem amount up to the full IPPS amount; or 2) payment of 50 percent of the full IPPS amount, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days up to the full IPPS amount. The second methodology is known as the "special payment methodology" and is for cases that exhibit exceptionally higher costs very early in the hospital stay.

If the MS-DRG's total number of discharges to post-acute care equals or exceeds the 55th percentile for all MS-DRGs and the proportion of short-stay discharges to post-acute care to total discharges in the MS-DRG exceeds the 55th percentile for all MS-DRGs, CMS will apply the post-acute care transfer policy to that MS-DRG and to any other MS-DRG that shares the same base MS-DRG. CMS does not revise the list of DRGs subject to the post-acute care transfer policy annually unless it is also making a change to a specific MS-DRG.

2. Changes for FY 2021

CMS proposed to make changes to a number of MS-DRGs effective for FY 2021. As a result, CMS proposed to add new MS-DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) to the list of MS-DRGs subject to the post-acute care transfer policy and the special payment methodology. CMS received one comment opposed to including these MS-DRGs on the list of those subject to the post-acute care transfer policy. The commenter indicated that CMS' policy will incent hospitals to keep these patients longer as inpatients. CMS disagrees with that comment and indicated that the predecessor MS-DRG to this new MS-DRG was also subject to the post-acute care transfer policy effectively resulting in no policy change.

**B. Inpatient Hospital Updates**

The inpatient hospital update for FY 2021 is calculated by determining the rate of increase in the hospital market basket for IPPS hospitals in all areas, subject to the following reductions:

- The 10-year moving average of economy-wide multifactor productivity.
- For hospitals that fail to submit quality information, the FY 2021 inpatient hospital update will be reduced by one quarter of the applicable percentage increase.
- For a hospital that is not a meaningful EHR user (and to which no exemption applies), the FY 2021 inpatient hospital update will be reduced by three-quarters of the market basket update.

The IHS Global Insight, Inc. (IGI) second quarter 2020 forecast (with historical data through the

first quarter of 2020) for the hospital market basket is 2.4 percent. The proposed rule estimate of the market basket was 3.0 percent. The lower final rule market basket is primarily driven by slower than anticipated compensation growth for both health related and other occupations that started in February 2020 and is expected to last throughout the anticipated recovery. IGI only produces market basket estimates quarterly and the second quarter 2020 market basket forecast is the most recent available.
For MFP, however, CMS is deviating from past practice of using the second quarter 2020 forecast. MFP estimates are produced using monthly macroeconomic forecasts. For MFP, CMS is using IGI's most recent macroeconomic outlook released in June of 2020. In past years, the difference between the second quarter forecast and the later June forecast was insignificant. However, this year there is considerable economic uncertainty related to the COVID-19 pandemic that makes use of a later data preferable.

Using the June forecast, IGI estimates MPF is -0.1 percent. Section 1886(b)(3)(B)(xi)(I) of the Act requires the Secretary to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. As subtracting a negative MFP figure would increase the hospital market basket, CMS is adopting an MFP adjustment of 0.0 percentage points.

One of four different applicable percentage increases that may apply to a hospital, depending on whether it submits quality data and/or is a meaningful EHR user, are shown in the following table.

| FY 2021 | 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 | -1.8 | 0.0 | -1.8 |
| MFP Adjustment | 0.0 | 0.0 | 0.0 | 0.0 |
| **Applicable Percentage Increase** | **2.4** | **0.6** | **1.8** | **0.0** |

For updates to the hospital-specific rate for SCHs and MDHs, CMS will adopt the same four possible applicable percentage increases shown in the table above.

### C. Sole Community Hospitals (SCHs) & Rural Referral Centers

1. Sole Community Hospitals (SCHs)

One of the criteria to be classified as a sole community hospital involves the percentage of patients drawn from the hospital's service area. "Service area" is defined as the area from which a hospital draws at least 75 percent of its inpatients during its most recent 12-month cost reporting period ending before the hospital applies for classification as an SCH. CMS proposed to amend §412.92(c)(3) to clarify where the applicable hospital cost reporting period is less than

12-months, the hospital's most recent 12-month or longer cost reporting period before the short period is used for the determination. CMS did not receive any comments on this proposal that it is finalizing without modification.

2. Rural Referral Centers (RRCs)

Rural Referral Centers (RRC) are rural hospitals that may geographically reclassify under special rules. To qualify as an RRC, a hospital must meet case-mix, discharge and other criteria. CMS annually revises the case mix index (CMI) and discharge criteria to qualify for RRC status. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, a rural hospital with fewer than 275 beds available for use must meet the specific geographic criteria and:

- Have a CMI value for FY 2019 that is at least—
  - 1.7049 (national—all urban), or
  - The median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) for the census region in which the hospital is located (see table on page 1096 of the display copy of the rule for the regional CMIs).
- Have at least 5,000 discharges (3,000 for an osteopathic hospital) for its cost reporting period that began during FY 2018.

The median number of discharges for urban hospitals in each census region is greater than the national standard of 5,000. Therefore, the minimum number of discharges a non-osteopathic hospital must have to qualify is 5,000 discharges.

The median regional CMIs and median regional discharges listed in the final rule reflect the March update of the FY 2020 MedPAR file containing data from bills received through March 2020. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its MAC.

To meet the minimum number of discharges criterion, the regulations require the hospital to use the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. CMS recently encountered a situation where the applicable cost reporting period was shorter than 12 months. The hospital would have met the discharge criterion based on 12 months of data but did not based on a short-period cost report. For this reason, CMS is modifying the regulations to clarify that if the applicable cost reporting period is shorter or longer than 12 months to determine whether the discharge criterion is met, the number of discharges will be annualized to reflect a 12-month cost reporting period. Commenters supported this proposal that CMS is finalizing without modification.

**D. Low-Volume Hospitals**

1. Background

Section 1886(d)(12) of the Act provides a payment in addition to a hospital's IPPS payment for each qualifying low-volume hospital beginning in FY 2005. To qualify as a low-volume hospital, the hospital must be more than a distance specified in the statute from another IPPS hospital and have fewer than a statutory specified number of discharges.

Originally, the hospital had to be 25 miles from another IPPS hospital and have fewer than 800 total discharges (Medicare and non-Medicare). These statutory criteria applied from FYs 2005 to 2010. However, by regulation, CMS established that a low-volume hospital could only qualify for the adjustment by having fewer than 200 total discharges. If a hospital qualified for the low-volume adjustment, it received a 25 percent adjustment to its payment for each Medicare discharge.

Subsequent statutory enactments for FYs 2011 to 2022 changed the distance and discharge criteria as well as the maximum number of discharges for a hospital to receive the full 25 percent adjustment. Above this maximum number, CMS is required to provide a declining linear adjustment up to a cut-off number of discharges. Beginning with FY 2023, the criteria revert to the original standards. See the following table for the distance and discharge criteria and the payment methodology specified in statute and regulations:

| Fiscal Year | Distance Criteria | Discharge Criteria | Payment Methodology |
|---|---|---|---|
| 2005 - 2010 | 25 miles | 200 Total Discharges | 25% |
| 2011 - 2018 | 15 miles | 1,600 Medicare Discharges | Medicare Discharges<200=25%; Declining Linear Adjustment. Up to 1,600 |
| 2019 - 2022 | 15 miles | 3,800 Total Discharges | Total Discharges<500=25%; Declining Linear Adjustment. Up to 3,800 discharges applied to each Medicare Discharge |
| 2023 and later | 25 miles | 200 Total Discharges | 25% |

2. FY 2019 – FY 2022

*Application Process*. CMS usually requires a hospital to make a written request for low-volume status by September 1. However, **due to late publication of the FY 2021 IPPS final rule, CMS is allowing hospitals until September 15 to make a written request for low-volume hospital status. The MAC must receive the written request by September 15 for the hospital to receive the low-volume adjustment for the federal fiscal year that begins October 1, 2020**. For a hospital whose request for low-volume hospital status is received after September 15, the MAC will apply the low-volume adjustment prospectively within 30 days of the date of a determination.

A hospital receiving the low-volume hospital payment adjustment for FY 2020 may continue to receive a low-volume hospital payment adjustment in FY 2021 by providing its MAC with a verification statement that it continues to meet the mileage criterion and provide information for the discharge criterion from its most recently submitted cost report.

*Distance Criterion*. For establishing that the hospital meets the mileage criterion, the use of a Web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest

hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will contact the hospital to obtain additional necessary information to process its application.

*Discharge Criterion*. For FY 2020 and subsequent fiscal years, the discharge determination is made using the hospital's most recently submitted cost report.

*Payment Methodology*. CMS provides the following payment formula to determine the low-volume hospital adjustment (LVHA) from FYs 2019 through 2022:

> LVHA = 0.25 – [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200).

## E. Disproportionate Share and Uncompensated Care

1. Background

Medicare makes DSH and UCP payments to IPPS hospitals that serve more than a threshold percent of low-income patients. Low-income is defined as Medicare eligible patients also receiving supplemental security income (SSI) and Medicaid patients not eligible for Medicare. To determine a hospital's eligibility for DSH and UCP, the proportion of inpatient days for each of these subsets of patients is used.

Prior to 2014, CMS made only DSH payments. Beginning in FY 2014, the ACA required that DSH equal 25 percent of the statutory formula and UCP equal the product of three factors:

- Factor 1: 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) without application of the ACA;
- Factor 2: The ratio of the percentage of the population insured in the most recent year to the percentage of the population insured in a base year prior to ACA implementation; and
- Factor 3: A hospital's uncompensated care costs for a given period relative to uncompensated care costs for that same period for all hospitals that receive Medicare DSH payments.

The statute precludes administrative or judicial review of the Secretary's estimates of the factors used to determine and distribute UCP. UCP payments are only made to hospitals eligible to receive DSH payments that are paid using the national standardized amount (SCHs paid on the basis of hospital specific rates, hospitals not paid under the IPPS and hospitals in Maryland paid under a waiver are ineligible to receive DSH and, therefore, UCP payments).

2. FY 2021 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. For the final rule, CMS used the Office of the Actuary's (OACT) July 2020 Medicare DSH estimates, which were based on the March 31, 2020 update of HCRIS and the FY 2020 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and

assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's July 2020 Medicare estimate of DSH is $15.171 billion (slightly lower than the estimate in proposed rule). **The Factor 1 amount is seventy-five percent of this amount or $11.378 billion.** The Factor 1 for 2021 is about $1.06 billion less than the final Factor 1 for FY 2020.

OACT's estimates for FY 2021 began with a baseline of $14.004 billion in Medicare DSH expenditures for FY 2017. The table below shows the factors applied to update this baseline to the current estimate for FY 2021.

**Factors Applied for FY 2018 through FY 2021 to Estimate Medicare DSH Expenditures Using 2017 Baseline**

| FY | Update | Discharge | Case-Mix | Other | Total | Estimated DSH Payment (in billions) |
|---|---|---|---|---|---|---|
| 2018 | 1.018088 | 0.983 | 1.018 | 1.0336 | 1.0530 | 14.747 |
| 2019 | 1.0185 | 0.966 | 1.009 | 1.02035 | 1.0129 | 14.937 |
| 2020 | 1.031 | 0.891 | 1.039 | 1.01957 | 0.9731 | 14.536 |
| 2021 | 1.029 | 1.036 | 0.983 | 0.99595 | 1.0437 | 15.171 |

- The discharge factor represents the increase in the number of Medicare FFS inpatient hospital discharges (based on Medicare claims data adjusted by a completion factor).
- The case-mix column shows the increase in case-mix for IPPS hospitals.
- The "other" column shows the increase in other factors affecting Medicare DSH estimates, including the difference between the total inpatient hospital discharges and the IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in other columns (such as the change in rates for the 2-midnight stay policy). The "other" column also includes a factor for Medicaid expansion due to the ACA.

The table below shows the factors that are included in the "update" column of the table above. All numbers are based on projections from the President's FY 2021 Budget.

| FY | Market Basket Percentage | Affordable Care Act Payment Reductions | Multifactor Productivity Adjustment | Documentation and Coding | Total Update Percentage |
|---|---|---|---|---|---|
| 2018 | 2.7 | -0.75 | -0.6 | 0.4588 | 1.8088 |
| 2019 | 2.9 | -0.75 | -0.8 | 0.5 | 1.85 |
| 2020 | 3.0 | 0 | -0.4 | 0.5 | 3.1 |
| 2021 | 3.0 | 0 | 0 | 0.5 | 2.9 |

*Comment/Responses:* Most comments on Factor 1 raised concerns about the adverse economic effects resulting from the COVID-19 PHE and its potential impact on the estimate of Factor 1. Many raised the concern that there is a discrepancy between the current macroeconomic conditions and the actual inputs used to estimate Factor 1 in the proposed rule. Others highlighted that the proposed decrease in Factor 1 of $1.06 billion is inconsistent with the current economic conditions, such as forecasts of higher unemployment rates that will likely result in higher Medicaid enrollments. These stakeholders strongly

urged CMS to use more recent, or alternative data sources, to account for this projected increase in Medicaid beneficiaries in the calculation of Factor 1.

CMS states that it has taken into consideration the concerns commenters raised because of the COVID-19 PHE in making its projections of Factor 1. It notes that the updated factors for "Discharges" and "Case Mix" incorporate the latest estimates from the OACT of the impact of COVID-19 on the Medicare program. It highlights that the estimated increases in new Medicaid enrollees used for Factor 1 are consistent with the updated Factor 2 calculation.

Commenters also continue to express concern about the transparency in the methodology used by OACT to estimate Factor 1. CMS reiterates its response to similar comments from prior years stating that Factor 1 is not estimated in isolation from other OACT projections. The Factor 1 estimates are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget and Midsession Review of the President's Budget and notes that its actuarial projections are subject to periodic review by independent experts to ensure their validity and reasonableness.

3. FY 2021 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. For FYs 2014-2017, the statute required CMS to use the Congressional Budget Office' (CBO) estimate of the uninsured rate in the under 65 population from before enactment of the ACA for FY 2013. For FY 2018 and subsequent years, the statute requires Factor 2 to equal the percent change in the number of individuals who are uninsured from 2013 until the most recent period for which data are available. In 2018, CMS began using uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population.[28]

For FY 2021, CMS estimated in the proposed rule that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2020 and 2021 was 9.5 percent. For purposes of the final rule, OACT has added an addendum to its memo to reflect an updated methodology for uninsured rate projection to reflect the impact of the COVID-19 PHE, as discussed in its response to comments (summarized below).[29] As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates Factor 2 for FY 2021 (weighting the portion of calendar years 2020 and 2021 included in FY 2021) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2020: 10.3 percent.
- Percent of individuals without insurance for CY 2021: 10.2 percent.
- Percent of individuals without insurance for FY 2021 (0.25 times 0.103) +(0.75 times 0.102): 10.2 percent

[28]The NHEA estimate reflects the rate of uninsured in the U.S. across all age groups and residents (not just legal residents) who usually reside in the 50 states or the District of Columbia. The NHEA data are publicly available on the CMS website at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/index.html

[29] See https://www.cms.gov/files/document/addendum-certification-rates-uninsured.pdf

Factor 2 = 1-|((0.0102-0.14)/0.14)| = 1- 0.2714 = 0.7286 (72.86 percent)

**CMS calculated Factor 2 for the FY 2021 final rule to be 0.7286 or 72.86 percent, and the uncompensated care amount for FY 2021 to be $11.378 billion x 0.7286 = $8,290,014,521** which is about $61 million less than the FY 2020 UCP total of about $8.351 billion; the percentage decrease is about 0.73 percent. The final rule estimate, however, is about 6 percent higher than the uncompensated care estimate in the FY 2021 proposed rule of $7.817 billion. The below tables show the Factor 1 and Factor 2 estimates for FY 2020 and the final factors for FY 2021:

**FY 2021 Change in UCP ($ in billions)**

| | FY 2020 | FY 2021 | $ Change | % Change |
|---|---|---|---|---|
| Factor 1 | $12.438 | $11.378 | -$1.06 | -8.5% |
| Factor 2 | 0.6714 | 0.7286 | +.0572 | +8.5% |
| UCP | $8.351 | $8.290 | -$0.061 | -0.73% |

*Comment/Responses:* As with comments on Factor 1, most commenters raised concerns about the adverse economic effects resulting from the COVID-19 PHE and its impact on the underlying uninsured rates used in the calculation of Factor 2. Stakeholders urged CMS to update its projections on the rate of uninsurance due to the COVID-19 PHE citing the increase in the unemployment rate and the likely loss of employer-sponsored health insurance. Commenters provided estimates developed by consulting groups of both the uninsured rate and uncompensated care amounts. One commenter estimated one to two billion dollars in additional uncompensated care funds and uninsured rates of 11 to 12 percent.

In response, CMS notes that OACT has updated its projection of the rate of uninsurance for purposes of calculating the final Factor 2 for FY 2021 given the unprecedent impact of the COVID-19 PHE and more recent available data regarding levels of uninsurance. CMS refers readers to the addendum to the OACT memo for further details on the methodology and updated assumptions used in the calculation of the projection of the uninsurance rate. This estimate considers more recent historical data on the rate of unemployment, as published by the Bureau of Labor Statistics (BLS), as well as economic projections using the BLS data from the monthly Blue-Chip Economic Indicators report. Based on these data, CMS updates its rate of uninsurance to 10.3 percent for CY 2020 and 10.2 percent for CY 2021 (up from 9.5 percent used in the proposed rule for both years). This results in an uncompensated care amount for FY 2021 that is closer to FY 2020 levels than the proposed rule estimate.

4. Factor 3 for FY 2021

a. Background & Methodology Used to Calculate Factor 3 in Prior Fiscal Years

Factor 3 equals the proportion of hospitals' aggregate uncompensated care attributable to each IPPS hospital (including Puerto Rico hospitals). The product of Factors 1 and 2 determine 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 will receive.

For Factor 3, the statute requires the Secretary to: (1) define uncompensated care; (2) determine 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 IPPS hospitals for treating the uninsured.

From FY 2014 through FY 2017, CMS used Medicaid inpatient days where the patient is not eligible for Medicare and Medicare inpatient days for SSI eligible patients (collectively known as low income patient days) as a proxy for hospital uncompensated care costs while it made improvements to Worksheet S-10 of the Medicare hospital cost report. Worksheet S-10 was specifically designed for reporting hospital uncompensated care costs.

For FY 2017, CMS moved from using 1 year of data to using 3 years of data to allocate UCP. This policy was intended to limit year-to-year fluctuations in Factor 3 and the resulting uncompensated care payments. It also allowed CMS to transition from using low-income patient days to Worksheet S-10 to distribute uncompensated care payments.

In 2016 and 2017, CMS issued two transmittals to improve instructions for reporting Worksheet S-10 data. In November 2016, CMS issued Transmittal 10 which made a number of changes to Worksheet S-10 including that hospitals may report discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period as charity care. This clarification was effective for cost reporting periods beginning prior to and on or after October 1, 2016. Effective for cost reporting periods beginning on or after October 1, 2016, Transmittal 10 provides that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

Transmittal 11 issued in September, 2017[30] clarified effective October 1, 2013:

- Full or partial discounts given to uninsured patients who meet the hospital's charity care policy *or financial assistance* policy/uninsured discount policy may be included on Line 20, Column 1 of Worksheet S-10; and
- The CCR would not be applied to deductible and coinsurance amounts and non-reimbursed Medicare bad debt.

Further, effective October 1, 2016, Transmittal 11 clarified that only discounted charity care or financial assistance policy charges rather than full charges should be reported on line Worksheet S-10 line 20. For cost reporting periods beginning on or after October 1, 2016, these instructions significantly improved clarity for hospitals about reporting charity care and financial assistance discounts, actual amounts received for charges written off to charity care and reporting of non-reimbursed bad debt.

[30] Transmittal 11 is available for download on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf.

In FY 2018, CMS began transitioning to use of Worksheet S-10 by using two years of low-income patient days[31] and one year of Worksheet S-10 data (FY 2014). In FY 2019, CMS continued that transition by using one year of low-income patient days[32] and two years of Worksheet S-10 data (FY 2014 and FY 2015).

In FY 2020, CMS used a single year of data—the FY 2015 Worksheet S-10 cost report data in the methodology to determine Factor 3. It concluded that the FY 2015 Worksheet S-10 data were the best available audited data and noted that it had begun auditing the FY 2017 data in July 2019 with the goal of having that data available for future rulemaking.

b. Proposal to Use Audited FY 2017 Data to Calculate Factor 3 for FY 2021

CMS finalizes its proposal to use a single year of Worksheet S-10 data from FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals except for Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. For these hospitals CMS will continue to use the low-income insured days proxy to calculate Factor 3 for one more year as discussed below. CMS continues to believe that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less accurate result. In addition, FY 2017 cost reports reflect the revisions to the S-10 Worksheet instructions that were effective on October 1, 2017.

CMS notes that uncompensated care payments to hospitals whose FY 2017 Worksheet S-10 data have been audited represent about 65 percent of the total uncompensated care payments for FY 2021. CMS used data from the HCRIS extract updated through February 19, 2020 for the proposed rule. For the final rule, CMS finalizes the use of the June 30 HCRIS extract to calculate Factor 3.

*Comment/Responses:* The comments and responses fall into several categories:

Date of HCRIS Data Extract Used for Proposed and Final Rule

Several commenters urged CMS to use the latest HCRIS extract available for the calculation of Factor 3 for use in redistribution of uncompensated care payments to hospitals. Most of the commenters preferred the use of a June 30 HCRIS extract, pointing out that CMS has used a June quarterly extract in both the FY 2018 and FY 2019 IPPS/LTCH final rules. Another commenter urged CMS to use the February or March HCRIS data extract for future proposed rules and the June HCRIS extract for FY 2021 and future final rules. CMS agrees with commenters that recommended using the June 2020 HCRIS data for calculating Factor 3 for FY 2021, due to the PHE, which, for some hospitals, delayed the filing of amended cost reports information and other corrections in time for the March HCRIS extract. With respect to using the February or March HCRIS for all future proposed rules, CMS states that it intends to use the most recent data available for the applicable rulemaking, which generally means the December HCRIS extract. It also states that it intends to use the respective March HCRIS for future final rules.

[31] Medicaid inpatient days were from the two fiscal years beginning prior to the Medicaid expansion (FY 2012 and FY 2013) while SSI days were from FY 2014 and FY 2015).
[32] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

Use of a Single Year of FY 2017 Worksheet S-10 Data for Calculation of Factor 3

Commenters were split on the use of a single year of FY 2017 Worksheet S-10 data for the calculation of Factor 3 for FY 2021. Those in support note that the FY 2017 cost reports are the most recent reports that have been subject to audit and that these audits continue to improve the accuracy and reliability of Worksheet S-10 data over time. In addition, commenters believed that it would be inappropriate to blend audited data with unaudited data, which could lead to inaccurate uncompensated care payments for some hospitals. Several also pointed out that FY 2017 cost reports reflect the first year of reported data under the revised Worksheet S-10 instructions. Those in opposition expressed concern that using a single year of data would lead to significant variation in year-to-year payments, especially given potential outside factors that may affect a hospital's finances. Using multiple years of data mitigates these year-to-year fluctuations, though commenters varied in which historical years would be the best to use.

CMS strongly believes that using one year of audited FY 2017 Worksheet S-10 data is the best choice for calculation of Factor 3. It states that using unaudited FY 2016 and/or (audited/unaudited) FY 2015 data would dilute the effect of its considerable auditing efforts and introduce unnecessary variability into the calculation if it used multiple years of data. It also agreed with commenters that the quality of FY 2017 Worksheet S-10 data should be improved given that it is the first year of data reported using the revised Worksheet S-10 instructions based on Transmittal 11.

Auditing Process

Several commenters agreed that the data from audited FY 2017 Worksheet S-10s have improved in accuracy when compared to previous years. Still others expressed concerns and suggested improvements for future audits such as:

- Implement a comprehensive audit process, like the audit process used for the wage index, noting that Worksheet S-10 audits should receive the same level of scrutiny.
- Improve transparency in the audit process by making the audit material and protocols publicly available.
- Allow providers additional time to respond to adverse adjustments, resolve differences, and submit supporting documentation.
- Work with MACs in developing the Worksheet S-10 audit process to promote clarity and consistency among audits done by MACs.
- Audit all hospitals and utilize a single auditor, or at least establish and enforce a formal and uniform audit process.

CMS acknowledges the commenters concerns about the audit process. It notes that its audit protocols are provided to the MACs in advance of the audit to assure consistency and timeliness in the audit process. It notes that it does not have sufficient audit resources to implement an audit and appeals process for the Worksheet S-10 that would be similar to the process used for the wage index audits. It also notes that the wage index impacts a far greater proportion of national hospital payments than the proportion impacted by the Medicare uncompensated care payments. CMS is also reluctant to establish a fixed start date for audits across MACs because it would like to retain

the flexibility to use its limited audit resources to address and prioritize audit needs across CMS programs each year. It also stresses that it will not make the audit and review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only.

c. Proposal to Use Most Recent Available Single Year of Audited Worksheet S-10 Data to Calculate Factor 3 for All Subsequent Fiscal Years

CMS finalizes its proposal that for FY 2022 and all subsequent years, it would use the most recent single year of cost report data that have been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to calculate Factor 3 for all eligible hospitals, with the exception of IHS and Tribal hospitals. It believes that such a policy would help providers have greater predictability for planning purposes. CMS also indicates in response to comments that if a hospital has relatively different data between cost report years, it potentially would be diluting the effect of its considerable auditing efforts and introducing unnecessary variability into the calculation if it were to use multiple years of data to calculate Factor 3. It also notes that it is not feasible for it to audit all hospitals, but it expects the number of audits of Worksheet S-10 will continue to increase from previous years.

Given the unique nature of IHS and Tribal hospitals and of the patient populations served, CMS discussed potential restructuring of the Medicare DSH and uncompensated care payments to these hospitals beginning in FY 2022 in the proposed rule. Using it exceptions and adjustments authority under section 1886(d)(5)(I)(i), CMS believes that it would be appropriate to adjust payments to IHS and Tribal hospitals through the creation of a new IHS and Tribal hospital Medicare DSH payment. It states that the methodology determining the DSH payments would mirror the calculation of the Medicare DSH payment under 1886(d)(5)(F) except that the payment would be determined at 100 percent of the calculated amount rather than the 25 percent of the calculated amount as required under section 3133 of the ACA. CMS sought comment on this potential restructuring of the Medicare DSH and uncompensated care payments to IHS and Tribal hospitals beginning in FY 2022. It also stated that will consider input received on this issue through consultation with IHS and Tribal hospitals.

Commenters expressed support for the use of low-income days proxy in the calculation of Factor 3 for FY 2021. They also noted the difficulty IHS and Tribal hospitals would face if Worksheet S-10 data were used to determine uncompensated care payments for these hospitals—one commenter estimated that only two IHS and Tribal hospitals would receive an increase in their uncompensated care payments, while the remaining IHS and Tribal hospitals would see decreases in their uncompensated care payments. Another commenter noted that IHS and Tribal hospitals face a unique legal standing such that they do not fit well into the current framework for determining uncompensated care payments. CMS finalizes the use of low-income insured days proxy to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2021. It is not finalizing a methodology for future years for these hospitals and believes further consideration of these hospitals' Worksheet S-10 data and other factors is necessary.

d. Definition of "Uncompensated Care"

With respect to the definition of "uncompensated care," CMS, as in prior years, finalizes its proposal that "uncompensated care" would be defined as the amount on line 30 of Worksheet S-10, which is the cost of charity care (line 23) and the cost of non-Medicare bad debt and nonreimbursable Medicare bad debt (line 29). CMS notes that a common theme of almost all the definitions that it explored is that they include both "charity care" and "bad debt."

As in the past, some commenters suggested that uncompensated care should include shortfalls from Medicaid, CHIP, and State and local indigent care programs. However, CMS restates its reasons for excluding Medicaid shortfalls from the definition of uncompensated care and further adds that even if it were to adjust the definition of uncompensated care to include Medicaid shortfalls, it would be operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid "shortfalls." Further, in some states, providers return a portion of their Medicaid revenues to the State via provider taxes, making the computation of "shortfalls" even more complex.

A few commenters requested additional information from CMS on how payments furnished by Congress, as well as payments made by the Health Resources and Services Administration (HRSA) for uninsured COVID-19 patients will be treated, pointing out that such payments may not necessarily offset uncompensated care. CMS recognizes the concerns and will consider these concerns in developing future program guidance. It notes that a term and condition of the HRSA Uninsured Program is the following "The recipient will not include costs for which payment was received in cost reports or otherwise seek uncompensated care reimbursement through federal or state programs for items or services for which payment was received." Note, however, that CMS recently updated a Frequently Asked Questions document[33] on the CMS website that says:

> Question: Should PRF payments offset expenses on the Medicare cost report?
>
> Answer: No, providers should not adjust the expenses on the Medicare cost report based on PRF payments received.

e. Methodological Considerations for Calculating Factor 3

*Merger Multiplier for Acquired Hospital Data*

CMS modifies the annualization policy that was finalized in the FY 2019 IPPS/LTCH final rule with respect to merged hospitals that annualized the uncompensated care data if a hospital's cost report does not equal 12 months of data.[34] CMS notes that in situations when the merger effective date does not coincide with the start date of the surviving hospital's cost reporting period, the policy of annualizing the acquired hospital's data before combining data across hospital cost reports could substantially overestimate the acquired hospital's UCC. Annualizing acquired hospital's data may double-count UCC for the portion of the year that overlaps with the remainder of the surviving hospital's cost reporting period.

[33] https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

[34] CMS defines a merger as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider.

To address this issue, CMS finalizes its proposal not to annualize the acquired hospital's data when the merger effective date occurs partway through the surviving hospital's cost reporting period. It would use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. CMS will calculate a multiplier to be applied to an acquired hospital's UCC. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. CMS would then apply this multiplier to the acquired hospital's unannualized UCC data to determine the final portion of the acquired hospital's UCC that should be added to that of the surviving hospital for purposes of determining Factor 3. CMS provides some illustrative examples in the rule of how these calculations could work.

*Newly Merged Hospitals*

CMS continues its policy to treat hospitals that merge after the development of the final rule like new hospitals. Consistent with its policy adopted in the FY 2015 IPPS/LTCH PPS final rule, CMS finalizes its proposal that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. If the hospital's cost reporting period is less than 12 months, CMS will annualize its data for purposes of the Factor 3 calculation. In addition, CMS continues its policy that the interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available the time of the development of the final rule. For FY 2021, this data will be the FY 2017 cost report available for the surviving CCN at the time the final rule is developed. At cost report settlement, CMS will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2021 cost report.

*Annualization and Long Cost Reports*

CMS finalizes it proposal to continue its policy for providers with multiple cost reports by annualizing uncompensated care cost data reported on the Worksheet S-10 if a hospital's cost report did not equal 12 months, except in the case of mergers as described above. In addition, it will continue its policy to use data from a cost report that is equivalent to 12 months or if no such cost report exists, the cost report that was closest to 12 months annualized within the federal fiscal year. CMS modifies, however, its policy where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. CMS finalizes its proposal to use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data for the latter fiscal year is used in the Factor 3 methodology. The past policy included the criterion that the hospital has multiple cost reports beginning in the same fiscal year, which CMS no longer believes is a necessary condition.

*New Hospitals for Purposes of Factor 3*

CMS finalizes its proposal to continue its "new hospital" policy methodology where a new hospital with a CCN established after October 1, 2015 eligible for DSH based on its FY 2021 cost

report would receive uncompensated care payments based on its FY 2021 uncompensated care costs as a percent of FY 2017 national uncompensated care costs. The new hospital would not receive interim uncompensated care payments before cost report settlement because CMS would have no FY 2017 uncompensated care data on which to determine those interim payments.

*Indian Health Service and Tribal Hospitals and Subsection(d) Puerto Rico hospitals that have a FY 2013 cost report.*

For FY 2021, CMS finalizes its proposal to continue determining Factor 3 IHS, Tribal and Puerto Rico hospitals based on Medicaid days from FY 2013 and the most recent update of SSI days. CMS also will continue its policy to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the 2017 IPPS/LTCH PPS final rule.

*All-Inclusive Rate Providers*

For FY 2021, CMS continues to believe that all-inclusive rate providers (AIRPs) should be excluded from the CCR trim methodology. It further has concerns that there are rare situations where an AIRP has a ratio of total UCC to total operating costs of greater than 50 percent. Specifically, CMS finalizes its proposal that when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its FY 2017 cost report, it would use the CCR from Worksheet S-10, line 1 of their FY 2015 cost report to re-calculate their UCC. CMS states that it identified a few AIRPs that have UCC in excess of 50 percent of their total operating costs, and believes that its approach produces a more accurate estimate of the AIRPs UCC for purposes of determining Factor 3, while continuing to reflect the information on uncompensated care included in the AIRP's FY 2017 cost report.

*CCR Trim Methodology*
Similar to the FYs 2018, 2019, and 2020 process, CMS finalizes its proposal to continue using the following steps for trimming CCRs in FY 2021.

| Methodology for Trimming CCRs | |
|---|---|
| Step 1 | Remove Maryland hospitals and all-inclusive rate providers |
| Step 2 | For FY 2017 cost reports, CMS would calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year.<br><br>Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. |
| Step 3 | Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2017 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S-3, Part I, Line 14, Column 15. |
| Step 4 | Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling"). |

| | |
|---|---|
| | Under the final rule, the statewide average CCR would apply to 13 hospitals, of which 3 have FY 2017 Worksheet S-10 data. |
| Step 5 | For providers that did not report a CCR on Worksheet S-10, Line 1, CMS would assign them the statewide average CCR as determined in step 3. |

After completing the steps above, CMS will re-calculate the hospitals uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable).

*Uncompensated Care Data Trim Methodology*
CMS finalizes its proposal to continue the trim methodology for potentially aberrant UCC that it finalized in the FY 2019 and FY 2020 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2017 are an extremely high ratio (greater than 50 percent) of its total operating costs, data from the FY 2018 cost report would be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2017 would be trimmed by multiplying its FY 2017 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2018 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2017 for purposes of determining Factor 3 for FY 2021. For hospitals whose FY 2017 cost report has been audited, CMS will not apply the trim methodology.

CMS amends the regulation at §412.106 by adding a new paragraphs (g)(1)(iii)(C)(7) and (8) to reflect the methodology for computing Factor 3 for FY 2021 and subsequent years for all eligible hospitals, except IHS and Tribal hospitals.

f. Proposals Related to the Per Discharge Amount of Interim Uncompensated Care Payments

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, CMS calculates a per discharge amount of interim uncompensated care by dividing the hospital's total uncompensated care payment amount by the hospital's 3-year average of discharges. This per discharge payment amount is used to make interim uncompensated care payments to each projected DSH eligible hospital. These interim payments are reconciled following the end of the year.

To reduce the risk of overpayments of interim uncompensated care payments and the potential for unstable cash flows for hospitals and MA plans, CMS finalizes its proposed voluntary process through which a hospital may submit a request to its MAC for a lower discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. The hospital would have to provide documentation to support a likely significant recoupment – for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000. The only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC. It does not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Several commenters offered support for this proposal and noted that such a policy would mitigate discharge growth discrepancies that could lead to an overestimate of the per-discharge amount of interim uncompensated care payments, which could cause unstable cash flows for hospitals. Another commenter noted that it seemed unlikely hospitals would want to request lower or zero

per-claim uncompensated care payments because of inherent incentives to maximize cash flows. CMS states that it will continue to examine this issue but is finalizing its proposal without modification.

g. Process for Notifying CMS of Merger Updates and to Report Upload Issues

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS 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.

For FY 2021, CMS finalizes its proposal that after the publication of the FY 2021 IPPS/LTCH PPS final rule, hospitals will have 15 business days from the date of public display to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. CMS acknowledges that this is less time compared to previous years, but states that there is only a limited amount of time to review submitted information by hospitals and to implement the finalized policies before the beginning of the fiscal year. CMS believes that if there are any remaining merger updates and/or upload discrepancies after the final rule, 15 days from the date of public display should be sufficient time to make any corrections to Factor 3 calculations.

Several commenters expressed concern related to the proposed 15-business day deadline to submit comments on the accuracy of the supplemental data files after the FY 2021 IPPS/LTCH final rule is submitted. A few commenters requested at least 30 days to review the files to ensure the accuracy of the data. In response, CMS believes the 15-days is more than sufficient as hospitals do not enter into mergers without advance planning. It also notes that historical FY 2017 cost reports are publicly available on a quarterly basis on the CMS website for analysis and review of cost report data, which provides another opportunity for affected parties to review cost report data.

Impact Analysis

The regulatory impact analysis presented in Appendix A of the final rule includes the estimated effects of the changes to UCP for FY 2021 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,401 hospitals that are projected to be eligible for DSH in FY 2021. CMS estimates use FY 2017 Worksheet S-10 data to determine Factor 3.

The total amount of UCP is estimated at $8.290 billion, about a 0.73 percent decrease from FY 2020 UCP (about $61 million). Changes in FY 2021 UCP compared to FY 2020 are accounted for by a decrease in Factor 1 and an increase in Factor 2, as well as slightly fewer hospitals being eligible to receive DSH. Factor 1 is estimated to decrease from $12.438 billion to $11.378 billion while Factor 2 is estimated to increase from 67.14 percent to 72.86 percent. The payment decrease for any individual hospital will vary as payment impacts solely from Factor 3 are redistributive. A percent change in UCP payments lower than negative 0.73 percent indicates that hospitals within that category are projected to experience a larger decrease compared to the average for all hospitals, and a percent change greater than negative 0.73 percent indicates the

category of hospitals is receiving a smaller decrease in UCP than the average for all hospitals. The table below shows impacts for selected categories of hospitals.

| Hospital Type | Dollar Difference FY 2020-FY 2021 ($ in millions) | Percent Change |
|---|---|---|
| All Hospitals | -$61 | -0.73% |
| Urban | -31 | -0.39 |
| Large Urban | +31 | 0.65 |
| Other Urban | -62 | -2.04 |
| Rural | -30 | -5.70 |
| Beds: 0-99 (Urban) | +7 | 2.42 |
| Beds: 250+ (Urban) | -16 | -0.29 |
| New England (Urban) | -24 | -9.68 |
| Middle Atlantic (Urban) | -74 | -7.03 |
| South Atlantic (Urban) | +38 | 4.62 |
| East South Central (Urban) | +50 | 2.55 |
| West South Central (Urban) | -70 | -4.11 |
| Mountain (Urban) | -38 | -10.14 |
| Pacific (Urban) | +58 | 8.82 |
| Major Teaching | -18 | -0.59 |
| Non-Teaching | -21 | -0.84 |
| Voluntary | +3 | 0.06 |
| Proprietary | -32 | -2.55 |
| Government | -32 | -1.25 |

Under its proposal, rural hospitals are projected to receive a larger percentage decrease in UCP (5.70%) than urban hospitals (0.39%) in FY 2021 compared to FY 2020. Urban hospitals in the New England, the Middle Atlantic, West South Central, and Mountain regions are the most negatively affected. Rural hospitals in all regions are expected to receive larger than average decreases, except for rural hospitals in the East North Central, South Atlantic, and Pacific regions. The variation by teaching status is minimal and the percent change in payments is similar to the overall average payment decrease of 0.73 percent. Proprietary and government hospitals are projected to receive larger than average decreases of 2.55 and 1.25 percent respectively, whereas voluntary hospitals are projected to stay relatively the same as the prior year (0.06 percent increase).

### F. Allogeneic Hematopoietic Stem Cell Acquisition Costs

Allogeneic hematopoietic stem cell transplants involve collecting or acquiring stem cells from a healthy donor's bone marrow, peripheral blood, or cord blood for intravenous infusion to the recipient. Currently, Medicare pays for allogeneic hematopoietic stem cell acquisition costs as part of Medicare's IPPS payment. For cost reporting periods beginning on or after October 1, 2020, section 108 of the Further Consolidated Appropriations Act (FCAA) of 2020 requires allogeneic hematopoietic stem cell acquisition costs to be made on a reasonable cost basis instead of through the IPPS.

1. Reasonable Cost Payment.

CMS proposed to revise the regulations to:

- Require the hospital to formulate a standard acquisition charge for allogeneic hematopoietic stem cells based on costs expected to be reasonably and necessarily incurred in the acquisition of hematopoietic stem cells for all patients.
- Reduce the standard charge by the corresponding ancillary cost-to-charge ratios to determine the hospital's reasonable costs.
- Pay Medicare's share of the hospital's reasonable cost based on the ratio of Medicare to total patients receiving allogeneic hematopoietic stem cell transplants.
- Provide interim payments over the course of the year and reconcile the hospital's interim payments with its Medicare reasonable costs at the end of each cost reporting period.
- Require the hospital to maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells. The itemized statement would identify standard charges, the name of the donor and prospective recipient and the recipient's health insurance number.

*Comments/Responses*: Comments were received in the following categories:

Standard Acquisition Charges. Commenters strongly objected to requiring hospitals to formulate a standard acquisition charge for allogeneic hematopoietic stem cell acquisition costs for a variety of complex reasons. CMS agreed and will allow hospitals to continue their current charging practices for donor search and hematopoietic stem cell acquisition costs on the Medicare recipient's transplant claim under revenue code 0815. The use of revenue code 0815, "should include all services required to acquire stem cells from a donor, as previously defined, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes."

Interim Payments. Commenters indicated that CMS' methodology for determining interim payments using the Medicare cost report is problematic because cost report data is not yet available for allogeneic hematopoietic stem cell transplants. CMS agreed and will use the Provider Statistical and Reimbursement Report (PS&R) method to determine interim payments for the hospital's first cost reporting period beginning on or after October 1, 2020. Under the PS&R method, interim payments will equal total Medicare charges billed under revenue code 0815 multiplied by the individual hospital's overall CCR to determine total estimated cost, divided by 26 to determine the subsequent biweekly interim payment amounts.

For the cost reporting periods after the initial period, interim payments will be determined using the cost report filed for the initial period and each subsequent period. The cost report will contain the actual charges by ancillary cost center billed in aggregate under revenue code 0815 and converted to reasonable cost using the corresponding ancillary cost-to-charge ratios. The total of these ancillary costs would then be divided by 26.

After the interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the

contractor that costs have increased. The contractor may also lower the interim rate if it has evidence that actual costs may fall significantly below the computed rate.

Payment Based on Cost Reporting Periods. Some commenters expressed concern that reasonable cost payment is effective on the basis of cost reporting periods meaning some hospitals will receive reasonable cost payment earlier than others depending on the start date of the hospital's cost reporting period. While CMS acknowledged the validity of the comment, the statutory provision is effective on the basis of cost reporting meaning CMS does not have authority to address this issue.

Itemized Statement. A few commenters noted that many itemized statements may be maintained for a single recipient, as there may be several evaluations and work-ups of potential donors before a match is identified. CMS agreed and is modifying the proposed regulation text to reflect that there may be multiple invoices or billing statements for acquisition costs included in the itemized statement in the record for a single recipient. Records must be for the person receiving the services (donor or recipient; for all donor sources, the hospital must identify the prospective recipient), and include the recipient's Medicare beneficiary identification number.

Medicare Cost Share. Commenters either supported or suggested alternatives for how to identify Medicare share of the hospital's reasonable costs. As CMS is not adopting the proposal for a standard acquisition charge but is instead requiring hospitals bill their actual charges for Medicare allogeneic hematopoietic stem cell acquisition costs, there is no need to calculate a Medicare share of the costs. CMS will be able to directly calculate the actual Medicare costs.

2. Definition of Hematopoietic Stem Cell Acquisition Costs.

CMS proposed that hematopoietic stem cell acquisition costs would only include costs for which stem cells are obtained from a donor (other than the recipient himself or herself). Costs would include:

- Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor; tissue typing of donor and recipient; donor evaluation;
- Physician preadmission/pre-procedure donor evaluation services;
- Costs associated with the collection procedure such as, general routine and special care services, procedure/operating room and other ancillary services, and apheresis services;
- Post-operative/post-procedure evaluation of donor; and
- The preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

*Comments/Responses*: Commenters agreed with the costs that CMS proposed to include in hematopoietic stem cell acquisition costs. One commenter asked whether costs associated with transporting hematopoietic stem cells are included in acquisition costs. CMS is finalizing its proposed definition of hematopoietic stem cell acquisition costs modified to include transportation costs consistent with this comment.

3. Cost Reporting.

There is currently a standard cost center on the Medicare hospital cost report for allogeneic stem cell acquisition costs. However, this cost center is only used for reporting direct expenses, and does not provide a method for determining other routine and ancillary costs that are part of the allogeneic stem cell acquisition costs. CMS is currently developing a worksheet similar to the Worksheet D-4 for solid organs that will allow providers to report direct expenses, routine and ancillary costs for allogeneic hematopoietic stem cell acquisition costs. Changes to the forms and instructions will be described in more detail in a forthcoming Paperwork Reduction Act (PRA) package, with comment period. The PRA package will address providers' requests for a standardized format for data collection.

*Comments/Responses*: Commenters generally agreed with CMS' assessment of the current cost reporting form and instructions and the need for the changes CMS described in the proposed rule. Some commenters suggested specific cost report changes that CMS will consider as it develops new cost reporting forms and instructions specifically for hematopoietic stem cell acquisition costs.

CMS also noted that, unlike hospitals that do solid organ transplants, there is no requirement that hospitals be certified to do hematopoietic stem cell transplants.

One commenter asked about how Medicare Advantage (MA) organizations will pay hospitals for hematopoietic stem cell acquisition costs. CMS responded that MA plans are required to pay non-contracted hospitals the same amount as if the patient were in Medicare fee-for-service. For contracted hospitals, the amount paid is negotiated between the MA plan and the hospital.

4. Budget Neutrality.

The statute requires the new reasonable cost payment for allogeneic hematopoietic stem cell acquisition costs to be adopted without increasing or decreasing Medicare spending. CMS proposed to make a -0.01 percent adjustment ($15.9 million) to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral. This estimate reflected charges reported on the hospital's inpatient claim in revenue center code 0815 (which is reflected in the MedPAR field for the Revenue Center Allogeneic Stem Cell Acquisition/Donor Services) reduced to costs using the hospital's overall operating CCR that is used for outlier payments. Commenters supported CMS' methodology for how to determine a budget neutrality adjustment.

Using later information, CMS estimates costs for acquisition of allogeneic hematopoietic stem cells at $16.2 million and CMS will apply a budget neutrality factor of -0.02 percent.

**G. CAR-T Clinical Trial Cases**

CMS proposed to create new MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Immunotherapy for CAR-T cell therapy cases. To calculate the relative weight, CMS proposed not using clinical trial cases where the hospital does not have a cost for the CAR-T cell therapy

product. Similarly, CMS proposed to adjust payment for clinical trial cases to not pay for the cost of the CAR-T cell therapy product that the hospital did not incur.

The proposed adjustment was 0.15 which was determined based on ratio of the costs of clinical trial cases to non-clinical trial cases using the December update of the FY 2019 MedPAR. Clinical trial cases were identified as those cases with diagnosis code Z00.6 or having standardized drug charges of less than $373,000 which is the average charge for the two CAR-T cell therapy products currently on the market.

Hospitals are required to bill clinical trial cases with diagnosis code Z00.6. When diagnosis code Z00.6 is on the claim, CMS will determine payment by multiplying the full relative weight for MS-DRG 018 by 0.15. CMS will update the adjustor based on more recent data for the final rule.

*Comments/Responses:* Public comments did not disagree with adjusting the IPPS payment where the hospital does not have a cost for the CAR-T product but did disagree with how to identify particular cases that would be subject to this adjustment. Some commenters noted that hospitals will not have a CAR-T cost but will use the CAR-T product for "expanded use access" or "out of specification." Other comments noted that there are clinical trial cases where the hospital incurs the full cost of the CAR-T product and the clinical trial is for a different product. CMS is modifying its policy in the final rule to also not apply the payment adjustment when the case is in a clinical trial to evaluate a different product than CAR-T. Also, using final rule data, CMS is changing the adjustment from 0.15 to 0.17. The adjustment will apply to expanded use access cases where the hospital incurs no drug cost.

**H. Hospitals with a High Percentage of End Stage Renal Disease (ESRD) Discharges**

Medicare provides an additional payment to hospitals if it provides dialysis treatment during an inpatient stay to 10 percent or more of its discharges. Discharges to MS-DRG 652 (Kidney Transplant), MS-DRG 682 (Renal Failure with MCC), MS-DRG 683 (Renal Failure with CC), MS-DRG 684 (Renal Failure without CC/MCC) and MS-DRG 685 (Admit for Renal Dialysis) are excluded from determining the 10 percent. CMS proposed to create the following MS-DRGs that it also proposed to exclude from the 10 percent determination:

- MS-DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis),
- MS-DRG 650 (Kidney Transplant with Hemodialysis with MCC),
- MS-DRG 651 (Kidney Transplant with Hemodialysis without MCC).

CMS also proposed to remove MS-DRG 652 (because this MS-DRG no longer includes cases receiving hemodialysis) and MS-DRG 685 (because it is deleted) from the list of excluded MS-DRGs that count towards the 10 percent threshold. CMS is finalizing this proposal without modification.

## I. Hospital Readmissions Reduction Program (HRRP)

CMS finalizes automatic adoption of applicable periods beginning with FY 2023, as discussed further below. No changes are made to the Hospital Readmissions Reduction Program (HRRP) measures, the methodology for calculating the payment adjustment, or other program features.

1. Background

The HRRP reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level. The list of conditions to which the HRRP applies in FY 2020 is: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective total hip arthroplasty (THA)/total knee arthroplasty (TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft surgery (CABG).

A hospital subject to the HRRP receives an adjustment factor that is between 1.0 (no reduction) and 0.9700 (the greatest possible reduction of 3 percent) of base operating DRG payments. Beginning with FY 2019, hospitals are assigned to one of five peer groups based on the proportion of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligibles[35] and the HRRP formula compares a hospital's performance to the median for its peer group.

Using the March update to the MedPAR file for a 3-year "applicable period," hospitals are grouped by quintiles (five peer groups) based on the proportion of dual-eligible patients. The payment adjustment for a hospital is calculated using the following formula comparing a hospital's excess readmissions ratio to the median excess readmission ratio (ERR)[36] for the hospital's peer group, where "payment" refers to base operating DRG payments, dx refers to an HRRP condition (i.e., AMI, HF, pneumonia, COPD, THA/TKA, or CABG), and $NM_M$ is a budget neutrality factor (neutrality modifier)[37] that is the same across all hospitals and all conditions.

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM_M * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

Once hospitals have had a chance to review and correct their HRRP calculations for a fiscal year, CMS displays the readmissions payment adjustment factors in Table 15 on the associated IPPS/LTCH final rule web page on its website.

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[35] Dual eligible is defined as a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except that (beginning with FY 2021 payment), patient beneficiaries who die in the month of discharge will be identified using the previous month's data as sourced from the State MMA files.

[36] An Excess Readmissions Ratio (ERR) is calculated for each HRRP condition as the ratio of predicted-to-expected readmissions. Predicted readmissions are the number of unplanned readmissions predicted for a hospital based on the hospital's performance with its case mix and its estimated effect on readmissions. Expected readmissions are the number of unplanned readmissions expected for an average hospital with similar case mix.

[37] Using the most recently available full year of MedPAR data, CMS compares total Medicare savings across all hospitals and calculates a multiplicative factor to produce the same savings as the previous method when applied to each hospital's payment adjustment.

CMS reminds readers of a previously adopted change that begins to take effect in FY 2021. In the FY 2020 IPPS/LTCH final rule, the definition of dual eligibles was modified, effective with FY 2021, in order to avoid undercounting the dual eligible status of beneficiaries who die in the month of a hospital discharge.[1]

Additional resources on HRRP are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program. Certain requirements of the HRRP area codified at §§412.152 through 412.154.

2. Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

The applicable three-year period for which data are collected for calculating the readmission payment adjustment factor has been adopted through rulemaking each year. In the FY 2020 IPPS/LTCH final rule and following past patterns, CMS adopted the applicable period for FY 2022 as the three-year period from July 1, 2017 through June 30, 2020. The proportion of dual eligibles, excess readmissions ratios and the payment adjustment factors (including aggregate payments for excess readmissions and aggregate payments for all discharges) are based on claims data from the applicable period.

In this rule, CMS finalizes automatic adoption of the applicable period beginning with FY 2023. Consistent with previously adopted periods, beginning in FY 2023, the applicable period for the HRRP will be the 3-year period beginning one year advanced from the start of the applicable period for the previous program fiscal year. That is, for FY 2023, the applicable period for HRRP measures and for determining dual eligibility is the 3-year period from July 1, 2018 through June 30, 2021. The same rule will apply for all subsequent years unless otherwise specified by the Secretary, which CMS says would occur through notice and comment rulemaking. CMS believes that this change streamlines the process and provides additional clarity and consistency to the HRRP. The change is codified in regulatory text at §412.152 by revising the definitions of "applicable period" and "applicable period for dual-eligibility."

Applicable periods for FYs 2020 through 2023 are shown in the table below.

| HRRP "Applicable Periods" | |
|---|---|
| **Payment Year** | **Discharge Dates** |
| FY 2020 | July 1, 2015 – June 30, 2018 |
| FY 2021 | July 1, 2016 – June 30, 2019 |
| FY 2022 | July 1, 2017 – June 30, 2020 |
| FY 2023 | July 1, 2018 – June 30, 2021 |

3. Identification of Aggregate Payments for FY 2021

CMS finalizes that for FY 2021, it will continue to use the same methodology for calculating aggregate payments for the excess readmissions portion of the HRRP formula, which includes using the March update of the fiscal year MedPAR data corresponding to the applicable period. The same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. This methodology includes the

discharge diagnoses for each applicable condition/procedure based on a list of specific ICD-10-CM and ICD–10–PCS code sets, and exclusion of admissions for patients enrolled in Medicare Advantage (MA) as identified in the Medicare Enrollment Database. The neutrality modifier will continue to be calculated using the most recently available full year of MedPAR data.

4. Confidential Reporting of Stratified Readmissions Data

As promised in the FY 2020 IPPS/LTCH final rule, CMS indicates that it included data on the six readmissions measures stratified by patient dual eligible status in the confidential hospital-specific reports provided to hospitals in the spring of 2020. Results were provided using two disparity methodologies: the within-hospital disparity method compares readmissions rates for dual eligibles and other beneficiaries, and the dual eligible outcome measure compares performance in care for dual eligibles across hospitals. These methods differ from the HRRP stratification and will not be used for any payment calculations or publicly reported.

5. Impact Analysis

In the regulatory impact analysis section of the final rule CMS estimates that 2,583 hospitals, or 85 percent of those eligible, will be penalized under the HRRP in FY 2021, with aggregate penalties representing 0.68 percent of payments to hospitals. (An estimated dollar total of penalties is not provided.) A table shows the variation in these impacts by hospital characteristics. In general, larger hospitals and teaching hospitals are more likely than average to be penalized under the HRRP but the penalties for these groups represent a smaller than average share of payments.

**J. Hospital Value-Based Purchasing (VBP) Program**

No changes are made to the Hospital Value-Based Purchasing (VBP) Program for FY 2021. The previously adopted measures; domain weights (25 percent each across the four domains); case minimums; and payment adjustment methodologies are continued. Readers are referred to the discussion below of data validation for Hospital VBP Program patient safety measures that overlap with the Hospital-Acquired Condition (HAC) Reduction Program (section IV.M.3).The final rule includes tables displaying previously adopted baseline and performance periods, and previously adopted and newly estimated performance standards for FYs 2023 through 2026. A summary table with the previously adopted measures is shown at the end of this summary section.

1. Background

Under the Hospital VBP 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 2 percent contribution to the VBP incentive payment funding pool (a reduction to each hospital's base operating DRG payments) 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 program.

For each payment year, CMS specifies through rulemaking a VBP Program 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 Hospital VBP Program are Inpatient Quality Reporting (IQR) Program measures that have been included on the *Hospital Compare* website for at least one year prior to the start of the relevant 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.

Further information on the program is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing. Certain requirements for the Hospital VBP Program are codified at §§412.160 through 412.167.

2. Baseline and Performance Periods; Performance Standards

The final rule includes tables with the previously adopted baseline and performance periods for FYs 2023 through 2026. Additional tables show previously adopted and newly estimated performance standards for those fiscal years, with updates from the proposed rule.

CMS notes that in response to the COVID-19 public health emergency, it announced an Extraordinary Circumstances Exception (ECE) in March 2020 that affected data used for scoring the Hospital VBP Program. Under that policy, CMS provided a national exception for reporting of data for the fourth quarter of 2019, October 1, 2019 – December 31, 2019 (Q4 2019) and the first two quarters of 2020, January 1, 2020 – March 31, 2020 and April 1, 2020 – June 30, 2020 respectively (Q1 2020 and Q2 2020), but stated that data for these quarters that was voluntarily submitted would be used for scoring in these programs.

Modifying that policy, the interim final rule with comment (IFC) issued by CMS in late August 2020 (85 FR 54820) finalized that no claims data or chart-abstracted data reflecting services provided from January 1, 2020 through June 30, 2020 will be used in calculations for the Hospital VBP Program. Readers are referred to the IFC for more details. (HPA has made a summary of the IFC available to clients.) The final rule tables identify which baseline and performance periods are affected by this policy.

3. Impact Analysis

CMS estimates that the total amount available for VBP Program payments for FY 2021 is approximately $1.9 billion (i.e., 2.0 percent of base operating DRG payments). A table in the regulatory impact analysis section of the final rule shows the estimated effects of VBP payments for FY 2021 by type of hospital based on TPS data for FY 2020. Across all hospitals the net estimated VBP adjustment averages 0.165 percent; averages by type of hospital are shown.

CMS has posted on the FY 2021 IPPS final rule web page a Table 16A which includes proxy hospital-specific value-based incentive payment adjustment factors for FY 2021 based on 2020 TPSs. Final FY 2021 adjustment factors will be posted as Table 16B after hospitals have been able to review and correct their actual TPSs for FY 2021. At that time the final exchange function slope, and estimated amount available for the FY 2021 program year will also be provided.

**Summary Table: Hospital VBP Program Measures and Domains by Payment Year**

| Measure | NQF # | 2020 | 2021 | 2022 | 2023/ 2024 |
|---|---|---|---|---|---|
| **Clinical Outcomes Domain** | | | | | |
| Acute Myocardial Infarction (AMI) 30-day mortality rate | 0230 | X | X | X | X |
| Heart Failure (HF) 30-day mortality rate | 0229 | X | X | X | X |
| Pneumonia (PN) 30-day mortality rate | 0468 | X | X | X | X |
| Complication rate for elective primary total hip arthroplasty/total knee arthroplasty | 1550 | X | X | X | X |
| Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate | 1893 | | X | X | X |
| CABG 30-day mortality rate | 2558 | | | X | X |
| **Safety Domain** | | | | | |
| CMS Patient Safety and Adverse Events Composite* | 0531 | | | | X |
| Central Line Associated Blood Stream Infection (CLABSI) | 0139 | X | X | X | X |
| Catheter Associated Urinary Tract Infection (CAUTI) | 0138 | X | X | X | X |
| Colon and Abdominal Hysterectomy Surgical Site Infections | 0753 | X | X | X | X |
| Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia | 1716 | X | X | X | X |
| Clostridium Difficile Infection (CDI) | 1717 | X | X | X | X |
| Perinatal Care: elective delivery < 39 weeks gestation | 0469 | X | Removed | | |
| **Person and Community Engagement Domain** | | | | | |

| Summary Table: Hospital VBP Program Measures and Domains by Payment Year | | | | | |
|---|---|---|---|---|---|
| **Measure** | **NQF #** | **2020** | **2021** | **2022** | **2023/ 2024** |
| **Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)**<br>Communication with Nurses<br>Communication with Doctors<br>Responsiveness of Hospital Staff<br>Communication About Medicines<br>Cleanliness and Quietness of Hospital Environment<br>Discharge Information<br>Overall Rating of Hospital<br>3-Item Care Transition measure | 0166<br><br><br><br><br><br><br><br>0228 | X | X | X | X |
| **Efficiency and Cost Reduction Domain** | | | | | |
| Medicare Spending per Beneficiary | 2158 | X | X | X | X |
| NQF = National Quality Forum<br>*The predecessor measure, the AHRQ PSI–90 patient safety composite was removed beginning with FY 2019. | | | | | |

## K. Hospital-Acquired Conditions (HAC) Reduction Program

CMS finalizes automatic adoption of applicable periods beginning with FY 2023, and changes to data validation procedures. No changes are made to program measures, data collection processes, scoring methodology, or other program policies.

### 1. Background

Under the Hospital Acquired Condition (HAC) Reduction Program, which was implemented beginning in FY 2015, a 1-percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile with respect to a set of HAC measures. Currently, performance is assessed on six measures: five healthcare-associated infection (HAI) measures from the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and the CMS PSI 90 patient safety measure.[38]
Beginning in FY 2017 CMS began to use the "Winsorized Z-Score Method" for determining a hospital's score for each program measure. The Total HAC Score for a hospital is calculated by giving each measure an equal weight and then summing its weighted measure Winsorized z-scores. These Total HAC Scores are then used to define the top quartile of hospitals (i.e., worst performers) subject to the penalty. An extraordinary circumstances exception policy was adopted for the HAC Reduction Program beginning in FY 2016.
More information on the program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program. Certain requirements of the HAC Reduction Program are codified at §§412.170 through 412.172.

[38] Prior to FY 2019, measures were separated into two separately weighted domains for purposes of calculating a hospital's Total HAC Score. For example, in FY 2018 Domain 1 (PSI-90) was weighted at 15% and Domain 2 (the NHSN measures) was weighted at 85%.

2. Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

CMS has previously finalized a 24-month "applicable period", or performance period, for the HAC Reduction Program. The applicable period has been adopted annually in the IPPS/LTCH final rule. For example, the applicable period previously adopted for FY 2022 is the 24-month period from July 1, 2018 through June 30, 2020 for the PSI-90 measure, and January 1, 2019 through December 31, 2020 for the NHSN measures.
In this rule, CMS finalizes the automatic adoption of applicable periods for FY 2023 and all subsequent program years. Specifically, beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures will be the 24-month period beginning 1 year after the start of the applicable period for the previous program year. For example, for FY 2023, the applicable period for the CMS PSI 90 measure is the 24-month period from July 1, 2019 through June 30, 2021, and the applicable period for CDC NHSN HAI measures is the 24-month period from January 1, 2020 through December 31, 2021. For all subsequent years, the 24-month periods will be advanced by 1 year unless the Secretary specifies otherwise through notice and comment rulemaking. CMS believes that this change streamlines the process and provides additional clarity and consistency to the program. The change is codified in regulatory text at §412.170 by modifying the definition of "applicable period."

3. HAC Reduction Program Data Validation

In the FY 2019 IPPS/LTCH final rule, CMS adopted a HAC Reduction Program data validation process to replace the one used for the IQR Program. (This was necessitated by removal of HAC Reduction Program measures from the IQR Program.) Under the policy, the five chart-abstracted NHSN measures will be subject to validation under the HAC Reduction Program beginning with Q3 2020 discharges for FY 2023 payment. This reflects the timing of adoption of the data collection requirements for the NHSN measures for the HAC Reduction Program. All subsection (d) hospitals are eligible for random selection for the data validation sample because they are all subject to the HAC Reduction Program. Sample sizes were continued from the IQR Program: 400 randomly selected hospitals and 200 hospitals selected using targeting criteria. Hospitals eligible for targeted selection are those that failed validation in the previous year; submit data to NHSN after the data submission deadline has passed; have not been randomly selected in the past 3 years; passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or failed to report to NHSN at least half of actual infection events detected as determined through the previous year's validation.

In the FY 2020 IPPS/LTCH final rule, CMS modified the number of hospitals targeted from exactly 200 hospitals to "up to 200 hospitals," and clarified that it will randomly select one pool of 400 subsection (d) hospitals for validation of chart-abstracted measures in both programs. All the hospitals will be included for the HAC Reduction Program, whereas for the IQR Program, CMS will remove any hospitals without an active notice of participation in that program. The process will begin with the third quarter (Q3) 2020 infectious events, which is the beginning of the HAC Reduction Program validation process. After the random selection of 400 hospitals, CMS will select the targeted sample of up to 200 hospitals for validation under both programs. CMS also adopted a "true event" filtering method to better target events that meet NHSN HAI criteria.

In this rule, CMS finalizes changes to the data validation process for the HAC Reduction Program to align with changes made to the Hospital Inpatient Quality Reporting Program measure validation process, as summarized in section VIII.A.3 below. Specifically, the hospital selection and submission quarters beginning with FY 2023 Hospital IQR and HAC Reduction Programs validation will be aligned so that only one pool of hospitals will be required to submit data for validation.

*Aligning data submission quarters*. To align data submission quarters across the two programs, CMS finalizes that for FY 2023 HAC Reduction Program data validation, it will use only data for the third and fourth quarters of 2020 for both the random and targeted validation pools. The schedule for data validation that is being replaced under the HAC Reduction Program for FY 2023 (detailed in a table in the final rule) would have included data for these two quarters and for the first two quarters of 2021. For FY 2024, CMS will use data from all of calendar year 2021 for both the HAC Reduction Program and the IQR Program. The data submission deadline for chart-abstracted measures will be the middle of the fifth month following the end of the reporting quarter.

*Aligning hospital selection*. Hospital selection for data validation is also aligned with the IQR Program. Beginning with data validation for FY 2024 payment, the total pool will be reduced from up to 600 (up to 400 randomly selected and up to 200 targeted hospitals) to up to 400 (up to 200 randomly selected and up to 200 targeted hospitals). These will be the same hospitals selected for data validation under the IQR Program to the extent that the IQR Program has measures for those hospitals. CMS believes that reducing the number of hospitals selected for data validation by about one-third will maintain a sufficient sample size for a statistically meaningful estimate of hospitals' reporting accuracy and streamline the validation process for both programs.

*Requiring digital files*. CMS finalizes that beginning with FY 2023 data validation, hospitals submitting medical records for validation of HAC Reduction Program measures must submit them as digital files. Specifically, hospitals must submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. Currently, hospitals have a choice of submitting paper copies of medical records or submitting through secure transmission of electronic versions of patient records. Submission via secure transmission can either entail downloading or copying the digital image of the patient chart onto CD, DVD, or flash drive, or submission of PDFs using a CMS-approved secured file transfer system. Under the new policy CMS will only accept PDF copies submitted through a CMS-approved secured file transfer system, and will no longer accept CD, DVD, or flash drives containing digital images of patient charts or paper charts, beginning with Q1 2021 data submissions for FY 2024 program year validation. CMS will continue to reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

In discussing the proposal to require digital files, CMS notes that almost two-thirds of medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, use the option to submit PDF copies of medical records as electronic files. CMS believes that electronic submission can be a more effective and efficient process for the hospitals selected for validation

and requiring electronic file submission reduces the burden of coordinating, copying, and shipping to the CDAC numerous paper-based pages of medical records.

In the Collection of Information Requirements section of the final rule, CMS estimates that the annual decrease in burden resulting from the changes to the HAC Reduction Program data validation process will total 14,400 hours. Using their estimated cost of $38.80 per hour, estimated savings from the burden reduction totals $558,720 across all hospitals each year.

4. Impact Analysis

The impact analysis section of the final rule includes a table (updated from the proposed rule) that shows the estimated FY 2021 distribution of hospitals in the worst performing quartile of Total HAC scores by hospital characteristic. The estimates are based on data for the FY 2021 performance period.

While by definition, 25 percent of hospitals overall will be in the worst quartile and subject to the penalty (estimated 777 hospitals total), the estimated proportion varies from about 18 percent for urban hospitals with fewer than 100 beds to 48 percent of teaching hospitals with 100 or more medical residents. High-DSH and safety net hospitals are also more likely than others to be in the worst performing quartile. No estimate of the dollar amount of HAC Reduction Program penalties is provided.

| **Summary Table: HAC Reduction Program Measures and Performance Periods for Payment Years 2019-2021** | | | | |
|---|---|---|---|---|
| | **NQF #** | **FY 2019** | **FY 2020** | **FY 2021** |
| CMS Patient Safety and Adverse Events Composite (CMS PSI 90) | 0531 | X | X | X |
| *Applicable Time Period (Performance Period)* | | *10/1/15-6/30/17* | *7/1/16-6/30/18* | *7/1/17-6/30/19* |
| NSHN Measures | | | | |
| Central Line-associated Blood Stream Infection (CLABSI) | 0139 | X | X | X |
| Catheter-associated Urinary Tract Infection (CAUTI) | 0138 | X | X | X |
| Colon and Abdominal Hysterectomy Surgical Site Infections | 0753 | X | X | X |
| Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia | 1716 | X | X | X |
| Clostridium Difficile Infection (CDI) | 1717 | X | X | X |
| *Applicable Time Period for NHSN measures (Performance Period)* | | *1/1/16-12/31/17* | *1/1/17-12/31/18* | *1/1/18-12/31/19* |

## L. Payments for Indirect and Direct Graduate Medical Education Costs

Teaching hospitals receive payments from Medicare to compensate them for their indirect medical education (IME) and direct graduate medical education (DGME) costs. These payments are based on the number of full-time equivalent (FTE) residents trained by the hospital subject to a cap based on the number of residents the hospital claimed for IME and DGME payment in 1996.

CMS includes provisions in the regulations that allow for temporary modification of a hospital's FTE cap when a residency program or a teaching hospital closes. For an individual resident to be considered displaced and a hospital eligible for a cap adjustment for continuing to train the resident, the resident must be physically present at the hospital training on the day prior to or the day of the hospital or program closure. This policy will not allow for a cap adjustment when a hospital is training a displaced resident who: 1) left the program after its closure was announced but before the hospital or the program closed; 2) is doing a planned rotation at another hospital on the day the hospital or program closed; or (3) matched into the GME program at the closing hospital or program but has not yet started training.

To address the first group of residents, CMS proposed to change the requirement from physically training in the in the hospital on the day the program closed to training in the hospital on the day the program or hospital closure is announced. To address the second and third group of residents, CMS proposed to allow funding to be transferred temporarily when the residents are not physically at the closing hospital/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital/closing program.

To apply for the temporary increase in the Medicare resident cap, the receiving hospital is required to submit a letter to its MAC within 60 days of beginning the training of the displaced residents. CMS is modifying the requirement for information included in this letter to no longer require the full social security number for each resident. Instead, only the last four digits of the resident social security number would be required.

CMS notes that if a hospital is training above its caps, only the number of cap slots may be temporarily transferred meaning there is no guarantee that a hospital's cap will be adjusted for training a displaced resident. If there are more displaced residents than available cap slots, the slots may be apportioned, according to the closing hospital/program's discretion.

*Comments/Responses:* Significant comments and responses were in the following areas:

Retroactivity: Commenters asked CMS to use its authority under section 1871 of the Act to make the new policy retroactive to include the summer 2019 closure of Hahnemann University Hospital. These commenters indicated that a retroactive effective date would be in the public interest as it would compensate hospitals that took action to provide training to displaced residents.

Retroactive rulemaking is only authorized when it is in the public interest or necessary to comply with statutory requirements. CMS indicated that retroactive rulemaking is not necessary to comply with statutory requirements or assist displaced Hahnemann residents with finding alternative positions.

Closing Hospital Authority: Some commenters wanted the FTE cap to travel with the resident and not be dependent on the closing hospital or program to agree to an FTE cap reduction to improve certainty for displaced residents that they will be able to find positions. CMS believes the decision about how to allocate FTE cap slots is best left under the authority of the closing hospital/program and its sponsor who are familiar with the details of the program.

Protecting Medical Residents: Some comments recommended specific protections that CMS should provide to displaced residents. CMS does not believe that this is its role and indicated that organizations overseeing the operation of residency programs are in a better position to protect residents' rights.

Resident Slots as a Commodity: Some public comments asked CMS to clarify that the sale of resident caps from a closing hospital is not permissible. CMS responded that there are statutory provisions which make clear how residents FTE caps from closing hospitals are distributed by the Secretary. FTE resident caps are not a commodity that a closing hospital can offer for sale.

CMS is finalizing the proposal with a modification to remove the word "match" from the definition of displaced resident to make clear that a displaced resident is any resident who is accepted into a GME program at a closing hospital or program but has not yet started training.

## M. Rural Community Hospital Demonstration Program

### 1. Background

The Rural Community Hospital Demonstration program allows up to 30 rural community hospitals to receive reasonable cost payment for covered inpatient hospital services furnished to Medicare beneficiaries. The program has been in place since January 1, 2005 with a statutory expiration date that has been extended twice. The latest extension opened the program to newly participating hospitals. Expiration of the program for individual hospitals will vary based on the hospital's cost reporting period and when it began participating in the program but will generally be 5 years from when the program was last extended or the hospital first began participating. By FY 2023, the program will have expired for all participants unless extended again by statute.

The statute requires CMS to make the demonstration program budget neutral by applying an adjustment to IPPS rates that affects all hospitals rather than only demonstration program participants. CMS describes the budget neutrality calculation in detail. In summary, CMS compares reasonable cost payments to what IPPS payments would have been in the absence of the demonstration. IPPS rates are adjusted for the difference. Interim reasonable cost payments from as submitted cost reports are initially used and then later reconciled as cost reports become final.

2. FY 2021 Budget Neutrality Adjustment

CMS identifies 22 hospitals that will participate in the program in FY 2021 (one withdrew since the publication of the proposed rule). Of the seven hospitals scheduled to end participation during FY 2021, four will end participation before September 30, 2021. CMS prorates the reasonable cost amounts for these hospitals for the portion of their cost reporting periods in the demonstration that are within FY 2021. Using updated data, CMS estimates that the demonstration program will cost $39,825,670 in FY 2021, and it applies a budget neutrality adjustment factor to the IPPS standardized amounts of 0.999626.

As of the date of publication of the final rule, CMS does not have completed cost reports for all hospitals participating in the demonstration program during FY 2016; thus, it does not include in the offset amount the difference between estimated and actual expenses of the demonstration program for FY 2016. It will include that difference in the budget neutrality offset amount for FY 2022.

## N. Market-Based MS-DRG Relative Weights

1. Overview

Executive Order (EO) 13813 *Promoting Healthcare Choice and Competition Across the United States* was issued on October 12, 2017. EO 13877 *Improving Price and Quality Transparency in American Healthcare to Put Patients First* was issued on June 24, 2019. The goal of the first EO is to increase consumer choice and promote "competition in healthcare markets by removing and revising government regulation." The goal of the second EO is to promote price transparency. CMS cites these orders as the reason why it promulgated the Hospital Price Transparency final rule (84 FR 65538). Under this rule, CMS is requiring hospitals to make the following publicly available beginning January 1, 2021:

1. gross charge;
2. payer-specific negotiated charge;
3. de-identified minimum negotiated charge;
4. de-identified maximum negotiated charge; and
5. discounted cash price.

The rule then reviews the history of cost-based payment for hospital services, the IPPS and the use of charges reduced to cost to set the relative weights and make outlier payments. This history raises concerns for CMS that "chargemaster (gross) rates rarely reflect the true market costs" and CMS sets a goal of Medicare reducing its reliance on the hospital chargemaster and adjusting Medicare payment rates so that they reflect the relative market value for inpatient items and services.

EO 13890 *Protecting and Improving Medicare for Our Nation's Seniors* was issued on October 3, 2019. This EO describes the "market benefits provided under the Medicare Advantage [MA] program as providing, 'efficient and value-based care through choice and private competition.'" In the proposed rule, CMS looked to MA and the commercial market for "approaches to modify

Medicare FFS payments to…encourage more robust price competition, and otherwise to inject market pricing into Medicare FFS reimbursement."

In order to reduce the Medicare program's reliance on the hospital chargemaster, CMS proposed that hospitals would be required to report:

1. the median payer-specific negotiated charge the hospital has negotiated with all of its MA plans, by MS-DRG; and
2. the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA plans, by MS-DRG.

Hospitals would be required to report this information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021, to be used in setting the IPPS MS-DRG relative weights beginning in FY 2024.

For third-party payers that do not negotiate rates by MS-DRG, the hospital would determine and report the median payer-specific negotiated charges by MS-DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS-DRG. CMS believes that use of these data in the MS-DRG relative weight setting methodology would represent a significant and important step in reducing the Medicare program's reliance on hospital chargemasters, and would better reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

2. Market-Based MS-DRG Relative Weight Estimation

a. Overview

Section 1886(d)(4)(A) of the Act requires the Secretary to establish a classification of inpatient hospital discharges by DRG. Section 1886(d)(4)(B) of the Act requires that the Secretary establish a weighting factor which reflects the relative hospital resources within a DRG relative to the average across all DRGs. Consistent with the desire to reduce the Medicare program's reliance on the hospital chargemaster, as well as to inject market pricing into Medicare FFS reimbursement, CMS indicated in the proposed rule that it is contemplating using market data from MA plans and 3rd party payers to set the relative weights consistent with this statutory mandate. This system would replace the relative weight methodology that uses charges on Medicare claims in combination with cost-to-charge ratios from Medicare cost reports.

b. Research Comparing Medicare, Medicare Advantage Organization, and Commercial Payment Rates

CMS' literature review indicates that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less.[39] Another study found that

[39] Berenson RA, Sunshine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. Health Aff (Millwood). 2015;34(8):1289-1295.

MA plans paid 5.6 percent less for hospital services compared to FFS Medicare.[40] A third study found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. Further, "there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS."[41]

Taken as a whole, CMS believes research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are generally not as well-correlated with Medicare IPPS payment rates. Considering the public availability of payer-specific negotiated charges starting in 2021 and its desire to reduce the Medicare program's reliance on the hospital chargemaster consistent with EOs 13813 and 13890, CMS believes it could adjust the methodology for calculating the MS-DRG relative weights to reflect a more market-based approach under sections 1886(d)(4)(A) and 1886(d)(4)(B) of the Act.

c. Proposed Market-Based Data Collection

While CMS does not explicitly state it proposed this new data collection under the authority of sections 1815(a) and 1833(e) of the Act, it does cite these authorities as providing for no Medicare payments unless a provider has furnished information requested by the Secretary to determine its Medicare payments. CMS proposed that the data collected be furnished through the Medicare hospital cost reports. All of the data would become publicly accessible on the Hospital Cost Report Information System (HCRIS) dataset in a de-identified manner and would be usable for analysis by third parties. The data would be de-identified since the hospital transparency rule directs the hospital to calculate and report a median rate and thus a specific rate negotiated between a hospital and a specific third-party would not be reported on its hospital cost report.

The hospital price transparency final rule requires that hospitals make standard charges for all items and services publicly available via a single machine-readable file and also make publicly available a consumer-friendly list of standard charges for at least 300 shoppable services. CMS proposed that hospitals would calculate the median payer-specific negotiated charge by MS-DRG using the payer-specific negotiated charge data by MS-DRG from the single machine-readable file for all items and services.

To determine the median payer-specific negotiated charge for MA organizations for a given MS-DRG, a hospital would list, by MS-DRG, each discharge in its cost reporting period that was paid for by an MA organization and the corresponding payer specific negotiated charge. Once each discharge and its corresponding MA negotiated rate is arrayed, the hospital would calculate

[40] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. Health Aff (Millwood). 2016;35(8):1444-1451.
[41] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? The Journal of Health Care Organization, Provision, and Financing. 2018;55(1-8)

and report the median MA negotiated rate on its cost report. CMS would separately require the same process to be followed for all for other (non-MA) 3rd party payer median negotiated charges.

CMS proposed to use the same definitions of "payer specific negotiated charge" and "items and services" that it used in the hospital price transparency rule. The rule explains that an MS-DRG is a type of service package consisting of items and services based on patient diagnosis and other characteristics. CMS proposed this definition of items and services because it captures the types of items and services, including service packages, that a hospital uses to calculate and report the median payer-specific negotiated charges.

An MA organization is a public or private entity organized and licensed by a state as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements. CMS proposed to use this established definition of an MA organization. CMS proposed to define "third-party payer" as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service.

CMS recognizes that hospitals may negotiate rates with third party payers as a percent discount off chargemaster rates, on a per diem basis, or by MS-DRG or other similar DRG system. There may be hospitals that do not negotiate charges for service packages by MS-DRG or for service packages that could be crosswalked to an MS-DRG. Given the variety of negotiated payment arrangements, CMS requested comments on whether and how to use data to determine the relative weights where data is not collected by MS-DRGs as well as alternative ways to capture market-based information for the potential use in Medicare FFS payments.

As an alternative, CMS considered requiring hospitals to submit a median of the actual payments received rather than just the median of the negotiated rates. CMS provides an example where the payer-specific negotiated charge is $30,000 with a 3rd party payer for major joint replacement paid under the All Patient Refined (APR)-DRG system (equivalent to MS-DRG 470). The hospital and payer have agreed to additional payment above a stop loss threshold ($150,000) based on 50 percent of charges as well as 60 percent of the cost of implanted hardware.

In this example, the hospital's payer-specific negotiated charge for a major joint replacement (MS-DRG 470 equivalent) is $30,000. However, the resulting payment per discharge will vary, depending on whether the patient's cost exceeded the stop loss threshold or the patient received implanted hardware. Under CMS' proposal, the hospital would only consider the $30,000 negotiated rate in determining the median. Under the alternative proposal, the hospital would consider the additional payments above the stop-loss threshold and for implantable equipment when considering the median payment to report. CMS requested comment on this alternative approach as well as the potential burden of calculating and submitting a median negotiated reimbursement relative to a median negotiated charge.

CMS proposed that this policy would apply to IPPS hospitals in the 50 states, DC and Puerto Rico. The policy would exclude CAHs that are not paid on the basis of negotiated rates and hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model.

Federally owned and operated hospitals as well as hospitals operated under the Indian Health Care Improvement Act that do not receive payment based on negotiated rates would also be excluded.

d. Potential Market Based MS-DRG Relative Weight Methodology Beginning in FY 2024

CMS requested comments on whether to use the data that hospitals report beginning with the cost reporting period ending in FY 2021 for determining the MS-DRG relative weights, beginning in FY 2024. If CMS adopts this idea, it said it would provide further details in the FY 2021 IPPS/LTCH PPS final rule. The proposed rule outlined the following steps for incorporating these data into the relative weight calculation:

- Step One: Standardize the Median MA Organizations Payer-Specific Negotiated Charges. Remove the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the current MS-DRG relative weight calculation for those effects.
- Step Two: Create a Single Weighted Average Standardized Median MA Organization Payer-Specific Negotiated Charge by MS-DRG Across Hospitals. For each MS-DRG, CMS would use each hospital's transfer-adjusted case count to weight the standardized payer-specific negotiated charge as it does under the current MS-DRG relative weight methodology (84 FR 42621). CMS would further consider whether to use unadjusted Medicare case counts, or other alternative approaches based on the review of public comments.
- Step Three: Create a Single National Weighted Average Standardized Payer Specific Negotiated Charge Across all MS-DRGs. CMS would create a single national weighted average across MS-DRGs of the results of Step Two, where the weights are the national Medicare transfer adjusted case counts by MS-DRG (or the unadjusted case counts if that is what is used for Step 2).
- Step Four: Calculate the Market-based Relative Weights. For each MS-DRG, the result from Step 2 for each MS-DRG would be divided by the result from Step 3 across all MS-DRGs to create each MS-DRG's relative weight.
- Step Five: Normalize the Market-based Relative Weights. As under the current cost-based MS-DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration such that aggregate payments neither increase or decrease as required by section 1886(d)(4)(C)(iii) of the Act.

CMS requested comments on the above methodology including alternatives and suggested refinements as well as:

- Whether CMS should continue to estimate and publicly provide the MS-DRG relative weights using the current cost-based estimation methodology as well as the revised methodology;
- Whether to provide a transition to any new market-based MS-DRG methodology, and, if so, on the appropriate design of any such transition; and

- Other ways to further reduce the role of hospital chargemasters in Medicare IPPS payments and further reflect market-based approaches in Medicare FFS payments.

*Comments/Responses:* There were comments in support of collecting only median negotiated rates between MA payers and hospitals rather than all private payers. CMS agreed with these comments and is only requiring the reporting of MA negotiated rates and not all private payer negotiated rates. In addition, CMS is not requiring hospitals to consider MA plan reimbursement amounts when reporting median negotiated rates as that information is not currently reported under the price transparency initiative and would significantly increase reporting complexity given the variety of payment arrangements that private payers may use. CMS will also continue to publish cost-based weights for IPPS hospitals as a basis for comparison to market-based relative weights.

Final Action: CMS is finalizing its proposal with a modification not to require reporting of median private payer rate negotiated for all third-party payers. Rather, hospitals will only need to report this information for MA payers. CMS is also not requiring reimbursement amounts to be reported. Hospitals only need to report negotiated rates. This data collection requirement is effective for cost reporting periods ending on or after January 1, 2021. As stated in the proposed rule, further instructions for the reporting of this market-based data collection requirement on the Medicare cost report will be discussed in a forthcoming revision of the Information Collection Request currently approved under OMB control number 0938-0050, expiration date March 31, 2022.

Many of the public comments and CMS' responses were a repeat of those found in CMS' final outpatient rule in 2019 on hospital transparency data. The following is a selection of other significant comments and responses:

General: Commenters indicated that MA negotiated rates are not representative of the hospital resources. CMS uses costs in combination with charges to set the relative weights making them already reflective of market-based information. Other commenters suggested the proposal only changes the relative weight and will not increase market competition in any way. A number of commenters that supported the proposal indicated that it would make payment subject to less manipulation and inflation by hospital-set chargemaster prices.

CMS' response to all of these comments is that its goal in using market-based negotiated rates for the MS-DRG relative weights is to reduce Medicare's reliance on chargemasters to set rates and establish IPPS rates that are reflective of private markets. As hospitals would not negotiate rates that result in a loss, CMS believes use of negotiated rates will reflect relative hospital resources. CMS disagrees that the current relative weight system already reflects market rates given the comments that the hospital's chargemaster rarely reflects true market costs.

Circularity and Comparability: Some commenters indicated that median payer-specific negotiated charge for MA organizations reflect the rates paid under Medicare FFS meaning there would be no mechanism for the relative weights to reflect changes in costs or value. A commenter suggested that hospitals are required to be paid Medicare FFS rates by MA

organizations with which they do not contract, so the reported charges might not reflect negotiated charges.

Many commenters expressed concern about capability to account for different negotiation tactics (episodes of care, separately negotiated outlier payments, stop loss provisions, quality payment, capitated payments, claw-back provisions or acquisition costs) when reporting median negotiated rates. Commenters suggested that MA patients may be healthier and have lower risk while the FFS population may be older and have more comorbidities. Commenters also discussed that some commercial payers may cover certain services that are not covered by Medicare.

CMS acknowledged that MA rates and Medicare FFS rates are often similar and/or are highly reliant on one another. However, MA rates to contracted hospitals are not required to be the same as (or based on) Medicare FFS rates; the Medicare statute only requires MA organizations to pay FFS rates to a health care provider for services furnished to an MA enrollee when the MA organization does not have a contract with the health care provider. There may be limited impact on the relative weights given the highly reliant nature between MA organization and Medicare FFS rates, but over time markets will adjust to this policy and further influence the Medicare FFS payments. CMS will continue to explore differences between MA patients and FFS patients using the MA data being collected.

Free Speech, Anti-Trust and Sharing of Proprietary Data: Several commenters expressed concern about sharing negotiated rates that are confidential and proprietary. A few commenters expressed concern that in health care markets with a small number of payers, these proposals would allow for the re-identification of the median payer-specific negotiated charge.

There were also comments that forced disclosure of negotiated rates unconstitutionally compels speech in violation of the First Amendment when there are alternative ways of CMS achieving its public policy goals. Commenters argued that requiring providers to report payer-specific negotiated rates crosses into infringement of antitrust laws and places hospitals in an untenable position of having to choose between violating their contractual obligations for confidentiality and violating the new rule.

CMS dismissed confidentiality concerns saying negotiated rates are already made available through explanation of benefits provided to patients. Further, the information CMS will be using is a summary measure, not the individually negotiated rate. CMS cited several court precedents that upheld required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome

Reporting Instructions: Several commenters requested information on how to account for specific items that are reported by hospitals on the Medicare cost report. Among other items, hospitals requested clarification about how to account for disproportionate share hospital payments, uncompensated care payments, graduate medical education payments, pass through payments, outlier payments, transfer adjustments, quality program payments, negotiated per diems, percentage of charge arrangements, rate plus percentage of charge for devices, etc. CMS believes that hospitals already have sufficient information based on the instructions

provided within this final rule to do the required reporting. There will also be forthcoming information through the revision of the Information Collection Request currently approved under OMB control number 0938-0050, expiration date March 31, 2022, to report this data on the Medicare cost report for cost reporting periods ending on or after January 1, 2021. CMS may provide additional guidance as necessary.

Legal Authority: There were comments that CMS had not articulated a sufficient policy basis for requiring reporting of payer-specific negotiated charges under sections 1815(a) and 1833(e) of the Act. Other commenters argued that CMS did not adequately explain why market prices, rather than costs, are a better measure of hospital resources and, therefore, the proposed rule constitutes an arbitrary and capricious rulemaking, violating the Administrative Procedure Act. Other comments suggested CMS should await final disposition of the lawsuit on the hospital price transparency litigation before moving forward with this policy.

CMS cited sections 1815(a) and 1833(e) of the Act that provide authority to collect data for purposes of determining the amount of payments due to the provider under the Medicare program. Sections 1886(d)(4)(A) and (B) of the Act provide the Secretary with authority to establish the MS-DRG system and relative weights. As relative resources are accounted for when hospitals establish the cost of services, and costs of services are considered when negotiating with payers, CMS believes these statutory authorities apply to its policy. As CMS did not cite the same authority for its proposal as are under dispute in the hospital transparency case, CMS does not believe moving forward with this policy needs to await final disposition of that litigation.

Negotiated Charges by MS-DRG: A commenter disagreed that there is a standard charge by MS-DRG. The commenter acknowledged services provided for a particular MS-DRG are quite similar across patients; however, the commenter stated that hospitals generally do not establish a standard charge for an inpatient admission. CMS believes that since hospitals assign the underlying ICD-10-CM principal diagnosis, and any other secondary diagnosis codes and ICD-10-PCS procedure codes, which determine how patients are assigned to an MS-DRG, that hospitals are able to associate items and services to MS-DRGs for each discharge. Additionally, hospitals that are not as familiar with MS-DRGs have access to the most current publicly available version of the MS-DRGs.

Regulatory Burden: Many commenters expressed concern with the timing of the implementation and stated that CMS has underestimated the time, resources, and cost required for hospitals to meet the requirements by January 1, 2021. Commenters argued that due to the burden of the current COVID-19 public health emergency, CMS should delay implementation. A few commenters provided a range of estimates for complying with the requirements of this final rule from as little as 120 hours of work and a $10,000 cost to 6,000 hours of work per year and $210,000 in costs.

CMS disagreed with these concerns noting that the payer-specific negotiated charges used by hospitals to calculate the medians would be reported for service packages that hospitals are required to make public under the Hospital Price Transparency final rule (84 FR 65524), beginning in January 1, 2021. Price transparency information can be crosswalked to MS-DRGs.

Additionally, the majority of Medicare certified hospitals have cost reporting periods that end between July and September of each year. Hospitals also have a 5-month period after their cost reporting periods end to submit the Medicare cost report. This means that the majority of hospitals will not submit their Medicare cost report until, at the earliest, November 2021.

After considering the public comments, CMS is revising its burden estimates although it does not believe estimates provided by the commenters provided are reasonable given the fact that hospitals are already required to publicly report the payer-specific negotiated charge information. CMS is increasing the initial estimate of 10 hours associated with reporting the median payer-specific negotiated charge to 15 hours, in order to account for the additional effort commenters described. CMS is maintaining the estimate for the hours associated with recordkeeping at 5 for a total of 20 hours of annual burden per hospital

Penalties for Not Reporting: A commenter stated that hospitals that do not report median negotiated charge information would not receive any Medicare reimbursement. The commenter stated that this punitive action is exceptionally harsh and should be reconsidered. CMS responded that sections 1815(a) and 1833(e) of the Act provide that no Medicare payments will be made to a provider unless it has furnished information requested by the Secretary to determine payment amounts due under the Medicare program. If a Medicare provider does not furnish required payment information on the cost report, the hospital risks not receiving any Medicare payments.

New Technology: A few commenters questioned how the provisions in this regulation will impact new technology and hospital ambulatory settings within provider-based arrangements. CMS responded that its policy does not affect new technology add-on payments nor does it make changes to the ambulatory payment policies.

Other Ideas for Reducing Reliance on the Chargemaster: A number of commenters suggested alternative ideas for reducing reliance on the hospital chargemaster including use of the Direct Cost Model which derives data from hospital cost accounting systems to submit an allowable cost per discharge or outpatient service. CMS looks forward to working with the stakeholder community to adjust any finalized policy through future rulemaking prior to the FY 2024 effective date.

Standardizing Negotiated Rates in Relative Weight Calculation: A few commenters suggested that CMS needs to standardize negotiated rates to account for disproportionate share hospital payments, uncompensated care payments, graduate medical education payments, pass through payments, outlier payments, transfer adjustments, quality program adjustments or other value-based purchasing arrangements in addition to other variables. CMS responded that the standardizing adjustments under the market-based weight model would parallel those made under the current cost-based weight system.

Payment Impacts and Transition Period: Several commenters requested that CMS implement a transition period to monitor for unintended consequences of the new market-based MS-DRG relative weight methodology. Other commenters urged CMS to provide ample transition time and clarity on the impact of changes by region and institution, while making efforts to minimize

disruptions to the reimbursement system and provide certainty to hospitals and health care providers.

In response to comments about payment impacts, CMS indicated that it intends to provide an analysis of the market-based data for public review, prior to the implementation of the new MS-DRG relative weight methodology in FY 2024. As it will use MA negotiated rates rather than all private payer negotiated rates to set the relative weights, CMS believes the payment impacts will be modest as MA negotiated rates are well correlated with the relative weights already being used.

Medical Devices: There were comments expressing concern with the exclusion of costs associated with the overhead, handling, and other operating expenses associated with high-cost implantable devices. CMS responded that cost of medical devices will be associated with the negotiated price of the MS-DRG.

**V. Changes to the IPPS for Capital-Related Costs**

National Capital Federal Rate for FY 2021. For FY 2020, CMS established a national capital Federal rate of $462.33. CMS proposed a national capital Federal rate of $468.36 for FY 2021. The final FY 2021 capital rate will be $466.22.

*Update Factor:*

For FY 2021, CMS will increase the national capital Federal rate by 1.1 percent based on the capital input price index (CIPI) of 1.1 percent and other factors shown in Table 1 below. For FY 2021, CMS projects a 0.5 percent total increase in the case-mix index. CMS estimates that real case-mix increase will equal 0.5 percent for FY 2021. The net adjustment for change in case-mix is the difference between the projected total increase in case-mix and real increase in case-mix. Therefore, CMS is applying an adjustment for case-mix change in FY 2021 of 0.0 percentage points. There is no adjustment for FY 2019 reclassification and recalibration or forecast error correction.

**Table 1**

| CMS FY 2020<br>UPDATE FACTOR TO THE CAPITAL FEDERAL RATE | |
|---|---|
| FY 2014-based CIPI | 1.1 |
| Intensity | 0.0 |
| Case-Mix Adjustment Factors: | |
| Projected Case-Mix Change | 0.5 |
| Real Across DRG Change | -0.5 |
| Net Case-Mix Adjustment (Projected - Real) | 0.0 |
| *Subtotal* | 1.1 |
| Effect of FY 2019 Reclassification and Recalibration | 0.0 |
| Forecast Error Correction | 0.0 |
| *Total Proposed Update* | 1.1 |

*Other Adjustments:*

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS is reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes below the 25th percentile and capping reductions in wage indexes at 5 percent) in the budget neutrality adjustment. CMS determines a net GAF budget neutrality adjustment of -0.16 percent (0.9984) in two steps as follows:

- Isolate the impact of just the change to the wage data (e.g. without the increase to the lowest quartile wage indexes and 5 percent cap on wage index decreases) on FY 2021 payments. Adjustment = 1.0021.
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases on the FY 2021 payments. Adjustment = 0.9963.

The budget neutrality adjustment for changes in the GAFs will be 0.9984 (1.0021 x 0.9963). CMS incorporates an adjustment for MS-DRG changes and recalibration of the relative weights of 0.9988. This combined adjustment for GAFs and MS-DRG changes and recalibration is 0.9971 (0.9988 x 0.9984) or -0.29 percent.

For FY 2021, CMS is taking outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.36 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.02 percentage points for amounts refunded to hospitals. This makes capital outlier payments 5.34 percent of total capital payments. Therefore, the FY 2021 outlier adjustment factor is 0.9466 (-5.34 percent), compared to 0.9463 (-5.37 percent) in FY 2020. The net change is 0.03 percent (0.9466/0.9463). Thus, the outlier adjustment increases the FY 2021 capital federal rate by 0.03 percent.

*Final Rule Calculation:*

The final rule includes the following chart to show how each of the factors and adjustments affect the computation of the FY 2021 national capital Federal rate compared to the FY 2020 national capital Federal rate.

**Comparison of Factors and Adjustments:**
**FY 2020 and FY 2021 Capital Federal Rate**

| | FY 2020 | FY 2021 | Change | Percentage Change |
|---|---|---|---|---|
| Update Factor* | N/A | 1.0110 | 1.0110 | 1.10 |
| GAF/DRG Adjustment Factor* | N/A | 0.9971 | 0.9971 | -0.29 |
| Outlier Adjustment Factor** | 0.9463 | 0.9466 | 1.0003 | 0.03 |
| Capital Federal Rate | $462.33 | $466.22 | 1.0084 | 0.84 |

* The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2020 to FY 2021 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2021 is a net change of 0.9971 (or -0.29 percent).
** The outlier adjustment 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 2021 outlier adjustment factor is 0.9463/0.9466, or 1.0003 (or 0.03 percent).

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2021 of $466.22, a 0.84 percent increase over the FY 2020 rate of $462.33

Exception Payments. The final rule continues exception payments if a 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 is paid 85 percent 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

### A. Rate-of-Increase in Payments to Excluded Hospitals

Most hospitals are paid under prospective payment systems. However, some hospitals continue to be paid based on reasonable costs subject to a per discharge limit updated annually under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. Hospitals that continue to be paid reasonable costs subject to a limit include 11 cancer hospitals, children's hospitals, and hospitals located in the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Religious non-medical health care institutions are also paid reasonable costs subject to a limit.

The annual update to the TEFRA limit is based on IGI's 2020 2nd quarter forecast of the hospital market basket for FY 2021 and is estimated at 2.4 percent. As explained earlier, there is no subtraction in FY 2021 for MFP.

### B. Report on Adjustment (Exception) Payments

TEFRA hospital cost limits may be adjusted for specific factors after the hospital submits its Medicare cost report. 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. Total adjustment payments made to IPPS-excluded hospitals during FY 2019 were $44,068,703 as shown by hospital type in the below table.

| Class of Hospital | Number | Excess Cost Over Ceiling | Adjustment Payments |
|---|---|---|---|
| Children's Hospitals | 5 | $9,145,476 | $2,459,468 |
| Cancer Hospitals | 2 | $63,425,853 | $41,609,235 |
| Total | 7 | $72,571,329 | $44,068,703 |

## C. Critical Access Hospitals

The Frontier Community Health Integration Project (FCHIP) Demonstration[42] is designed to develop and test new models of care by permitting enhanced reimbursement for telemedicine, nursing facility, ambulance, and home health services. Ten CAHs in Montana, Nevada, and North Dakota participated in the 3-year demonstration beginning August 1, 2016.

The demonstration was intended to be budget neutral through reduced transfers and admissions to other health care providers that offset any increase in payments under the waivers. However, if that is not the case, CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to all CAHs nationwide beginning with FY 2020. The final budget neutrality estimates for the FCHIP demonstration will be based on costs incurred during the entire demonstration period, which is August 1, 2016 through July 31, 2019.

Based on the currently available data, the estimate of costs under the demonstration remain uncertain. CMS proposed to delay the implementation of any budget neutrality adjustment and will revisit this policy in rulemaking for FY 2022. Commenters agreed with this proposal.

# VII. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

## A. Background

Since FY 2016, LTCHs have been paid under a dual-rate payment structure. An LTCH case is either paid at the "LTCH PPS standard federal payment" when the criteria for site neutral payment rate exclusion are met or a "site neutral payment rate" when the criteria are not met. Site neutral cases will be paid an IPPS comparable amount. The criteria for exclusion from the site neutral payment remain the same for FY 2021:

- Case cannot have a principal diagnosis relating to a psychiatric diagnosis or rehabilitation (the DRG criterion).
- Case must be immediately preceded by discharge from an acute care hospital that included at least 3 days in an intensive care unit (the ICU criterion).
- Case must be immediately preceded by discharge from an acute care 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 (the ventilator criterion).

To be paid the LTCH PPS standard federal payment, the case must meet the DRG criterion and either the ICU or ventilator criterion.

CMS updates payments for LTCHs using a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment

[42] The FCHIP Demonstration was authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275).

rate (50 percent LTCH standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS final rule made conforming changes to the regulations to implement the extended transitional blended payment.

| Summary of Changes to LTCH PPS Rates for FY 2021* | |
|---|---|
| **Standard Federal Rate, FY 2020** | $42,677.64 |
| **Final Rule Update factors** | |
| Update as required by Section 1886(m)(3)(C) of the Act (including MFP reduction) | +2.3% |
| Penalty for hospitals not reporting quality data (including MFP reduction) | -2.0% |
| **Net update, LTCHs reporting quality data** | +2.3% (1.023) |
| **Net update LTCHs not reporting quality data** | 0.3% (1.003) |
| **Final Rule Adjustments** | |
| Average wage index budget neutrality adjustment | 1.0016837 |
| Permanent budget neutrality adjustment factor of 0.991249 for the cost of the elimination of the 25-percent threshold policy for FY 2021 (and subsequent years); removal of FY 2020 adjustment factor of 0.990737 | 1.000517 |
| **Standard Federal Rate, FY 2021** | |
| LTCHs reporting quality data ($42,677.64*1.023*1.0016837*1.000517) | $43,755.34 |
| LTCHs not reporting quality data ($42,677.64*1.003*1.0016837*1.000517) | $42,899.90 |
| **Fixed-loss Amount for High-Cost Outlier (HCO) Cases** | |
| LTCH PPS standard federal payment rate cases | $27,195 |
| Site neutral payment rate cases (same as the IPPS fixed-loss amount) | $29,051 |
| **Impact of Policy Changes on LTCH Payments in 2021** | |
| Total estimated impact | -1.1% (-$40 million) |
| LTCH standard federal payment rate cases (75% of LTCH cases) | +2.2% (+$74 million) |
| Site neutral payment rate cases (25% of LTCH cases)** | -24% (-$114 million) |
| *More detail is available in Table IV: "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2021". Table IV does not include the impact of site neutral payment rate cases.<br>** 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. LTCH PPS MS-DRGs and Relative Weights

1. Background

Similar to FY 2020, the annual recalibration of the MS-LTC-DRG relative weights for FY 2021 is determined using data only from claims qualifying for LTCH PPS standard federal rate payment and claims that would have qualified if that rate had been in effect. The MS-LTC-DRG relative weights are not used to determine the site neutral payment rate and site neutral payment case data are not used to develop the relative weights.

2. Patient Classification into MS-LTC-DRGs

CMS continues to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates are also

incorporated into the MS-LTC-DRG system for FY 2021 since the two systems share an identical base. MS-DRG changes are described elsewhere in this summary and details can be found in section II.D. of the preamble of the final rule.

3. Development of the MS-LTC-DRG Relative Weights

In developing the FY 2021 relative weights, CMS uses its current methodology and established policies related to the hospital-specific relative-value methodology, volume-related and monotonicity adjustments, and the steps for calculating the relative weights with a budget neutrality factor (described in more detail below).

4. Relative Weights Source Data

The FY 2021 relative weights are derived from the March 2020 update of the FY 2019 MedPAR file. These data are filtered to identify LTCH cases meeting the established site neutral payment exclusion criteria. The filtered data are trimmed to exclude all-inclusive rate providers, Medicare Advantage claims, and demonstration project participants, yielding the "applicable LTCH data." (CMS notes there were no data from any LTCHs paid under a demonstration project in the march 2020 update.) The applicable LTCH data are used with Version 38 of the GROUPER to calculate the FY 2021 MS-LTC-DRG relative weights.

5. Hospital-Specific Relative-Value Methodology (HSRV)

CMS continues to use its HSRV methodology in FY 2021, unchanged from FY 2020, to mitigate relative weight distortions due to nonrandom case distribution across MS-LTC-DRGs and charge variation across providers. The HSRV methodology scales each LTCH's average relative charge value by its case mix.

6. Volume-related adjustments

CMS continues to account for low-volume MS-LTC-DRG cases as follows:

- If an MS-LTC-DRG has at least 25 cases, it is assigned its own relative weight.
- If an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges; CMS finds that there are 251 such MS-LTC-DRGs. CMS then determines a relative weight and average length of stay for each quintile; each quintile's weight and length of stay are then assigned to each MS-LTC-DRG within that quintile. (CMS directs readers to http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these low-volume MS-LTC-DRGs.)
- If an MS-LTC-DRG has zero cases after data trims are applied (CMS identifies 347 of these MS-LTC-DRGs), it is cross-walked to another MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness in order to assign an appropriate proposed 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 11 transplant, 2 "error" and 15 psychiatric or rehabilitation MS-LTC-DRGs. (CMS directs readers to

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these zero-volume MS-LTC-DRGs.)

CMS will assign a 0.0 relative weight for the 11 transplant MS-LTC-DRGs since no LTCH has been certified by Medicare for transplantation coverage. CMS also will assign a 0.0 relative weight for the 2 "error" MS-LTC-DRGs (998 and 999) which cannot be properly assigned to an MS-LTC-DRG group. CMS will not calculate a weight for the 15 psychiatric and rehabilitation proposed MS-LTC-DRGs because these MS-LTC-DRGs would never include any LTCH cases meeting the site neutral payment rate exclusion criteria.

7. Treatment of Severity Levels, Monotonicity Adjustments

Each MS-LTC-DRG contains one, two or three severity levels; resource utilization and relative weights typically increase with higher severity. When relative weights decrease as severity increases in a DRG ("nonmonotonic"), CMS combines severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained. Adjustments for nonmonotonicity in determining the FY 2021 MS-LTC-DRG final relative weights are shown in Table 11 in section VI. of the Addendum to the final rule.

8. Selected Steps for Determining the MS-LTC-DRG Relative Weights

CMS continues its methodology of calculating the relative weights by first removing cases with a length of stay of 7 days or less (Step 1) and then removing statistical outliers (Step 2). The effect of short stay outlier (SSO) cases (those with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) is adjusted for 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 (Step 3).

CMS applies its existing two-step methodology to achieve budget neutrality for the FY 2021 MS-LTC-DRG and relative weights update (Step 7). First, a normalization adjustment is applied to the recalculated relative weights to ensure that the recalibration does not change the average case mix index (1.25878 proposed for FY 2021). Second, a budget neutrality factor is applied to each normalized relative weight (0.9993445 proposed for FY 2021).

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the final rule (pages 1,453 to 1,468 of the display copy).

**C. Changes to the LTCH PPS Payment Rates and Other Changes**

1. Overview LTCH PPS Payment Rate Adjustments

Only LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. The LTCH PPS uses a single payment rate to cover both operating and capital-related costs, so that the LTCH market basket includes both operating and capital cost categories.

2. Annual Update for LTCHs

Based on IGI's second-quarter 2020 forecast, the annual update to the LTCH PPS standard federal payment rate is equal to 2.3 percent. CMS notes that the proposed update of 2.9 percent was developed before the economic impacts of the COVID-19 pandemic. As discussed in section VII.D of the final rule (summarized below), CMS rebases and revises the 2013-based LTCH market basket to reflect a 2017 base year.

In determining the multifactor productivity adjustment for FY 2021, because of the economic uncertainty caused by the COVID-19 pandemic, CMS believes it is more appropriate to use IGI's June 2020 macroeconomic forecast (-0.1) instead of the second quarter IGI forecast (0.7) that the agency would normally use. CMS notes that subtracting a negative (-0.1) would have resulted in a 0.1 percentage point increase to the update, and the statute does not permit a productivity increase to the update. Thus, CMS applies an MFP adjustment of 0.0 percentage points to the market basket update.

Thus, the update is equal to the 2017-based LTCH market basket of 2.3 percent less 0.0 percentage points (PP) for multifactor productivity. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update is further reduced by 2.0 percentage points. CMS notes that the "other adjustment" under section 1886(m)(4)(F) of the Act does not apply for FY 2021. The LTCH update for FY 2021 is as follows:

| Factor | Full Update | Reduced Update for Not Submitting Quality Data |
|---|---|---|
| LTCH Market Basket | 2.3% | 2.3% |
| Multifactor Productivity | 0.0 PP | 0.0 PP |
| Quality Data Adjustment | 0.0 | -2.0 PP |
| Total | 2.3% | 0.3% |

3. Area Wage Levels and Wage-Index

CMS finalizes its proposal to adopt the revised labor market area delineations announced in OMB Bulletin No. 18-04 effective for FY 2021 under the LTCH PPS. This is consistent with the changes finalized for the IPPS for FY 2021 as described in section III.A. of this summary. Accordingly:

- 34 counties (and county equivalents) formerly considered part of an urban CBSA are considered to be located in a rural area;
- 47 counties (and county equivalents) located in rural areas are considered to be located in urban areas; and
- Some urban counties shift from one urban CBSA to another urban CBSA or shift between existing and new CBSAs.

Because some LTCHs will experience decreases in their wage index values, CMS implements a budget neutral transition policy to help mitigate significant negative impacts that LTCHs may experience due to the adoption of the revised OMB delineations. CMS will apply a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index from the prior fiscal year;

thus, an LTCH's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020.

As noted above, CMS rebases and revises the 2013-based LTCH market basket to reflect a 2017 base year. CMS finalizes an FY 2021 labor-related share of 68.1 percent based on IGI's second quarter 2020 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (63.7%) and capital costs (4.4%). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related; administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services. CMS notes that the difference from the FY 2020 labor-related share is attributable to the revision to the base year cost weights, the revision to the starting point of the calculation of base year from 2013 to 2017, and the use of an updated IHS Global Inc. forecast and reflecting an additional year of inflation.

CMS computes the wage index in a manner that is consistent with prior years, taking into account the revised labor market area delineations announced in OMB Bulletin No. 18-04. It calculates an area wage level budget neutrality adjustment of 1.0016837.

4. Elimination of the 25 percent Rule

In the FY 2019 IPPS rule, CMS adopted a policy to eliminate the 25 percent rule. This rule would have paid LTCHs at an IPPS comparable amount for all discharges not meeting the criteria to be paid the LTCH standard rate above 25 percent of the LTCH's total discharges. CMS adopted a policy to make elimination of this policy budget neutral through two temporary one-time adjustments to the LTCH standardized amount (0.990878 for FY 2019 and 0.990737 for FY 2020) and one permanent one-time adjustment to the LTCH standardized amount of 0.991249 for FY 2021 and subsequent years. A one-time temporary adjustment means the adjustment is removed for the following year while a one-time permanent adjustment stays on the rate and is not removed.

For FY 2021, CMS removes the 0.990737 adjustment (calculated by applying a factor of 1/0.990737) and applies the permanent one-time adjustment of 0.991249. CMS calculates an adjustment factor of 1.000517 for FY 2021 and subsequent years for the elimination of the 25 percent rule.

5. LTCH Standard Federal Payment Rate Calculation

CMS calculates the following LTCH PPS standard federal payment rates for FY 2021:

- $43,755.34 for LTCHs reporting quality data, calculated as follows: $42,677.64 (FY 2020 payment rate) * 1.023 (statutory update factor) * 1.0016837 (area wage budget neutrality factor) * 1.000517 (25% threshold budget neutrality factor) = $43,755.34

- $42,899.90 for LTCHs not reporting data to the LTCH QRP, calculated as follows: $42,677.64 (FY 2020 payment rate) * 1.003 (statutory update factor less quality adjustment)

* 1.0016837 (area wage budget neutrality factor) * 1.000517 (25% threshold budget neutrality factor) = $42,899.90

6. Cost-of-Living (COLA) Adjustment

CMS continues updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states. The COLA is determined by comparing Consumer Price Index growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city. The COLA is capped at 25 percent and updated every 4 years. Shown below are the FY 2021 COLAs.

| Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2021 | |
|---|---|
| **Alaska** | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.25 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.25 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.25 |
| All other areas of Alaska | 1.25 |
| **Hawaii** | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.21 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

7. High-Cost Outlier (HCO) Case Payments

Section 1886(m)(7)(A) of the Act requires CMS to reduce the LTCH standard federal payment rate by 8 percent for HCOs. Section 1886(m)(7)(B) requires CMS to set the outlier threshold such that estimated outlier payments equal 99.6875 percent of the 8 percent estimated aggregate payments for standard federal payment rate cases (that is, 7.975 percent). Based on LTCH claims from the March 2020 update of the FY 2019 MedPAR file and CCRs from the March 2020 update of the PSF, CMS calculates an HCO threshold of $27,195 for FY 2021 which CMS estimates will result in 7.975 of LTCH standard federal payment rate cases being paid as HCOs. The HCO payment continues to equal 80 percent of the estimated care cost and the outlier threshold (adjusted standard rate payment plus fixed-loss amount). If an HCO case is also an SSO case, the HCO payment will equal 80 percent of the estimated case cost and the outlier threshold (SSO payment plus fixed-loss amount).

CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2021, CMS finalizes a fixed-loss amount for site neutral payment rate cases of $29,051. CMS also applies a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2021. Consistent with the policy adopted in FY 2019, CMS the HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments.

8. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS continues its policy of including an applicable operating Medicare DSH and uncompensated care payment amount in the calculations of the "IPPS comparable amount" (42 CFR §412.529) and the "IPPS equivalent amount" (§412.534 and §412.536). For FY 2021, the DSH/uncompensated care amount equals 75.90 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

**D. Rebasing of the LTCH Market Basket**

1. Background

CMS proposed to rebase and revise the LTCH market basket based on data from cost reports beginning in FY 2017. The current LTCH market basket is from a 2013 base year. CMS did not receive any comments on its proposed policies, and it finalizes the proposal without modification.

2. 2017-Based LTCH Market Basket Cost Categories and Weights

To determine the index, CMS uses only those LTCHs that have a Medicare average length of stay that is within 25 percent of the LTCH's average length of stay for all patients. CMS believes this selection criterion will result in a more accurate reflection of the structure of costs for Medicare covered days. This selection criterion is the same as was used for the FY 2013-based LTCH market basket.

The selection criterion results in exclusion of 9 percent of LTCH providers. Included LTCH providers had an average Medicare length of stay of 25 days; an all patient average length of stay of 27 days, and aggregate Medicare utilization (based on days) of 58 percent. Excluded LTCH providers had an average Medicare length of stay of 27 days, average facility length of stay of 70 days, and aggregate Medicare utilization of 15 percent.

The LTCH market basket includes seven categories of costs plus a residual "all other" category. CMS derives the cost weights the same way for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket with the exception of home office/related organization contract labor:

(1) Wages and Salaries. Costs reported on Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91, and 93 and the proportion of overhead salaries that are attributed to Medicare allowable costs centers.

(2) Employee Benefits. Costs reported on Worksheet S-3, part II, column 4, lines 17, 18, 20, and 22. Worksheet S-3 is voluntary for LTCHs. Only 20 percent of LTCHs reported these data. However, CMS believes it has a large enough sample to produce a reasonable employee benefits

cost weight because it did not change materially after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region).

(3) Contract Labor. Costs reported on Worksheet S–3, part II. Only 44 percent of LTCHs voluntarily reported costs on Worksheet S-3 part II. CMS's analysis indicates there is a large enough sample to produce a reasonable contract labor cost weight.

(4) Pharmaceuticals. Costs reported on Worksheet B, part I, column 0, lines 15 and 73 and then removing a portion of these costs attributable to salaries (adjusted by the ratio of Worksheet A, column 1, lines 15 and 73 divided by the sum of Worksheet A, columns 1 and 2, lines 15 and 73).

(5) Professional Liability Insurance. Premiums, paid losses and self-insurance costs reported on Worksheet S-2, part I, columns 1 through 3, line 118.

(6) Home Office/Related Organization Contract Labor. Costs reported on Worksheet S–3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551 for those LTCH providers reporting total salaries on Worksheet S-3, part II, line 1. For the 2013-based LTCH market basket, CMS used the 2007 Benchmark Input-Output expense data published by the Bureau of Economic Analysis. CMS believes the proposed methodology for the 2017-based LTCH market basket is a technical improvement over the prior methodology because it represents more recent data that is representative compositionally and geographically of LTCHs.

(7) Capital. Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93.

(8) All Other. Reflects all remaining costs that are not captured in the seven cost categories listed.

CMS excludes those LTCHs with cost weights that are less than or equal to zero for a category as well as those cost weights that are in the top and bottom 5 percent for all cost categories except home office/related organization contract labor. For this cost category, CMS finalizes its proposal to remove the top 1 percent only as not all LTCHs have a home office and the cost weight for this category may appropriately be zero.

| Major Cost Categories | 2013 Weight | 2017 Weight |
|---|---|---|
| Wages and Salaries | 41.5 | 42.6 |
| Employee Benefits | 6.5 | 6.2 |
| Contract Labor | 5.9 | 4.4 |
| Professional Liability | 0.9 | 0.5 |
| Pharmaceuticals | 7.6 | 6.2 |
| Home Office/Related Organization Contract Labor | N/A | 1.9 |
| Capital | 9.7 | 9.9 |
| All Other | 27.8 | 28.3 |

CMS provides further detail on the data sources used to derive weights within the capital and all other category. The final detailed cost weights including the subcomponents of capital and all other are found in table E4 (beginning on page 1,496 of the display copy).

3. Selection of Proposed Price Proxies

CMS uses the same price proxies for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket with one highly technical change to how CMS proposes to determine the weight for chemicals—a subcomponent of the all other category.

4. FY 2021 Market Basket Update for LTCHs

CMS finalizes an FY 2017-based LTCH market basket update of 2.3 percent for FY 2021. If continued, the FY 2013-based LTCH market basket update would have been 2.4 percent. The FY 2013-based LTCH market basket and the FY 2017-based LTCH market basket differed by 0.2 percentage points or less for each year between FYs 2016-2019 and forecast for FY 2020 through FY 2023. The FY 2017-based LTCH market basket averaged 0.1 percentage point lower in this time period than the FY 2013 LTCH market basket.

5. FY 2021 Labor-Related Share

The labor-related share of the LTCH standard federal rate is adjusted for area differences in costs. The remaining portion of the LTCH standard federal rate is a uniform national amount. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market.

CMS uses the same labor-related categories of costs for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket: wages and salaries; employee benefits; professional fees: labor-related services; administrative and facilities support services; installation, maintenance, and repair services; all other: labor-related services; and a portion of the capital-related costs from the 2017-based LTCH market basket. Professional fees: labor-related services include a proportion of the home office/related organization contract labor costs.

The final labor-related share for FY 2021 is 68.1 percent compared to 66.3 percent based on the 2013-based LTCH market basket. The different contribution of each cost weight category to the overall difference is shown in the table below:

| Major Cost Categories | 2013-Based LTCH MB | 2017-Based LTCH MB |
|---|---|---|
| Wages and Salaries | 46.6 | 47.1 |
| Employee Benefits | 7.2 | 6.8 |
| Professional Fee: Labor-Related | 3.4 | 4.4 |
| Administrative and Facilities Support Services | 0.9 | 1.0 |
| Installation, Maintenance, and Repair Services | 2.1 | 2.1 |
| All Other: Labor-Related Services | 2.0 | 2.3 |
| Subtotal | 62.2 | 63.7 |
| Labor-Related Portion of Capital (46%) | 4.1 | 4.4 |
| Total Labor-Related Share | 66.3 | 68.1 |

## E. Impact of Payment Rate and Policy Changes to LTCH PPS Payments

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2020 to FY 2021, will result in a decrease of 1.1 percent or $40 million in aggregate payments from $3.774 billion to $3.733 billion for the 363 LTCHs included in this impact analysis. CMS attributes this decrease primarily to the rolling end to the statutory transitional blended payment rate for site neutral payment cases. This impact results from a decrease in payment for site neutral cases of $114 million and an increase in payment of LTCH standard federal payment rate cases of $74 million.

CMS indicates that there will no longer be any transitional payment for site-neutral cases in FY 2021 like there was in FY 2020 based on the start date of the LTCH's cost reporting period. The lack of a transitional payment will result in a reduction in payment estimated at 24 percent or approximately $114 million for the 25 percent of cases that are estimated to be paid at a site neutral rate.

For the approximately 75 percent of cases estimated to be paid at the standard federal rate, payment is estimated to increase 2.2 percent or approximately $74 million. This increase is primarily due to the proposed 2.3 percent annual update to LTCH standard federal rate for FY 2021 and a 0.5 percent decrease in the proportion of FY 2021 LTCH payments attributed to high cost outliers.

CMS estimates that high cost outliers in FY 2020 will be about 8.005 percent of estimated total LTCH PPS standard federal payment rate payments. As it does annually, CMS proposes to set the high cost outlier threshold for LTCH standard federal payment rate cases so that 7.975 percent of total payment are made as high cost outliers. The difference between the 8.005 percent figure for FY 2020 and the estimate of 7.975 percent for FY 2021 accounts for the 0.03 percent reduction in payment for high cost outliers.

CMS was unable to model the impact of LTCH PPS payment changes for site neutral payment rate cases as it did for standard federal payment rate cases. Thus, Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2021" in the final rule shows the detailed impact by location, participation date, ownership type, region, and bed size for only LTCH PPS standard federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases. CMS reports that regional differences in impacts are largely due to updates to the wage index.

| Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2021 | | |
|---|---|---|
| | **Number of LTCHs** | **Estimated Percent Change in Payments per Discharge** |
| **All LTCH providers** | 360 | 2.1% |
| **By Location:** | | |
| **Rural** | 18 | 1.7% |
| **Urban** | 342 | 2.3% |
| **By Ownership Type:** | | |
| **Voluntary** | 60 | 2.3% |
| **Proprietary** | 290 | 2.2% |
| **Government** | 10 | 2.4% |
| **By Region** | | |
| **New England** | 10 | 1.8% |
| **Middle Atlantic** | 23 | 2.2% |
| **South Atlantic** | 62 | 2.1% |
| **East North Central** | 55 | 2.2% |
| **East South Central** | 31 | 1.9% |
| **West North Central** | 22 | 1.9% |
| **West South Central** | 105 | 2.3% |
| **Mountain** | 29 | 2.0% |
| **Pacific** | 23 | 2.9% |
| *More detail is available in Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2021" on pages 2127-2128 of the display copy. | | |

Tables. The complete set of tables providing detail on the LTCH PPS for FY 2021 is accessible at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Regulations-and-Notices-Items/LTCH-PPS-CMS-1716-F.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending.

## VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, changes are made to the quality reporting programs that apply to acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. In addition, requirements under the Medicare and Medicaid Promoting Interoperability Program are modified.

### A. Hospital Inpatient Quality Reporting (IQR) Program

As further described below, CMS makes changes to the IQR Program that (1) modify the data validation program, (2) gradually increase the number of cases for which electronic clinical quality measure (eCQMs) must be submitted, and (3) begin public reporting of hospital performance on eCQMs on *Hospital Compare* or its successor website.[43]

No changes are made to IQR Program measures or policies regarding the retention, removal, addition, or updating of measures or other program policies. The data submission requirements

[43] On September 3, 2020 CMS announced the launch of the *Care Compare* website which merges *Hospital Compare* and other CMS healthcare compare tools available through the Medicare.gov web page.

for chart-abstracted measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, and the CDC NHSN measure remaining in the IQR Program are maintained without change. These include procedural requirements and deadlines, sampling and case thresholds, data accuracy and completeness acknowledgement, reconsideration and appeals, and the Extraordinary Circumstances Exception policy.

More information on the IQR Program is available at https://www.qualitynet.org/inpatient/iqr. A summary table at the end of this section shows previously adopted IQR Program measures for FYs 2020 through 2024.

1. Reporting and Submission Requirements for eCQMs

Under the IQR Program for FY 2023 (reporting period of CY 2021) hospitals must submit data for four self-selected eCQMs chosen from a list of nine possible eCQMs. Beginning with FY 2024 payment (CY 2022 reporting), hospitals are to report four measures: three are to be chosen by the hospital from among a list of eight possible eCQMs and the fourth must be reported by all hospitals: the Safe Use of Opioids – Concurrent Prescribing eCQM. (The summary table at the end of this section lists the eCQMs available for reporting.)

In this rule, CMS increases the number of quarters for which hospitals must report eCQMs and modifies the file identification elements for eCQM reporting. No changes are made to eCQMs that must be reported or the data submission deadlines. The requirements that hospitals must use EHR technology certified to the 2015 Edition for certified electronic health record technology (CEHRT) and that EHRs be certified to all available eCQMs are continued.

The number of quarters for which a hospital must report eCQM data under the IQR Program is increased over 3 years. Currently, for the four eCQMs that it reports, a hospital must submit one self-selected quarter of data. Under the final rule, this requirement is progressively increased to four quarters of data as follows, where prior to four quarters of reporting the self-selected quarters need not be consecutive:

- For FY 2023 payment (CY 2021 reporting) hospitals must report data for 2 self-selected calendar quarters
- For FY 2024 payment (CY 2022 reporting) hospitals must report data for 3 self-selected calendar quarters
- For FY 2025 payment (CY 2023 reporting) and subsequent years, hospitals must report data for all 4 calendar quarters.

CMS believes this change will produce more comprehensive quality measure data and a more reliable and accurate picture of hospital performance. It notes that 97 percent of hospitals successfully submitted one quarter of data for four self-selected eCQMs for 2018.

Many commenters asked that this change be moderated by delaying it until after the COVID-19 public health emergency is ended or increasing the number of data quarters required more gradually. In response CMS first notes that it issued a nationwide ECE with respect to certain IQR Program data submission deadlines and will continue to monitor the impact of COVID-19

and issue additional ECEs as necessary. CMS emphasizes that hospitals that are adversely affected by the public health emergency or have vendors that are unable to support the required eCQM reporting may apply for an individual ECE. The ECE policy provides relief for specific hardships preventing hospitals from electronic reporting. Second, CMS points out that for several years it has reduced or delayed eCQM requirements to give hospitals and vendors time to upgrade systems, train staff and otherwise prepare. It believes that the gradual increase in reporting requirements balances the need for increased reporting with recognition of the time needed by hospitals and vendors to implement the changes. It notes that under the final rule, hospitals will only have to report eCQM data for two quarters of calendar 2021 by the February 2022 data submission deadline.

With respect to concerns about the reliability and validity of eCQMs, CMS recognizes the extraction methodology differs from that for chart-abstracted measures, but its data validation studies have found more than half of eCQMs have agreement rates of 80 percent or more. It believes this is sufficient to increase reporting, and states that it is continuing to analyze the validation process and results.

Comments regarding the need for better transparency and understanding of data validation results and causes of mismatches will be taken into account as CMS makes further refinements to the eCQM validation process. Stakeholders are directed to the opportunity for an educational review process.

CMS disagrees with commenters requesting that hospitals be given 18 months to implement changes in eCQM reporting requirements. It distinguishes changes to reporting of existing eCQMs from adding new eCQMs to electronic health record systems, because data specifications need not be updated in order to report data for an additional calendar quarter. CMS notes that in the proposed rule for the Physician Fee Schedule (PFS) for 2021 (85 FR 50265), it proposes a transition period that allows hospitals the flexibility to use for the IQR Program either: (1) technology certified to the 2015 Edition criteria for CEHRT as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537-41608), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 50271). Considering the announced enforcement discretion this flexibility is provided until August 2, 2022, after which technology certified to the 2015 Edition Cures Update standards must be used.

CMS thanks commenters for feedback on challenges hospitals face in reporting eCQMs through the QualityNet secure portal. It began transitioning to the Next Generation of the Hospital Quality Reporting (HQR) System for eCQM reporting with the 2019 reporting period to improve the experience for program stakeholders. CMS will continue to make improvements to the system.

Responding to comments, CMS clarifies that hospitals may continue to meet the reporting requirements by submitting eCQM data using the Quality Reporting Document Architecture (QRDA) I, a zero-denominator declaration, or a case threshold exemption. QRDA I files are expected to reflect data for one patient per file per quarter, which includes all patient encounters, eCQMs and applicable data elements for those measures. The maximum file size is 10 MB.

Users may submit multiple quarters of patient data within one batch file with a maximum of 14,999 QRDA I files in a batch. CMS encourages hospitals to submit the volume of batches needed to fully represent their patient population for the reporting quarter. The HQR System will break down the information by quarter. Submitters are encouraged to test early and often to prevent the likelihood of structural data errors and patient file rejection.

No changes are made to the eCQM submission deadlines. CMS notes that in the FY 2017 IPPS/LTCH PPS final rule the Hospital IQR Program eCQM submission deadline was aligned with that of the Medicare Promoting Interoperability Program to be the end of 2 months following the close of the calendar year. The submission deadline may be moved to the next business day if it falls on a weekend or federal holiday. Therefore, CMS clarifies that the data submission deadline for the eCQM data for the IQR Program, regardless of how many quarters of data must be reported, will be the 2 months following the end of the calendar year. For example, for the 2021 reporting period/FY 2023 payment determination, the deadline is February 28, 2022. Hospitals will continue to self-select which quarters are reported, which may include non-consecutive quarters, until all four quarters are required.

With respect to file identification, CMS adds EHR Submitter ID as a fifth key element for file identification beginning with reporting for FY 2023 payment. The other data elements contained in the QRDA I file format for file identification are: (1) CMS Certification Number (CCN); (2) CMS Program Name; (3) EHR Patient ID; and (4) Reporting period specified in the Reporting Parameters Section of the CMS Implementation Guide for the applicable reporting year. (See https://ecqi.healthit.gov/qrda). In situations where a hospital uses multiple vendors to submit QRDA I files, the EHR Submitter ID prevents a file previously submitted by another vendor from being overwritten. The EHR Submitter ID for hospitals is the CCN, and for vendors is the Vendor ID assigned by QualityNet.

2. Data Submission and Reporting of Hybrid Measures

The IQR Program includes one measure that is calculated using a hybrid of claims data and data reported by the hospital through EHR Technology. The Hybrid Hospital-Wide Readmission (HWR) measure will be open for reporting in two voluntary reporting periods (July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023) and will be a mandatory measure beginning with the FY 2026 payment determination. For purposes of reporting this measure, hospitals must use EHR technology certified to the 2015 Edition for CEHRT, and to submit the required data elements using the QRDA I file format.

In this rule, CMS finalizes that the requirements for using the 2015 Edition and QRDA I file format will also apply to any future hybrid measure adopted for the IQR Program. As noted earlier, in the PFS proposed rule for 2021, CMS would allow hospitals to use technology

certified to the 2015 Edition criteria or technology certified to the 2015 Edition Cures Update standards during a transition period.

3. Validation of IQR Program Data

CMS finalizes its proposals to combine the validation processes for chart-abstracted data and eCQM data over time. It notes that only one clinical process of care measure subject to chart-abstracted data validation (the sepsis measure) remains in the IQR Program for the 2021 reporting period (FY 2023 payment). The changes include seven elements, listed as follows.

(1) *Modify data submission quarters.* The quarters of data used for both chart-abstracted and eCQM data validation will be aligned over time. The FY 2023 payment determination will be a transition year. Instead of requiring that hospitals selected for data validation provide samples for four quarters (Q3 2020 – Q2 2021) for chart abstracted measures, these data must be provided only for Q3 and Q4 of 2020. For the FY 2024 payment determination, the data validation for chart-abstracted measures will require data submission for Q1-Q4 of 2021. No change is made to the quarters for data validation of the eCQMs; for these measures, hospitals provide data for a sample of charts for the self-selected calendar quarter of 2020 for which the hospital has elected to report the eCQMs.

(2) *Expand targeting criteria to include hospital selection for eCQMs.* The previously adopted separate data validation process for eCQMs will be eliminated beginning with the FY 2024 payment determination, and eCQMs will be incorporated into the data validation process established for chart-abstracted measures. A single pool of hospitals will be selected for validation, and a selected hospital will submit data for both chart-abstracted measures and eCQMs. The current criteria for targeted validation[44] will continue to apply. A hospital that has been granted an Extraordinary Circumstances Exception under the IQR Program could still be selected for validation under the targeting criteria.

(3) *Reduce validation pool from 800 to 400 hospitals.* Beginning with data validation for FY 2024 payment, the number of hospitals randomly selected for validation is reduced from the current 400 hospitals to up to 200 hospitals, and the number of hospitals selected for targeted validation will remain at 200, for a total of up to 400 hospitals. The 200-hospital random sample will also be used for validation of the NHSN HAI measures used for the HAC Reduction Program. (See section IV.M of this summary above.) The change from a fixed 400-hospital random sample to "up to 200" hospitals for IQR Program validation is made in recognition that although all hospitals are subject to the HAC Reduction Program, a small percentage do not participate in the IQR Program.

[44] The criteria target any hospital (1) with abnormal or conflicting data patterns (examples are offered in the final rule); (2) with rapidly changing data patterns defined as a hospital that improves its quality for one or more measure sets by more than 2 standard deviations from one year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$); (3) that submits data to NHSN after the Hospital IQR Program data submission deadline has passed; (4) that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated; (5) that has not been randomly selected for validation in any of the previous 3 years; (6) that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; or (7) that failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

(4) *Remove exclusions for eCQM validation selection.* Exclusion criteria that have applied for eCQM validation[45] will be removed beginning with validation affecting the FY 2024 payment determination. The combined validation pool of up to 200 hospitals for validation of chart-abstracted measures and eCQMs will be chosen without regard to these exclusion criteria. CMS notes that a hospital affected by an ECE may be unable to supply data regarding eCQMs but still supply data for validation of HAIs and chart-abstracted measures.

(5) *Require electronic file submissions for chart-abstracted measure validation data.* Beginning with data validation for the FY 2024 payment determination (Q1 2021 data submissions), hospitals submitting medical records for validation of IQR Program measures must submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. Hospitals may no longer submit the required records via paper copies, DVDs, CDs, or flash drives. CMS will reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

(6) *Align the eCQM and chart-abstracted data validation scoring processes.* The separate validation scoring for chart-abstracted measures and eCQMs will be combined into a single score. However, because eCQM validation does not currently assess the accuracy of the eCQMs reported by the hospital, the combined score will weight the chart-abstracted measure agreement rate at 100 percent. Hospitals will still be required provide at least 75 percent of the requested medical records for eCQM validation. Because under the final rule the number of eCQM validation cases will increase over time as more quarters of eCQM reporting are required, CMS anticipates that in the future it will propose increasing the weight of the eCQM validation score as more data permit calculation of a statistically robust validation score for eCQMs. This would be done through rulemaking.

(7) *Update the educational review process to address eCQM validation results.* The process established for chart-abstracted data validation under which a hospital may request an educational review if it believes it has been scored incorrectly or has questions about its validation results is adapted to include eCQM validation. A hospital will have 30 days after receiving eCQM validation results, which occurs annually, to contact the Validation Support Contractor and request a written review. This review will be provided to the requesting hospital through a CMS-approved secure file transmission process.

CMS clarifies that while there will be a single pool for selection of hospitals for data validation, the IQR Program and the HAC Reduction Program will continue to have separate processes for validating submitted data, scoring and applying any payment adjustment. That is, failing data validation for one program will not directly affect validation under the other program.

No changes are made to the number of cases that hospitals selected for data validation are required to submit. However, CMS notes that this final rule expands the number of quarters for which hospitals must report eCQMs under the IQR Program. As a result, hospitals selected for data validation must submit validation data for each quarter for which eCQM data were

[45] For eCQM data validation, CMS currently excludes any hospital that (1) has been selected for chart-abstracted measure validation; (2) has been granted an Extraordinary Circumstances Exception; or (3) does not have at least 5 discharges for at least one eCQM included in its QDRA I submissions.

submitted. For example, for validation of 2021 eCQM data affecting the FY 2024 payment determination, hospitals will report a total of 16 requested cases from 2 calendar quarters of data (8 cases x 2 quarters). This will increase to 32 requested cases (8 cases x 4 quarters) for validation of 2023 eCQM data affecting the FY 2026 payment determination and for subsequent years.

The table below, reproduced from the final rule, summarizes the finalized validation process.

| | Quarters of Data Required for Validation | Scoring |
|---|---|---|
| **Finalized Process for Validation Affecting the FY 2023 Payment Determination** | | |
| Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals | 3Q 2020<br>4Q 2020 | At least 75% validation score |
| eCQM Validation: Up to 200 Random Hospitals | 1Q 2020 - 4Q 2020 | Successful submission of at least 75% of requested medical records |
| **Finalized Process for Validation Affecting the FY 2024 Payment Determination and Subsequent Years** | | |
| COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals | 1Q 2021 - 4Q 2021 | Chart-abstracted Measures: At least 75% validation score (weighted at 100%)<br>And<br>eCQMs: Successful submission of at least 75% of requested medical records |

4. Public Display of eCQM Data

Hospital performance on eCQMs has not been publicly reported on *Hospital Compare.* Initially the measures were voluntary, and CMS stated that it needed time to assess the data and develop a strategy for public reporting. This has included development of the data validation process for eCQMs. Analysis of data validation for the 2017 and 2018 reporting periods included more than 1,200 patient records across 190 hospitals per reporting period. CMS found that hospitals successfully submitted the requested medical records within the required time period, and that agreement rates between the eCQM submissions and the CDAC review of medical records exceeded 80 percent. CMS now concludes that eCQM data are accurate enough to be publicly reported in the aggregate.

CMS finalizes that public reporting of eCQM data will begin with data reported in 2021 for the FY 2023 payment determination, with a clarification that these data will be posted in a downloadable data set on the *https://data.medicare.gov/* web page before publishing it on the *Hospital Compare* or successor website "sometime in the future." Initial public availability of these data in a downloadable data set will be made as early as the fall of 2022, and as more eCQM data are progressively reported CMS will additionally display the information on *Hospital Compare.* CMS notes that under its current policy for *Hospital Compare,* if a hospital has 25 or fewer eligible cases combined over a measure's reporting period, it will replace the data with a footnote indicating that the number of cases is too small to reliably determine a

hospital's performance. CMS further notes that there are no longer any eCQMs that have similar chart-abstracted measures for comparison.

Just as it does for other IQR Program measures, CMS plans to publish state and national rates for each eCQM with a sufficient level of hospital reporting to reliably calculate and display these data. CMS refers readers to the 2021 OPPS/ASC proposed rule regarding its proposals for the Overall Hospital Quality Star Ratings, which is based on IQR Program data posted on *Hospital Compare*. These proposals include peer grouping of hospitals in calculation of the ratings.

Along with other IQR Program measures, eCQM data will be available for hospitals to review during the 30-day preview period. Any updates to posting locations will be conveyed through routine communication channels to hospitals, vendors, and Quality Improvement Organizations. These include memos, emails, and notices on the QualityNet and eCQI Resource Center websites.

CMS disagrees with commenters requesting a delay in public display due to COVID-19 or to allow hospitals more time to prepare. It notes that 2021 is the fifth year for which hospitals will submit eCQM data, and that validation of data submitted for 2017 and 2018 supports public display. CMS continues to monitor the impact of the COVID-19 public health emergency may have on the national comparability of IQR Program measures, and notes that public reporting will begin with eCQM data for the 2021 reporting period. Because 97 percent of hospitals successfully reported eCQMs as required for 2018, CMS does not agree with the suggestion of some commenters that a dry run is needed before public reporting begins. As noted earlier, CMS has found that most eCQM data has a high agreement with chart review during validation.

5. Impact Analysis

In the Collection of Information Requirements section of the final rule, CMS estimates a total additional burden on hospitals resulting from the proposal to expand reporting quarters for eCQMs and the associated increase in quarters of eCQM validation of $253,480 across hospitals for the three-year period beginning with the FY 2023 payment determination.

In the Regulatory Impact Analysis section of the final rule, CMS estimates that for FY 2021, 37 hospitals will not receive the full market basket rate of increase for failure to meet the IQR Program requirements or choosing not to participate in the program, but are meaningful users under the Medicare Promoting Interoperability Program. Under the final rule, these hospitals will receive an update factor of 1.8 percent. Another 30 hospitals are estimated to receive a combined payment reduction of 2.4 percentage points, for an update of 0 percent, because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.

| **Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure** | | | | | |
|---|---|---|---|---|---|
| | **2020** | **2021** | **2022** | **2023** | **2024** |
| **Chart-Abstracted Process of Care Measures** | | | | | |
| Severe sepsis and septic shock: management bundle (NQF #500) | X | X | X | X | X |

| Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure | | | | | |
|---|---|---|---|---|---|
| | **2020** | **2021** | **2022** | **2023** | **2024** |
| PC-01 Elective delivery < 39 weeks gestation (NQF#0469) | X | X | X | X | X |
| ED-1 Time from ED arrival to departure for admitted patients (NQF#0495) | X | Removed | | | |
| ED-2 Time from admit decision to ED departure for admitted patients (NQF #0497) | X | X | Removed | | |
| IMM-2 Immunization for influenza (NQF #1659) | X | Removed | | | |
| VTE-6 Incidence of potentially preventable VTE | X | Removed | | | |
| **Electronic Clinical Quality Measures1** | | | | | |
| AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) (NQF #0163)<br>STK-2 Antithrombotic therapy for ischemic stroke (NQF #0435)<br>STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)<br>STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)<br>STK-6 Discharged on statin (NQF #0439)<br>STK-8 Stroke education<br>STK-10 Assessed for rehabilitation services (NQF #0441)<br>VTE-1 VTE prophylaxis (NQF #0371)<br>VTE-2 ICU VTE prophylaxis (NQF #0372)<br>ED-1 Time from ED arrival to departure for admitted patients (NQF#0495)<br>ED-2 Time from admit decision to ED departure for admitted patients (NQF #0497)<br>PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469)<br>PC-05 Exclusive breast milk feeding (NQF #0480)<br>EDHI-1a Hearing screening prior to discharge (NQF 1354)<br>CAC- 3 Children's asthma care – 3<br>Safe Use of Opioids – Concurrent Prescribing | Report 4 of the following 15 eCQMs:<br>AMI-8a<br>CAC-3<br>ED-1<br>ED-2<br>EHDI-1a<br>PC-01<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06<br>STK-08<br>STK-10<br>VTE-1<br>VTE-2 | Report 4 of the following 8 eCQMs:<br>ED-2<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06<br>VTE-1<br>VTE-2 | Report 4 of the following 9 eCQMs:<br>ED-2<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06<br>VTE-1<br>VTE-2<br>Safe use of Opioids | Report Safe use of Opioids and 3 of the following 8 eCQMs:<br>ED-2<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06<br>VTE-1<br>VTE-2 |
| **Healthcare-Associated Infection Measures** | | | | | |
| Central Line Associated Bloodstream Infection (CLABSI) | X | X | Removed | | |
| Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy | X | X | Removed | | |
| Catheter-Associated Urinary Tract Infection (CAUTI) | X | X | Removed | | |
| MRSA Bacteremia | X | X | Removed | | |
| Clostridium Difficile Infection (CDI) | X | X | Removed | | |
| Healthcare Personnel Influenza Vaccination (NQF #0431) | X | X | X | X | X |
| **Claims-Based Measures** | | | | | |
| **Mortality** | | | | | |
| Pneumonia 30-day mortality rate | X | Removed | | | |
| Stroke 30-day mortality rate | X | X | X | X | X |
| COPD 30-day mortality rate | X | Removed | | | |

| Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure | | | | | |
|---|---|---|---|---|---|
| | **2020** | **2021** | **2022** | **2023** | **2024** |
| CABG 30-day mortality rate | X | X | Removed | | |
| **Readmission/Coordination of Care** | | | | | |
| Hospital-wide all-cause unplanned readmission (NQF #1789) | X | X | X | X | X* |
| Hybrid (claims+EHR) hospital-wide readmission** | Voluntary | | | | |
| Excess days in acute care after hospitalization for AMI (NQF #2881) | X | X | X | X | X |
| Excess days in acute care after hospitalization for HF (NQF #2880) | X | X | X | X | X |
| Excess days in acute care after hospitalization for PN (NQF #2882) | X | X | X | X | X |
| **Patient Safety** | | | | | |
| PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351) | X | X | X | X | X |
| THA/TKA complications | X | X | X | Removed | |
| **Efficiency/Payment** | | | | | |
| AMI payment per 30-day episode of care (NQF #2431) | X | X | X | X | X |
| Heart Failure payment per 30-day episode of care (NQF # 2436) | X | X | X | X | X |
| Pneumonia payment per 30-day episode of care (NQF #2579) | X | X | X | X | X |
| THA/TKA payment per 30-day episode of care | X | X | X | X | X |
| **Patient Experience of Care** | | | | | |
| HCAHPS survey + 3-item Care Transition Measure (NQF #0166 and #0228) | X | X | X | X | X |
| *Beginning with the FY 2026 payment determination, this measure will be replaced by the Hybrid HWR measure.<br>**This measure will be mandatory beginning in FY 2026. Two more voluntary reporting periods will be held before that (July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023). | | | | | |

## B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in FY 2014 and follows many of the policies established for the Hospital IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program. Currently, there are 11 PPS-exempt cancer hospitals.[46] No policy has been adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS has previously indicated its intention to address the issue in future rulemaking. Five initial measures were previously adopted for FY 2022, as shown in a table below. Technical specifications for measures and other program information are available on the QualityNet.org website at https://qualitynet.org/pch/pchqr.

In this rule, CMS finalizes modifications to the CLABSI and CAUTI measures that adopt updated measure specifications from the CDC beginning with FY 2023. The revised measures

[46] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html.

were endorsed by the NQF in October 2019. The revisions employ a new risk adjustment methodology that calculates measure rates that are stratified by patient locations within hospitals, including oncology units. CMS believes that the stratified measures make them more representative of the quality of care within PCHs, and improve comparisons of performance, especially when PCHs compared with other acute care hospitals which already use the updated methodology.

Public display of the revised measures will begin in the fall of 2022 using data from 2021. Prior versions of the measures will not be displayed. Measures previously finalized for public display are shown in the table below.

In response to a comment, CMS notes that while the risk adjustment model for these measures does not include COVID-19, the Centers for Disease Control and Prevention is collecting an optional data element regarding a patient's concurrent COVID-19 infection, which could be used to indicate confirmed COVID-19 infection for patients with HAIs. However, COVID-19 status is not available for every patient with a CLABSI or CAUTI incident, which limits analytic opportunities.

Other PCHQR Program measures and policies will continue unchanged.

| **PCHQR Program Measures for 2022 and 2023** | |
|---|---|
| **Measure** | **Public Display Began** |
| **Safety and Healthcare Associated Infection** | |
| Colon/Abdominal Hysterectomy SSI (NQF #0753) | 2019 |
| NHSN CDI (NQF #1717) | 2019 |
| NHSN MRSA bacteremia (NQF #1716) | 2019 |
| NHSN Influenza vaccination coverage among health care personnel (NQF #0431) | 2019 |
| NHSN CLABSI (NQF #0139) | Deferred until 2022 |
| NHSN CAUTI (NQF #0138) | Deferred until 2022 |
| **Clinical Process/Oncology Care** | |
| Oncology: Plan of Care for Pain (NQF #0383) | 2016 |
| The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210) | |
| The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215) | |
| **Intermediate Clinical Outcomes** | |
| The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216) | |
| The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213) | |
| **Patient Experience of Care** | |
| HCAHPS (NQF #0166) | 2016 |
| **Claims-Based Outcomes** | |
| Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy | 2020 |
| 30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188) | |

| PCHQR Program Measures for 2022 and 2023 | |
|---|---|
| Surgical Treatment Complications for Localized Prostate Cancer | |

## C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP was first implemented in FY 2014, as required under section 1886(m) of the Act. Further developed in rulemaking, the LTCH QRP 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 must meet LTCH QRP patient assessment and quality data reporting requirements or be subject to a 2.0 percentage point update factor reduction. LTCHs submit data on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument to CMS using the Quality Improvement Evaluation System Assessment Submission and Processing (QIES ASAP) system.

No changes are made to the LTCH QRP in this rule. The table below displays the measures previously adopted for the LTCH QRP for FYs 2020 through 2022.

| LTCH QRP Measures, by Year | | | | |
|---|---|---|---|---|
| **Measure Title** | **FY 2019** | **FY 2020** | **FY 2021** | **FY 2022** |
| NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) | X | X | X | X |
| NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139) | X | X | X | X |
| Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) | X | Replaced | | |
| Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury | | X | X | X |
| Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) | X | X | Removed | |
| Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) | X | X | X | X |
| NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) | X | X | Removed | |
| NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717) | X | X | X | X |
| All-Cause Unplanned Readmissions for 30 Days Post Discharge from LTCHs (NQF #2512) | Removed | | | |
| Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) | X | X | X | X |
| Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) | X | X | X | X |
| 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 | X | X | X |
| Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) | X | X | X | X |

| LTCH QRP Measures, by Year | | | | |
|---|---|---|---|---|
| **Measure Title** | **FY 2019** | **FY 2020** | **FY 2021** | **FY 2022** |
| NHSN Ventilator Associated Event Outcome Measure | X | X | Removed | |
| Medicare spending per beneficiary MSPB-PAC LTCH | X | X | X | X |
| Discharge to Community PAC LTCH* | X | X | X | X |
| Potentially Preventable Readmissions 30 Days Post LTCH Discharge | X | X | X | X |
| Drug Regimen Review Conducted with Follow-up | | X | X | X |
| Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay | | X | X | X |
| Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate | | X | X | X |
| Transfer of Health Information to the Provider – PAC Measure | | | | X |
| Transfer of Health Information to the Patient – PAC Measure | | | | X |
| * Measure updated to remove baseline nursing facility patients beginning in FY 2020. | | | | |

## D. Medicare and Medicaid Promoting Interoperability Program

A hospital that is not identified as a meaningful user of CEHRT under the Medicare Promoting Interoperability Program is subject to an update factor reduction equal to three quarters of the market basket. In the impact analysis section of this final rule, 153 hospitals are estimated to fail to meet the meaningful use requirements for FY 2021 payment and will receive an update factor of 0.6 percent. An additional 30 hospitals are estimated to fail both the meaningful use and IQR Program requirements and under the final rule will receive an update factor of 0.0 percent.

1. Reporting Periods in 2022

A continuous 90-day reporting period was previously adopted for the Medicare and Medicaid Promoting Interoperability Program in 2021 for new and returning participants. CMS finalizes an extension of the continuous 90-day reporting period for the Medicare Promoting Interoperability Program EHR in 2022. It reminds readers that under the statute, the Medicaid Promoting Interoperability Program will end in 2021. Reporting periods for these programs are codified in the definition of *EHR reporting period* at §495.4.

2. Query of Prescription Drug Monitoring Program (PDMP) Measure

CMS discusses the history of the PDMP measure, which in past rulemaking was added as an optional measure for EHR reporting periods in 2019 and 2020 and finalized to be a mandatory measure for FY 2021. Hospitals electing to report this measure report "yes" if for least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

In this rule, CMS finalizes a change that continues the Query of PDMP measure as a voluntary measure for EHR reporting periods in 2021, worth 5 bonus points. In light of the variation in how providers interact with PDMPs, CMS now agrees with stakeholders that it would be

burdensome to require this measure in 2021 reporting and that more time is needed before the measure is made mandatory for performance-based scoring. PDMPs themselves are still maturing, and they are not yet consistently integrated into EHR workflow. CMS notes that a recent assessment of PDMPs by the Office of the National Coordinator for Health Information Technology (ONC) found that one-third of hospitals reported integration of PDMP queries into the EHR workflow.[47] Further, the SUPPORT for Patients and Communities Act of 2018 (P.L 115-271) included new federal funding and requirements for PDMPs, and mandated use of PDMPs by certain Medicaid providers. CMS also describes other federal efforts underway to develop a standardized approach to integration of PDMPs and EHRs, involving CMS, CDC, ONC and private sector stakeholders.

3. Change in Measure Name

CMS changes the name of the Health Information Exchange Objective measure "Support Electronic Referral Loops by Receiving and Incorporating Health Information" to "Support Electronic Referral Loops by Receiving and Reconciling Health Information."

4. Scoring the Medicare Promoting Interoperability Program for EHR Reporting Periods in 2021

To be considered a meaningful user an eligible hospital or CAH must meet all of the following requirements:

- Report on all the required measures across all four objectives, unless an exclusion applies*
- Report "yes" on all required yes/no measures, unless an exclusion applies*
- Attest to completing the actions included in the Security Risk Analysis measure*
- Achieve a total score of at least 50 points.

*Failure on this requirement results in a total score of zero.

Taking into account the changes finalized in this rule, the scoring methodology for 2021 is shown in the following table.

**Performance-Based Scoring Methodology for EHR Reporting Periods in 2021**

| Objective | Measures | Maximum Points |
|---|---|---|
| e-Prescribing | e-Prescribing | 10 points |
| | *Bonus:* Query of Prescription Drug Monitoring Program (PDMP) | 5 points (bonus) |
| Health Information Exchange | Support Electronic Referral Loops by Sending Health Information | 20 points |
| | Support Electronic Referral Loops by Receiving and Reconciling Health Information | 20 points |
| Provider to Patient Exchange | Provide Patients Electronic Access to Their Health Information | 40 points |

[47] CMS refers readers to https://www.healthit.gov/buzz-blog/health-it/new-data-show-nearly-one-third-of-hospitals-can-access-pdmp-data-within-their-ehr

| Objective | Measures | Maximum Points |
|---|---|---|
| Public Health and Clinical Data Exchange | Choose any two of the following:<br>Syndromic Surveillance Reporting<br>Immunization Registry Reporting<br>Electronic Case Reporting<br>Public Health Registry Reporting<br>Clinical Data Registry Reporting<br>Electronic Reportable Laboratory Result Reporting | 10 points |

5. eCQM Reporting Periods and Criteria for 2021, 2022 and 2023

As part of being a meaningful user under the Medicare and Medicaid Promoting Interoperability Programs, eligible hospitals and CAHs must report on eCQMs selected by CMS. For the 2021 reporting period eligible hospitals and CAHs must report on four of the available eCQMs for one self-selected quarter of data during the calendar year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program. The 8 eCQMs available for 2021 reporting are:

- STK-2 Discharged on antithrombotic therapy for ischemic stroke (NQF #0435)
- STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)
- STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)
- STK-6 Discharged on statin (NQF #0439)
- VTE-1 Venous thromboembolism (VTE) prophylaxis (NQF #0371)
- VTE-2 ICU VTE prophylaxis (NQF #0372)
- ED-2 Median time from admit decision to ED departure for admitted patients (NQF #0497)
- PC-05 Exclusive breast milk feeding (NQF #0480)
- Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e).

The Safe Use of Opioids measure was also finalized as a mandatory measure beginning with the 2022 reporting period. At that time, eligible hospitals and CAHs must report that measure and three others selected from among the eight.

In this rule, CMS finalizes a change to progressively increase the number of quarters for which a hospital must report eCQM data under the Promoting Interoperability Programs over a 3-year period. A parallel change is adopted for eCQM reporting for the IQR Program, as discussed in section VIII.A.1 above. Currently, for the four eCQMs that it reports, an eligible hospital or CAH must submit one self-selected quarter of data. Under the final rule, this requirement is progressively increased to four quarters of data as follows:

- For 2021 reporting an eligible hospital or CAH must report data for 2 self-selected calendar quarters
- For 2022 reporting an eligible hospital or CAH must report data for 3 self-selected calendar quarters
- For 2023 reporting and subsequent years, an eligible hospital or CAH must report data for all 4 calendar quarters.

Additionally, CMS finalizes that the data submission period will continue to be the 2 months following the end of the respective calendar year. For example, for the 2021 reporting period/FY 2023 payment determination, the deadline is February 28, 2022. Hospitals will continue to self-select which quarters are reported, which may include non-consecutive quarters, until all four quarters are required.

The response to comments parallels that in section VIII.A.1 with respect to the same provision of the IQR Program. This includes response to comments suggesting a delay until after the COVID-19 public health emergency. Specific to the Promoting Interoperability Program, the March 2020 guidance on Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals extended the respective deadlines for submission of hardship extension requests by eligible hospitals and CAHs.

6. Public Reporting of eCQMs

Consistent with the IQR Program policy discussed in section VIII.A.4 above, CMS finalizes that eCQM data will be publicly reported. Specifically, public reporting will begin with the eCQM data reported by hospitals in 2021 for the FY 2023 payment determination. CMS clarifies that these data will be made available in a downloadable database on the *https://data.medicare.gov/* web page as early as the fall of 2022. As more eCQM data are reported it will post hospital performance on *Hospital Compare* or its successor website. Along with other IQR Program measures, eCQM data will be available for hospitals to review during the 30-day preview period. Response to public comments parallels that with respect to the IQR Program eCQM reporting that is summarized above.

7. Technical Corrections to Regulatory Text

CMS makes several technical corrections to regulatory text. Of note, it corrects the transition factors for Puerto Rico hospitals whose first payment year under the program is 2018, at §495.104(c)(5)(viii) so that all four years of the transition are referenced.

8. Future Direction of the Medicare Promoting Interoperability Program

In the proposed rule, CMS sought comment on the future direction of the Medicare Promoting Interoperability Program. CMS indicated that it will continue to consider changes to the program for future years to support goals including reducing administrative burden, supporting alignment with the Quality Payment Program and the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT.

In particular, CMS will consider potential areas of overlap with the 21st Century Cures Act final rule (85 FR 25642), including information blocking, transitioning from the Common Clinical Data Set (CCDS) to the United States Core Data for Interoperability (USCDI), finalization of a new certification criterion for a standards-based Application Programming Interface, and other updates to 2015 Edition certification criteria and the ONC Health Information Technology Certification Program.

Comments it received will be considered for future policy making. CMS refers readers to the PFS proposed rule (85 FR 50265) which provides an opportunity to comment on its proposal to align the Promoting Interoperability Program with updates to the 2015 Edition certification criteria finalized in the Office of the National Coordinator's final rule implementing the 21st Century Cures Act.

## IX. Changes for Hospitals and Other Providers

### A. Submission of Electronic Patient Records to Quality Improvement Organizations

1. Background

A Quality Improvement Organization (QIO) is an organization comprised of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare. Current law authorizes QIOs to have access to the records of providers, suppliers, and practitioners under Medicare in order to perform their functions. Providers and practitioners are required to provide patient care data and other pertinent data to the QIO when the QIO is collecting review information. CMS proposed to make electronic submission the default method of submission, mandating all providers and practitioners who provide patient records to the QIO to submit them in electronic format unless they have an approved waiver.

2. Proposed Changes

CMS proposed:

- To define "patient record" as all patient care data and other pertinent data or information (whether or not part of the medical record) relating to care or services provided to an individual patient, in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.
- Patient records must be delivered in electronic format, unless a QIO approves a waiver. Initial waiver requests by those providers that are required to execute a written agreement with the QIO would be expected to be made at the time of the written agreement although the waiver could be requested later if necessary. Other providers and practitioners who are not required to execute a written agreement with a QIO would request a waiver by giving the QIO notice of their lack of capability to submit patient records in electronic format.
- Establish reimbursement rates of $3.00 per patient record that is submitted to the QIO in electronic format and $0.15 per page for requested patient records submitted by facsimile or by photocopying and mailing (plus the cost of first-class postage for mailed photocopies), after a waiver is approved by the QIO. Only one reimbursement would be provided by the QIO for each patient record submitted, per request, even if a particular patient record is submitted to the QIO using multiple different formats, in fragments, or more than once in response to a particular request.

These proposed changes would be applicable to all providers and practitioners providing patient records to QIOs for purpose of QIO reviews. CMS proposed a number of regulatory changes to ensure that reimbursement is permitted for all healthcare providers and practitioners,

on the same basis and at the same rates. It is further streamlining all of the regulations related to submission and payment for providing medical records to be in the same section of the regulations.

CMS proposed to remove a step-by-step analysis of how the cost of photocopying was calculated from the regulations. That same step-by-step analysis for the updated rate is included in the preamble to the regulations and is also furnished for the $3.00 electronic record fee and $0.15 facsimile fee.

These fees were determined by using the annual salary and fringe benefits cost of a GS-5, step 5 medical records clerk ($53,918 per year or $26 per hour) in combination with assumptions about productivity and workload for electronic patient records plus the additional costs of a photocopier and supplies for photocopied records and a telephone for facsimile records.

CMS estimates these policies will save $71.8 million over 5 years; $37.6 million from reimbursement for sending patient records via facsimile, photocopying and mailing and $34.2 million from payment to QIOs to cover the cost of scanning and uploading paper-based patient records.

*Comments/Responses*: One commenter indicated that CMS should eliminate reimbursement for patient records submitted by photocopying, mailing and facsimile and only pay for electronic submission of patient records to encourage modernization. CMS disagreed saying that up to 20 percent of providers may lack the capacity to submit patient records in electronic format. There were no other comments. CMS is finalizing all of the above proposals without modification.

**B. Mandatory Provider Review Reimbursement Board (PRRB) Electronic Filing**

1. Background

The PRRB is an independent board for resolving payment disputes typically arising from certain Medicare Part A final determinations (usually cost report audit appeals). Staff support is provided to the PRRB by CMS' Office of Hearings (OH). On August 16, 2018, the OH and the Board released the OH Case and Document Management System (OH CDMS)—a web-based portal where providers can file appeals and the PRRB can release outgoing electronic correspondence and Board decisions with immediate system notification of an action. This system is already in use by all MACs and many others that have appeals before the PRRB.

2. Technical Changes to Support Electronic Filing

The OH proposed technical changes to the regulations consistent with use of the OH CDMS electronic system:

- Update the definitions of "date of receipt" and "reviewing entity" to indicate that submissions to an electronic filing system are considered received on the date of electronic delivery.
- "In writing or written" means hard copy or electronic submission. (Date of receipt by a party

or affected nonparty continues to be presumed to be 5 days after the date of issuance).

- Technical changes are made throughout to apply terms to both hard copy and electronic submissions.
- Update provisions related to subpoenas, so that it generally conforms to other technical changes being proposed except for adding "If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena must be sent by certified mail" in accordance with section 205(d) of the Act.

3. Intention to Revise Board Instructions to Require Mandatory Electronic Submissions

No earlier than FY 2021, the PRRB may require that all new submissions be filed electronically using OH CDMS. Stakeholders can access the Electronic Filing webpage located at: https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Electronic-Filing. The OH recommends that parties to PRRB appeals, who have not already done so, sign up for and begin using OH CDMS as soon as possible to allow time to become familiar with the system and avoid any issues that may arise if signing up for the system is delayed until after use of the system becomes mandatory.

*Comments/Responses*: Public comments were largely positive to these proposals although there were a number of comments addressing specific issues:

Schedule of Providers (SOP). A few commenters stated that SOPs for group appeals should be accepted in PDF format like every other document filed in PDF format via OH CDMS. CMS will consider this comment for future OH CDMS instructions.

System Downtime. A few commenters stated that there should be an exception to mandatory electronic filing if a user is unable to access OH CDMS for a filing deadline due to system downtime. CMS responded that this issue is not significantly different from those associated with hard copy filings where the regulations already provide allowances if a reviewing entity is unable to conduct business in the usual manner.

Single System Representative. One commenter expressed concern about what happens if its single system representative is no longer employed. CMS responded that it is the responsibility of the provider and/or representative to notify the PRRB to maintain updated information for a system representative.

Batch Uploads. Appeals that involve a large number of providers must be entered individually rather than as a group. The commenter requested the ability to do batch uploads to make electronic filing more appealing than paper filing. OH CDMS does not have this functionality yet but CMS will consider it as it upgrades the system.

Mandating Electronic Filing: Some commenters asked that mandatory electronic filing not be required and, if it will be required, hospitals be given more than 60 days advanced notice. CMS believes it is reasonable to require electronic appeals further noting the system has been available for close to two years. Nevertheless, CMS will provide at least 120 days notice prior to requiring electronic reporting.

Duplicate Appeals. One commenter stated that OH CDMS requires users to conclusively state that the appeal issues are not pending in any other appeal, but a user can never know with absolute certainty whether another party has mistakenly filed an appeal on a duplicate issue. CMS responded that it is reasonable to expect a provider or its representative to know of any appeals that have been filed.

Security Concerns: One commenter expressed concern about requiring applicants to provide their Social Security number for a limited credit check. CMS outlined how OH CDMS is part of a larger enterprise identity management system ("EIDM") that authenticates individual users of many CMS data systems. There is a system-wide EIDM security.

Presume Date of Receipt: Several commenters suggested that CMS revise the regulatory definition of "date of receipt" so that the 5-day presumption of receipt does not apply to PRRB decisions or other documents issued electronically to providers. All parties to an appeal are notified of the decision instantaneously. CMS responded that it did not propose any changes to "date of receipt." It further indicated that the present regulatory text continues to serve its original purposes of avoiding any problem of verifying when a document or other material is actually received to begin a review period.

**C. Medicare Bad Debt Policy**

1. Background

Under the Medicare program, beneficiaries may be responsible for payment of premiums, copayments, deductibles, and coinsurance amounts that are related to covered services. In accordance with section 1861(v)(1) of the Act and regulations at §413.89, Medicare pays some of the uncollectible deductible and coinsurance amounts to certain providers, suppliers and other entities eligible to receive reimbursement for bad debt of Medicare beneficiaries. To be an allowable Medicare bad debt, the debt must meet all of the following criteria (see §413.89(e) and Provider Reimbursement Manual (PRM), Chapter 3, Section 308):

- The debt must be related to covered services and derived from deductible and coinsurance amounts.
- The provider must be able to establish that reasonable collection efforts were made.
- The debt was actually uncollectible when claimed as worthless.
- Sound business judgment established that there was no likelihood of recovery at any time in the future.

Statute prohibited the Secretary from making changes to Medicare bad debt policies on August 1, 1987 for hospitals in effect. This moratorium ended for cost reporting periods beginning on or after October 1, 2012. CMS is using the FY 2021 IPPS rule to clarify certain Medicare bad debt policies that have been the subject of litigation, and generated interest and questions from stakeholders over the past several years. Additionally, CMS will recognize the new Accounting Standards Update (ASU) – Topic 606 for revenue recognition and classification of Medicare bad debts and make technical corrections to the regulations.

CMS proposed to make many of these changes effective retroactively under the authority of section 1871(e)(1)(A)(ii) of the Act that allows retroactive rulemaking when the alternative is contrary to the public interest. The proposed rule explained why it would be in the public interest for these policies to apply retroactively. In other circumstances, CMS proposed prospective changes to the regulations effective for cost reporting periods beginning on or after October 1, 2020.

2. Proposed Revisions to Regulations

a. Reasonable Collection Efforts. CMS proposed significant revisions to §413.89(e)(2). Currently, this section of the regulation only states that "the provider must be able to establish that reasonable collection efforts were made." More detailed requirements were in the PRM. Below is a list of items CMS proposed be added to this section of the regulation:

*Non-Indigent Beneficiaries*. Reasonable collection efforts are only required from non-indigent beneficiaries. CMS proposed to add §413.89(e)(2)(i) that states: "A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes." The preamble indicates this policy is not new and has existed since the promulgation of Medicare bad debt policy.

*Comment/Response*: Some commenters were supportive of the proposal to codify the definition of a non-indigent beneficiary because it would provide clarity to Medicare bad debt policies. Other commenters suggested the definition should not be applied retroactively. CMS indicated that retroactive codification of the definition of a non-indigent beneficiary serves to promote a public interest of providing clarity because the definition has existed inherently in the longstanding bad debt collection effort policies that applied, and continue to apply, to a non-indigent beneficiary. Prospective application would create more confusion in that it would suggest a change in CMS policy and the potential for providers to resubmit past cost reports. CMS is finalizing this policy as proposed.

*Issuance of a Bill*. CMS proposed to codify requirements currently in the PRM into §413.89(e)(2) including the following:

- The collection effort must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.
- For cost reporting periods beginning before October 1, 2020, the effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.
- For cost reporting periods beginning on or after October 1, 2020, the effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:
    - The date of the Medicare remittance advice.
    - The date of the remittance advice from the beneficiary's secondary payer, if any.

- The collection effort must also include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort.

CMS proposed to make all of the above requirements effective retroactively except for the provisions that have an effective date of cost reporting periods beginning on or after October 1, 2020. For the regulations that have retroactive effect, the rule indicates the policies are long-standing from the PRM that are being codified in regulation.

The provisions effective on or after October 1, 2020 are intended to give more precise meaning to the term "shortly after." For cost reporting periods beginning prior to October 1, 2020, providers are only required to issue a bill "shortly after discharge or the death of the beneficiary." For cost reporting periods beginning on or after October 1, 2020, the requirement is to issue a bill on or before 120 days after the latter of the date of the Medicare remittance advice or the date of remittance advice from the beneficiary's secondary payer, if any.

*Comments/Responses*: Commenters were supportive of CMS' proposal and also requested that the proposed timeframe within which to issue a bill to the beneficiary also include a third circumstance of the date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary. CMS agreed and is modifying its final rule policy to consistent with this comment.

A few commenters requested that CMS further define "personal contacts" with beneficiaries to collect the unpaid deductibles and coinsurance amounts, and whether personal contacts can include communication methods such as email and text message. CMS responded that the definition of a "personal contact" means an encounter where two or more people are in visual or physical proximity to each other or a face-to-face encounter. It did not address whether "personal contacts" can include email and text messages.

Final Decision: CMS is finalizing the above policy as proposed with a modification to indicate that for cost reporting periods beginning on or after October 1, 2020, reasonable collection effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following: 1) the date of the Medicare remittance advice; 2) the date of the remittance advice from the beneficiary's secondary payer, if any; or 3) the date of the notification that the beneficiary's secondary payer does not cover the service(s) furnished to the beneficiary

*120-day Collection Effort and Reporting Period for Writing Off Bad Debts*. CMS is making two changes in this section of the rule. First, CMS is adding a requirement to §413.89(e)(2) that a bill cannot be considered uncollectible until at least 120 days have passed since the provider first attempted to receive payment. If the provider receives partial payment, the 120-day period restarts. This policy will be effective retroactively as CMS states that it merely codifies in regulation what was an established policy in the PRM. CMS indicates that the requirement to restart the 120 days upon receiving a partial payment is a clarification of a policy CMS established in response to inquiries.

Second, CMS is revising an existing provision of the regulations (§413.89(f)) to clarify that any payment on the account made by the beneficiary, or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report. If the collection is made in a cost reporting period after the debt has been written off as uncollectible, the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered. However, the amount of such reduction in the period of recovery must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period. CMS proposes to make this policy effective retroactively.

*Comments/Responses*: While some commenters were supportive of the proposal, other commenters objected to the policy as unnecessarily requiring hospitals to keep their accounts receivable open for longer periods of time. Commenters were not supportive of a retroactive effective date for the codification of this provision as they believed providers would be confused by the applicability of the policy for various cost reporting periods.

CMS responded that its longstanding position, asserted in court cases and legal documents over the years, is that if the provider continues to receive money, then the account is not a worthless account without value. This longstanding bad debt policy has existed in Medicare guidance, including the PRM, for decades. Giving the regulatory provision retroactive effect does not affect prior transactions or impose additional duties or adverse consequences upon providers or beneficiaries, nor does it diminish rights of providers or beneficiaries. CMS is finalizing its policy as proposed.

*Similar Collection Effort and Collection Agency Fees*. As indicated above, CMS proposed to modify §413.89(e)(2) to add the following provision: The collection effort must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.

This proposed provision of the regulation codifies an existing provision of the PRM. CMS clarifies confusion over how this policy has been understood. Similar collection efforts mean that the provider must take the same actions to collect Medicare and non-Medicare debts alike. For example, if a provider elects to refer its non-Medicare accounts to a collection agency, the provider must similarly refer Medicare accounts of "like amount" without regard to class of patient.

The collection agency's effort to collect the debt must also be similar between Medicare and non-Medicare patients. This means that for comparable amounts, the collection agency must use similar collection practices for both accounts. The effort must constitute a genuine, rather than a token, collection effort. Collection accounts that remain at a collection agency cannot be claimed by the provider as a Medicare bad debt. Further, a fee charged by a collection agency can be considered an allowable administrative expense but cannot be written off to bad debt. CMS proposed to make this policy effective retroactively.

*Comments/Responses* Some commenters suggested that accounts at a collection agency have little to no value and providers simply place them with collection agencies for the small possibility of a collection. Other commenters suggested that if a payment were to be made on an

account while at a collection agency, providers could reconcile the amount paid and record it as a recovery on the provider's subsequently submitted cost report.

CMS responded that it has been its longstanding policy that an account that remains at a collection agency remains in a collection effort status, and thus cannot be claimed as a Medicare bad debt.

Some commenters suggested that further definitions be set forth for what constitutes a genuine, and not a token collection effort. CMS responded that a genuine, rather than a token, collection effort has been addressed in PRM §310 as "also including… subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort." As CMS has asserted in the past in policy statements and proceedings, a genuine collection effort requires the provider to engage in prompt and continuous collection efforts, over at least 120 days, advising the beneficiary of the amounts to be collected, engaging in subsequent follow up and billing, and may include the provider engaging a collection agency.

CMS is finalizing this policy as proposed.

*Documentation of Reasonable Collection Efforts*. CMS proposed to add §413.89(e)(2)(A)(i)(6) to codify long-standing provisions of the PRM related to documentation of reasonable collection efforts.

The provider must maintain and, upon request, furnish to the Medicare contractor documentation of the provider's collection effort, whether the provider performs the collection effort in house or whether the provider uses a collection agency to perform the required collection effort on the provider's behalf. The documentation of the collection effort must include: the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the patient account history documents which show the dates of various collection actions such as the issuance of bills, follow-up collection letters, reports of telephone calls and personal contact, etc. CMS proposed to make this policy effective retroactively.

*Comments/Responses*: Commenters disagreed with setting forth documentation requirements in regulation suggesting the need for flexibility makes these issues more appropriate for sub-regulatory guidance. CMS cited other provisions of regulations that provide documentation requirements but indicated the provisions are sufficiently general to allow for needed flexibility. CMS is finalizing this policy as proposed.

b. Determining Indigency. For beneficiaries that are not Medicaid eligible, CMS indicates that the PRM requires that the beneficiary's total resources be considered when a provider evaluates a beneficiary's indigence. CMS propose new paragraph (e)(2)(ii)(A) that provides for determining indigence for beneficiaries that are not Medicaid eligible as follows:

1. The beneficiary's indigence must be determined by the provider, not the beneficiary;
2. The provider must take into account a beneficiary's total resources which include, but are not limited to, an analysis of assets (only convertible to cash and unnecessary for the

beneficiary's daily living), liabilities, and income and expenses. The provider may consider any extenuating circumstances that would affect the determination of the beneficiary's indigence; and

3. The provider must determine that no source other than the beneficiary (for example, a legal guardian) would be legally responsible for the beneficiary's medical bill.

CMS proposed to make this policy effective retroactively.

*Comments/Responses*: Like for other issues, there were objections to retroactive application of these policies with commenters indicating that the PRM guidance was suggestive and not mandatory. CMS responded that its longstanding policy has been that PRM guidelines require a provider to take into account the beneficiary's total resources to include the consideration of a beneficiary's assets, income, liabilities and expenses and CMS is merely codifying longstanding policy. Comments were in the following areas:

Evaluation of Liabilities and Expenses: Many commenters suggested that only a patient's income be considered when determining whether a patient is indigent and also suggested that an evaluation of a patient's assets, liability and expenses requires additional resources and burden to the provider. CMS agrees that liabilities and expenses do not need to be reviewed once a patient is qualified as indigent based upon income and assets. However, CMS believes that assets must continue to be considered when they are convertible to cash, unnecessary for the beneficiary's daily living and can be used for the beneficiary's medical cost sharing expenses. If a beneficiary does not qualify for indigence based in income and assets, a further review of liabilities and expenses continues to be necessary to qualify a beneficiary's indigence.

Presumptive Eligibility Tools. Some commenters suggested that providers be permitted to use presumptive eligibility tools—such as those used to qualify patients for federal, state and local uncompensated care or charity care programs—to qualify Medicare beneficiaries for indigence determinations for Medicare bad debt purposes. CMS disagreed saying that many presumptive eligibility tools cursorily review a patient's financial status, based either on the patient's declaration or demographic presumptions, or income and presume one to be indigent.

Conflict with Other Indigence Programs. Commenters asserted that the proposal to codify the Medicare bad debt indigence evaluation criteria contradicts terms of indigence policies from other programs. These programs do not permit providers to inquire about a patient's assets, liabilities, or expenses, and therefore a provider's compliance with Medicare bad debt indigence policy would adversely cause providers to be non-compliant with other indigent policies. CMS distinguished other programs from Medicare's bad debt policy as other programs may pay beneficiaries directly while the bad debt program compensates providers for bad debts of its patients. Medicare's rules are relevant to this particular purpose while a determination of indigence for another program may have different purposes and program criteria.

Improvements in Beneficiary's Financial Position. Some commenters objected to having to conclude "that there has been no improvement in the beneficiary's financial status" once indigence is determined as a vague and burdensome requirement. CMS agreed with these comments and indicated that flexibility should be afforded to providers to not being continually

required to review a beneficiary's financial condition once indigence is determined. If a provider discovers that the beneficiary's financial condition has improved following the provider's determination of indigence, CMS expects the provider will no longer classify the beneficiary as indigent and implement reasonable collection efforts for the nonindigent beneficiary.

Final Action: CMS is finalizing its proposal with two modifications:

1. If indigence can be determined based solely on income and assets, no review of expenses and liabilities will be necessary although extenuating circumstances and expenses and liabilities may be reviewed if indigence is not established based on a review of income and assets; and
2. Monitoring for a change in a patient's financial status once indigence is determined will not be required although if the provider becomes aware of a change in financial circumstances, it must take that into account when determining indigence.

CMS is also requiring that the provider must maintain and, upon request, furnish its Medicare contractor with the provider's indigence determination policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence.

CMS will evaluate burden estimates for the recordkeeping requirements if they are not already accounted for the existing Paperwork Reduction Act approvals. As CMS changed its final rule policies based on public comment, it is finalizing these policies with an effective date for cost reporting periods beginning on or after October 1, 2020.

c. Dual Eligible Beneficiaries. Dual eligible beneficiaries are Medicare beneficiaries who are enrolled in Medicare (either Part A, Part B, or both), and are also enrolled in "full Medicaid" coverage and/or the Medicare Savings Program. Some of these dual eligible beneficiaries have full Medicaid coverage while others have partial Medicaid coverage where Medicaid may pay some or all of the beneficiary's Medicare cost sharing. The proposed rule provided a detailed discussion of these partial Medicaid programs as well as complex issues where Medicaid may not provide information on whether it has an obligation to pay for a Medicare beneficiary's liability because a provider is not enrolled in Medicaid or for other reasons.

To satisfy the reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether Medicaid (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. A provider satisfies this requirement by:

1. Billing the state Medicaid program to determine that no source other than the patient would be legally responsible for the patient's medical bill; for example, Title XIX, local welfare agency and guardian (the "must bill requirement"); and
2. Obtaining and submitting to the MAC, a Medicaid remittance advice (RA) from the state Medicaid program (the "RA requirement"). If a provider does not bill the state and submit the Medicaid RA to Medicare with its claim for bad debt reimbursement for dual eligible

beneficiaries, the result is that unpaid deductible and coinsurance amounts cannot be included as an allowable Medicare bad debt.

CMS proposed to codify this policy in §413.89(e)(2). Any amount that the state is obligated to pay, either by statute or under the terms of its approved Medicaid state plan, will not be included as an allowable Medicare bad debt, regardless of whether the state actually pays its obligated amount to the provider or provides the Medicaid RA indicating that it has no obligation to pay. However, the Medicare deductible and/or coinsurance amount, or any portion thereof that the state is not obligated to pay, can be included as an allowable Medicare bad debt. Unpaid deductible and coinsurance without collection effort documentation will not be considered as allowable bad debts. CMS proposed to make this policy effective retroactively.

CMS acknowledges that challenges exist for providers when states do not comply with the federal statutory requirements and suggests potential alternatives to the "must bill" policy and Medicaid RA that it could adopt in the final rule. CMS welcomed suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA and whether it should or could adopt such a policy effective for past cost reporting periods. Doing so would serve an important public interest by allowing providers with cases currently pending before the PRRB an avenue for timely and cost-effective resolution.

*Comments/Responses*: Like for other issues, there were objections to retroactive application of these policies with commenters indicating in this case that CMS' retroactive application lacks statutory authority and violates the bad debt moratorium. CMS disagreed and its response indicated that these or similar policies relevant to the time period under consideration were in place prior to the bad debt moratorium. Further, CMS provided citations to a number of court precedents that it believes directly upheld these policies (and one that prohibited CMS from liberalizing the policy during the moratorium) or supports retroactive application. As with other bad debt policies being codified, CMS indicates that these policies will reduce confusion rather than increase it by making past and current policy clearer. Other comments were on:

Must Bill Policy. Some commenters asserted that the must bill policy does not serve an important interest because states pay little, if anything, toward a dual eligible beneficiary's Medicare cost sharing. Some commenters noted that the crossover billing process sometimes fails for other various reasons. CMS disagreed reiterating that it believes the best documentation to evidence states' cost sharing liability for a dual eligible beneficiary is the Medicaid RA. If the Medicare crossover billing fails or is not completed in certain instances, the provider has the opportunity to work with its contractor to identify and resolve the issue.

Alternate Documentation to the RA not Furnished by the State. Commenters were disappointed CMS did not propose specific alternate documentation to the Medicaid RA. Commenters suggested some specific alternatives CMS could use as documentation of Medicaid's lack of payment obligation for Medicare coinsurance and deductibles.

CMS responded that alternate documentation must contain all of the following:

1. The state Medicaid notification that the state has no obligation to pay the beneficiary's Medicare cost sharing or notification evidencing the provider's inability to enroll in Medicaid for purposes of processing a crossover cost sharing claim;
2. Documentation setting forth the state's liability, or lack thereof, for the Medicare cost sharing; and
3. Documentation verifying the beneficiary's eligibility for Medicaid for the date of service.

For #1 above, the inability to enroll must be through no fault or deficiency of the provider. Sufficient evidence of this requirement would be documentation showing that the state Medicaid agency does not recognize the provider as a Medicaid provider type for purposes of processing a Medicare crossover cost sharing claim. In some states it may be difficult to supply evidence that the state will not enroll a specific provider type. In these circumstances, Medicare contractors will afford providers flexibility in producing acceptable evidence. CMS encourages states to consider separate enrollment pathways for Medicare providers that seek to enroll in Medicaid solely for the purposes of processing Medicare crossover claims for dually eligible beneficiaries.

For #2 above, documentation setting forth the state's lack of liability for the Medicare cost sharing can be produced by the provider, in part, from the state plan documents and may also include other documents such as state and state contractor fee schedules or payment rates, or other documents the provider produces that can be verified by the contractor. Medicare contractors will afford providers flexibility in producing documentation acceptable to evidence the state's Medicare cost sharing in the absence of a Medicaid RA.

For #3 above, documentation verifying the beneficiary's eligibility for Medicaid for the date of service could take the form of an eligibility report from a state's eligibility verification system. Medicare contractors will afford providers flexibility in producing acceptable evidence of the beneficiary's eligibility for Medicaid for the date of service.

CMS will work with the providers, states, and Medicare contractors on guidelines for acceptable alternative documentation to the Medicaid RA.

Final Action. CMS is finalizing its "must bill" policy and use of the Medicaid RA as documentation of the state's lack of obligation to pay Medicare beneficiary cost sharing. If this information is not available from the state, CMS is codifying the use of alternate documentation as outlined above. CMS is making all of these policies retroactive and will continue to evaluate alternative Medicaid RA documentation policy so that any policy refinements can be addressed in future rulemaking, if needed. Medicare contractors are being instructed to work with providers to resolve cases pending before the PRRB so that providers may experience relief and burden reduction through the application of this rule to their existing cases.

d. Accounting Standard Update Topic 606 and Accounting for Medicare Bad Debt

(1) Accounting Standard Update (ASU) Topic 606.

The Financial Accounting Standards Board's (FASB) ASU 2014-09, Revenue from Contracts with Customers (Topic 606), was published in May 2014 with the first implementation period in

2018. Under the ASU Topic 606, an amount representing a bad debt would generally no longer be reported separately as an operating expense in the provider's financial statements, but will be treated as an "implicit price concession," and included as a reduction in patient revenue. Topic 606 makes other related changes.

To implement Topic 606, CMS proposed to modify the regulations to add that, effective for cost reporting periods beginning on or after October 1, 2020 that "bad debts, also known as 'implicit price concessions' are amounts considered to be uncollectible from accounts that were created or acquired in providing services" and "bad debts, also known as 'implicit price concessions,' charity, and courtesy allowances represent reductions in revenue."

*Comments/Responses*: Commenters agreed with CMS' policy but requested that it be adopted retroactive to the effective date of Topic 606. CMS is not adopting the policy retroactively as CMS' prior policy was not the policy described by Topic 606. Retroactive implementation in this case could require provider to change past reporting practices unnecessarily.

(2) Medicare Bad Debt and Contractual Allowances

CMS indicates that many providers are incorrectly writing off Medicare-Medicaid crossover bad debts to a contractual allowance account because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. Other providers are writing these amounts off to a contractual allowance account because the Medicaid remittance advice referenced the unpaid amount as a "Medicaid contractual allowance."

These Medicare-Medicaid crossover claims amounts do not meet the classification requirements for a Medicare bad debt because the amounts were written off to a contractual adjustment or allowance account instead of a bad debt expense account. CMS proposed to add paragraph (c)(3) to §413.89(c) to clarify that, effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession).

*Comments/Responses*: Commenters did not support the precise regulatory language and suggested an alternative. Other commenters objected to the proposal as increasing burden because it will require a change in accounting practices that are permissive under Generally Accepted Accounting Principles. One commenter suggested that providers classify their Medicare-Medicaid crossover bad debt as contractual allowances and contractors reimburse them for a portion of these contractual allowance amounts. There were various opinions on whether this change should be applied retroactively to the effective date of ASU Topic 606, CMS sub-regulatory guidance on this issue or prospectively.

CMS responded that it is never appropriate for a provider to write off Medicare-Medicaid crossover bad debt amounts to a contractual allowance account simply because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. It is likewise inappropriate to present these amounts to Medicare for reimbursement as Medicare bad debts. CMS agreed with comments on the regulatory language and will substitute

"must not be written off to a contractual allowance account but must be charged to an uncollectible receivables account that results in a reduction in revenue" instead of an "expense account" as to where a bad debt can be written off. CMS is not codifying this policy retroactively as it is a change from prior policy.

## X. Medicare Payment Advisory Commission (MedPAC) Recommendations

In its March 2020 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the "Hospital Value Incentive Program (HVIP)." HVIP would replace the current hospital quality programs. CMS responded that consistent with the statute, it is establishing an applicable percentage increase for FY 2020 of 2.4 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with statutory requirements. CMS does not have the authority to eliminate the current quality programs or establish HVIP.

## APPENDIX: IPPS Regulatory Impact Analysis Table

### TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2021

| | Number of Hospitals[1] | Hospital Rate Update and Adjustment under MACRA (1)[2] | FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | FY 2021 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2021 MGCRB Reclassifications (4) [5] | Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Application of the Frontier State Wage Index and Outmigration Adjustment (6) [7] | All FY 2021 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| **All Hospitals** | 3,201 | 2.8 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 2.5 |
| **By Geographic Location:** | | | | | | | | |
| Urban hospitals | 2,462 | 2.9 | 0.0 | 0.0 | -0.1 | 0.0 | 0.1 | 2.5 |
| Rural hospitals | 739 | 2.6 | -0.3 | 0.1 | 1.1 | -0.2 | 0.1 | 2.2 |
| **Bed Size (Urban):** | | | | | | | | |
| 0-99 beds | 635 | 2.8 | -0.5 | -0.1 | -0.7 | 0.1 | 0.3 | 2.0 |
| 100-199 beds | 756 | 2.9 | -0.1 | 0.0 | -0.1 | 0.1 | 0.2 | 2.4 |
| 200-299 beds | 426 | 2.9 | -0.1 | 0.0 | 0.3 | 0.1 | 0.1 | 2.4 |
| 300-499 beds | 422 | 2.9 | 0.0 | -0.1 | 0.0 | 0.0 | 0.2 | 2.4 |
| 500 or more beds | 223 | 2.8 | 0.2 | 0.1 | -0.3 | -0.1 | 0.0 | 2.7 |
| **Bed Size (Rural):** | | | | | | | | |
| 0-49 beds | 312 | 2.5 | -0.6 | 0.0 | 0.2 | -0.1 | 0.2 | 2.0 |
| 50-99 beds | 254 | 2.5 | -0.3 | 0.0 | 0.8 | -0.1 | 0.1 | 2.1 |
| 100-149 beds | 95 | 2.6 | -0.3 | 0.2 | 1.4 | -0.2 | 0.0 | 2.2 |
| 150-199 beds | 39 | 2.7 | -0.2 | 0.3 | 1.3 | -0.1 | 0.2 | 2.3 |
| 200 or more beds | 39 | 2.7 | -0.1 | 0.1 | 1.8 | -0.2 | 0.0 | 2.2 |
| **Urban by Region:** | | | | | | | | |
| New England | | 2.9 | 0.1 | -0.8 | 1.8 | 2.3 | 0.1 | 2.7 |

| | Number of Hospitals[1] | Hospital Rate Update and Adjustment under MACRA (1)[2] | FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | FY 2021 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2021 MGCRB Reclassifications (4) [5] | Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Application of the Frontier State Wage Index and Outmigration Adjustment (6) [7] | All FY 2021 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| | 112 | | | | | | | |
| Middle Atlantic | 305 | 2.9 | 0.0 | 0.6 | 0.3 | -0.4 | 0.2 | 2.8 |
| South Atlantic | 381 | 2.9 | 0.0 | 0.1 | -0.3 | -0.3 | 0.0 | 2.5 |
| East North Central | 160 | 2.8 | 0.0 | -0.5 | -0.8 | -0.3 | 0.6 | 2.0 |
| East South Central | 402 | 2.9 | 0.0 | 0.1 | -0.5 | -0.3 | 0.0 | 2.5 |
| West North Central | 144 | 2.9 | 0.0 | 0.0 | -0.4 | -0.3 | 0.0 | 2.4 |
| West South Central | 364 | 2.8 | 0.0 | 0.1 | -0.6 | -0.3 | 0.0 | 2.5 |
| Mountain | 172 | 2.8 | -0.1 | -0.5 | -0.2 | 0.1 | 0.3 | 1.8 |
| Pacific | 372 | 2.8 | 0.1 | -0.1 | 0.3 | 0.7 | 0.1 | 2.7 |
| Puerto Rico | 50 | 2.9 | 0.1 | -0.9 | -1.0 | 0.2 | 0.1 | 1.8 |
| **Rural by Region:** | | | | | | | | |
| New England | 19 | 2.7 | -0.1 | 0.2 | 0.4 | -0.2 | 0.0 | 2.4 |
| Middle Atlantic | 50 | 2.6 | -0.2 | 0.3 | 1.2 | -0.2 | 0.0 | 2.2 |
| South Atlantic | 114 | 2.5 | -0.3 | 0.1 | 0.9 | -0.1 | 0.0 | 2.2 |
| East North Central | 89 | 2.4 | -0.4 | 0.0 | -0.3 | 0.1 | 0.3 | 2.0 |
| East South Central | 114 | 2.7 | -0.2 | 0.4 | 1.6 | -0.2 | 0.1 | 1.9 |
| West North Central | 144 | 2.8 | -0.2 | -0.1 | 2.0 | -0.3 | 0.1 | 2.3 |
| West South Central | 136 | 2.8 | -0.3 | 0.0 | 1.9 | -0.3 | -0.1 | 2.2 |
| Mountain | 49 | 2.3 | -0.6 | -0.2 | 0.0 | -0.1 | 1.2 | 2.2 |
| Pacific | 24 | 2.5 | -0.2 | 0.2 | 1.0 | -0.1 | 0.0 | 2.1 |
| **By Payment Classification:** | | | | | | | | |
| Urban hospitals | 2,049 | 2.9 | 0.0 | 0.0 | -0.5 | 0.1 | 0.1 | 2.5 |
| Rural areas | 1,152 | 2.8 | 0.0 | 0.1 | 1.0 | -0.2 | 0.1 | 2.5 |

| | Number of Hospitals[1] | Hospital Rate Update and Adjustment under MACRA (1)[2] | FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | FY 2021 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2021 MGCRB Reclassifications (4) [5] | Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Application of the Frontier State Wage Index and Outmigration Adjustment (6) [7] | All FY 2021 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| **Teaching Status:** | | | | | | | | |
| Nonteaching | 2,037 | 2.8 | -0.2 | 0.0 | 0.0 | 0.1 | 0.1 | 2.2 |
| Fewer than 100 residents | 907 | 2.9 | -0.1 | 0.0 | 0.1 | 0.0 | 0.2 | 2.5 |
| 100 or more residents | 257 | 2.8 | 0.3 | 0.1 | -0.1 | -0.1 | 0.1 | 2.7 |
| **Urban DSH:** | | | | | | | | |
| Non-DSH | 505 | 2.8 | -0.2 | 0.1 | -0.4 | -0.2 | 0.2 | 2.2 |
| 100 or more beds | 1,289 | 2.9 | 0.0 | -0.1 | -0.5 | 0.2 | 0.1 | 2.5 |
| Less than 100 beds | 351 | 2.9 | -0.3 | -0.1 | -0.5 | 0.2 | 0.2 | 2.1 |
| **Rural DSH:** | | | | | | | | |
| SCH | 259 | 2.4 | -0.3 | -0.1 | 0.0 | -0.1 | 0.0 | 2.1 |
| RRC | 545 | 2.8 | 0.1 | 0.1 | 1.2 | -0.2 | 0.1 | 2.6 |
| 100 or more beds | 36 | 2.9 | 0.1 | 0.2 | -0.2 | -0.3 | 0.0 | 2.3 |
| Less than 100 beds | 216 | 2.7 | -0.4 | 0.1 | 0.6 | -0.3 | 0.2 | 2.2 |
| **Urban teaching and DSH:** | | | | | | | | |
| Both teaching and DSH | 739 | 2.9 | 0.1 | 0.0 | -0.6 | 0.1 | 0.1 | 2.6 |
| Teaching and no DSH | 74 | 2.9 | -0.1 | 0.1 | -0.4 | -0.2 | 0.1 | 2.4 |
| No teaching and DSH | 901 | 2.9 | -0.1 | -0.1 | -0.4 | 0.4 | 0.1 | 2.3 |
| No teaching and no DSH | 335 | 2.8 | -0.4 | 0.1 | -0.6 | -0.2 | 0.2 | 2.2 |
| **Special Hospital Types:** | | | | | | | | |
| RRC | 483 | 2.9 | 0.1 | 0.1 | 1.2 | -0.2 | 0.2 | 2.6 |
| SCH | 304 | 2.4 | -0.2 | 0.0 | 0.0 | 0.0 | 0.0 | 2.1 |
| MDH | 145 | 2.5 | -0.4 | 0.2 | 0.1 | -0.2 | 0.1 | 2.0 |
| SCH and RRC | 149 | 2.4 | -0.2 | 0.0 | 0.5 | -0.1 | 0.1 | 2.1 |
| MDH and RRC | 25 | 2.6 | -0.3 | 0.0 | 0.6 | -0.1 | 0.0 | 2.3 |

| | Number of Hospitals[1] | Hospital Rate Update and Adjustment under MACRA (1)[2] | FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | FY 2021 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2021 MGCRB Reclassifications (4) [5] | Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Application of the Frontier State Wage Index and Outmigration Adjustment (6) [7] | All FY 2021 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| **Type of Ownership:** | | | | | | | | |
| Voluntary | 1,885 | 2.8 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 2.5 |
| Proprietary | 827 | 2.9 | -0.1 | -0.1 | 0.0 | 0.0 | 0.1 | 2.4 |
| Government | 488 | 2.8 | 0.1 | 0.1 | -0.1 | 0.0 | 0.0 | 2.5 |
| **Medicare Utilization as a Percent of Inpatient Days:** | | | | | | | | |
| 0-25 | 641 | 2.8 | 0.1 | 0.1 | -0.5 | -0.1 | 0.0 | 2.6 |
| 25-50 | 2,114 | 2.8 | 0.0 | 0.0 | 0.1 | 0.0 | 0.1 | 2.5 |
| 50-65 | 373 | 2.7 | -0.2 | 0.0 | 0.4 | 0.4 | 0.2 | 2.2 |
| Over 65 | 49 | 2.8 | -0.7 | -0.2 | -0.9 | -0.3 | 0.1 | 1.7 |
| **FY 2021 Reclassifications by the Medicare Geographic Classification Review Board:** | | | | | | | | |
| All Reclassified Hospitals | 900 | 2.8 | 0.0 | 0.1 | 1.5 | -0.2 | 0.1 | 2.6 |
| Non-Reclassified Hospitals | 2,301 | 2.8 | 0.0 | -0.1 | -0.9 | 0.1 | 0.1 | 2.4 |
| Urban Hospitals Reclassified | 722 | 2.8 | 0.0 | 0.1 | 1.3 | -0.2 | 0.1 | 2.6 |
| Urban Non-Reclassified Hospitals | 1,752 | 2.9 | 0.0 | -0.1 | -1.0 | 0.1 | 0.1 | 2.4 |
| Rural Hospitals Reclassified Full Year | 309 | 2.6 | -0.3 | 0.1 | 2.0 | -0.2 | 0.1 | 2.2 |
| Rural Non-Reclassified Hospitals Full Year | 418 | 2.6 | -0.3 | 0.0 | -0.4 | -0.2 | 0.2 | 2.1 |
| All Section 401 Reclassified Hospitals | 467 | 2.8 | 0.1 | 0.1 | 1.0 | -0.2 | 0.1 | 2.6 |
| Other Reclassified Hospitals (Section 1886(d)(8)(B)) | 54 | 2.7 | -0.3 | 0.2 | 2.2 | -0.3 | 0.0 | 2.1 |

[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 2019, and hospital cost report data are from reporting periods beginning in FY 2018 and FY 2017.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 2.4 percent update to the national standardized amount and the hospital-specific rate (the estimated 2.4 percent market basket update with the by 0.0 percentage point for the multifactor productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 38 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 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 0.99798in 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 2017 cost report data and 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 1.000426.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2021 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2021. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic reclassification budget neutrality factor of 0.986583.

[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.993433.

[7] 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 not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2020 to FY 2021 including an estimated decrease in outlier payments of 0.2 percent (from our current estimate of FY 2020 outlier payments of approximately 5.3 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this final rule calculated for purposes of this impact analysis). This column also includes the effects of the adoption of the revised labor market area delineations in OMB Bulletin 18-04 and the effects of the transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.