Fiscal Year 2022 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule Summary

On August 2, 2021 the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2022 policies and rates for Medicare's inpatient prospective payment systems (IPPS) for acute care hospitals and the long-term care hospital (LTCH) prospective payment system (PPS). The final rule will be published in the *Federal Register* on August 13, 2021.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1752-F and CMS-1762-F) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in LTCHs 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. The proposed rule included several requests for information (RFI) on quality measures, interoperability and health equities. CMS summarizes those comments and indicates that it will address the issues they raise in future rulemaking.

The proposed rule also, included provisions on section 1115 waiver days for determining the Medicare disproportionate share percentage (DSH) percentage, organ acquisition payment and implementation of graduate medical education (GME) provisions of the Consolidated Appropriations Act (CAA), 2021. In the final rule, CMS indicates that due to the number and nature of the comments received the DSH and GME proposals, it intends to address the public comments in a separate document. Organ acquisition payment is absent from the final rule but CMS made a similar statement in a fact sheet released with the rule about addressing public comments in a later document.

CMS makes many data files available to support analysis of the final rule. These data files are generally available at: FY 2022 IPPS Final Rule Home Page | CMS. Numbered tables that were historically included in the IPPS/LTCH rule are now only available on the CMS website at the above hyperlink.

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

CMS estimates that policies and rates in the final rule will increase FY 2022 combined operating and capital payments to approximately 3,195 acute care hospitals paid under the IPPS by about $2.3 billion. The increase in operating payment rates, increases in capital payments, increases in payments due to implementation of the imputed floor, and other changes will increase hospital payments in FY 2022 by $3.7 billion or 3.1 percent. Medicare DSH and uncompensated care payments are estimated to decrease by approximately $1.4 billion. The estimated percentage increase in all IPPS payments is 2.6 percent.

A. Inpatient Hospital Operating Update

The final rule will increase IPPS operating payment rates by 2.5 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.5 percent rate increase is the net result of a market basket update of 2.7 percent less an annual multi-factor productivity (MFP) adjustment of 0.7 percentage points; and an adjustment of +0.5 percentage points for documentation and coding required by section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA). The payment rate update factors are summarized in the table below.

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 2.0 percent increase rather than a 2.5 percent increase.

Factor	Percent Change
FY 2022 Market Basket	2.7
Multifactor productivity adjustment	-0.7
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	2.5

Hospitals that fail to participate successfully in the Hospital Inpatient Quality Reporting (IQR) Program or are not meaningful users of EHR do not receive the full payment rate increase. The below table shows the update (before application of the 0.5 percentage point increase for documentation and coding). The reduction is ¼ of the market basket for hospital failing IQR, ¾ of the market basket for hospitals that are not meaningful users of EHR and 100 percent of the market basket for hospitals failing both programs.

Updates for Hospitals Failing IQR and/or EHR

	Penalty	Market Basket	Market Basket Net of MFP	Reduction (Percentage Points)	Update	Hospitals
No IQR	25% of the MB	2.7%	2.0%	-0.675	1.325%	68
No EHR	75% of the MB	2.7%	2.0%	-2.025	-0.025%	97
No IQR/EHR	100% of the MB	2.7%	2.0%	-2.7	-0.7%	24

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2022 payments increasing 2.6 percent. Not all policy changes are reflected in this total. For example, the total does not include estimated reductions to Medicare uncompensated care payments and increases in new technology add-on payments (NTAP). The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2022 increase in payment rates	+2.5[1]
Imputed Floor Wage Index	+0.2
Residual	-0.1[2]
Total	+2.6

[1]Weighted average of hospital-specific rate update of 2.0 and 2.5 percent for all other hospitals.
[2]CMS explains the residual and the total may be explained by "interactive effects among various factors" that CMS cannot isolate.

In prior years, CMS provided an estimate of the amount paid in outlier payments in the current fiscal year (FY 2021 in this case) compared to the 5.1 percent removed from the current fiscal year rates to fund the outlier pool. The difference compared to the 5.1 percent estimated to be removed from the fiscal year rates was presented as a contributor to the increase or decrease in payments. The estimated outlier payments compared to the 5.1 percent target for the current year is not provided in the FY 2022 final rule. CMS states "because the MedPAR claims data for the entire FY 2021 period would not be available until after September 30, 2021, we are unable to provide an estimate of actual outlier payments for FY 2021 based on FY 2021 claims data in this final rule."

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	2.6%
Urban	2.6%
Rural	2.8%
Major Teaching	2.6%

To the extent the impact on a given hospital category deviates from the national average of 2.6 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with all other hospitals. The impact would be redistributive from a policy that is budget neutral. The redistributive payment changes are reasonably modest. Most 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 269 urban hospitals so that it is not below the wage index for the rural area of its state. CMS calculates a national rural floor budget neutrality adjustment factor of 0.992868 (-0.71 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 average change in payments; and urban hospitals in the New England region can expect a 3.7 percent increase in payments relative to the rural floor not being applied, primarily due to the application of the rural floor in Massachusetts.

Imputed Floor: The imputed floor was established by section 9831 of the American Rescue Plan Act (ARPA) enacted by Congress on March 11, 2021. Under section 9831, CMS is required to use a formula to establish a statewide wage index floor in all urban states, Washington, DC and Puerto Rico. The imputed floor provision is not subject IPPS budget neutrality. CMS estimates the imputed floor will increase payment to 69 hospitals by $195 million.

Frontier Wage Index and Outmigration. In the IPPS impact table, CMS includes a column for the frontier hospital wage index floor that increases payments by about $64 million to 44 hospitals and the out-migration adjustment that increases payments about $55 million to 245 hospitals.

New Technology Add-On Payments (NTAP). NTAP payments are not subject to budget neutrality. CMS is continuing NTAP payments for 23 technologies for which it estimates payments of $858 million in FY 2022. In addition, CMS is approving 10 applications for NTAP under either the breakthrough technology or qualified infection disease product (QIDP) pathways for FY 2022. CMS estimates that costs for these technologies will be $151.2 million in FY 2022. Another 7 applications are being approved for NTAP payments under the traditional pathway. CMS estimates the costs of these technologies will be $424.8 million in FY 2022. In total, CMS estimates that NTAP payments will be approximately $1.4 billion in FY 2022.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 13.2 percent or about $1.1 billion. More detail on these calculations is in section V.E.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2022 payments to an estimated 2,938 hospitals or 85 percent of all hospitals. The readmissions penalty is estimated to affect 0.63 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 2022.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute 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 2022.

Hospital Acquired Conditions (HAC) Reduction Program. As a result of the special scoring rule for FY 2022, all HVBP program adjustment factors for all hospitals will reflect a net-neutral payment adjustment. This adjustment policy is fixed for FY 2022, and HVBP program adjustments will not change as a result of subsequent availability of newer MedPAR data after the publication of this final rule.

Rural Community Hospital Demonstration Program. CMS estimates costs for the Rural Community Hospital Demonstration Program at $65.8 million for FY 2022 and $3.8 million from prior year reconciled cost reports. CMS is applying a budget neutrality adjustment to the IPPS standardized amounts based on total costs of $69.6 million.

The Frontier Community Health Integration Project (FCHIP) Demonstration. FCHIP is designed to develop and test new models of care by permitting enhanced reimbursement for telemedicine, nursing facility, ambulance, and home health services. Ten Critical Access Hospitals (CAHs) in Montana, Nevada, and North Dakota participated in the 3-year demonstration beginning August 1, 2016. If the program is not budget neutral, CMS is required to apply a budget neutrality adjustment to all CAH payments. Based on the currently available data, CMS indicates that the FCHIP demonstration project was budget neutral and no adjustment to CAH payments is necessary.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2022 (before adjustments):

	Update
Full Update	2.0%
No EHR	1.325%
No IQR	-0.025%
No EHR/IQR	-0.7%

The applicable percentage changes listed above are prior to budget neutrality factors applied to the standardized amount and the documentation and coding adjustment. The adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 1.000107 (an increase of 0.01 percent);
- Wage index, 1.000712 (an increase of 0.07 percent);
- Geographic reclassification, 0.986737 (a reduction of 1.33 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.998035 or -0.20 percent;
- Transitioning reductions to the wage index of 0.99987 or -0.01 percent;
- The outlier offset factor is 0.949 or -5.1 percent;
- The rural community hospital demonstration program adjustment is 0.999361 or -0.06 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, transitioning reductions to the wage

index, the outlier adjustment and rural community hospital demonstration project are removed from the FY 2021 standardized amount before the FY 2022 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	2.0%
DRG Recalibration	0.01%
Wage index	0.07%
Geographic Reclassification	0.012%
25th Percentile	0.07%
Transition Budget Neutrality	0.102%
Outlier	0.000%
Rural Community Hospital	-0.027%
Doc and Coding	0.500%
Net Change*	2.70%

*Net change is the product of the prior factors, not the addition

The increase in the capital rate is 1.37 percent from $466.21 to $472.60. The combined increase in the operating standardized amount and the capital rate will be 2.6 percent for FY 2022.

Note that the standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 2030. 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. (The sequester reduction is currently suspended through December 31, 2021).

STANDARDIZED AMOUNTS FY 2022

	Full Update=2.0%	Reduced Update Failed IQR = 1.325%	Reduced Update Failed EHR = -0.025%	Reduced Update Failed IQR and EHR = -0.7%
Wage Index >1.0				
Labor (67.6%)	$4,138.28	$4,056.12	$4,110.89	$4,028.74
Non-Labor (32.4%)	$1,983.43	$1,944.05	$1,970.30	$1,930.93
WI<=1.0				
Labor (62%)	$3,795.46	$3,720.11	$3,770.34	$3,695.00
Non-Labor (38%)	$2,326.25	$2,280.06	$2,310.85	$2,264.67
National Capital Rate (All Hospitals)	$472.60			

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 $29,064 for FY 2021. 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 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 2022 outlier threshold. CMS is adopting an outlier threshold for FY 2022 of $30,988. CMS projects that the proposed outlier threshold for FY 2022 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.29 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.9471 to the capital federal rate to fund operating and capital outlier payments respectively.

Normally, CMS would calculate the outlier threshold based on the latest claims and cost report data. For FY 2022, the latest year of claims data would be the March, 2021 update to the FY 2020 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data would be the March, 2021 update of the Provider-Specific File (PSF) for 2019 and 2020. However, as CMS explains elsewhere in the final rule, it is continuing to use data from prior to the COVID-19 public health emergency (PHE) to determine the relative weights and outlier threshold. Public comments agreed with this policy. Other comments repeated issues raised in past years. CMS responded as it did in prior years and is making no changes to its outlier methodology (apart from not using data that spans the period of the PHE).

FY 2022 outlier threshold methodology. CMS is following past practice targeting total outlier payments at 5.10 percent of total operating DRG payments including the adjustment for outlier reconciliation explained below (including outlier, all wage adjustments and uncompensated care payments but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program).

Charge Inflation. Consistent with the policy to use data from prior to the PHE to determine the FY 2022 outlier threshold, CMS is using the March, 2019 update of MedPAR for FY 2018 charges and the March 2020 update of MedPAR for FY 2019 charges to determine a charge inflation factor. CMS determined the 1-year average annualized rate-of-change in charges per case for FY 2022 by comparing the average covered charge per case of:

	Charges	Cases	Average Charge Per Case
FY 2018	$584,618,863,834	9,493,830	$61,578.82
FY 2019	$604,209,834,327	9,221,466	$65,522.10
Annual Rate of Increase			1.064 (6.4%)
Raised to the 3rd Power for years of Inflation			1.20469 (20.4%)

CCRs. The adjustment methodology compares the national average case-weighted operating and capital CCRs from the 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	Capital	% Change	Factor	Factor Squared for 2 Years of Inflation
March 2019 PSF	0.254027	0.0207300	-2.55%	0.974495	0.94964
March 2020 PSF	0.247548	0.0019935	-3.84%	0.96165	0.92477

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 is reflecting reconciliation in the determination of the FY 2022 outlier threshold.

For the FY 2022 outlier threshold, CMS will use the historical outlier reconciliation amounts from the FY 2016 cost reports (cost reports with a beginning date on or after October 1, 2015, and on or before September 30, 2016). CMS indicates these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC. For the FY 2022 final rule, CMS is using the March 2021 extract of the Hospital Cost Report Information System (HCRIS).

CMS determined reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2016 for FY 2022). It then subtracts that amount (expressed as percentage points) from the 5.1 percent of total operating IPPS payments that CMS is targeting as outlier payments for the payment year.

In the final rule, CMS estimates that reconciliation in FY 2016 resulted in 24 hospitals (20 hospitals from the March, 2021 update to HCRIS and an additional 4 hospitals made available to CMS outside of the HCRIS process) being owed $19.371 million or -0.02196 percent of total operating IPPS payments. This figure rounds to -0.02 percent. Subtracting -0.02 percentage points from 5.10 percent is 5.12 percent. CMS will target 5.12 percent of operating payments as outliers assuming that -0.02 percentage points of that amount will be repaid to hospitals under the reconciliation process. Reconciliation will have the effect of slightly decreasing the outlier threshold ($30,988 compared to $31,108) to target a slightly higher percentage of 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. For capital, CMS estimates the ratio of reconciled outlier payments to total payments is -0.02 percent based $1,784,117 in reconciled capital outlier payments owed to 22 hospitals (19 from HCRIS and 3 outside of HCRIS).

FY 2020 Outlier Payments. CMS' current estimate, using available FY 2020 claims data, is that actual outlier payments for FY 2020 were approximately 5.47 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 2020 are equal to the projected 5.1 percent of total MS-DRG payments.

FY 2021 Outlier Payments. CMS says that FY 2021 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2021.

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

A. Adoption of the MS-DRGs and the 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 changes require CMS to make a series of annual positive adjustments to offset prior negative ones through FY 2023. For FY 2022, consistent with MACRA, CMS is implementing a positive 0.5 percentage point adjustment to the standardized amount.

There have been ongoing differences between CMS and public commenters regarding whether CMS should restore an additional 0.7 percentage point reduction made to the IPPS standardized amounts in FY 2017. MACRA specified that CMS restore 3.0 percent of 3.2 percent in cumulative reductions. After MACRA was enacted, CMS applied an additional reduction of 0.7 percent or 3.9 percent in cumulative reductions to meet the requirements of the American Tax Relief Act (ATRA).

Public commenters have asserted that CMS is required to restore this additional 0.7 percentage point reduction not contemplated when Congress enacted MACRA. CMS disagrees arguing that it "see[s] 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 ATRA adjustment made in FY 2017." In February, a United States Circuit Court sided with the Secretary ruling that the law precludes the Court's intervention.

B. Changes to Specific MS-DRG Classifications

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

In the FY 2021 IPPS proposed rule, CMS proposed to change the deadline to request updates to the MS-DRGs from November 1 to October 20 of each year.[1] CMS stated this would provide more time to evaluate requests. Due to the PHE, CMS waived the delayed effective date and maintained the deadline of November 1, 2020 for FY 2022 MS-DRG classification change requests. For FY 2023 MS-DRG classification change requests, CMS is maintaining the November 1 deadline. CMS expects to reconsider a change to the deadline for FY 2024. **To be considered for any updates or changes in FY 2023, comments should be submitted by November 1, 2021** to the CMS MS-DRG Classification Change Request Mailbox at: MSDRGClassificationChange@cms.hhs.gov.

CMS appreciates comments recommending an additional submission deadline, such as earlier in the year, and will consider this for future rulemaking.

[1] 85 FR 32472

This test version of the ICD-10 MS-DRG GROUPER software, Version 39, the draft version of the ICD-10 MS-DRG Definitions Manual, Version 39, and the supplemental mapping files in Table 6P.1a and Table 6P.1b of the FY 2021 and FY 2022 ICD-10-CM diagnosis and ICD-10-PCS procedure codes are available at https://www.cms.gov/MEdicare/MEdicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

This section of the preamble discusses changes that CMS finalizes to the MS-DRGs for FY 2022. For this final rule, CMS generally did not perform any further MS-DRG analysis of claims data. Except as otherwise noted, the MS-DRG analysis is based on ICD-10 claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 of the FY 2020 MedPAR file.

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 uses its clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In addition, CMS considers the number of patients who will have a given set of characteristics and notes it generally prefers not to create a new MS-DRG unless it would include a substantial number of cases.

CMS uses the 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.

In the FY 2021 final rule, CMS expanded these criteria to include the NonCC subgroup for a three-way severity level split.[2] 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.

[2]85 FR 58448

The table below, reproduced from the final rule, illustrates all five criteria and how they are applied to each CC. For FY 2022, CMS applied these criteria to each of the MCC, CC, and NonCC subgroups. 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

Criteria Number	**Three-Way Split** 123 (MCC vs CC vs NonCC)	**Two-Way Split** 1_23 MCC vs (CC+NonCC)	**Two-Way Split** 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

CC subgroup is warranted to determine if all criteria are satisfied in a three-way split. If the criteria are not met, CMS will determine if criteria are satisfied for a two-way split and apply the two-way split with the highest R2 value. 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 will evaluate the criteria for both of the two-way splits, but it will not also evaluate the criteria for a three-way split.

In the proposed rule, CMS analyzed how applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure for FY 2022. This analysis used both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file. CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would delete 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) create 58 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative rates and thus the payment rates. Table 6P.1c (proposed rule) contains the list of the 96 MS-DRGs that would be subject to deletion and the list of the 58 new MS-DRGs that would be proposed if the NonCC subgroup criteria were applied.

Because of the PHE, CMS had concerns about the impact of implementing these MS-DRGs changes and requested comments about whether it should delay application of the NonCC

subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023 and maintain the current structure of the MS-DRGs for FY 2022.

Several commenters supported delaying the application of the expanded three-way severity splitcriteria to the NonCC subgroup until FY 2023, a few suggested a delay until FY 2024, and one suggested until FY 2025. Commenters also requested a complete analysis of the MS-DRG changes proposed for FY 2023 in conjunction with the expanded three-way severity split for public review and comment. A commenter suggested that CMS examine the impact for surgicalversus medical MS-DRGs. CMS plans to perform and make publicly available a more detailed analysis of any future proposed changes with its annual claims analysis for MS-DRG classification change proposals. CMS will also take into consideration the suggestion to delay this proposal until FY 2024 or later, to allow the use of FY 2022 data.

CMS finalizes its proposal to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023 or later. CMS finalizes maintaining the current structure of the 32 MS-DRGs that currently have a three-way severity level split for FY 2022. CMS notes that Table 6P.11 associated with this rule displaces the volume (case counts) by each MS-DRG based on claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file.
2. Pre-MDC: MS- DRG 018 Chimeric Antigen Reception (CAR) T-Cell Therapy
Sixteen new ICD-10-PCS codes describing the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies will become effective for discharges on and after October 1, 2021 (listed in the rule). CMS finalizes its proposal to assign these services to MS-DRG 018. CMS also finalizes its proposal to revise the title for MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies would be assigned to MS- DRG 018.

CMS discusses the comments supporting and opposing its proposal. Several commenters supported CMS' proposal for both the listed ICD-10-PCS procedure codes and the title revision. Some commenters requested further classification from CMS on what the "Other Immunotherapies" terminology included because it was a broad term used across several therapeutic areas; some commenters requested other terminology for the title. A commenter recommended CMS consider additional factors when determining a permanent payment mechanism for tumor infiltrating lymphocytes (TIL) and other products including the patient diagnosis and product indication; cell collection methodologies; product administration methodologies; patient clinical care regimes; and product safety and toxicity profiles. Other commenters opposed the proposal to assign procedure codes describing non-CAR T-cell and other immunotherapies to this MS-DRG and to revising the title. Commenters discussed the resources used for CAR T-cell therapies and the concern that CMS' proposal may distort future rate setting.

CMS' response to these comments includes a description of its established process to examine the MS-DRG assignment for the predecessor code to determine the assignment of a new procedure code. CMS thinks it is appropriate to initially classify the procedure codes describing allogeneic CAR T-cell therapy and TIF therapy to the same MS-DRG because there are clinical similarities between these products including how they are administered, the complexity of the conditions they treat, and resource utilization. CMS notes that both therapies require a patient's

lymphocytes. CMS also states that when evaluating appropriate MS-DRG assignments for technologies, e.g., devices, it does not take into consideration how a specific device is manufactured compared to how other similar devices are manufactured. CMS disagrees that modifying Pre-MDC MS-DRG-018 to include other immunotherapies one year after it has been implemented carries a risk of creating additional payment uncertainty around CAR T-cell therapies and volatility in the weight of Pre-MDC MS-DRG 018. As discussed below (see section II.E.2), CMS finalizes maintaining the methodology for the relative weight calculation for the MS-DRG. CMS appreciates the suggestions to consider alternative terminology, but it believes it is premature to finalize any suggested titles. CMS will continue to work with stakeholders on this issue.

CMS states that it will continue to evaluate the data to determine further modifications to Pre-MDC MS-DRG are warranted. It plans to continue to work with stakeholders on additional options for consideration in this evolving field of cellular and gene therapies, including the creation of new and distinct MS-DRGs.

3. MDC 03 (Diseases and Disorders of Ear, Nose and Throat)

In the 2021 IPPS final rule, CMS created two base MS-DRGs, 140 and 143, with a three-way severity level split for new MS-DRGs 140, 141, and 142 (Major Head and Neck Procedures) and new MS-DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures). CMS received two separate requests to review and reconsider the MS-DRG assignments for a subset of procedure codes assigned to these MS-DRGs.

a. Major Head and Neck Procedures

A requestor asked CMS to review of the assignment of eight ICD-10-PCS codes (listed in the final rule). As summarized in the final rule, CMS believes the three procedure codes describing excision of subcutaneous tissue of chest, back and abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ) were inadvertently assigned to MS-DRGs 140, 141, and 142. CMS believes these codes are appropriately assigned to MDC 03. After reviewing comments, CMS finalizes its proposal to reassign these three procedure codes to MS-DRGs 143, 144, and 145 for FY 2022. CMS also finalizes its proposal to reassign these codes from Extensive O.R. procedures (MS-DRGs 981, 982, and 983) to Non-Extensive O.R. (MS-DRGs 987, 988, and 989) procedures for FY 2022.

b. Other Ear, Nose, Mouth and Throat O.R. Procedures

A requestor asked CMS to review 82 ICD-10-PCS codes (listed in Table 6P.1d) assigned to MS-DRGs 143, 144, and 145. After reviewing comments, CMS finalizes its proposal to maintain the current structure for these DRGs. CMS plans to continue to review the appropriateness of procedure code assignment to these MS-DRGs as part of its broader comprehensive procedure code analysis.

The requestor also asked CMS to review the assignment of three procedure codes describing the control of bleeding in the cranial cavity (0W310ZZ, 0W313ZZ, and 0W314ZZ) and suggested these codes should group to MS-DRGs 25, 26, and 27. CMS' clinical advisors reviewed these codes and concluded these procedures are consistent with the existing procedure codes included

in the logic for case assignment to MS-DRGs 25, 26, and 27 (further discussed in section II.D.10 of the final rule).

4. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Bronchiectasis

A requestor asked CMS to reassign four ICD-10-CM codes from MS-DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Diseases (COPD)) to MS-DRGs 177, 178, and 179 (Respiratory Infections and Inflammations). The requestor stated that bronchiectasis is more similar to cystic fibrosis than it is to COPD. After reviewing comments, CMS finalizes its proposal to maintain the assignment of the four diagnosis codes for bronchiectasis.

b. Major Chest Procedures

CMS summarizes its review of the procedures currently assigned to MS-DRGs 163, 164, and 165 (Major Chest Procedures) and MS-DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures).

After reviewing comments, CMS finalizes its proposal to reassign 26 procedure codes listed in the final rule (nine procedure codes describing repair of pulmonary or thoracic structures and 17 procedure codes describing procedures performed on the sternum or ribs) from MS-DRGs 166, 167, and 168 to MS-DRGs 163, 164, and 165 in MDC 04 for FY 2022. Based on the results of this review, CMS believes further analysis of these MS-DRGs is necessary and will continue to evaluate the procedures assigned to these MS-DRGs as additional claims data becomes available.

5. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Short-term External Heart Assist Device

Impella® Ventricular Support Systems are temporary heart assist device intended to support blood pressure and provide increased blood flow in patients with cardiogenic shock and need short-term support for up to 6 days. The ICD-10-PCS codes that describe the insertion of the Impella® heart assist devices are assigned to MS-DRG 215 (Other Heart Assist System Implant). To evaluate the clinical and resource use of procedures utilizing heart assist devices, CMS has been monitoring the data in MS-DRG 215 since the FY 2019 IPPS proposed rule. In the FY 2021 IPPS final rule, CMS discussed its findings that the weight for MS-DRG was seeing a significant reduction for each of the 4 years since CMS began using ICD-10 data in calculating the relative weights. In response to comments and concerns related to the PHE, CMS set the 2021 relative weight for MS-DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

CMS received a request to reassign certain cases reporting procedure codes describing the insertion of a percutaneous short-term external heart assist device from MS-DRG 215 to MS-DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization). The requestor stated there are two distinct clinical populations within

MS-DRG 215: high risk Percutaneous Coronary Intervention (PCI) patients receiving short term "intraoperative" external heart assist systems where the device is only used intraoperatively and is removed at the conclusion of the procedure, and patients in or at risk of cardiogenic shock requiring longer heart pump support and ICU stays. Based on claims analysis, the requestor observed that the cases with short-term external heart assist systems placed intraoperatively require fewer resources and should be reassigned from MS-DRG 215 into MS-DRGs 216, 217, and 218. The requestor stated this would clinically align the two distinctly different patient populations and address the potential decrease in the relative weight of MS-DRG 215.

CMS summarizes its review of this request. This analysis included ICD-10-PCS codes 02HA0RJ (Insertion of short-term external heart assist into heart, intraoperative, open approach), 02HA3RJ (Insertion of a short-term external heart assist device into heart intraoperative, percutaneous approach), and 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach). Because the Impella device code (ICD-10-PCS code 5A0221D) does not distinguish between a device used only intraoperatively from a device left in place after the operation, CMS did not include this code in its analysis. In addition, because MS-DRGs 216, 217, and 218 are defined by the performance of cardiac catherization, CMS expanded its analysis to also include MS-DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catherization with MCC, CC, and without CC/MCC).

CMS' clinical advisors reviewed the clinical issues and the claims data analysis and supported reassigning ICD-10 PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist devices to MS-DRGs 216, 217, 218, 219, 220 and 221. To compare and analyze the impact of these suggested modifications, CMS ran a simulation using the Version 38.1 ICD-10 MS-DRG GROUPER and the claims data from the March 2020 update of the FY 2019 MedPAR file. CMS also ran a simulation using the claims data from the September 2020 update of the FY 2020 MedPAR file. The table below, reproduced from the final rule, summarizes the results from the analyses using the March 2020 update of the FY 2019 MedPAR file. The results based on the claims data from the September 2020 update of the FY 2020 MedPAR file are similar (see table in final rule). The simulation shows that if the three ICD-10-PCS codes describing the intraoperative insertion of a short-term external heart assist device are moved to MS-DRGs 216, 217, 218, 219, 220, and 221 the average costs of the cases remaining in MS-DRG 215 increase by over $6,000, while the reassignment generally has a more limited effect on the average costs of MS-DRGs 216, 217, 218, 219, 220, and 221.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
215	All Cases	7,741	7.8	$68,234
	without 02HA0RJ, 02HA3RJ or 02HA4RJ	4,798	8.2	$73,009
216	All Cases	5,603	16.7	$74,413
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	7,490	14.8	$72,424
217	All Cases	1,885	9.5	$47,159
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,663	7.9	$47,837
218	All Cases	210	6.6	$37,778
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	488	4.3	$44,708

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
219	All Cases	15,597	10.9	$57,845
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	17,484	10.7	$58,781
220	All Cases	15,074	6.5	$39,565
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	15,852	6.4	$40,052
221	All Cases	2,417	4.5	$33,560
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,695	4.3	$35,250

For FY 2022, CMS proposed to reassign ICD-10-PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MS-DRG 215 to MS-DRGs 216, 217, 218, 219, 220 and 221.

CMS discusses the comments supporting and opposing this proposal. Commenters supporting this proposal stated this will create a more clinically balanced structure for hospital payments by better reflecting hospital resource utilization and creating a more clinically homogenous structure for patients that require intraoperative support of a short-term external heart assist device. A commenter stated this reassignment results in a relative weight for MS-DRG 215 that more accurately reflects the resource utilization of procedures within this MS-DRG and helps stabilize the relative weight of the MS-DRG. Other commenters opposed CMS' proposal noting that patients requiring intraoperative short-term external heart assist devices tend to be more severely ill and require increased resource utilization. Another commenter requested CMS re-evaluate this proposal once the MedPAR data has stabilized post the PHE.

Some commenters supported CMS' proposal but urged CMS from moving cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device into MS-DRGs 219, 220, and 221. These comments stated that cases should be assigned only to MS-DRGs 216, 217, and 218, based on the presence or absence of a secondary diagnosis describing a MCC or CC. Other commenters thought the intraoperative insertion of short-term external heart assist devices are comparable to those procedures mapping to MS-DRGs 216, 217, and 218, even when a cardiac catherization procedure is not performed. Other commenters raised known coding and documentation issues associated with coding errors stating the vast majority of these procedures require a cardiac catherization.

In response to comments, CMS' clinical advisors continue to believe the proposed MS-DRG assignments would be more clinically homogenous, coherent and better reflect hospital resource use because cases reporting a procedure code for an intraoperative insertion of a short-term external health assist device are generally less resource intensive and are clinically distinct from other cases reporting the insertion of other types of heart assist devices currently assigned to MS-DRG 215. In addition, CMS does not believe it would be appropriate to assign all cases to the "with cardiac catherization" MS-DRGs without the procedure being performed, regardless of the volume of cases. CMS acknowledges that accurate coding of external heart assist devices has been confusing, and it will continue to monitor the claims data for these procedures and continue to collaborate with the AHA to provide coding guidance.

After consideration of comments, CMS finalizes its proposal to reassign ICD-10-PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MS-DRG 215 to MS-DRGs 216, 217, 218, 219, 220 and 221, effective October 1, 2021.

b. Type II Myocardial Infarction

CMS received a request to review the MS-DRG assignment of ICD-10-CM diagnosis code I21.AI (Myocardial infarction type 2). Based on its analysis of GROUPER logic and input from its clinical advisors, CMS proposed to maintain the current structure of MS-DRGs 280 through 285 and not reassign diagnosis code I21.AI. CMS proposed modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 as a secondary diagnosis to group to MS-DRGs 222 and 223 when reported with qualifying procedures.

In response to concerns with this proposal, CMS discusses how a diagnosis code may define the logic for a MS-DRG assignment. A diagnosis code may be listed as a principal or secondary diagnosis, a secondary diagnosis, or only as a secondary diagnosis in the ICD-10 MS-DRG Definitions Manual. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code does not correspond to coding guidelines for reporting the principal diagnosis. Cases group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. The Medicare Code Editor (MCE) and other payer-specific edits identify inconsistencies in the coding guidelines or coverage policies. CMS notes that since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. This separation of the MS-DRG grouping and data editing functions allows the MS-DRG GROUPER to remain stable even though coding rules and coverage policies may change.

After consideration of comments CMS finalizes its proposal to maintain the current structure of MS-DRGs 280 through 285. CMS also finalizes its proposal to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 as a secondary diagnosis to group to MS-DRGs 222 and 223 when reported with qualifying procedures.

c. Viral Cardiomyopathy

CMS received three related requests to add ICD-10-CM diagnosis code B33.24 (Viral cardiomyopathy) to the list of principal diagnosis for MS-DRGs 314, 315, and 316 (Other Circulatory System Diagnoses). A table in the final rule lists the five ICD-10-CM diagnosis codes in subcategory B33.2. After reviewing comments, CMS finalizes its proposal to reassign ICD-10-CM diagnosis code B33.24 (Viral cardiomyopathy) from MDC 18 in MS DRGs 865 and 866 (Viral Illness) to MDC 05 in MS DRGs 314, 315, and 316 (Other Circulatory System Diagnosis).

d. Left Atrial Appendage Closure (LAAC)

CMS received a request to again review the MS-DRG assignment of cases involving LAAC procedures with an open approach. The requestor disagreed with CMS' FY 2021 IPPS final rule decision to move the three procedure codes describing the open occlusion of left atrial appendage to MS-DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures) and stated they were more appropriately assigned to MS-DRGs 228 and 229 (Other Cardiothoracic Procedures). A table in the final rule provides more information about the nine ICD-10-PCS procedure codes

that describe LAAC procedures. CMS' clinical advisors reviewed this request and continued to support the current assignments. CMS proposed to maintain the assignment of codes (02L70CK, 02L70DK, and 02L70ZK) for the open occlusion of the left atrial appendage in MS-DRGs 273 and 274.

A commenter expressed concern about the analysis summarized in the proposed rule and stated that based on their own analysis, it appeared the average length of stay and average costs of open occlusion of LAAC would be more clinically aligned with MS-DRGs 228 and 229. In response, CMS provides analysis using claims data from the March 2020 update of the FY 2019 MedPAR file, as well as the September 2020 update of the FY 2020 MedPAR file for all cases in MS-DRGs 273 and 274 and compared the results to cases with a procedure code describing an open LAAC procedure (see tables in the final rule). CMS acknowledges that the average costs of the small number of cases reporting LAAC procedures with an open approach generally have average costs greater than the average costs of the cases in MS-DRGs 273 and 274. CMS' clinical advisors continue to believe that maintaining the assignment of these procedures to MS-DRGs 273 and 274 improves clinical coherence.

After consideration of comments, CMS finalizes its proposal to maintain the assignment of codes (02L70CK, 02L70DK, and 02L70ZK) for the open occlusion of the left atrial appendage in MS-DRGs 273 and 274.

e. Surgical Ablation

CMS received a two-part request to review the MS-DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation.

Request to create a new MS-DRG. The first request was to create a new classification of surgical ablations MS-DRGs to better accommodate the costs of open concomitant surgical ablations.

CMS identified nine ICD-10-PCS codes that describe open surgical ablation (listed in the final rule). CMS' clinical advisors reviewed the GROUPER logic and believed this request would be better addressed by revising the surgical hierarchy in MDC 05 instead of creating new MS-DRGs. CMS proposed to revise the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures). Under this proposal, if a procedure describing a CABG and a procedure describing an open surgical ablation are present, the GROUPER logic would assign the coronary artery bypass (CABG) surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation.

Many commenters supported this proposal; other commenters stated the proposal did not address the increased resources required to treat patients with atrial fibrillation (AF) that are candidates for an open surgical ablation procedure at the same time of their CABG. Commenters were concerned that because of the added costs of performing these procedures at the same time, hospitals may likely schedule patients for separate procedures. Many commenters urged CMS to either create new MS-DRGs for these open concomitant procedures as originally requested or

assign these procedures to MS-DRGs that consider the added procedure and device costs required.

In response to these concerns, CMS discusses the analysis described in the proposed rule and provides additional analysis to evaluate the resources required to treat patients with AF that are candidates for an open surgical ablation procedure at the same time of their CABG (see tables in the final rule). The data analysis using the September 2020 update of the FY 2020 MedPAR file indicates that cases in MS-DRG 228 reporting a CABG procedure as well as an open ablation have an average length of stay that is longer than the average length of stay for all cases in MS-DRG 228 (12.8 days versus 10.2 days) and higher average costs when compared to all cases in MS-DRG 228 ($60, 327 versus $46,508). CMS found similar findings for MS-DRG 229. CMS also examined the redistribution of cases that is anticipated to occur by processing the claims data through the ICD-10 MS-DRG GROUPER Version 38 and also through the ICD-10 MS-DRG GROUPER Version 39. The largest number of cases moving out of MS-DRG 228 moved into MS-DRG 235, indicating these cases reported a procedure code for CABG and a cardiothoracic procedure, such as a surgical ablation, without procedure codes reporting a PTCA or a cardiac catherization. CMS found similar findings for cases moving out of MS-DRG 229 moving into MS-DRG 236. CMS also examined the average length of stay and average costs for all cases in MS-DRGs 231 through 236. The average length of stay and average costs of cases reporting a CABG procedure as well as a procedure describing an open ablation in MS-DRG as well as a secondary diagnosis of MCC are closer aligned to cases in MS-DRGs 233. Cases in MS—DRG 229 without secondary diagnosis of MCC are closer aligned to costs of cases in MS-DRGs 234 (see tables below reproduced from the final rule).

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Open Concomitant Ablation				
MS-DRG		**Number of Cases**	**Average Length of Stay**	**Average Costs**
228	Other Cardiothoracic Procedures with MCC – All Cases	4,419	10.2	$46,508
	Cases with procedure code for CABG and procedure code for open ablation	836	12.8	$60,327
229	Other Cardiothoracic Procedures without MCC - All cases	4,732	4.9	$29,885
	Cases with procedure code for CABG and procedure code for open ablation	824	7.9	$39,392

MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
231	Coronary Bypass with PTCA with MCC	745	12.4	$65,558
232	Coronary Bypass with PTCA without MCC	569	8.2	$46,079
233	Coronary Bypass with Cardiac Catheterization with MCC	9,572	12.5	$56,388
234	Coronary Bypass with Cardiac Catheterization without MCC	10,324	8.5	$39,406
235	Coronary Bypass without Cardiac Catheterization with MCC	9,371	9.7	$44,106

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
236	Coronary Bypass without Cardiac Catheterization without MCC	14,534	6.4	$31,170

CMS clinical advisors reviewed all the analysis and continue to believe that in open concomitant surgical ablation procedures, the CABG, mitral valve repair or replacement (MVR), and/or aortic valve repair or replacement (AVR) components of the procedure are more technically complex than the open surgical ablation procedure. They also believe that the proposed revision to the surgical hierarchy leads to a grouper that is more coherent and better accounts for resources expended to address more complex procedures. In cases where an open ablation is performed in combination with a coronary bypass procedure but without a PTCA or cardiac catherization procedure also being performed, the clinical advisors support the assignment of these cases to MS-DRG 233 and 234 and to change the titles of MS-DRGs 233 and 234 to include open ablation.

CMS finalizes its proposal to revise the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass) over MS-DRGs 228 and 229, effective October 1, 2021. CMS also finalizes the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS-DRGs 233 and 234 and change the titles to "Coronary Bypass with Cardiac Catherization or Open Ablation with and without MCC, respectively".

Request for reassignment. The second request was to reassign cases describing standalone percutaneous endoscopic surgical ablation from MS-DRGs 228 and 229 (Other Cardiothoracic Procedures) to MS-DRGs 219 and 220 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catherization). The codes and their corresponding MS-DRG assignments are listed in the final rule. Based on CMS' analysis and input from its clinical advisors, CMS proposed to maintain the current assignment of procedures describing percutaneous endoscopic surgical ablation.

Commenters disagreed with the proposal to maintain the current structure of MS-DRGs 219 and 220 and noted that payment for these MS-DRGs has been trending downward over the last five years. Commenters requested that CMS use its statutory authority to not reduce the relative weight and payments for these MS-DRGs. A few commenters noted that the reduction in payment for MS-DRGs 228 and 229 had resulted in hybrid standalone percutaneous endoscopic ablation and requested CMS either (1) maintain the relative weight of MS-DRGs 228 and 229 for a year and then reassess the data or (2) assign cases reporting standalone percutaneous endoscopic ablation from MS-DRGs 228 and 229 to the higher MCC severity level of its current base MS-DRG assignment.

In response to comments, CMS reiterates comments from previous rulemaking, including the FY 2021 IPPS/LTCH final rule (85 FR 58598), that it does not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data even if CMS has addressed relative weight fluctuations in specific circumstances such as when a relative weight would have declined by more than 20 percent in one year or where it did not have

sufficient MedPAR data to set accurate wights for low-volume MS-DRGs. CMS acknowledges the trending reduction in relative weights for MS-DRGs 228 and 229 (see figure in the final rule); it believes this weight change is appropriately driven by the underlying data in the 5 years since CMS began using the ICD-10 data in calculating the relative weights. CMS also notes that there are 809 ICD-10 PCS codes assigned to the GROUPER logic of MS-DRGs 228 and 229 in the ICD-10 MS-DRGs Definitions Manual Version 38.1 and procedure codes describing standalone ablation represent a small percentage. CMS reviews the analysis presented in the proposed rule, including the finding that percutaneous endoscopic surgical ablation procedure codes are less than 2% of the total cases in MS-DRG 228 and less than 10% of the total cases in MS-DRG 229. CMS also describes the analysis it performed to examine the request to reassign standalone percutaneous endoscopic ablation codes. Based on this analysis, CMS' clinical advisors do not support reassignment of these codes.

After consideration of comments, CMS finalizes its proposal to maintain the current structure of MS-DRGs 219 and 220 for FY 2022. CMS will continue to analyze these issues in future rulemaking.

f. Drug-eluting Stents

CMS received a request to review the MS-DRG assignments of coronary stents. CMS reviewed the procedure codes currently assigned to MS-DRGs 246 and 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent) and MS-DRGs 248 and 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent). Based on its review and input from its clinical advisors, CMS agrees that further refinement of these MS-DRGs may be necessary. CMS notes that evaluating this request requires an extensive analysis to assess potential impacts across the MS-DRGs. Therefore, CMS will review this request during its comprehensive procedure code review in future rulemaking.

In response to a request that CMS complete its analysis of these MS-DRGs for the FY 2023 proposed rule, CMS notes that the comprehensive procedure code review will be a multi-year project. CMS plans to provide more information on this analysis and methodology for conducting this review in future rulemaking.

6. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Knee Joint Procedures

CMS received a request to examine the procedure code combinations for procedures describing a right knee joint removal and replacement in MS-DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement). The requestor noted the right knee procedure code combinations grouped incorrectly to MS-DRG 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders); the left knee joint procedure combinations grouped correctly. Tables in the final rule list the procedure code combinations.
CMS reviewed the procedure code combinations and agreed with the requestor. During this review, CMS identified additional MS-DRGs in which the listed procedure code combinations

for the left knee joint are in the correct logic, but the listed procedure code combinations for the right knee join are excluded from the logic.

CMS proposed to add the three procedure code combinations (listed in the final rule) describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to MS-DRGs 461, 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) and MS-DRGs 466, 467, and 468 in MDC 08 and MS-DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures) in MDC 10.

A commenter identified 11 additional combinations that appeared to be missing from the logic for MS-DRGs 628, 629, and 630 in MDC 10 (listed in the final rule). The commenter also noted the difficulty in analyzing the logic list as some code combinations display the Removal code first and other combinations display the Replacement code first. CMS reviews these additional code combinations and agrees they were inadvertently missing from the logic for these DRGs in MDC 10. CMS states it performed further analysis and did not find any other combinations missing. CMS also notes it is working with its contractor, 3M HIS, to evaluate modifications to the logic list in these MS-DRGS to refine better display of these lists.

After consideration of comments, CMS finalizes its proposal to add the three procedural code combinations listed in the rule for removal and replacement of the right knee joint from the logic to MS-DRGs 461, 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) and MS-DRGs 466, 467, and 468 in MDC 08 and MS-DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures) in MDC 10. CMS also finalizes the 11 additional code combinations listed in the rule to the logic for MS-DRGs 628, 629, and 630 in MDC for FY 2022.

b. Pelvic Trauma with Internal Fixation

CMS received a request to reassign cases reporting a diagnosis code describing a pelvic fracture in combination with a procedure code describing repair of a pelvic fracture with internal fixation from the lower (NonCC) severity level MS-DRG of its current base MS-DRG assignment to the higher (MCC) severity level MS-DRG of its current base MS-DRG. The requestor provided relevant procedure and diagnosis codes (listed in tables in the proposed rule). Based on its review and input from its clinical advisors, CMS believed that further analysis of internal fixation for pelvic trauma cases in the claims data is warranted. Given the volume of these code combinations and corresponding data, CMS stated that additional time was needed for further analysis of the claims data to determine the causes of the fractures and other possible contributing factors to the length of stay and costs of these cases.

A commenter suggested that as part of the additional analysis, CMS should include trauma activations. Other commenters suggested that CMS reconsider the request and reassign these cases now and review additional data in future rulemaking. CMS reiterates there are other codes and code combinations requiring future review and CMS will work with stakeholders as it evaluates the data and considers further modifications to these MS-DRGs. CMS finalizes its proposal to maintain the structure of MS-DRGs 515, 516, and 517; MS-DRGs 907, 908, and 909; and MS-DRGs 957, 958, and 959 for FY 2022.

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

CMS received a request to create two new MS-DRGs for cases where the patient receives continuous renal replacement therapy (CCRT) during the inpatient stay.

To examine the impact of the use of CCRT, CMS examined claims from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for the top ten MS-DRGs reporting the use of CCRT (listed in the proposed rule). CMS observed a large variability in the differences in average costs from MS-DRG to MS-DRG; this indicates there may be other factors contributing to the higher costs. To further examine this variability, CMS also reviewed the claims data to identity the frequency and types of principal diagnoses that were reported. This evaluation also indicated a wide variance in the frequency and types of principal diagnoses reported with the use of CCRT. CMS did additional analyses to evaluate the frequency with which the use of CCRT is reported for different clinical scenarios to identify the top MDCs with the largest number of cases reporting CRRT. CMS' clinical advisors reviewed the clinical issues and the claims data and did not support creating new MS-DRGs for CCRT without regard to principal diagnosis (see tables in the final rule).

CMS concluded that depending on the number of cases in each MS-DRG, it is difficult to detect patterns of complexity and resource intensity. CMS believed the creation of new MS-DRGs for cases reporting the use of CRRT has the potential for creating instability in the relative weights and disrupt the integrity of the MS-DRG system. CMS did not propose to create new MS-DRGs for cases reporting CCRT.

A commenter supported CMS' proposal; another commenter suggested CMS group cases reporting the use of CRRT along with ICD-10-CM diagnosis codes N17.8 (Other acute kidney failure) and N17.9 (Acute kidney failure, unspecified) to the higher severity level MS-DRG of its current base MS-DRG assignment. CMS considers this suggestion outside the scope of the original proposal, and it may consider additional claims data analysis for these procedures in future rulemaking. CMS finalizes its proposal not to create new MS-DGs for cases reporting the use of CRRT for FY 2022.

8. MDC 16 (Diseases of Blood, Blood Forming Organs and Immunologic Disorders)

a. ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo

ANDEXXA® is a recombinant protein that rapidly reverses the anticoagulant effects of two direct oral anticoagulants when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages and gastrointestinal bleeding. ANDEXXA® received FDA approval on May 3, 2018; ANDEXXA® was approved for a new technology add-on payment in FY 2019 and the new technology add-on payments continued for FY 2021.[3] The manufacturer requested CMS review potential access issues for this drug after the new technology add-on payment expires. The manufacturer modeled payment and

[3] CMS continued the new technology add-on payments for FY 2021 (85 FR 58614 through 58615).

stated that approximately 59% of cases are likely to be paid less than the wholesale acquisition costs for ANDEXXA®.

In the final rule, CMS summarizes its analysis to evaluate the frequency that ANDEXXA® is reported for different clinical scenarios, using both claims' data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file. Using both MedPAR files, CMS also examined the claims data for the top ten MS-DRGs reporting administration of ANDEXXA® (see tables in the final rule). The claims data demonstrated the number of cases is small across the MDCs and MS-DRGs reflecting a wide variance in the frequency and average costs for cases reporting the use of ANDEXXA®. CMS could not identify another MS-DRG that would be a more appropriate for MS-DRG assignment. CMS' clinical advisors were concerned about making MS-DRG changes based on a specific single therapeutic agent instead of a group of related procedure codes.

CMS recognized the average costs of the small number of cases involving the administration of ANDEXXA® are greater when compared to the average costs of all cases in their respective MS-DRG and understands the requestors' concerns about continued access to this treatment. CMS stated it needs additional time to explore options to address low volume high-cost drugs outside of the MS-DRG. CMS did not propose any MS-DRG changes for cases involving the administration of ANDEXXA® for FY 2022.

Commenters supported CMS' proposal and agreed that options to address low volume high-cost drugs should be explored outside of the MS-DRG classification. CMS finalizes its proposal not to make any MS-DRG changes for cases involving the administration of ANDEXXA® for FY 2022. CMS also finalizes continuation of the new technology add-on payment for ANDEXXA® for FY 2022 (see discussion below in section D).

b. Cytokine Release Syndrome (CRS) Logic

CMS continues to monitor the six CRS codes (listed in the final rule) and their impact on resource use. Effective for discharges on and after October 1, 2021, three new ICD-CM-10 CM diagnosis codes will be available to describe complications of immune effector therapy based on the timeframe of the encounter and six new ICD-10-CM codes will be available to describe immune effector cell-associated neurotoxicity syndrome (ICANS) with varying degrees of severity (see tables below).

ICD-10-CM Code	Description
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

ICD-10-CM Code	Description
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4

ICD-10-CM Code	Description
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

CMS discussed the instructions for coding these diagnosis codes. The diagnosis codes describing a complication of the immune effector cellular therapy are to be sequenced first, followed by the applicable diagnosis code to identify the specified condition resulting from the complication. CMS proposed to revise the structure of MS-DRGS 814, 815, and 816 (Reticuloendothelial and Immunity Disorders) by updating the logic to reflect these new codes.

Commenters supported the proposed revision. A commenter requested CMS explain its rationale for the MS-DRG assignments and suggested CMS consider these codes as CCs or MCCs for any MS-DRG. In response, CMS discusses its established process to examine the MS-DRG assignment and the attributes for proposed assignments and designations of diagnosis or procedure codes. CMs finalizes its proposal to assign diagnosis codes T80.82XA to MDC 16 in MS-DRGs 814, 815, and 816. CMS also finalizes its proposal to revise the structure of MS-DRGs 814, 815, and 816 by removing the logic that includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code from MS-DRGs 814, 815, and 816 effective FY 2022.

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

CMS received a request to revise MS-DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures) and create a three-way severity level split instead of the current two-way severity level split. The requestor disagreed with CMS' FY 2021 IPPS final rule decision to change the designation of insertion of an IVC intraluminal device via percutaneous approach to a non-O.R. procedure (ICD-10-PCS code 06H03DZ). The requestor stated IVC filters are most often place in interventional radiology suites and require a high level of skill to prevent rupture of the vena cava. As an alternative, the requestor recommended reinstatement of the O.R. procedure status. The requestor provided relevant procedure and diagnosis codes (listed in the final rule). Based on its review and input from its clinical advisors, CMS concluded the claims data did not support a three-way severity split for base MS-DRG 829. CMS' clinical advisors continued to believe that procedure code 06H03DZ did not require the resources of an operating room. CMS proposed to maintain the current structure of MS-DRGs 829 and 830.

Commenters supported CMS' proposal. CMS finalizes its proposal to maintain the current structure of MS-DRGs 829 and 830, without modifications, for FY 2022.

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

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.

The reader is referred to the final rule for a discussion of comments and finalized proposals for the following:

- Bleeding in the cranial cavity when reported with a central nervous system diagnosis
- Excision of subcutaneous tissue and fascia, open approach
- Laser interstitial thermal therapy (LITT)
- Repair of the esophagus
- Drainage of urethra

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

CMS has a list of procedures that are considered O.R. procedures. CMS discusses 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. 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 Codes) and subject to public comment.[4] 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. Given the PHE, CMS believes it may be appropriate to allow additional time for the claims data to stabilize before selecting the timeframe for this analysis. CMS will provide more details on the methodology for conducting this review in future rulemaking.

For review of requests for FY 2022 consideration, CMS' clinical advisors considered the following for each procedure:

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

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

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. Some of the requests were not discussed in the proposed rule; CMS stated it will consider these requests as part of its comprehensive review of procedure codes.

In response to comments, CMS clarifies that when it states that a current non-O.R. procedure is frequently or generally performed in the outpatient setting, it is indicating that the resources involved in doing the procedure do not typically require an inpatient admission, it typically not the underlying reason for an admission, nor a major factor in the consumption of resources for an inpatient admission. CMS notes that an inpatient provider electing to perform a specific procedure in the operating or procedure room, does not automatically designate the procedure as an O.R. procedure under the IPPS. Alternatively, a procedure that is performed at the bedside does not constitute automatic designation of the procedure as a non-O.R. procedure.

The reader is referred to the final rule for a discussion of the 26 requests listed below.

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

- Open drainage of subcutaneous tissue and fascia

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

- Percutaneous introduction of substance into cranial cavity and brain
- Open drainage of maxilla and mandible
- Thoracoscopic extirpation of pleural cavities
- Open pleural biopsy
- Percutaneous revision of intraluminal devices
- Occlusion of left atrial appendage
- Arthroscopic drainage of joints
- Arthroscopic irrigation of joints
- Percutaneous reposition with internal fixation
- Open insertion and removal of spacer into should joint
- Open/percutaneous extirpation of jaw
- Open extirpation of subcutaneous tissue and fascia
- Open revision and removal of devices from subcutaneous tissue and fascia
- Open insertion of feeding device

- Laparoscopic insertion of feeding tube
- Endoscopic fragmentation and extirpation of matter of urinary tract
- Endoscopic removal of ureteral stent
- Endoscopic/transorifice inspection of ureter
- Endoscopic biopsy of ureter and kidney
- Transorifice insertion of ureteral stent
- Percutaneous insertion of ureteral stent
- Endoscopic dilation of urethra
- Open repair of scrotum
- Open drainage of vestibular gland
- Transvaginal repair of vagina
- Percutaneous tunneled vascular access devices

12. Changes to the MS-DRG Diagnosis Codes

Under the IPPS MS-DRG classification, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule[5], 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.[6] CMS developed nine guiding principles as meaningful indicators of expected resource use by 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.

[5]72 FR 47152 through 47171
[6]84 FR 42150 through 42152

CMS plans to continue a comprehensive CC/MC analysis using a combination of the prior mathematical analysis of claims data in combination with the guiding principles and will provide more details in future rulemaking. CMS will consider individual requests to change the severity level designation of specific ICD-10-CM diagnosis codes as it continues its comprehensive CC/MCC analysis. CMS invited comments regarding these principles, as well as other possible ways it can incorporate meaningful indicators of clinical severity.

In response to a comment, CMS clarifies that the guiding principles are not only applicable to CC or MCC conditions. Severity level determination will be based on the consideration of the clinical factors captured by these principles as well as the empirical analysis of the additional resources associated with the secondary diagnosis. CMS appreciates commenters willingness to partner with CMS on this initiative and notes that although it has already convened an internal workgroup comprised of clinicians, consultants, coding specialists, and other policy analysts it welcomes additional public feedback. Commenters can continue to submit their recommendations to the following email address: MSDRGClassificationChange@cms.hhs.gov by November 1, 2021.

In response to a request for an updated file, in May 2021, CMS made an updated impact resource use file available for public review using claims from the FY 2019 MedPAR file and the FY 2020 MedPAR file. The link to this file is posted at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

a. Potential Change to Severity Level Designation for Unspecified Diagnosis Code for FY 2022

As an interval step in the comprehensive review of severity level designations, CMS proposed a potential change to the severity level designations for "unspecified" ICD-10-CM diagnosis codes. For FY 2022, CMS considered changing the severity level diagnosis of all "unspecified" diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. CMS stated that the use of these "unspecified" diagnosis codes may contribute to less reliable data for researching clinical outcomes and more robust claims data would inform its decision making in determining the most appropriate CC subclass assignment.

In the final rule, CMS reviews the analysis for this proposal. The table below, reproduced from the final rule, summarizes the potential MCC/CC severity level changes.

POTENTIAL MCC/CC SUBCLASS MODIFICATIONS						
Severity Level – CC Subclass	**Version 38.1 Severity Level Number of Codes**	**Potential Version 39 Severity Level Number of Codes**	**Percent Change**	**Potential Version 39 Change to MCC subclass, Number of Codes**	**Potential Version 39 Change to CC subclass, Number of Codes**	**Potential Version 39 Change to NonCC subclass, Number of Codes**
MCC	3,278	2,771	-15.5%	N/A	0	507
CC	14,679	11,696	-20.3	0	N/A	2,983
NonCC	54,664	58,154	6.4%	0	0	N/A
Total	**72,621**	**72,621**	**N/A**	**0**	**0**	**3,490**

To understand how each chapter of ICD-10-CM might be affected by this proposal, CMS also compared the Version 38.1 to the potential Version 39 ICD-10 MS-DRG severity level list by each of the 22 chapters of the ICD-10-CM classification. These results are summarized in a table in the final rule. The Diseases of the Musculoskeletal System and Connective Tissue (M00-M99) chapter of ICD-10-CM would have the largest percentage reduction (29.2%) in codes. The diagnosis codes impacted by this proposed change in severity level designation are shown in Table 6P.2a associated with the proposed rule.

CMS solicited comments on adopting a change to the severity level designation of the 3,490 "unspecified" diagnosis codes currently designated as either CC or MCC, where there are other codes available in the code subcategory that further specify the anatomic site, to a NonCC for FY 2022. CMS was also interested in comments regarding whether this modification might present operational challenges and how CMS might foster reporting of the most specific diagnosis codes supported by the available medical record documentation.

Many commenters supported CMS' proposal, others questioned the need for the proposal, and others suggested a delay because of the PHE. In response to commenters questioning the need for the proposal, CMS provides examples of how the laterality of a condition impacts the severity of the diagnosis. Using the September 2019 update of the FY 2019 file for diagnosis codes that describe stage 3 pressure ulcers of the hip, CMS highlights that when taking laterality into account, the resources expended may not be as equally expressed in claims data using unspecified diagnosis as compared to using the specified laterality (see tables in the final rule). CMS disagrees with comments that laterality is not one of CMS' criteria for determining the severity level of a condition and states that this is a long-standing criterion and is inherent to the guiding principle "typically requires higher level of care". CMS states if a higher level of care is required to address the secondary diagnosis, then the laterality affected in most instances should be able to be determined in the course of the associated intensive monitoring, greater number of caregivers, and/or additional testing in most instances.

In response to comments recommending changes to the proposed list, CMS finalizes not including the 58 ICD-10-CM diagnosis codes (listed in a table in the final rule) for consideration of changing the severity level designation as part of "unspecified" diagnosis codes currently designated as either CC or MCC where there are other codes available in the code subcategory that further specify the anatomical site.

CMS also discusses the revisions, effective October 1, 2021, in the ICD-10-CM Official Guidelines for Coding and Reporting to provide additional guidance to the source documentation for code assignments. Sections I.B.13 and I.B.14 of the guidelines have been updates to address the need to document laterality in the medical record. CMS encourages review of the Official ICD-10-CM Coding Guidelines available on the CDC website at: http://www.cdc.gov/nchs/icd/icd10.htm.

Commenter recommended CMS delay any possible change to the designation of these codes for at least two years to give hospitals and clinicians time to prepare. Commenters stressed the

operational changes will create significant administrative burden when resources are already stretched due to the PHE.

After consideration of comments, CMS finalizes maintaining the severity level designation of all "unspecified" diagnosis codes currently designated as a CC or MCC when there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. CMS is finalizing its proposal for the Unspecified Code MCE edit (discussed in section D.14). CMS believes additional time is needed to educate providers about the need for proper documentation and to educate coders on the updated guidelines.

b. Additions and Deletions to the Diagnosis Code Severity Levels

The following tables[7] identify the finalized severity levels under Version 39 of the ICD-10 MS-DRGs for FY 2022:

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

c. CC Exclusions List

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 three requests related to the CC Exclusions List logic. The reader is referred to the final rule for a discussion of the requests listed below.

- Diagnosis codes for other specified diseases and conditions complicating pregnancy, childbirth, and puerperium
- Diagnosis codes describing oxygen dependence, chronic obstructive pulmonary disease with exacerbation, and chronic respiratory failure
- Diagnosis code for hypertensive heart disease with heart failure.

The following tables identify the finalized 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; and

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

- Table 6H.2 - Secondary Disorders Order Deletions to the CC Exclusion List.

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

The following tables[8] identify new, revised and deleted diagnosis and procedure codes for FY 2022:

- Table 6A - New Diagnosis Codes;
- Table 6B - New Procedure Codes;
- Table 6C - Invalid Diagnosis Codes;
- Table 6D - Invalid Procedure Codes and
- Table 6E – Revised Diagnosis Title.

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 manual file, along with the link to the mainframe and computer software for the MCE Version 39 (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 to examine specific code edit lists. The interested reader is referred to the final rule for discussion of the following edits:

- External causes of morbidity codes as principal diagnosis;
- Age conflict edit;
- Sex conflict edit;
- Unacceptable principal diagnosis edit; and
- Unspecified codes.

In the proposed rule, CMS requested comments on the potential creation of a new MCE code edit involving unspecified codes. Specifically, CMS proposed an MCE code edit which could trigger when an "unspecified" diagnosis code currently designated as either a CC or MCC, and has other codes available in that code subcategory to further specify the anatomic site, is entered. Table 6P.31 associated with the proposed rule listed the unspecified diagnosis codes subject to this edit. CMS stated this edit could signal to the provider that a more specific code is available to report. Many commenters supported this edit. CMS does not agree with the recommendation that it implement the edit using a phased approach but believes time is needed to educate providers (see discussion above in section B.12)

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

CMS finalizes implementation of a new code edit for "unspecified" codes where there are other codes available in that code subcategory that further specify the anatomic site. The implementation for this new edit is April 1, 2022. The list of codes subject to this edit are identified in Table 6P.3a associated with this final rule. CMS notes that by February 1, 2022 it will be releasing the ICD-10 Medicare Severity Diagnosis Related Group (MS-DRG) GROUPER Software and Medicare Code Editor (MCE) ICD-10 Software.

Future Enhancements. CMS has 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 continues to encourage 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, 2021 for FY 2022.

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.

CMS received a request to examine the MS-DRG hierarchy within MDC 05 (Diseases and Disorders of the Circulatory System). In the final rule, CMS reviews the analysis for this request. As summarized in the table below, reproduced from the final rule, CMS proposed to revise the surgical hierarchy for the MS-DRGs in MDC for FY 2022.

Proposed DRG Surgical Hierarchy: MDC 05	
215	Other Heart Assist System Implant
216 – 221	Cardiac Valve and Other Major Cardiothoracic Procedures
231 – 236	Coronary Bypass
222 – 227	Cardiac Defibrillator Implant
266 – 267	Endovascular Cardiac Valve Replacement and Supplement Procedures
268 – 269	Aortic and Heart Assist Procedures
228 – 229	Other Cardiothoracic Procedures
319 – 320	Other Endovascular Cardiac Valve Procedures

In response to a comment's suggestion that CMS sequence MS-DRGs 222-227 above MS-DRGs 231-236, CMS reviewed the data supporting the proposed revision. As discussed in the final rule, CMS examined the redistribution of cases anticipated to occur by comparing the MS-DRG

assignments in claims data from the March 2020 update of the FY 2019 MedPAR file through the ICD-10 MS-DRG GROUPER Version 38 to the same claims data through the ICD-10 MS-DRG GROUPER Version 39. CMS did similar analysis with the September 2020 update of the FY 2020 MedPAR file and found that a small number of cases, 84 and 23 cases, are anticipated to potentially shift or be redistributed into MS-DRGs 235 and 236, respectively. CMS' clinical advisors reviewed these data and comments related to open concomitant surgical ablation procedures (see discussion above in section B.5). CMS' clinical advisors continue to believe that the proposed revision to the surgical hierarchy is appropriate.

CMS finalized the proposed changes to the surgical hierarchy for the MS-DRGs in MDC 05 for FY 2022.

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 submit questions and comments to: nchsicd10cm@cdc.gov.
- For procedure codes submit questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

CMS discusses six new diagnosis codes describing conditions related to COVID-19 and 21 new procedure codes describing the introduction of therapies for COVID-19 treatment (see tables in the final rule).

In the proposed rule, CMS noted that during the March 2021 ICD-10 Coordination and Maintenance Committee meeting it announced that in addition to the October 1 annual update for ICD-10 codes it was considering an April 1 implementation date. CMS stated that if the April 1 implementation date was adopted, it would assign the approved codes to an MS-DRG(s) using its established process for assigning new diagnosis and procedure codes.
Several commenters expressed support for an April 1 update and encouraged the development of policies that expedite the assignment of new diagnosis and procedure codes to meets the needs of clinical advancements. CMS discusses the comments received on what criteria or factors should be considered for determining whether to consider a code request for an April 1 or October 1 implementation date.

In response to commenters opposing the additional April 1 implementation date, in the final rule CMS provides a sample timeline from the March 2021 ICD-10 Coordination and Maintenance Committee meeting materials to illustrate the process associated with the proposal. CMS notes that an additional implementation data would reduce the current 18-month timeframe for incorporating new diagnosis codes into the MS-DRGs. In response to concerns about coding

guideline updates, CMS states that if updates to the guidelines are necessary, the four Cooperating Parties for ICD-10 (AHA, AHIMA, CDC, and CMS) will evaluate and incorporate the necessary information into the appropriate section for all users of the classification accordingly. Coding guideline updates in response to April 1 code updates effective with discharges on and after April 1 will be valid beginning on April 1 of the fiscal year. As displayed in the sample timeline, all materials requiring updates would be made publicly available by February 1 for an April 1 code implementation, including coding guidelines.

CMS finalizes adopting an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022.

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

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[9], 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,[10] 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.
For FY 2022, CMS did not propose adding any MS-DRGs to the policy for replaced devices offered without cost or with a credit. The table below, reproduced from the final rule, lists the finalized MS-DRGs subject to this policy for FY 2022.

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG 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	140	Major Head and Neck Procedures with MCC
MDC 03	141	Major Head and Neck Procedures with CC
MDC 03	142	Major Head and Neck Procedures without CC/ MCC
MDC 05	215	Other Heart Assist System Implant

[9] 72 FR 47246 through 47251
[10] 76 FR 51556 and 51557

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG DRG**	**MS-DRG Title**
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
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	551	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
MDC 8	552	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

C. Recalibration of the 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. CMS ordinarily uses the MedPAR file (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the ratesetting year (e.g., FY 2020 for FY 2022). However, CMS proposed to use FY 2019 MedPAR data and FY 2018 HCRIS data to set the relative weights for FY 2022 rather than updating to the FY 2020 MedPAR and FY 2019 HCRIS data to avoid using data affected by the COVID-19 PHE. In the proposed rule, CMS explained its reasoning:

- FY 2020 Utilization Data is Atypical: CMS' analysis showed a decline in total admissions in FY 2020 compared to FY 2019 and a particularly sharp decline in elective surgeries with a very high increase in admissions for respiratory illness. This analysis and a further analysis of case-mix showed that FY 2020 utilization was significantly different compared to FY 2019 utilization. CMS concluded from an analysis of vaccination rates among the U.S. population that FY 2022 is likely to be a more typical year (e.g., more similar to FY 2019 than FY 2020).
- Differential Impact of FY 2020 Utilization Data on Ratesetting: CMS presented a complex analysis of how the case-mix index and the outlier threshold would be impacted by using the FY 2019 versus the FY 2020 utilization MedPAR. From this analysis, CMS concluded that there would be a material effect on IPPS ratesetting from using atypical FY 2020 inpatient utilization rather than continuing to use the more typical utilization patterns from FY 2019.

The other major data source that CMS uses in setting the MS-DRG relative weights is Medicare hospital cost report data from the most recent quarterly HCRIS release. Typically, CMS would use cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking (FY 2019 for FY 2022). However, CMS noted that many FY 2019 cost reporting periods actually end in FY 2020 during the period of the COVID-19 PHE. CMS proposed to use cost report data from the FY 2018 HCRIS file in determining the proposed FY 2022 IPPS MS-DRG relative weights

Comments/Response: The vast majority of commenters were fully supportive of CMS' proposals. There were concerns about the PHE being ongoing due to the declining pace of vaccinations and new, more transmissible forms of the virus. These commenters were concerned about future data. CMS responded that the most recent vaccination and hospitalization data reported by the CDC support its assumption that there will be significantly lower risk of COVID-19 in FY 2022 and fewer hospitalizations for Medicare beneficiaries in FY 2022 than there were in FY 2020. However, the data that CMS cites to support its statement is from July 3rd, a date that precedes the latest surges in spread of the virus. Nevertheless, that does not change CMS' conclusion about using FY 2019 data as the better approximation of the FY 2022 inpatient experience for ratesetting. CMS is finalizing its proposal to use the FY 2019 data for the FY 2022 ratesetting.

In developing relative weights for the FY 2022, 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 (MA) claims and claims from facilities currently classified as CAHs are excluded. CMS used data from approximately 9,216,615 million Medicare discharges regrouped using the final FY 2022 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. This file is identical to the one used for the FY 2021 IPPS final rule.

For FY 2022, CMS did not propose any changes to its methodology and will calculate 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 2022. Use the link provided at the beginning of this summary. Select file #4 under FY 2022 Final Rule Data files (FY 2022 Final Rule: HCRIS Data File).

National Average CCRs. The FY 2022 CCRs are shown in the following table.

Group	FY 2021 CCR	FY 2022 CCR
Routine Days	0.422	0.422
Intensive Days	0.347	0.345
Drugs	0.190	0.187
Supplies & Equipment	0.304	0.297
Implantable Devices	0.300	0.293
Inhalation Therapy	0.148	0.147
Therapy Services	0.291	0.288
Anesthesia	0.074	0.071
Labor & Delivery	0.369	0.359
Operating Room	0.169	0.167
Cardiology	0.095	0.094
Cardiac Catheterization	0.102	0.100
Laboratory	0.108	0.106
Radiology	0.138	0.136
MRIs	0.070	0.070
CT Scans	0.034	0.034
Emergency Room	0.149	0.147
Blood and Blood Products	0.272	0.270
Other Services	0.350	0.344

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). 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. For FY 2021, CMS adopted a differential payment—17 percent of the full IPPS payment—or these cases to recognize hospitals' lower costs. CMS also excluded CAR-T cases billed with a clinical trial indicator or less than $373,000 in drug costs—

the average sales price of the two CAR-T cell products approved to treat relapsed/refractory diffuse large B-cell lymphoma in drug costs—from the relative weight calculation.

CMS proposed to adopt these same policies for FY 2022. Public commenters indicated that CMS should consider changing the thresholds for eliminating cases for the relative weight calculation. However, CMS indicated that since it is using the same FY 2019 claims data to set the relative weights, it would retain the same policies for when a CAR-T clinical trial case would be excluded.

Other commenters indicated that the IPPS payment does not recognize the full costs of treating a CAR-T patient. These commenters requested that CMS incorporate average sales pricing into the determination of the IPPS relative weight to fully recognize the cost of the CAR-T product. CMS declined to do so saying that the IPPS is not a cost-reimbursement system and instead is intended to represent the relative resources of cases classified within one MS-DRG compared to others.

There were also comments asking CMS to create a unique cost center for CAR-T products such that hospitals can charge consistent with its higher costs. CMS reiterated its prior reply to this comment that hospitals are free to set their charges for CAR-T products consistent with other drugs and supplies. Further, hospitals may request approval to change charging practices to voluntarily lower its charges and its CCR.

The final rule relative weights were normalized by an adjustment factor of 1.820829 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.

Comments/Responses: A few commenters indicated that CMS' proposal to continue to use FY 2019 utilization data to set the MS-DRG relative weights means that no changes in case mix would be recognized in the setting the FY 2002 payment rates as would normally occur when updating to the latest utilization year. The commenters requested CMS consider whether an adjustment needs to be made for changes in case-mix. CMS explains that normalization is one part of a two-step process to ensure that recalibration does not increase costs. The second part is a budget neutrality adjustment to the IPPS rates. CMS responds to the comment stating "even putting aside the methodological issues with [adjusting the normalization factor by an estimate of real case mix growth], we note that such an increase in the normalization factor would be offset by a larger budget neutrality adjustment."

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 Payment 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[11]; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Beginning with FY 2021, certain transformative new devices and Qualified Infectious Disease Products (QIDPS) may qualify for a new technology add-on payment under an alternative pathway.[12] Also, beginning with FY 2022, a drug approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), may also qualify for an new technology add-on payment under an alternative pathway.[13] CMS refers more broadly to "certain antimicrobial products" instead of referring to a particular FDA program for antimicrobial products.

a. New Technology Add-on Payment Criteria

Newness Criterion. 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]:

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.

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 makes a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

[11] Capital costs are not included in the add-on payments for a new medical service or technology and new technology add-on payments are not made for capitol-related costs (72 FR 47307 through 47308).
[12] 84 FR 42292 through 42297; regulations at § 412.87(c) and (d)
[13] 85 FR 58736
[14] 74 FR 43813 and 43814

Cost Criterion.

Because of the PHE, for FY 2022 ratesetting CMS finalizes its proposal to use the FY 2019 MedPAR claims data, instead of FY 2020 MedPAR data (discussed above in this summary and in section I.F. of the preamble of this rule). Consistent with this final policy, for the FY 2023 threshold values, CMS finalizes using FY 2019 claims data to evaluate whether the charges of the cases involving a new medical service or technology will exceed the cost thresholds. The finalized MS-DRG thresholds applicable to FY 2023 are included in the data files associated with the FY 2022 final rule on the CMS website.[15]

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[16], 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

[15] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[16] 84 FR 42288 through 42292

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 years).

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

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. In the FY 2021 final rule, CMS clarified that a new medical device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation.

Alternative Pathway for Certain Antimicrobial Products. Beginning with FY 2021, if a new medical product is designated by the FDA 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. Beginning with FY 2022, a drug approved under FDA's LPAD pathway, 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 products will still need to meet the cost criterion. For the new technology add-on payment under these alternative pathways, the product must receive marketing authorization for the indication covered by the QDIP or LPAD designation.

c. Additional Payment for New Medical Service or Technology

In the FY 2020 IPPS final rule[17], 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 or approved under the LPAD pathway, 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

[17] 84 FR 42297 through 42300

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 or approved under the LPAD pathway, 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 Medicare payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for a QDIP or LPAD) of the estimated costs of the new technology or medical service. CMS notes that add-on payments for new medical services or technologies are not subject to budget neutrality.[18]

d. Evaluation of Eligibility Criteria for New Services or Technology Applications

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. In the FY 2021 IPPS final rule, CMS clarified that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year that the application is being considered.

In the FY 2021 IPPS final rule, CMS finalized its policy for conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that otherwise meet the new technology add-on payment alternative pathway but do not receive FDA approval by July 1.[19] 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.

e. Applications

For FY 2023, 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 2023.

[18] 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.
[19] 85 FR 58739 through 58742

CMS invites any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence needed in the agency's coverage decisions. In addition, stakeholders with questions about Medicare's coverage, coding, and payment processes, or questions about how to navigate these processes, can contact the Council on Technology and Innovation (CTI) at CTI@cms.hhs.gov.[20]

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

On December 15 and 16, 2020, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications. In their evaluation of individual applications, CMS considers the presentations made at the town hall meeting and written comments received by December 28, 2020. Where applicable, CMS summarizes comments in the discussion of the individual applications in the proposed rule. Comments that are unrelated to the "substantial clinical improvement" criterion are not summarized.

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/icd-10/2021-icd-10-pcs. 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 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

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.

[20] The CTI was established under section 942(a) of Pub. L. 108-173 and oversees the agency's cross-cutting priorities on coordinating coverage, coding and payment processes for new technologies, including drug therapies. CTI's "Innovator's Guide" is available at https://www.cms.gov/Medicare/Coverage/CouncilonTechnology/Downloads/Innovatiors-Guide-Master-7-23-15.pdf.

a. Continuation of New Technology Add-On Payments for FY 2022 for Technologies Still Considered to be New

CMS proposed continuing the new technology add-on payments for nine technologies it still considered new for FY 2022. In a comment, the manufacturer for Azedra® stated that the newness period for this drug should either start with the first sale which would be June 6, 2019 instead of July 30, 2018 or when the drug was available in the market on May 21, 2019. CMS agrees with the commenter and concludes that the newness date for Azedra® should begin on the date of market availability, May 21, 2019. In addition, based on information provided by the manufacturer, CMS updates the maximum new technology add-on payment for Jakafi®.

CMS finalizes the continuation of ten new technology add-on payments for technologies still considered new for FY 2022. Information about these ten technologies is provided in a table in the final rule and summarized below.

Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments (NTAP) Still Considered New for FY 2022			
Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**Proposed Maximum NTAP Amount for FY 2022**
Balversa™	4/12/2019	10/1/2019	$3,563.23
Jakafi®	5/24/2019	10/1/2019	$4,475.38
BAROSTIM Neo™ System	8/16/2019	10/1/2020	$22,750
FETROJA® (Cefiderocol)	11/19/2019 (commercially available in US 2/24/2020)	10/1/2020	$7,919.86
Optimizer® System	10/23/2019	10/1/2020	$14,950
RECARBIO™	7/16/2019 (commercially available in US 1/6/2020)	10/1/2020	$3,532.78
Soliris®	6/27/2019	10/1/2020	$21,199.75
XENLETA™	8/19/2019 (commercially available in US 9/10/2019)	10/1/2020	$1,275.75
ZERBAXA®	6/03/2019	10/1/2020	$1,836.98
Azedra®	5/21/2019	10/01/2019	$98,150.00

b. Extension of New Technology Add-On Payments

As previously discussed, CMS finalizes its proposal to use the FY 2019 MedPAR claims data for FY 2022 ratesetting. CMS also finalizes its proposal to use its authority to allow for a one-year extension of new technology add-on payments for technologies that would have otherwise had new technology add-on payments discontinued beginning with FY 2022. The 13 technologies with a one-year extension of NTAPs for FY 2022 are listed in a table in the final rule and summarized below.

One Year Extension for Technologies Approved with FY 2021 New Technology Add-on Payments (NTAP) That Would Otherwise Be Discontinued in FY 2022			
Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**Proposed Maximum NTAP Amount for FY 2022**
Cablivi®	2/6/2019	10/1/2019	$33,215
Elzonris™	12/21/2018	10/1/2019	$144,116.04
AndexXA™	5/3/2018	10/1/2018	$18,281.25

One Year Extension for Technologies Approved with FY 2021 New Technology Add-on Payments (NTAP) That Would Otherwise Be Discontinued in FY 2022			
Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**Proposed Maximum NTAP Amount for FY 2022**
Spravato®	3/5/2019	10/1/2019	$1,014.79
Zemdri	6/25/2018	10/1/2018	$4,083.75
T2 Bacterial® Panel	5/24/2018	10/1/2019	$97.50
ContaCT	2/13/2018 (commercially available in US 10/1/2018)	10/1/2020	$1,040
Eluvia™ Drug-Eluting Vascular Stent System	9/19/2018 (commercially available in US 10/4/2018)	10/1/2020	$3,646.50
Hemospray®	5/7/2018 (commercially available in US 7/1/2018)	10/1/2020	$1,625
IMFINZI®/TECENTRIQ®	3/18/2019*	10/1/2020	$6,875.90
NUZYRA®	10/02/2018 (commercially available in US 2/1/2019)	10/1/2020	$1,552.50
SpineJack® System	8/30/2018(commercially available in US 10/11/2018)	10/1/2020	$3.654.72
Xospata®	11/28/2018	10/1/2019	$7,312.50
*Infinizi approval date was 3/27/2020 and Tecentriq approval was 3/28/2019; the newness data for the NTAP is 3/18/2019 for both technologies.			

Commenters overwhelmingly supported CMS' proposal to allow for a one-year extension of new technology add-on payments for FY 2022 for those technologies with add-on payments that would otherwise be discontinued beginning with FY 2022. Based on information provided by the manufacturer, CMS updated the maximum new technology add-on payment for Elzonris™.

CMS summarizes the comments received in response to its request about the appropriate method to determine a cost per case for technologies sold on a subscription basis, such as ContaCT. Specifically, CMS requested comments on whether the cost per case be estimated based on subscriber hospital data and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year the technology may be eligible for the new technology add-on payment. Commenters agreed that in determining the cost per case for these technologies, CMS should limit its analysis to subscriber hospitals and update the cost analysis on an annual basis. A commenter noted that an alternative methodology involving estimating the number of patients who would be eligible to receive treatment utilizing a technology sold on a subscription basis would likely result in a payment amount that does not adequately reflect the estimated average cost of such service or technology as required by statute.
CMS will take these comments into consideration in future rulemaking where applicable.

For FY 2022, CMS believes the cost per case from the ContaCT applicant's original cost analysis is still appropriate to be used for the calculation of the maximum new technology add-on payment for a case involving ContaCT.

Regulatory Impact. The table below, reproduced from the final rule, are CMS' estimates for the 23 technologies with continued new technology add-on payments in FY 2022.

FY 2022 Estimates for Technologies with Continued New Technology Add-On Payments			
Technology Name	**Estimated Cases**	**FY 2022 NTAP amount (65 % or 75 %)**	**Estimated Total FY 2022 Impact**
Andexa Xa	5,402	$18,281.25	$98,755,312.50
Azedra	400	$98,150.00	$39,260,000.00
BAROSTIM NEO System	722	$22,750.00	$16,425,500.00
Caplacizumab	131	$33,215.00	$4,351,165.00
ContaCT	69,336	$1,040.00	$72,109,440.00
Erdafitinib (Balversa)	50	$3,563.23	$178,161.50
Esketamine (SPRAVATO)	6,400	$1,014.79	$6,494,656.00
Eluvia Drug-Eluting Vascular Stent System	2,453	$3,646.50	$8,944,864.50
Elzonris	247	$144,116.04	$35,596,661.88
FETROJA	6,355	$7,919.86	$50,330,710.30
Hemospray	12,700	$1,625.00	$20,637,500.00
IMFINZI/TECENTRIQ	4,296	$6,875.90	$29,538,866.40
Jakafi	140	$4,475.38	$626,553.20
NUZYRA	16,899	$1,552.50	$26,235,697.50
Optimizer System	1,500	$14,950.00	$22,425,000.00
RECARBRIO	762	$3,532.78	$2,691,978.36
Soliris	13,680	$21,199.75	$290,012,580.00
Spinejack	1,572	$3,654.72	$5,745,219.84
T2 Bacteria Test Panel	37639	$97.50	$3,669,802.50
XENLETA	35246	$1,275.75	$44,965,084.50
Xospata	1,875	$7,312.50	$13,710,937.50
ZERBAXA	30,117	$1,836.98	$55,324,326.66
Zemdri	2,500	$4,083.75	$10,209,375.00

5. FY 2022 Applications for New Technology Add-On Payments: Traditional Pathway

CMS received 26 applications for new technology add-on payments for FY 2022. Four applicants withdrew their applications prior to the issuance of the proposed rule. Five applications were withdrawn prior to the issuance of the final rule: lifileucel, narsoplimab, TERLIVAZ (terlipressin), ciltacabtagene autoleucel, and Nexobrid. Two applicants, ISC-REST and Oluminant, did not receive FDA approval by July 1, 2021 and therefore are not eligible for consideration for new technology add-on payments for FY 2022.

The summary below provides a high-level discussion of the 15 remaining new technologies; readers are advised to review the final rule for more detailed information.

CMS approves seven of the applications for new technology add-on payments for FY 2022:

- RYBREVANT™ (amivantamab),
- COSELA™ (trilaciclib),
- ABECMA® (idecabtagene vicleucel),
- StrataGraft™,
- Tecartus™ (brexucabtagene autoleucel),
- VEKLURY® (remdesivir), and
- ZEPZELCA™ (lurbinectedin).

a. Aidoc Briefcase for Pulmonary Embolism (PE)

Aidoc Medical Ltd. Submitted an application for Briefcase for PE, an artificial intelligence (AI)-based solution for triage and notification of suspected PE. The applicant states the device assists hospitals and radiologist by flagging and communicating suspected PE based on computed tomography pulmonary angiography (CPTA) examinations. The applicant states that with Briefcase for PE, CTPA images are automatically forwarded to the applicant's cloud-based engine and analyzed by an AI algorithm, When the technology detects a suspected PE, the radiologist is alerted via a user interface of the Aidoc Worklist Application that is installed on the radiologist's desktop. The applicant asserts that the notification prompts the radiologist to review the CPTA images and communicate with the clinical staff to begin treatment for a PE sooner than what would have occurred with the typical radiology first-in-first-out (FIFO) reading queue.

Newness. Briefcase for PE received FDA 510(k) clearance on April 15, 2019. The FDA clearance was based on substantial equivalence to the predicate device, Briefcase for Intracranial Hemorrhage (IHI); both of these devices use AI algorithms to analyze images and highlight cases for further action. Briefcase for ICH received FDA 510(k) clearance on August 1, 2018; the predicate device for Briefcase for ICH is Viz AI's ContaCT. An ICD-10-PCS procedure code (XXE3X27) to identify use of this technology was approved effective October 1, 2021

For the first criterion (same or similar mechanism of action), the applicant stated no other FDA approved or cleared technology uses the same mechanism of action for computer-aided triage and prioritization of PE. For the second criterion (same or different MS-DRG), the applicant expected patients evaluated for PE or suspected PE using this technology will be assigned to the same DRGs as patients evaluated for PE or suspected PE under the current workflow. For the third criterion (treatment of the same or similar disease or patient population), the applicant reiterated no other technology is comparable to Briefcase for PE. CMS believes that Briefcase for PE would be used for a different disease and patient population than Briefcase for ICH and ContaCT.

In the proposed rule, CMS discussed its concerns that the technology might not meet the substantial similarity criteria as the applicant asserted that Briefcase for ICH and Briefcase for PE are identical in all aspects and differ only with respect of the training algorithm for PE and ICH. CMS did not believe the training on the algorithm for PE and ICH images distinguishes the mechanism of action for Briefcase for PE from Briefcase for ICH or ContaCT (the predicate device for Briefcase for ICH). In response to these concerns, the applicant cited the FDA definition of mechanism of action, which is "the means by which a product achieves its intended therapeutic effect or action" in support that the analysis of CTPA images for a suspected findings of PE and subsequent computer-assisted triage and notification is the new mechanism of action. The applicant also commented that while Briefcase for PE and its predicate technologies are all AI-based triage and notification systems, these technologies focus on different patient populations and would be assigned to different MS-DRGs. After consideration of this information, CMS believes that Briefcase for PE uses a new mechanism of action to achieve a therapeutic outcome when compared to existing treatments. CMS concludes that this technology is not substantially similar to an existing technology and meets the newness criterion.

CMS summarizes the comments it received, including those submitted by the applicant, in response to its question as how AI, an algorithm, or software may be viewed as identifying a unique mechanism of action. Commenters stated that these technologies should be evaluated for newness in the same way as CMS evaluates any other medical device applying for new technology add-on payment. Commenters stated that human intelligence and human processes are not FDA approved or cleared technologies and should not be used as a comparator to evaluate if any technology meets the definition of newness. A commenter discussed the "model drift" phenomenon which can occur over time due to changes in healthcare workflows, practices, populations, and data. According to the commenter, when this occurs the underlying algorithm does not automatically change and adapt resulting in output predications that are less accurate over time. When this occur, the commenter stated the algorithms should be subjected to extensive statistical testing and modified as necessary for continued use in clinical care. CMS will take these comments into consideration in future rulemaking where applicable.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. In the proposed rule, CMS requested more information about the methodology the applicant used to select the diagnosis codes for its cost calculations. After reviewing the additional information provided by the applicant in response to CMS' concerns, CMS concludes that Briefcase for PE meets the cost criterion.

The applicant also provided additional comments on technologies sold on a subscription basis. The applicant recommended that the cost per unit of technologies sold on a subscription basis should be based on data only from current subscribers and yearly updates to the cost per unit analysis are reasonable to reflect changes in subscribers and thus the overall cost per unit. CMS appreciates these comments, and it will continue to consider these issues in future rulemaking.

Substantial Clinical Improvement. The applicant states that Briefcase for PE substantially improves the ability to diagnose PE by pre-reading CTPAs, automatically identify suspected PE and notify the radiologists to review the study sooner than under the FIFO workflow. The applicant asserts that because of the reduction in the time to review the case, treatment can be initiated sooner which would reduce mortality and length of stay related to PE. The applicant provided data from the FDA pivotal study to support its assertions and unpublished real-word data maintained by Aidoc. The applicant also submitted a retrospective, single-site study which concluded that the system has a high diagnostic performance for the automatic detection of PE on CPTA exams and reduces the time for a diagnostic workup. The applicant also submitted five additional clinical studies about the importance of the time to communication of PE findings, initiation of treatment, and clinical outcomes; these studies did not involve the use of Briefcase for PE.

In the proposed rule, CMS discussed its concerns that the information provided only compares the technology to unassisted FIFO workflow and not against existing electronic or manual forms for prioritization of review of radiologic examinations. CMS was also concerned that the studies did not account for other improvements in caring for patients with suspected PE. In addition, CMS noted that the applicant did not provide any data on potential effects associated with the clinical decision support tool, such as treatment delays due to false negatives, and did not directly measure the effect of its technology on actual treatment outcomes.

The applicant submitted comments in response to CMS' concerns, including additional clinical evidence presenting information about the effect of the technology on clinical outcomes. After reviewing all the data, CMS continues to remain unable to determine that Briefcase for PE represents a substantial clinical improvement over existing treatments. CMS is still concerned that the studies did not directly access outcomes using the technology but relied on the assumption that faster treatment leads to better outcomes.

CMS finalizes Breakthrough for PE does not meet the criteria for new technology add-on payments.

b. RYBREVANT™ (amivantamab)

Johnson & Johnson submitted an application for RYBREVANT™, a bispecific monoclonal antibody for the treatment of metastatic non-small cell lung cancer (NSCLC). The applicant stated that RYBREVANT™ inhibits the epidermal growth factor receptor (EGFR) and c-MET tyrosine kinase signaling pathways involved in the pathogenesis of NSCLC by binding EGFR and c-MET targets present on the outside of the cell. According to the applicant approximately 85 percent of all lung cancers are NSCLC; EGFR mutations are present in 10 to 15 percent of these patients. EGFR mutations are categorized as either common EGFR or atypical EGFR mutations; common EGFR mutations can be treated with therapies that work inside the cell which atypical mutations do not respond well to current treatments. The most frequently observed atypical EGFR mutations, exon 20 insertion mutations, affect 4 to 10 percent of NSCLC patients with an EGFR mutation.

Newness. RYBREVANT™ received Breakthrough Therapy designation from the FDA for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutation whose disease has progressed on or after platinum-based chemotherapy. RYBREVANT™ was approved by the FDA on May 21, 2020 for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. A unique ICD-10-PCS procedure code to identify the use of the technology (XW033B7 and XW043B&) was approved effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant stated that RYBREVANT™'s mechanism of action for treating NSCLC is unique and that no other antibody therapy targets EGFR and MET mutations simultaneously. According to the applicant, the most common first-line treatment for these patients is platinum-based chemotherapy and there no standard of care after progression for second-line treatment. For the second criterion (same or different MS-DRG), the applicant did not expect the use of a RYBREVANT™ to affect the DRG assignment. For the third criterion (treatment of the same or similar disease or patient population), the applicant stated that RYBREVANT™ treated a distinct patient population with metastatic NSCLC: metastatic NSCLC with exon 20 insertion mutation whose disease has progressed on or after platinum-based chemotherapy.

The applicant submitted a comment reiterating that RYBREVANT™ meets the newness criterion. After reviewing all the information, CMS believes that RYBREVANT™ has a unique

mechanism of action for treating NSCLC via bispecific antibody therapy targeting EGFR and MET mutations simultaneously. CMS also agrees that RYBREVANT™ treats a new patient population, EGFR mutations. CMS concludes that RYBREVANT™ meets the newness criterion and the newness period will begin May 21, 2020.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. In the proposed rule, CMS raised concerns about the methodology used to calculate the appropriate threshold and case weighted threshold value. CMS also requested additional information on the population used for the sampling of cases for the cost determination. The applicant provided clarifications about their analysis. After reviewing this information, CMS concludes that RYBREVANT™ meets the cost criterion.

Substantial Clinical Improvement. In the proposed rule, CMS discussed the information provided to support the applicant assertion that RYBREVANT™ represents a substantial clinical improvement over existing technologies. This included analysis of electronic health data records of over 2 million active US cancer patients (Flatiron Health database) and three presentations describing the ongoing Phase 1 trial. The applicant stated that the RYBREVANT™ results appear promising and based on available data with current therapies, it appears to have a longer median progression free survival and response rate among patients with exon 20 insertion mutations as compared to current therapies.

CMS also discussed several concerns about whether the technology meets the substantial clinical improvement criterion, including the fact that the Phase 1 trial is ongoing and the information presented are potentially partial results and might be overestimating treatment effects. CMS was also concerned that without formal comparisons to other therapies, it may be difficult to determine if differences between treatments are due to amivantamab's potentially superior efficacy or other confounding variables.

The applicant submitted comments including additional information addressing CMS' concerns regarding substantial clinical improvement. After reviewing this information, CMS concludes that RYBREVANT™ represents a substantial clinical improvement because it offers a treatment option for patients with metastatic NSCLC with exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. CMS notes that RYBREVANT™ is the first and only FDA approved treatment for this indication.

CMS finalizes RYBREVANT™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of the RYBREVANT™ will be identified by ICD-10-PCS codes XW033B7 and XW043B7. RYBREVANT™ is administered in 26 treatments annually and is estimated that the annual cost of the product will be $180,000 per patient. Based on information provided by the applicant on the administration of RYBREVANT™, the estimated cost per patient for RYBREVANT™ is $9,855.22. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving RYBREVANT™ is $6,405.89.

c. Breyanzi® (lisocabatagene maraleucel)

Juno Therapeutics submitted an application for Breyanzi®, a CAR T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells for the treatment of adult patients with r/r diffuse large B-cell lymphoma (DLBCL) after at least two prior therapies.[21] The applicant stated that DLBCL is the most common type of NHL in the U.S. First-line immune-chemotherapy results in long-lasting remission in more than 50% of patients. Approximately 10 to 15% of patients will have primary refractory disease and an additional 20 to 25% will relapse following an initial response to therapy. Available treatment after two or more lines of systemic therapy includes CAR T-cell immunotherapy with YESCARTA and KYMRIAH, and treatment with KETRUDA (a programmed death receptor-1-blocking antibody. The applicant noted that the safety profiles of these therapies exclude many r/r DLBCL patients from undergoing treatment.

Newness. The applicant submitted a BLA for Breyanzi® in October 2019 and was approved by the FDA on February 5, 2021. Breyanzi® was granted Breakthrough Therapy Designation on December 15, 2016. Cases reporting the use of Breyanzi® are coded with unique ICD-10-PCS codes (XW033N7 and XW043N7); the applicant noted that Breyanzi® would likely map to MS-DRG 016 (Autologous Bone Marrow Transplant or T-Cell Immunotherapy).

For the first criterion (same or similar mechanism of action), the applicant stated the mechanism of action for Breyanzi® differs in two ways from previously approved therapies for DLBCL. First, the therapy differs from other CAR T-cells because the CD4 and CD8 T-cells are cultured separately and the Breyanzi® infusion is configured to contain the same dosage of both cell types. The applicant asserted that controlling the dosage of CD4 and CD8 CAR T-cells is different from other CAR T-cell therapies and could provide for higher safety and efficacy. The second difference is the presence of an EGFRt cell surface tag on the CAR T-cell which could facilitate depletion of CAR T cells. The administration of cetuximab, which binds to the EGFRt surface tag, could clear the CAR T-cells from the patient. According to the applicant, depleting CAR T-cells when a patient achieves a long-term remission could hypothetically allow recovery of normal B cells and reduce risk of infections.

For the second criterion (same or different MS-DRG), the applicant acknowledged that Breyanzi® would likely map to the same MS-DRG as other FDA-approved CAR T-cell therapies. For the third criterion (same or similar disease or patient population), the applicant discussed how Breyanzi® fills an unmet need and would be indicated as a third-line treatment option for patients with r/r DLBCL, who cannot be treated with existing CAR T-cell therapies.

In the proposed rule, CMS discussed its concerns that a different production and/or dosage did not represent a different mechanism of action as compared to FDA-approved CAR T-cell therapies. It was also concerned that the existence of an EGFRt cell surface tag is a potential way to treat an adverse reaction and not critical for the treatment of r/r DLBCL. In addition, CMS noted that the FDA label for YESCARTA and KYMRIAH does not exclude patients with r/r

[21] Juno Therapeutics submitted an application for a new technology add-on payment for Breyanzi® for FY 2021 under the name Liso-cel (isocabatagene maraleucel) (85 FR 32647-32652).

DLBCL so it is not clear if Breyanzi® would treat a patient population different from these CAR T-cell therapies.

A commenter, the manufacturer of a competitor CAR T-cell product, stated that despite small differences in production and dosage, they agreed with CMS that Breyanzi® mechanism of action does not represent a different mechanism of action as compared to YESCARTA and KYMRIAH and also treats the same or similar type or disease and patient population. The applicant submitted a comment explaining Breyanzi's unique mechanism of action and the unique attribute of the EGFRt cell surface tag. The applicant also discussed that Breyanzi® has been shown to be safe and effective for patient populations excluded from registrational trials for YESCARTA and KYMRIAH. In addition, patients with follicular lymphoma grade 3b (FL3b) are excluded from Medicare coverage for YESCARTA and KYMRIAH under the NCD 110.24 for CAR T-cell therapy but are covered for Breyanzi®.

After reviewing the additional information, CMS continues to believe that Breyanzi® is generally intended to treat the same or similar disease in the same patient population as existing CAR T-cell technologies and uses the same mechanism of action as previously approved CAR T-cells that recognizes CD-19 expressing cancer cells, and map to the same MS-DRG. CMS concludes that Breyanzi® is considered new and not substantially similar to YESCARTA and KYMRIAH for the specific subpopulation of patients with FL3b.

Cost. In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion and raises concerns about the methodology used to calculate the appropriate threshold and case weighted threshold value. CMS stated that because the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy it is not sure how representative this data is for calculating a cost to charge ratio (CCR) for CAR T-cell therapies.

Commenters strongly opposed that CAR T-cell therapies would be ineligible for new technology add-on payments consent with section 1886(d)(5)(K)(ix) of the Act. In addition, MedPAC provided general comments about the cost criterion as it relates to CAR T-cell therapies. MedPAC stated that CMS should provide a more detailed discussion of the NTAP cost criterion. It was also concerned that the current cost criterion provides an incentive for manufacturers and hospitals to increase their prices and charges; the Commission might examine ways to improve how Medicare pays for new products. CMS discusses the methodology for the cost criterion, including the spreadsheet included with the new technology add-on payment application which details step-by-step calculations for applicants. CMS welcomes any further comments from the public and MedPAC on ways to better balance manufacturer incentives to innovate with value and affordability for beneficiaries and taxpayers.

The applicant provided additional information about the methodology used in their calculation of a CAR T-cell CCR. After consideration of the comments received and the information provided by the applicant, CMS concludes that Breyanzi® meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Breyanzi® represents a treatment option for a patient population unresponsive to, or ineligible for, current available treatments,

including existing CAR T-cell therapies. The applicant described important populations that were excluded from the registrational trials for YESCARTA and KYMRIAH and stated these trials did not include adequate numbers of Medicare patients. The applicant stated that 41% of the subjects treated with Breyanzi® were over the age of 65 years and have a similar safety and efficacy profile as younger patients. The applicant also provided information from Phase I and Phase II studies. The applicant also provided comparison between the safety profiles of Breyanzi®, YESCARTA and KYMRIAH.

In the proposed rule, CMS discussed its concerns that no published studies directly compared Breyanzi® with YESCARTA and KYMRIAH, the available CAR T-cell therapies for treatment of r/r DLBCL. It was also concerned with the lack of long-term data supporting the effectiveness and efficacy of Breyanzi® and the generalizability of the Phase 1 trial to the Medicare population. CMS also was concerned that there was no evidence for the use of the activation EGFRt cell surface tag and that this feature has not yet been tested in humans in conjunction with Breyanzi® treatment.

The applicant submitted additional information in response to CMS' concerns. CMS still has concerns that the evidence does not indicate Breyanzi® demonstrates an improved safety profile compared to existing therapies. In addition, CMS notes the applicant did not provide data for the specific population of patients with FL3b, the population that CMS considers a new population for treatment. CMS also remains concerns that there is no human evidence supporting the potential use of the EGFRt cell surface tag to alleviate severe toxicities in patients. CMS concludes it is unable to determine whether Breyanzi® represents a substantial clinical improvement for the specific subpopulation for which it would be eligible for new technology add-on payments.

CMS finalizes Breyanzi® does not meet the criteria for new technology add-on payments.

d. COSELA™ (trilaciclib)

GI Therapeutics submitted an application for COSELA™, a myelopreservation therapy that has the potential to mitigate chemotherapy induced myelosuppression (CIM). COSELA™ is indicated to decrease the incidence of CIM in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

Newness. COSELA™ received FDA's NDA approval on February 12, 2021. Two new ICD-10-PCS codes were approved to uniquely identify administration of COSELA™ (XW03377 and XW04377) effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant stated that COSELA™ has a unique mechanism of action as a competitive inhibitor of CDK 4/6, enzymes that control the cell cycle and cell division. The applicant stated this protects all hematopoietic cells from the DNA damaging effects of certain chemotherapies. For the second criterion (same or different MS-DRG), the applicant stated that COSELA™ will be assigned to the same MS-DRGs as existing technologies but did not explicitly identify the appropriate DRGs. For the third criterion (same or similar disease or patient population), the applicant stated that COSELA™ is the only

preventive therapy given as a 30-minute infusion administered prior to chemotherapy to reduce chemotherapy related side effects.

In the proposed rule, CMS discussed its concerns that COSELA™ treated the same patient population and disease as existing therapies. After reviewing the additional information submitted by the applicant, CMS believes that COSELA™ has a unique mechanism of action to decrease the incidence of chemotherapy-induced myelosuppression. CMS does not believe that COSELA™ treats a new patient population since it treats patients before they encounter side effects from chemotherapy-induced myelosuppression. CMS concludes that COSELA™ has a unique mechanism of action and meets the newness criterion. CMS considers the beginning of the newness period to be the data of FDA approval, February 12, 2021.

Cost. In the proposed rule, CMS raised concerns about the ICD-10 codes used in the analysis and the applicant's selection of claims to use in the analysis. Based on the applicant's clarification of the cost analysis and submission of addition information, CMS concludes that COSELA™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that COSELA™ offers a treatment option for patients unresponsive to or ineligible for currently available treatments and improves clinical outcomes as compared to current treatments. In the proposed rule, CMS was concerned that the information included only one published peer reviewed article and that most of the studies submitted by the applicant had sample sizes fewer than 100 participants.

The applicant provided comments reiterating and clarifying the reasons why COSELA™ demonstrates substantial clinical improvement over current alternatives. After consideration of this additional information, CMS concludes that COSELA™ demonstrates a substantial clinical improvement over existing technologies in decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for ES-SCLC.

CMS finalizes COSELA™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of the COSELA™ will be identified by ICD-10-PCS codes XW03377 and XW04377. Based on information provided by the applicant, the cost of on the administration of COSELA™ is $8,502 per hospitalization. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving COSELA™ is $5,526.30.

e. Ellipsys® Vascular Access System (Ellipsys)

Avenu Medical submitted an application for Ellipsys, a device that enables percutaneous creation of an arteriovenous fistula (pAVF). A physician inserts a crossing needle through the proximal radial artery and pierces an adjacent vein in the forearm, then uses a specialized catheter to bring the artery and vein together and "welds" the two vessels together with thermal resistance energy, creating an anastomosis. The applicant stated that before the approval of Ellipsys, the only means of creating an AVF was through open surgery (sAVF).

Newness. Ellipsys received 510(k) clearance from the FDA on August 2019, for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site for patients requiring dialysis. This 510(k) updated the Instructions for Use (IFU) to allow an additional procedure step for balloon dilation of the anastomosis junction at the radial artery and adjacent outflow vein of the AVF immediately after creation of the AVF with the system. The applicant stated the device was originally approved under a De Novo clearance on June 22, 2018. Two ICD-10-PCS codes (X2KB317 and X2KC317) to identify these procedures, was approved effective October 1, 2021. The applicant states that Ellipsys uses thermal resistance energy and WavelinQ uses radiofrequency energy.

For the first criterion (same or similar mechanism of action), the applicant stated that Ellipsys uses a new mechanism of action, a balloon angioplasty, as compared to its initial clearance. The applicant states the balloon angioplasty is now an explicit inclusion in the IFU. For the second criterion (same or different MS-DRG), the applicant stated that Ellipsys is assigned to the same MS-DRGs as existing technologies. For the third criterion (same or similar disease or patient population), the applicant stated that Ellipsys will be used to treat the same or similar disease or same or similar patient population as current treatments.

In the proposed rule, CMS discussed its concerns that the mechanism of action for Ellipsys may be the same or similar to the original version of the system which received FDA approval on June 22, 2018. CMS stated it was not clear that the explicit addition of the balloon angioplasty in the IFU changes the mechanism of action of the device. CMS noted that balloon dilation was performed during the procedure using Ellipsys before the change in the IFU. If the current device was substantially similar to the original version of Ellipsys, CMS believed the newness period would begin on June 22, 2018 and because the 3-year anniversary data of the device onto the U.S. market (June 22, 2021) would occur in FY 2021, the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2022.

A comment from a competitor stated they believed that the mechanism of action of Ellipsys has not changed and is the same as the original version approved on June 22, 1018. The commenter also stated that Ellipsys is assigned to the same MS-DRGs and treats the same disease and patient population as the earlier version and the device should not be considered new. The applicant submitted a comment discussing why they believe that Ellipsys is not substantially similar to other current technologies because it uses a new mechanism of action.

After reviewing the comments, CMS continues to have the same concerns discussed in the proposed rule. CMS notes that even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered “new” for purposes of a new technology add-on payments if it is “substantially similar” to another medical product that was approved or cleared by the FDA and has been on the market for more than 2 to 3 years. CMS believes the device function is unchanged from the De Novo version and is not a new mechanism of action. CMS also believes that the two versions of the technology are intended to treat the same or similar disease in the same or similar patient population. CMS considers the beginning of the newness period for the device to begin on June 22, 2018, which is the date the original version of the

Ellipsys system received FDA approval. Because the 3-year anniversary date of Ellipsys will occur in FY 2021, the device does not meet the newness criterion.

CMS finalizes Ellipsys does not meet the newness criterion and is not eligible for new technology add-on payments.

f. ENSPRYNG™ (satralizumab-mwge) Injection (ENSPRYNG)

Genetech submitted an application for ENSPRYNG, an interleukin-6 (IL-6) receptor antagonist, indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 antibody (AQP4-IgG) positive. According to the applicant. ENSPRYNG is the first subcutaneous, the first self-administered, and the third of only three FDA-approved drugs available for the treatment of NMOSD. The applicant stated there are two other FDA-approved therapies for patients with AQP4-IgG positive NMOSD: SOLARIS[22] which was approved in 2019 and UPLIZNA which was approved in 2020.

NMOSD is a rare, inflammatory, potential life-threatening autoimmune central nervous system (CNS) disorder primarily characterized by severe, unpredictable relapses of optic neuritis and/or acute longitudinally extensive transverse myelitis. It has an estimated prevalence of 0.1-10 per 100,000 individuals; it affects nearly 15,000 individuals in the U.S. NMOSD occurs in all ages and disproportionately affects African and Asian females aged 30 to 40 years. Over 75 percent of patients experience repeated relapses and disability accumulates with each relapse.

Newness. ENSPRYNG received FDA approval on August 14, 2020 and was commercially available on August 24, 2020. ENSPRYNG was granted both Fast Track designation and Breakthrough Therapy designation by FDA. A new ICD-10-PCS code for the administration of ENSPRYNG (XW01397) was approved effective October 1,2021.

For the first criterion (same or similar mechanism of action), the applicant stated that ENSPRYNG is an IL-6 receptor antagonist that disrupts inflammatory effects that contribute to the pathophysiology of NMOSD. The applicant discussed the possible mechanism of action of other drugs to treat NMOSD and concluded that none of these drugs bind and block soluble and membrane-bound IL-6 receptors and inhibit IL-6 signaling. For the second criterion (same or different MS-DRG), the applicant acknowledged that ENSPRYNG may be assigned to the same MS-DRG as existing technology. For the third criterion (same or similar disease or patient population), the applicant stated that ENSPRYNG may not involve the treatment of the same or similar patient populations because SOLIRIS may be contraindicated in patients with unresolved serious Neisseria meningitis infections. In addition, the applicant noted that both SOLIRIS and UPLIZNA are IV administered and all patients might not want IV treatment.

In the proposed rule, CMS noted that UPLINZA may also be a treatment option for patients with meningococcal disease. CMS also questioned whether patients unwilling to receive an IV infusion constitutes a new patient population for NMOSD.

[22] SOLIRIS was approved for new technology add-on payment in FY 2021.

Based on comments received, including clarifications provided by the applicant, CMS concludes that ENSPRYNG has a unique mechanism of action and is not substantially similar to existing treatment options. However, CMS does not agree with the applicant that ENSPRYNG does not involve the treatment of the same or similar patient population as existing technologies. CMS reiterates its concern that patients unwilling to receive an IV infusion does not constitute a new patient population for NMOSD. CMS believes the beginning of the newness period is when ENSPRYNG became commercially available, on August 24, 2020.

Cost. After reviewing clarifications provided by the applicant, CMS concludes that ENSPRYNG meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that ENSPRYNG significantly improves clinical outcomes as compared to other treatment options; the improvements are not accompanied by serious safety concerns; is the only approved subcutaneous administered treatment; and substantially improves the treatment of Medicare beneficiaries. The applicant stated that initiation of treatment during the inpatient hospital admission provides adequate training on how to perform the injection and facilitates the continuation of therapy when the patient is discharged. In addition, the applicant stated that a comparison between ENSPRYNG and SOLIRIS cannot be made due to difference is trial design and study population.

In the proposed rule, CMS discussed its concerns that the data did not demonstrate improved outcomes over existing FDA approved treatments for NMOSD. CMS was interested in comparison of outcomes such as time to first relapse and annual relapse rate. In addition, CMS was concerned the benefits are only related to the outpatient administration of the medication and the evidence did not support clinical improvement in the inpatient setting.

CMS acknowledges the comments it received in support of ENSPRYNG to ensure that Medicare beneficiaries with NMOSD have access to appropriate treatment in the inpatient setting.
The applicant also submitted additional information in response to CMS' concerns. CMS still has concerns that the evidence does not indicate ENSPRYNG demonstrates an improved safety profile compared to existing therapies and that ENSPRYNG offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. CMS notes the applicant did not provide data to demonstrate improved outcomes. CMS also disagrees with the applicant's assertion that CMS is taking a new policy position with regard to how an applicant demonstrates substantial clinical improvement. CMS describes its review of each application and states that every application is evaluated on its own data and merit. CMS states that the applicant's examples of various previously approved technologies, did not consider the differences between applications and the variations in currently available technology that an applicant is compared against for purposes of showing substantial clinical improvement. CMS concludes it is unable to determine that ENSPRYNG meets the substantial clinical improvement criterion.

CMS finalizes ENSPRYNG does not meet the criteria for new technology add-on payments.

g. ABECMA® (idecabtagene vicleucel)

Celgene Corporation submitted an application of idecabtagene vicleucel, a B-cell maturation antigen (BCMA) directed genetically modified autologous CAR T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least three prior therapies including an IMiD, a PI, and an anti-CD38 antibody.

Newness. ABECMA® received FDA approval on March 26, 2021. A unique ICD-10-PCS codes for administration of ABECMA® will be effective starting October 1, 2021 (XW033L7 and XW043L7).

For the first criterion (same or similar mechanism of action), the applicant stated that ABECMA® does not use the same or similar mechanism of action as other therapies used to treat RRMM or CAR T-cell therapies approved to treat different diseases. The ABECMA® CAR is comprised of a murine extracellular single chain variable fragment (scFv)-BCMA targeting domain, a CD8 alpha (α) hinge and transmembrane domain, a CD3-zeta (ζ) T-cell activation domain, and a 4-1BB (CD137) costimulatory domain. This structure is unique to ABECMA®; no other CAR T-cell therapy is comprised of the combination of these targeting, hinge and transmembrane, activation, and costimulatory domains. The applicant also discussed how the mechanism of action differs from other therapies, including Blenrep.

For the second criterion (same or different MS-DRG), the applicant acknowledged that ABECMA® would be assigned to the same MS-DRG as other FDA-approved CAR T-cell therapies (MS-DRG 018). For the third criterion (same or similar disease or patient population), the applicant states that ABECMA® is indicated for a specific population of patients with MM having received four prior therapies.

In the proposed rule, CMS was concerned that ciltacabtagene autoleucel may have a similar mechanism of action and treat the same or similar patients to that of ABECMA®. Ciltacabtagene autoleucel withdrew its application prior to the issuance of this final rule. After consideration of comments, including information provided by the applicant, CMS concludes that ABECMA® has a new mechanism of action as it is the only CAR T-cell therapy available for the treatment of adult patients with RRMM after four or more prior lines of therapy. CMS considers the beginning of the newness period to commence on the date of FDA approval, March 26, 2021.

Cost. CMS appreciates the comments and clarification that the applicant provided about their calculation of a CAR T-cell CCR. CMS concludes that ABECMA® meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the treatment represents a substantial clinical improvement over existing therapies because the clinical efficacy and safety data indicate that idecabtagene vieleucel improves the treatment of patients with RRMM as compared to existing therapies. To support these conclusions, the applicant cited results from the KarMMA study, a single-arm, open-label, phase 2 trial of idecabtagene vieleucel (CMS notes this study had not been peer-reviewed) and the results from the KarMMA-RW study. The KarMMA-RW study was conducted to assess treatment patterns in real-world RRM patients with characteristics similar to the KarMMA population and to compare treatment outcomes in this

cohort vs idecabtagene vieleucel.in the KarMMa study. The applicant used published studies to also provided a comparison of the efficacy of idecabtagene vieleucel and Xpovio and Blenrep.

In the proposed rule, CMS was concerned, due to the lack of randomization, there was sufficient evidence to establish the efficacy of ABECMA® compared with current alternative. It raises the question of whether the superior outcomes for ABECMA® in the KarMMA study were due do more effective therapy, or other factors, such as differences in patient population or treating oncologist. CMS also noted that the studies chose to use ORR as a measure of substantial clinical improvement instead of OS data.

The applicant provided a comment explaining why ABECMA® demonstrated significant clinical improvement and additional information about the KarMMA study. CMS agrees that the updated analysis provided by the applicant demonstrated significant and clinically meaningful improvements in ORR, OS, and progression-free survival (PFS) for patients treated with ABECMA®. CMS concludes that ABECMA® demonstrates substantial clinical improvement over available treatments.

CMS finalizes ABECMA® meets **all three criteria for new technology add-on payments and approves add-on payments for FY 2022**. Cases involving the use of the ABECMA® will be identified by ICD-10-PCS codes XW033K7 and XW043K7. Based on information provided by the applicant, the cost of on the administration of COSELA™ is $419,500 per patient. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving ABECMA® is $272,675.

h. INDIGO® Aspiration System with Lightning Aspiration Tubing

Penumbra submitted an application for the INDIGO® Aspiration system with Lightning Aspiration Tubing (INDIGO® with Lightning), an intelligent mechanical thrombectomy aspiration system used in the treatment of pulmonary emboli, deep vein thrombosis, and peripheral arterial thromboembolism. INDIGO® with Lightning is composed of a mechanical thrombectomy aspiration pump (the Penumbra Engine) that is packaged with INDIGO® CAT12 (12 French) and CAT8 (8 French). Lightning, a clot detection/blood loss reduction technology, is embedded in the Penumbra Engine pump and tubing.

Newness. INDIGO® with Lightning is a system with multiple components which have been reviewed by FDA both separately and as part of an overall system which includes catheters, tubing and a vacuum pump for treatment of pulmonary emboli (PE) and thrombosis in the peripheral arterial venous system (PAVS). The various FDA clearance dates is discussed in the proposed rule and summarized in a table, reproduced below. Eight unique ICD-10-PCS codes to identify the technology are effective October 1, 2021. The various FDA clearance dates are discussed in the final rule and summarized in a table, reproduced below.

INDIGO® System	**Indication**	**Reference Number**	**Date of Clearance**
INDIGO® - Penumbra Embolectomy Aspiration System	PAVS	K142870	May 26, 2015
INDIGO® - Advanced 110 Aspiration Tubing	PAVS	K180939	May 3, 2018
INDIGO® - INDIGO Aspiration System	PE	K192833	December 20, 2019
INDIGO® - Penumbra ENGINE Pump and Canister	PAVS	K180105	March 8, 2018

INDIGO® System	Indication	Reference Number	Date of Clearance
INDIGO® - LIGHTNING Aspiration Tubing	PAVS	K193244	March 13, 2020
INDIGO® - LIGHTNING Aspiration Tubing	PE	K200771	April 22, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PAVS	K192981	May 28, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PE	K202821	November 18, 2020

For the first criterion (same or similar mechanism of action), the applicant stated that INDIGO® with Lightning differs from other mechanical thrombectomy devices because the Penumbra Engine utilizes a unique mechanism of action that enables and optimizes thrombus removal procedures by differentiating between thrombus and blood, limiting blood loss. The applicant stated that other devices do not provide aspiration using a vacuum and the Lightning tubing performs clot detection using a proprietary algorithm. For the second criterion (same or different MS-DRG), the applicant stated that INDIGO® with Lightning would be assigned to the same MS-DRGs as existing technologies. CMS believes the device is intended for a patient population that is similar to the patient population treated by existing thrombectomy devices.

In the proposed rule, CMS discussed several concerns about whether the technology meets the substantial similarity criteria and whether it should be considered new. CMS stated the applicant did not provide enough information to determine whether INDIGO® with Lightning has a unique mechanism of action, including how the mechanism of the action of the Penumbra pump is different than existing systems.

Several commenters asserted that INDIGO® with Lightning was substantially similar to other technologies and did not meet the newness criterion. The applicant provided clarification about the two components of the device and the associated dates of FDA clearance. The applicant also provided additional information about the mechanism of action of the separator and how it differs from other existing thrombectomy systems. After reviewing this additional information, CMS believes this technology represents a new mechanism of action due to the way in which the sensors and smart technology control the opening and closing of the valve which allows automated intermitted aspiration. CMS concludes that INDIGO® with Lightning meets the newness criterion and the newness period begins on March 13, 2020 for PAVS and April 22, 2020 for PE, the date each technology was cleared by the FDA.

Cost. CMS concludes INDIGO® with Lightning meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that INDIGO® with Lightning results in lower rates blood loss during the procedure, lower major bleeding event rates, reduced ICU stays and reduced procedure times over existing technologies. In the proposed rule, CMS discussed its concern that the applicant relied mostly on studies of INDIGO® without Lightning to substantiate its claims regarding INDIGO® with Lightning. CMS was also concerned that the applicant did not explicitly indicate the comparator for each of its claims in support for substantial clinical improvement.

Several commenters did not believe that INDIGO® with Lightning met the requirements for substantial clinical improvement; a commenter asserted that the evidence was robust and demonstrated substantial clinical improvement. The applicant provided comments and additional

information in response to CMS' concerns. CMS remains concerned that the applicant primarily used data from studies that utilized INDIGO® without Lightning to demonstrate superior outcomes using INDIGO® with Lightning. CMS concludes it is unable to determine that INDIGO® with Lightning represents a substantial clinical improvement over existing technologies.

CMS finalizes INDIGO® with Lightning does not meet the criteria for new technology add-on payments.

i. Pure-Vu® System

Motus GI holdings, Inc. submitted an application for the Pure-Vu® System, an FDA cleared system designed to connect to currently marketed colonoscopes to avoid aborted and delayed colonoscopies due to poor visualization of the colon mucosa by providing high intensity intra-procedural cleansing of the colon during a colonoscopy. The Pure-Vu System is comprised of a Workstation (WS) that controls the function of the system and a disposable Oversleeve that is mounted on a colonoscope and inserted into the patient. The applicant states that the Pure-Vu® System is indicated in patients requiring therapeutic or diagnostic colonoscopies where the bowel has not been adequately prepared and would be used in situations that do not allow adequate bowel preparations, such as lower gastrointestinal bleed (LGIC).

Newness. The Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 and was not sold until January 27, 2017. The applicant stated the device was initially allocated for clinical evaluations but 10 institutions purchased the device outside of a clinical study. Additional minor modifications were made and the system received additional 510(k) clearances on December 12, 2017 and June 21, 2018. The current marketed Pure-Vu® System was granted 510(k) clearance on June 6, 2019 and was commercially available as of September 19, 2019. A unique ICD-10-PCS code (XDPH8K7) was approved effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant described how the system has a different mechanism of action that existing technologies. The applicant noted that the ClearPath system, a colonoscopy system by the company Easy Glide, received FDA clearance, but was never fully brought to the U.S. market. ClearPath was listed as the predicate device for the initial version of the Pure-Vu® System approved on September 22, 2016. For the second criterion (same or different MS-DRG), the applicant stated the Pure-Vu® System is assigned to the same MS-DRGs as existing technologies. For the third criterion (same or similar disease or patient population), the applicant stated the system involves treatment of the same or similar type of disease and patient population as existing technology.

In the proposed rule, CMS discussed its concerns that the Pure-Vu® System's mechanism of action is similar to the version that received initial 510(k) clearance in September 2106 or other versions of the system and whether the limited availability is consistent with commercial availability. CMS was also concerned that the Pure-Vu® System is similar to other existing irrigation systems that irrigate the colon using water and gas.

The applicant provided clarifying information comparing the mechanisms of action of the Pure-Vu® System and its predicate device, the ClearPath system. The applicant also provided

information about market availability; the applicant stated the Pure-Vu® System was only sold on a limited basis as part of a beta launch to obtain potential investigators to participate in clinical trials. Based on this additional information, CMS concludes the Pure-Vu® System has a new mechanism of action as compared to the ClearPath system and traditional colonoscopes. CMS is still unsure of the appropriate date on which the newness period should begin and whether it is new for FY 2022.

Cost. In the proposed rule, CMS noted that the MS-DRGs used in the cost analysis were not limited to those describing conditions liking to require a colonoscopy. For example, the applicant included all cases assigned to MS-DRG 291 (Heart Failure and Shock with MCC). In response to these comments, the applicant submitted a revised cost criterion analysis that limited the number of MS-DRGs to only the top 12 in terms of case volume. Based on this revised analysis, CMS concludes that the Pure-Vu® System meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the Pure-Vu® System allows rapid and full visualization of the colon, which will improve diagnosis and the effectiveness of treatment. The applicant provided information from a self-sponsored, U.S.-based, multicenter, prospective, single arm study of 94 hospitalized patients and three outpatient clinical studies. The applicant used the Boston Bowel Preparation Scale (BBPS) to evaluate the rate of improved bowel cleansing level.

In the proposed rule, CMS noted that although the applicant provided studies in support of the Pure-Vu® System improvement of bowel preparation, it did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes based on the use of the Pure-Vu® System. In addition, no studies compared the efficacy of the Pure-Vu® System to other existing methods or products for bowel irrigation.

The applicant submitted comments and additional data to address CMS' concerns. CMS remains concerned that the studies based on the BBPS scale do not provide information indicating that improved BBPS directly leads to improved clinical outcomes. CMS also remains concerned about the lack of studies comparing the Pure-Vu® System to other existing methods for removing debris from the colon. CMS concludes it is unable to determine the Pure-Vu® System represents a substantial clinical improvement over existing technologies.

CMS finalizes the Pure-Vu® System does not meet the criteria for new technology add-on payments.

j. Rapid ASPECTS

iSchema View (which is in the process of a name change to Rapid AI) submitted an application for Rapid ASPECTS a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using computed tomography (CT) image data. The Software automatically registers images and segments and analyzes ASPECTS[23] Regions of lnterest (ROIs). Rapid ASPECTS extracts image data for the

[23] The Alberta Stroke Program Early CT score (ASPECTS) is a 10-point quantitative topographic CT scan score developed to offer the reliability and utility of a standard CT examination with a reproducible grading system to

ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an AI algorithm into a single ASPECT Score. The applicant states that Rapid ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known Middle Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion, for evaluation of extent of disease. The extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. Rapid ASPECTS is not intended for primary interpretation of CT images, it is used to assist physician evaluation. The applicant asserted that Rapid ASPECTS has been validated in patients with known MCA or ICA occlusion prior to ASPECT scoring. The applicant described Rapid ASPECTS as a machine learning-based automated software for assessments of ASPECTS.

Newness. The applicant stated that Rapid ASPECTS received 510(k) clearance as a CADx software device on June 26, 2020 and the first installation occurred September 1, 2020. A unique ICD-10-PCS code (XXE0X07) was approved effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant asserted Rapid ASPECTS uses a new mechanism of action (machine learning) to assess CT scans and develop a single ASPECT score in approximately 2 minutes. According to the applicant, this software remains the only FDA-cleared ASPECTS software and the only stroke imaging software to receive a CADs clearance by the FDA. For the second criterion (same or different MS-DRG), the applicant stated that cases involving Rapid ASPECTS would be assigned to the same MS-DRGs as cases involving patients confirmed with an eligible large vessel occlusion (LVO) by a positive CTA. For the third criterion (same or similar disease or patient population), the applicant stated the system involves treatment of the same or similar type of disease and patient population as the existing stroke population.

In the proposed rule, CMS discussed its concern that machine learning to assess CT scans and the synthesis of a single ASPECT score represents a unique mechanism of action. CMS was also concerned that the mechanism of action Rapid ASPECTS uses to assess stroke imaging was not distinct from other automated imaging analysis tools, or the traditional hospital workforce.

The applicant submitted comments about the mechanism of action stating based on the framework for AI/ML that is differentiated within the FDA product codes for diagnostic imaging products, Rapid ASPECTS has a unique mechanism of action. The application discussed the difference between CADt classification which applied to the ContaCT/Viz and the CADe/x classification which applies to Rapid ASPECTS.[24] Specifically, the applicant states that Rapid ASPECTS informs the end user about treatment decisions and that the RAPID ASPECTS is the only automated software that has been clear by the FDA with the CADe/x designation. CMS believes that Rapid ASPECTS does not use the same or a similar mechanism of action to achieve therapeutic outcomes and provides a standard of care score that characterizes the severity and extent of an LVO, which informs the end user of treatment decision. CMS concludes Rapid ASPECTS meets the newness criterion.

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assess early ischemic changes on pretreatment CT studies in patients with acute ischemic stroke of the anterior circulation.

[24] CADt products are limited to determining and notifying the end user of suspicion of a disease. CADe/x classification informs the end user about treatment decisions.

Cost. The applicant provided clarification and additional information about the cost analysis and CMS concludes that Rapid ASPECTS meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by improving accuracy of ASPECT scoring which improve both treatment decisions and the time to treatment. The applicant also asserted it improves diagnostic decisions by reducing inter-rate variability of ASPECT scoring.

In the proposed rule, CMS discussed its concern that the Rapid ASPECT score was derived from a small sample of expert radiologists and might not be representative of radiologists in the U.S. CMS also wondered whether individuals participating in these studies may have altered their behaviors by interacting with other computer-generated ratings. CMS was also concerned that the primary outcome is the correlation between the ASPECT scoring of experts and Rapid ASPECTS and it was not obvious how this high correlation is indicative of substantial clinical improvement. CMS also acknowledged that the applicant submitted the AHA/ASA guidelines and a review of stroke literature as support for clinical improvement, but these guidelines do not provide evidence that Rapid ASPECTS provides substantial clinical improvement over current care.

The applicant provided additional information and data analysis to address CMS' concerns. CMS is still concerned whether the use of Rapid ASPECTS significantly improves clinical outcomes for PE patients as compared to currently available treatments because the applicant did not measure the impact of the technology on outcome measures such as mortality, length of stay, and disability. CMS discusses the outcome data demonstrated by ContaCT. CMS concludes that it is unable to determine that Rapid ASPECTS represents a substantial clinical improvement over existing systems.

CMS finalizes Rapid ASPECTS does not meet the criteria for new technology add-on payments.

k. Steripath®Micro™ Blood Culture System

Magnolia Medical Technologies submitted an application for the Steripath®Micro™ Blood Culture System (also referred to as the Steripath®Micro™ Initial Specimen Diversion Device (ISDD®) ("Steripath Micro"). The applicant described the Steripath®Micro™ ISDD® as a proprietary and patent-protected single-use, disposable device for the collection of blood cultures used to reduce blood culture contamination. According to the applicant the Steripath®Micro™ ISDD® uses a syringe-driven (or blood culture bottle-driven) architecture that uses negative pressure to flip a proprietary internal bladder, which creates a gentle negative pressure to divert and sequester the initial 0.6 to 0.9 ml of blood. The initial specimen is the portion known to most likely contain contaminants. Once diversion is complete the user presses a button to isolate the diverted blood and automatically a second independent blood flow pathway opens to collect the blood specimen into the syringe (or blood culture bottle) for culture.

Newness. Steripath®Micro™ ISDD® is a Class II medical device that received 510(k) clearance from the FDA on October 8, 2020. The 510(k) clearance was based on substantial equivalence to an earlier version of the device, Steripath®Gen2, which received clearance on February 28, 2020. According to the applicant, the Steripath® ISDD® product portfolio, including the Steripath®Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination. A new ICD-10-PCS procedure code (XXE5XR7) was approved effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant discussed current alternative treatments to avoid blood contamination and asserted that manual diversion, passive diversion and the Steripath® Gen2 device are not comparable alternatives to Steripath®Micro™. For the second criterion (same or different MS-DRG), the applicant did not indicate whether Steripath®Micro™ ISDD® would be assigned to the same MS-DRGs as cases representing patients with traditional or competing technologies blood collection methods. For the third criterion (same or similar disease or patient population), the applicant stated that Steripath®Micro™ ISDD® was designed to address a specific and broader patient population that any other FDA approved technology available to prevent blood culture contamination and addresses the unmet needs of patients with low blood volume, hypovolemic and hypotensive and patients with difficult intravenous access (DIVA).

In the proposed rule, CMS discussed its concerns that the Steripath®Micro™ ISDD® is substantially similar to the Steripath® Gen2 in that both devices utilize negative pressure. CMS believes the newness date for Steripath®Micro™ ISDD® would begin on February 28, 2020. CMS also requested comments on whether there are other FDA-cleared products designed to reduce blood culture contamination.

The applicant provided additional information and indicated that the Steripath®Micro™ ISDD® was cleared by the FDA on October 8, 2020 but the commercial launch date was March 31, 2021. A few commenters stated that Steripath®Micro™ ISDD® was needed for patients with DIVA. After consideration of the information, CMS continues to believe the mechanism of action of the Steripath®Micro™ ISDD® is substantially similar to the predicate device, Steripath® Gen2ISDD®. Based on information on the Magnolia Medical Steripath® Gen2 website, CMS also believes that the DIVA population may already be served by the Steripath® Gen2ISDD®. Lastly CMS believes cases involving both of these products would be assigned to the same MS-DRG.

CMS concludes that the Steripath®Micro™ ISDD® is substantially similar to the Steripath® Gen2ISDD®. Since the Steripath® Gen2ISDD® received marketing authorization on February 28, 2020 CMS considers the newness date for the Steripath®Micro™ ISDD® to begin on this date.

Cost. The applicant provided additional information, including supplementary cost analysis. CMS concludes that Steripath®Micro™ ISDD® meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the Steripath®Micro™ ISDD® represents a substantial clinical improvement over existing technologies by its ability to reduce

blood contamination with skin flora and improves clinical outcomes by reducing clinically significant adverse events (such as a decrease in inappropriate antibiotic use).

In the proposed rule, CMS discussed its concerns that much of the evidence supports the overall clinical value of reducing blood contamination by manual diversion over no diversion, but did not directly link the Steripath®Micro™ ISDD® to improved clinical endpoints. In addition, comparative studies between Steripath®Micro™ ISDD® and either manual diversion or competitor devices were not provided, and CMS was concerned that the standard of care used in the studies (that is, no diversion) was an appropriate comparator for this technology.

The applicant and additional commenters discussed the reasons that Steripath®Micro™ ISDD® is a substantial clinical improvement over existing technologies. After reviewing the information, CMS continues to remain concerned that the studies do not include the Steripath®Micro™ ISDD® and does not believe this is the only device available to treat DIVA patients. CMS concludes it is unable to determine that the Steripath®Micro™ ISDD® meets the substantial clinical improvement criterion.

CMS finalizes the Steripath®Micro™ ISDD® does not meet the criteria for new technology add-on payments.

l. StrataGraft™ Skin Tissue

Stratatech Corporation submitted an application for the StrataGraft™ Skin Tissue, a viable, bioengineered, regenerative skin construct (BRSC) consisting of an epidermal layer of viable, fully stratified, allogenic NIKS® keratinocytes growing on a dermal layer composed of viable dermal fibroblasts embedded in a collagen-rich matrix. The applicant stated that StrataGraft™ is intended for the treatment of adult patients with severe thermal burns that contain intact dermal elements and require surgical intervention (referred to as severe thermal burns (STB). StrataGraft™ is produced in a rectangular format of approximately 100 cm^2, approximately 8 cm by 12.5 cm.

The applicant explained that the StrataGraft™ skin tissue promotes durable wound closure and regenerative healing for adult patients with STB. In addition to providing immediate wound coverage and epidermal barrier function, the viable metabolically active keratinocytes and fibroblast provide sustained expression and secretion of growth factors, cytokines, and wound healing factors. The applicant states that StrataGraft™ skin tissue does not engraft but promotes regenerative healing and eliminates the need for autografting to attain definitive closure of wounds.

Newness. On June 15, 2021, the FDA approved for StrataGraft™ for the treatment of adult patients with thermal burns containing intact dermal elements (remaining deep skin layers) for which surgical intervention is clinically indicated (deep partial thickness burns (DTB)). A unique ICD-10-PCS code (XHRPXF7) was approved effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant stated that that the mechanism of action of StrataGraft™ skin tissue is not the same or similar to existing technology for the treatment of STB. StrataGraft™ skin tissue works by sustained expression and secretion of

growth factors, cytokines, and wound healing factors, which are anticipated to promote regenerative healing and durable wound closure which reduces or eliminates the need of autologous skin harvesting. For the second criterion (same or different MS-DRG), the applicant indicated that StrataGraft™ skin tissue would be assigned to the same MS-DRGs as patients receiving standard of care (autograft) or existing technologies to treat STB. For the third criterion (same or similar disease or patient population), the applicant claimed that StrataGraft™ skin tissue will treat a burn patient population that may not achieve durable wound closure with treatment using standard of care or existing technologies. The applicant acknowledged that the label for StrataGraft™ skin tissue will not be limited to this population.

In the proposed rule, CMS discussed its concerned that there may be other biologic dressings that use some combination of keratinocytes, collagen, glycosaminoglycans, cytokines, and other growth factors in either a single, double, or triple layer configuration. CMS also wanted additional clarification about the population that will be treated with StrataGraft™ skin tissue.

The applicant provided additional information to address CMS' concerns. Several commenters also provided support for the newness of StrataGraft™ skin tissue. After consideration of this information, CMS agrees that StrataGraft™ utilizes a unique mechanism of action for DPT burns because it is a regenerative technology that allows the growth of a patient's own tissue and functions as a protective barrier. CMS notes that it believes that StrataGraft™ treats the same or similar patient population as existing technologies; other current treatments are used for the elderly patient population. CMS concludes that StrataGraft™ meets the newness criterion. The newness period begins on the date of FDA approval, June 15, 2021.

Cost. CMS concludes StrataGraft™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that StrataGraft™ skin tissue is a substantial clinical improvement for the treatment of adult patients with STB with intact dermal elements because it achieves a significant rate of durable wound closure while minimizing or eliminating the complications associated with autograft harvest. CMS summarizes the information provided by the applicant, including two controlled and randomized studies, STRATA2011 and STRATA2016.

In the proposed rule, CMS discussed its concerns about the lack of data comparing StrataGraft™ skin tissue to other biologic dressings and requested information about whether there are any dressings that may be approved for burns that demonstrates durable wound closure. CMS was also concerned that the sample size of 30 patients in STRATA2011 is sufficient to generalize the results to the Medicare population. CMS noted that the STRATA2016 study has not been published and since the results of the study were not provided in full, it may not have the complete outcomes and study results for these patients.

The applicant provided additional information, including a newly published study of the STRATA2016 trial, to address CMS' concerns. Several commenters also provided support for the newness of StrataGraft™. After consideration of this information, CMS concludes that StrataGraft™ demonstrates substantial clinical improvement by facilitating durable wound closure without the need for skin harvest and/or autograft.

CMS finalizes that StrataGraft™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of StrataGraft™ will be identified by ICD-10-PCS code XHRPXF7. Based on information provided by the applicant, the average cost of StrataGraft™ for a patient is $6,800 (17 sheets x 4000 per sheet). For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving StrataGraft™ is $4,420.

m. Tecartus™ (brexucabtagene autoleucel)

Kite Pharma submitted an application for Tecartus, a CAR T-cell immunotherapy for the treatment of adult patients with relapse and refractory (r/r) mantle cell lymphoma (MCL).[25] Tecartus is a single infusion product consisting of autologous T-cells engineered to express an anti-CD19 chimeric antigen receptor. According to the applicant, this therapy targets the CD19 antigen on the cell surface of normal and malignant B cells.

The applicant stated that MCL is a rare and aggressive subtype of non-Hodgkin lymphoma (NHL), accounts for 3-6% of all cases of NHL and has distinct characteristics which differentiate it from diffuse large B-cell NHL. According to the applicant there is no standard of care for second-line and higher chemotherapy when a patient has r/r MCL. The applicant stated inhibitor, a Bruton's tyrosine kinase (BTK) inhibitor, is the most common third-line therapy for patients with r/r MCL and a more selective BTK inhibitor, acalabrutinib, was approved for patients with r/r MCL.

Newness. FDA approved the Tecartus BLA on July 24, 2020 for the treatment of adult patients with r/r MCL. Tecartus was granted breakthrough therapy designation for the treatment of patients with r/r MCL on June 15, 2018 and received an orphan drug designation in 2016 for the treatment of MCL, acute lymphoblastic leukemia, and chronic lymphocytic leukemia. Cases reporting the administration of Tecartus are coded with XW23346 and XW24346 and assigned to MS-DRG 016 (Autologous Bone Marrow Transplant or T-Cell Immunotherapy).

For the first criterion (same or similar mechanism of action), the applicant stated Tecartus is the first CAR T-cell immunotherapy for the treatment of r/r MCL. The applicant stated that Tecartus is different from other previously approved CAR T-cell therapies because it is a distinct cellular product that requires a unique manufacturing process which results in differences in potency, cellular impurities, and formulation of the final product. The applicant stated that the product is distinct from other currently available CAR T-cell therapies, YESCARTA and KYMRIAH; Tecartus does not use the same mechanism of action as other treatments currently used to treat r/r MCL.

For the second criterion (same or different MS-DRG), the applicant noted that patients would be assigned to MS-DRG 018 (CAR T-cell Immunotherapies). The applicant asserted that Tecartus would be uniquely identified by ICD-10-PCS codes different from those used for YESCARTA and KYMRIAH. For the third criterion (same or similar disease or patient population), the applicant discussed the differences between r/r MCL and diffuse large b-cell lymphoma which

[25]Kite Pharma submitted an application for new technology add-on payment for Tecartus for FY 2021 under the name KTE-Xa9 (85 FR 32634).

are treated with YESCARTA and KYMRIAH. The applicant noted that patients treated by YESCARTA and KYMRIAH are not assigned to the ICD-10-CM diagnosis code C83.1X (MCL, unspecified site), which would be used for patients treated with Tecartus. The applicant concluded this distinction is evidence that Tecartus treats a different subtype of NHL as compared to other approved CAR T-cell therapies.

In the proposed rule, CMS discussed several concerns about whether the technology meets the substantial similarity criteria and whether it should be considered new. CMS noted that both YESCARTA and KYMRIAH are CD19 directed CAR T-cell therapies used for treating patients an aggressive subtype of NHL. CMS also did not understand why the production process for Tecartus provides a unique mechanism of action. In addition, CMS was concerned that this therapy may involve treatment of a similar type of disease when compared to existing CAR T-cell therapies.

A few commenters stated that Tecartus™ met the newness criterion; one commenter supported CMS' request for additional information. The applicant provided additional information describing the differences between Tecartus™ and existing treatment options. After reviewing this information, CMS agrees that Tecartus™ does not use the same or similar mechanism of action as other technologies used to treat r/r MCL because it is the only CAR T-cell therapy available for treatment of this disease. In addition, due to the differences based on histopathology, genetics, clinical characteristics, treatment approaches, and clinical outcomes, CMS agrees this is a unique disease population as compared to those treated by existing Car T-cell therapies. CMS concludes that Tecartus™ meets the newness criterion

Cost. CMS concludes that Tecartus™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Tecartus represents a new treatment option for an adult patient population unresponsive to, or ineligible for, currently available treatments and that the use of Tecartus significantly improves clinical outcomes for a patient with r/r MCL as compared to currently available therapies, including BTK inhibitors. The applicant provided information which included results from a Phase 2 study (ZUMA-2 study) and historical and meta-analyses. The applicant also provided information in response to CMS' prior concern about the generalizability of the ZUMA-2 study to the general Medicare population.

In the proposed rule, CMS discussed several concerns with the ZUMA-2 study. CMS was concerned about the relatively small, combined sample size from the literature search and the ZUMA-2 study and it was uncertain if the sample size and research presented support for extrapolating these results to the general Medicare population. CMS was also concerned about the potential for selection bias and its effects on results from the ZUMA-2 study, especially given the small sample size. In addition, CMS continued to raises issues about the lack of a direct study comparing outcomes of patients with r/r MCL treatment with Tecartus and BTK inhibitors.

A few commenters discussed the reasons why Tecartus™ demonstrated substantial clinical improvement; one commenter supported CMS' request for additional information. The applicant

provided additional information addressing CMS' concerns. After reviewing this information, CMS concludes that Tecartus™ represents a substantial clinical improvement over existing technologies for r/r MCL because it provides a treatment option for patients unresponsive to or ineligible for current treatments, including patients who have progressed following a prior BTK inhibitor. CMS also believes that the ORR of 93% seen after one dose with Tecartus™ and the differences in ORR between Tecartus™ and historical controls supports substantial clinical improvement.

CMS finalizes Tecartus™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of Tecartus™ will be identified by ICD-10-PCS codes XW033M7 and XW043M7.Based on information provided by the applicant, effective April 15, 2021, the WAC for Tecartus™ is $399,000 per patient. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Tecartus™ is $259,350.

n. VEKLURY® (remdesivir)

Gilead Sciences submitted an application for VEKLURY® a nucleotide analog that inhibits viral RNA-dependent RNA polymerase and demonstrates activity countering viral pathogens such as MERS, SARS, and SARS-CoV-2, the virus responsible for COVID-19.

Newness. On October 22, 2020, the FDA approved VEKLURY® for use in adults and pediatric patients (12 years of age and older) for the treatment of COVID-19 requiring hospitalization, VEKLURY® also has an EUA for pediatric patients 12 years of age or younger.

According to the applicant, VEKLURY® has been available under the EUA since May 2020. Between July 1, 2020 and September 30, 2020, Gilead entered into an agreement with the U.S. Government to allocate and distribute commercially available VEKLURY® and the first sale was completed on July 10, 2020. The applicant stated it transitioned to a more traditional, unallocated model of distribution as of October 1, 2020. VEKLURY® is uniquely identified by ICD-10-PCS codes XW033E5 and Xw045E5.

For the first criterion (same or similar mechanism of action), the applicant stated there are currently no other antiretroviral therapies that have received an EUA or an approval from FDA to treat COVID-19. The applicant discussed the difference between the mechanism of action of VEKLURY® and high titer COVID-19 convalescent plasma, which also received an EUA for the treatment of hospitalized patients with COVID-19. For the second criterion (same or different MS-DRG), the applicant stated that since there are no other antiretroviral therapies for the treatment of patients with COVID-19, VEKLURY® could not be assigned to same MS-DRG as existing technologies. For the third criterion (same or similar disease or patient population), the applicant stated that VEKLURY® represents a novel treatment option for patients with COVID-19 which is a separate disease than those caused by other coronaviruses.

In the proposed rule, CMS noted that Olumiant® has received an EUA by the FDA for treatment in combination with VEKLURY® for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients (Oluminant, did not receive FDA approval by July 1, 2021 and therefore is not eligible for consideration for new technology add-on payments for FY

2022). In addition, CMS noted that cases involving VEKLURY® may map to the same MS-DRGs as other treatments for COVID-19 and other treatments may treat the same disease and similar patient population as VEKLURY®.

The applicant provided additional input about the mechanism of action of VEKLURY®. After reviewing the information, CMS agrees that VEKLURY® does not use the same or similar mechanism of action when compared to existing therapies; VEKLURY® works as a nucleotide analog to inhibit viral replication. CMS continues to believe that VEKLURY® may involve the treatment of the same or similar type of disease and the same or similar patient population as existing technologies that treat COVID-19. CMS concludes that VEKLURY® meets the newness criterion.

Cost. CMS concludes VEKLURY® meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that VEKLURY® is a substantial clinical improvement because it shortens time to recovery in hospitalized patients with severe COVID-19; the applicant also asserted that VEKLURY® results in improved clinical status and a trend toward reduced mortality.

In the proposed rule, CMS discusses the peer reviewed published studies provided by the applicant, including the results from the ACTT-1 study. The ACTT-1 study is a multi-center, multi-country, adaptive, double-blinded, placebo-controlled, randomized clinical trial. CMS noted that the articles submitted by the applicant used study design that may be subject to bias, such as the adaptive and open label design.

In a comment, the applicant addressed CMS' concerns and provided additional studies demonstrating the effectiveness of VEKLURY®. CMS states this information addresses it concerns about the study design. Based on review of the additional information, CMS concludes that VEKLURY® meets the substantial clinical improvement criterion because it shortens time to recovery in patients hospitalized with severe COVID-19 and reduced mortality compared to patients receiving placebo.

CMS finalizes VEKLURY® meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of VEKLURY® will be identified by ICD-10-PCS codes XW033E5 and XW043E5.Based on information provided by the applicant, the cost per case for VEKLURY® is $3,120. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving VEKLURY® is $2,028. As discussed below (section F.8.), CMS finalizes an extension of the NCTAP through the end of the FY in which the PHE ends for all eligible products. CMS also finalizes that it will reduce the NCTAP for an eligible case by the amount of any new technology add-on payment. Therefore, cases involving the use of VEKLURY® in FY 2022 that are eligible for new technology add-on payments and NCTAP, the NCTAP will be reduced by a maximum of $2,028 for the same case.

o. ZEPZELCA™ (lurbinectedin)

Jazz Pharmaceuticals submitted an application for ZEPZELCA™, an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. ZEPZELCA™ is a marine-derived, synthetic antineoplastic compound that inhibits transcription-dependent replication stress and genome instability of tumor cells.

SCLC is an aggressive type of lung cancer and comprises approximately 15% of all lung cancers. According to the applicant, SCLC is the most aggressive form of lung cancer characterized by rapid disease progression and early metastatic spread. SCLC is sensitive to platinum-based chemotherapy but almost always relapse requiring subsequent lines of therapy. The applicant states that topotecan is the only treatment currently available for second line treatment.

Newness. The FDA approved ZEPZELCA™ on June 15, 2020 for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. ZEPZELCA™ will typically be administered in the outpatient clinic but because many patients with SCLC have comorbidities the applicant stated that initiation of treatment and possibly some additional infusions will be administered in the inpatient hospital setting. Two new unique 10-PCS codes were approved (XW03387 and XW04387) effective October 1, 2021.

For the first criterion (same or similar mechanism of action), the applicant stated that ZEPZELCA™ is a novel synthetic antineoplastic marine derived compound with a unique mode of action and chemical structure. According to the applicant, ZEPZELCA™ is a transcription inhibitor that binds DNA preferentially to quinine-rich sequences located within gene regulatory elements of oncogenic transcription factors and the silencing of their transcription program. The applicant stated that ZEPZELCA™ has been shown to induce immunogenic cell death. The application discussed the difference in the mechanism of action between ZEPZELCA™ and topotecan and other recently approved first line treatments for SCLC, TECENTRIQ and IMFINZI. For the second criterion (same or different MS-DRG), the applicant stated ZEPZELCA™ will map to MS-DRGs for other treatments for SCLC. For the third criterion (same or similar disease or patient population), the applicant stated it is indicated for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. CMS concludes that ZEPZELCA™ meets the newness criterion.

Cost. CMS concludes that ZEPZELCA™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that ZEPZELCA™ offers a significant clinical improvement for adult patients with metastatic disease with disease progression on or after platinum-based chemotherapy for five reasons, including improved safety and efficacy as compared to existing treatment options.

In the proposed rule, CMS discussed several concerns with the information provided by the applicant. CMS was concerned the results in overall response and survival rates were based on only one study, a single-arm, open label phase II basket study and that without a direct

comparison arm it may be more difficult to draw definitive conclusions. CMS also noted that the subset analyses generated from the primary basket study have small sample sizes and the authors of these studies stated that further research on larger populations is required to make firm conclusions.

In a comment, the applicant addressed CMS' concerns and provided additional studies demonstrating the effectiveness of ZEPZELCA™. Several commenters also discussed why ZEPZELCA™ is a substantial clinical improvement in the treatment of relapsed SCLC. After consideration of these comments, CMS concludes that ZEPZELCA™ provides a substantial clinical improvement because it fills an unmet need in second-line treatment for patients with ES-SCLC.

CMS finalizes ZEPZELCA™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2022. Cases involving the use of ZEPZELCA™ will be identified by ICD-10-PCS codes XW03387 and XW04387. Based on information provided by the applicant, the cost of ZEPZELCA™ is $13,266 per patient. For 2022, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving ZEPZELCA™ is $8,622.90

Regulatory Impact. CMS estimates total payments for the seven technologies approved under the traditional pathway will be approximately $498 million for FY 2022 (see table below reproduced from the final rule).

FY 2022 Estimates for New Technologies Approved Under the Traditional Pathway			
Technology Name	**Estimated Cases**	**FY 2022 NTAP amount (65 % or 75 %)**	**Estimated Total FY 2022 Impact**
Rybrevant	349	$6,405.89	$2,235,655.61
Abecma	179	$242,450.00	$43,398,550.00
Stratagraft	261	$44,200.00	$11,536,200.00
Tecartus	15	$242,450.00	$3,636,750.00
Trilaciclib	435	$5,526.30	$2,403,940.50
Veklury	174,996	$2,028.00	$354,891,888.00
Zepzelca	778	$8,622.90	$6,708,616.20

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

Under the alternative pathway for new technology add-on payments, a technology will be considered new and not substantially similar to an existing technology and will not need to meet the requirements that it represent a substantial clinical improvement over existing technologies. Applications for new technology add-on payments, must have FDA market authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS final rule, CMS finalized conditional approval for a technology submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) that did not receive FDA marketing authorization by the July 1 deadline for the particular fiscal

year for which the applicant applied for add-on payments.[26] 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.

In the FY 2021 IPPS rule, 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. CMS received 17 applications for new technology add-on payments under the alternative pathway. One applicant withdrew its applications, 13 of the technologies received a Breakthrough Device designation from the FDA and three have been designated as a QIDP. Two applicants withdrew their applications for the Neovasc Reducer™ and Thoraflex™ Hybrid Device prior to the issuance of this rule. Two technologies, CERAMENT® G and Phagenyx® System, did not meet the deadline of July 1, 2021 for FDA approval and are not eligible for consideration for new technology add-on payments for FY 2022. CMS notes that it did receive some comments requesting that CMS extend the policy that allows for conditional approval for certain antimicrobials (discussed above) to Breakthrough Devices that have not received FDA marketing authorization by July 1. CMS may consider this for future rulemaking

CMS provides background information on each application and discusses whether or not each technology would be eligible for new technology add-on payment for FY 2021 based on whether the technology meets 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 and LPADs, 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) Aprevo™ Intervertebral Body Fusion Device. Carlemed, INC. submitted an application for the Aprevo™ Intervertebral Body Fusion Device (aprevo™), an interbody fusion implant that stabilizes the lumbar spine column and facilitates fusion during lumbar fusion procedures for the treatment of spinal deformity. The implant device is custom made for patient-specific features by using CT scans to create 3D virtual models of the deformity.

The aprevo™ device received Breakthrough Device designation under the name "Corra" on July 1, 2020 for the Corra Anterior, Corra Transforaminal and Cora Lateral Lumbar Fusion System interbody device intended for use in anterior lumbar interbody fusion (ALIF), later lumber

[26] 85 FR 58737 through 58742

interbody fusion (LLIF) and transforaminal lumbar interbody fusion (TLIF). The applicant was granted FDA 510(k) clearance as a Class II medical devise for the ALIF and LLIF indications on December 3, 2020. FDA approved the TLIF indication on June 30, 2021 CMS states that the newness date for the ALIF and LLIF indications will be December 3, 2020 and the TLIF indications will be June 30, 2021. CMS concludes the device meets the cost criterion.

CMS **finalizes approval** of the aprevo™ Intervertebral Body Fusion for the ALIF, LLIF, and the TLIF indication for new technology payment for FY 2022. Cases involving this technology will be identified by the 12 new ICD-10-PCS codes listed in the final rule. Based on data provided from the applicant the cost of the device is $31,500. The maximum new technology add-on payment for a case involving the aprevo™ Intervertebral Body Fusion is $20,475 for FY 2022.

(2) aScope™ Duodeno. Ambu, Inc. submitted an application for the aScope™ Duodeno a single-use endoscope for endoscopy and endoscopic surgery within the duodenum. The aScope™ Duodeno was designed as a Breakthrough Device, indicated with the aScope Base (now aBox Duodeno), endo-therapy accessories (e.g., forceps) and other ancillary equipment (e.g., video monitor). aScope™ Duodeno received FDA 510(k) clearance as a 510-medical device on July 17, 2020. The beginning of the newness period will be July 17, 2020. CMS concludes that the device meets the cost criterion.

CMS **finalizes approval** of the aScope™ Duodeno for new technology add-on payment for FY 2022. Based on the available information, CMS believes the aScope™ Duodeno and EXALT™ Model D (discussed below) will share the same indication and will be identified by the same ICD-10-PCS codes (XFJB847 and XFJD847). Because CMS will be unable to separately identify these cases to apply two separate payment amounts for these technologies, CMS finalizes its proposal to use a case-weighted average to calculate a single cost to determine the new technology add-on payment amounts for both technologies. For this calculation, CMS assumes the following case-weighted percentage: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. This results in a case-weighted average cost of $2,639.36 for both technologies. The maximum new technology add-on payment for a case involving these technologies will be $1,715.59 for FY 2022.

(3) Caption Guidance™. Caption Health submitted an application for Caption Guidance™, an AI guided medical imaging acquisition software system indicated for the acquisition of cardiac ultrasound images. The applicant stated that the technology is classified by FDA as a software medical device (SaMD); in order to use the software, the Caption Guidance™ system must be installed on a compatible third-party ultrasound system. Caption Guidance™ is designated as a Breakthrough Device indicated to assist acquisition of cardiac ultrasound images and received FDA De Novo approval on February 7, 2020 for the same indication. The applicant stated that an updated version of the system received 510(k) clearance on April 16, 2020 on an expedited basis due to COVID-19; the first version of the technology was released commercially on September 15, 2020. CMS believes the newness date for this technology is when the device became available on the market, September 15, 2020.

The applicant provided cost analysis using the cost per case because the technology utilizes a subscription model for reimbursement. The applicant stated that Caption Guidance™ had been commercially available for less than 30 days prior to the application deadline and they calculated

the anticipated cost per case across all IPPS hospitals using the estimated number of Medicare and non-Medicare cases. CMS concludes that the Caption Guidance™ system meets the cost criterion.

CMS **finalizes approval** of the Caption Guidance™ system for new technology add-on payment for FY 2022. Cases will be identified by ICD-10-PCS code X2JAX47. Based on information from the applicant the cost of the system is $2,874. The maximum new technology add-on payment for a case involving the Caption Guidance™ system will be $1,868.10 for FY 2022.

(4) EXALT™ Model D Single Use Duodenoscope. Boston Scientific Corporation submitted an application for the EXALT™ Model D, a single-use, flexible duodenoscope indicated for diagnostic and therapeutic treatment of the pancreaticobiliary system during endoscopic retrograde cholangiopancreatography (ERCP) procedures. EXALT™ is designated as a Breakthrough Device, indicated for intended use with a Boston Scientific endoscopic video imaging system for endoscopy and endoscopic surgery within the duodenum, and received 510(k) clearance as a Class II medical device on December 13, 2019 for the same indication. CMS concludes the EXALT™ Model D meets the cost criterion.

CMS **finalizes approval** of EXALT™ Model D Single-Use Duodenoscope for new technology add-on payments for FY 2022. Based on the available information, CMS believes the aScope™ Duodeno and EXALT™ Model D (discussed above) will share the same indication and will be identified by the same ICD-10-PCS codes (XFJB847 and XFJD847). CMS finalizes its proposal to use a case-weighted average to calculate a single cost to determine the new technology add-on payment amounts for both technologies. For this calculation, CMS assumes the following case-weighted percentage: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. This results in a case-weighted average cost of $2,639.36 for both technologies. The maximum new technology add-on payment for a case involving these technologies will be $1,715.59 for FY 2022.

(6) FUJIFILM EP-7000X System. Fujifilm Corporation submitted an application for FUJIFILM EP-7000X System, an endoscopic video imaging system used for endoscopic observation, diagnosis, treatment, and image recording in minimally invasive surgeries of abdominal gynecologic and thoracic areas. The applicant stated the system allows for the visualization of hemoglobin oxygen saturation levels of blood in superficial tissue under a 2D endoscopic image, which helps identify tissue that is not appropriately oxygenated and thus potentially ischemic. The FUJIFILM EP-7000X System received Breakthrough Device designation on September 17, 2020 and FDA approval on June 30, 2021.

In the proposed rule, CMS discussed the cost analysis and noted that the costs of the FUJIFILM EP-7000X System did not include any operating costs. Therefore, even if the technology meets the cost criterion, no new technology add-on payment would be made for the FUJIFILM EP-7000X System because new technology add-on payments are only made for operating costs. The applicant provided a comment providing additional information. The commenter asserted that the video laparoscope and flexible endoscope are “minor equipment” and therefore are operating costs and not capital costs. CMS remains concerned that the cost for the FUJIFILM EP-7000X system only includes capital-related costs. CMS also states that the maintenance and processing

fees described by the applicant are not eligible to be included in new technology add-on payments. CMS notes that the flexible endoscope is not included on the Breakthrough Device designation and is therefore not eligible for add-on payments under the alternative pathway.

CMS **does not approve** new technology add-on payments for the FUJIFILM EP-7000X System for FY 2022.

(7) Harmony™ Transcatheter Pulmonary Valve (TPV) System. Medtronic submitted an application for Harmony™ Transcatheter Pulmonary Valve (TPV) System (Harmony™), a system consisting of a bioprosthetic heart valve developed from porcine pericardial tissue mounted on self-expanding nitinol struts sewn to a polyester fabric. Harmony™ received designation as a Breakthrough Device on May 1, 2019 for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract (RVOT). The applicant noted that the proposed indication for the pending FDA marketing authorization was more expansive than the indication for the Breakthrough Device status.

The Harmony™ System received FDA approval on March 26, 2021, with an indication for use in the management of pediatric and adult patients with severe pulmonary regurgitation who have a native or surgically-repaired RVOT and are clinically indicated for surgical pulmonary valve replacement. The applicant discussed how the Breakthrough Device Designation occurs early in the product development process and as clinical findings evolve, the FDA indications may not be identical to the proposed indication in the Breakthrough Device designation. The applicant requested that the new technology add-on payment eligibility apply to the full FDA-approved indication for the Harmony™ System. CMS reiterates that under § 412.87(c)(1), a new medical device under the alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation (85 FR 58736) and only the Breakthrough Device indication is applicable for purposes of new technology add-on payments under the alternative pathway.

In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS was concerned that the applicant's charge threshold analysis utilized a small sample of 55 cases, given that the applicant projected a case volume of over 1,000 cases for FY 2022. Based on additional information provided by the applicant, CMS concludes that the Harmony™ System meets the cost criterion.

CMS **finalizes approval** of the Harmony™ System for new technology add-on payments for FY 2022. CMS considers the beginning of the newness period to begin on March 26, 2021. Cases involving the Harmony™ System eligible for new technology add-on payments with be identified by ICD-10-PCS code 02RH38M. Based on information provided from the applicant the cost of the Harmony™ System is $41,500. The maximum new technology add-on payment for a case involving the Harmony™ System will be $26,975 for FY 2022.

(8) PRCFC (pathogen reduced cryoprecipitated fibrinogen complex). Cerus Corporation submitted an application for PRCFC, a blood product indicated for the treatment for fibrinogen (Fg) deficiency-related bleeding. PRCFC is designated as a Breakthrough Device indicated for control of massive bleeding associated with Fg deficiency and received FDA approval on

November 24, 2020 for the Breakthrough Designation and additional indications. CMS agrees that PRCFC meets the cost criterion.

CMS **finalizes approval** of PRCFC for new technology add-on payments for FY 2022 when used for control of massive bleeding associated with Fg deficiency. Cases involving the use of PRCFC eligible for new technology add-on payments will be identified by ICD-10-PCS codes: 30233D1 and 3024D1 in combination with one of the following ICD-10-CM codes: D65 or D68.2. Based on information from the applicant, the cost of PRCFC is $3,900 per patient. The maximum new technology add-on payment for a case involving the use of PRCFC will be $2,535 per patient for FY 2022.

(9) RECELL® Autologous Cell Harvesting Device. Avita Medical submitted an application for RECELL®, a standalone, single-use, battery-powered device used to process an autologous skin cell suspension for the treatment of acute thermal burns. RECELL® was granted Expedited Access Pathway (EAP) by FDA (which is considered part of the Breakthrough Devices Program by FDA[27]) on December 10, 2015 for use at the patient's point-of-care for preparation of an autologous epithelial cell suspension to be applied to a prepared wound bed. The suspension is used to achieve epithelial regeneration for definitive closure of burn injuries, particularly in patients having limited availability of donor skin for autografting. RECELL® received FDA PMA on September 20, 2018 for the treatment of acute thermal burn wounds; a narrower indication but within the scope of the EAP indication. According to the applicant, RECELL® was available for sale upon FDA approval although on a very limited basis primarily to burn centers involved with the clinical trials.

In the proposed rule, CMS believed that the beginning of the newness period for RECELL® begins with the date of approval by the FDA on September 20, 2018. Because the 3-year anniversary date of the entry of RECELL® onto the U.S. market will be September 20, 2021, CMS did not think that the device is eligible for new technology add-on payments for FY 2022.

In response to CMS' concerns, the applicant asserted that the eligibility date for the newness criterion for RECELL® should be the data when inpatient coding was available for the technology, October 1, 2019. CMS responds that in the FY 2005 final rule (69 FR 49002) it provided a detailed explanation for why using the date on which a specific code is assigned to a technology is not an appropriate test of newness. CMS notes that the applicant received FDA approval on September 20, 2018 and could have submitted an application for new technology add-on payments for earlier fiscal years under either the traditional or alternative pathways. CMS concludes that RECELL® does not meet the newness criterion.

CMS **does not approve** new technology add-on payments for the RECELL® for FY 2022.

(10) Shockwave C2 Intravascular Lithotripsy (IVL) System. Shockwave Medical Inc. submitted an application for the Shockwave IVL System, a device delivered through the coronary artery system that generates intermittent sonic waves within the target treatment site and disrupts calcium and allows subsequent dilation of a coronary artery stenosis using balloon pressure. Shockwave IVL System was designated as a Breakthrough Device in August 2019 for

[27] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.

lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. FDA approved the device on February 12, 2021 for the same indications. CMS considers the beginning of the newness period to be the date of FDA approval, February 12, 2021. CMS concludes that the Shockwave C2 IVL meets the cost criterion.

CMS **finalizes approval** of the Shockwave C2 IVL System for new technology add-on payments for FY 2022. Cases involving the use of the Shockwave C2 IVL System eligible for new technology add-on payments will be identified by four ICD-10-codes listed in the rule. Based on information provided by the applicant, the cost of the system for a case is $5,640. The maximum new technology add-on payment for a case involving the Shockwave C2 IVL System would be $3,666 for FY 2022.

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

(1) CONTEPO™ (fosfomycin). Nabriva Therapeutics U.S., Inc submitted an application for CONTEPO™, an intravenously administered epoxide antibiotic for the treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis (AP) caused by designated susceptible bacteria. CONTEPO™ is designated as a QIDP and anticipated FDA approval prior to July 1, 2021. CMS agrees that CONTEPO™ meets the cost criterion.

The applicant applied for a new technology add-on payment for the same indication for FY 2021 and received conditional approval for new technology add-on payments for FY 2021, pending FDA marketing authorization before July 1, 2021.[28] The applicant also requested that if the technology does not receive FDA marketing authorization by July 1, 2021, CMS conditionally approve CONTEPO™ for new technology add-on payments for FY 2022.

The applicant provided additional information about its FDA approval status. The applicant stated that because of delays with FDA onsite inspections due to ongoing FDA travel restrictions, CONTEPO™ did not receive FDA approval by the July 1, 2021 deadline. The applicant stated it will keep CMS informed on the FDA approval status.

CMS **finalizes conditional approval** for CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization before July 1, 2022. If CONTEPO™ receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases involving this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments will be made for cases involving the use of CONTEPO™ for FY 2022.

Cases involving the use of CONTEPO™ eligible for new technology add-on payments will be identified by ICD-10-PCS codes XW033K5 and XW043K5. Based on information provided from the applicant the cost of the drug administered over 12.5 days is $3,500. The maximum new technology add-on payment for a case involving CONTEPO™ will be $2,625 for FY 2022 (75 percent of the average cost of the technology).

[28] 85 FR 58724

(2) FETROJA® (cefiderocol). Shionogi & Co. submitted an application for Cefiderocol, an injectable siderophore cephalosporin indicated for the treatment of hospital-acquired (HABP)/ventilator-associated bacterial pneumonia (VABP). FETROJA® was designated as a QIDP for HABP/VABP and received FDA marketing approval for this indication on September 25, 2020.[29] CMS agrees that FETROJA® meets the cost criterion,

CMS **finalizes approval** of FETROJA® for new technology add-on payments for FY 2022 when used for the treatment of HABP/VABP. Cases eligible for new technology add-on payments will be identified by ICD-10-PCS codes XW033A6 and XW043A6. Based on information provided from the applicant the cost of the drug is $11,439.79. The maximum new technology add-on payment for a case involving FETROJA® will be $8,579.84 for FY 2022 (75 percent of the average cost of the technology).

(3) RECARBIO™. Merck submitted an application for RECARBIO™, a fixed-dose combination of imipenem (a penem antibacterial), cilastatin (a renal dehydropeptidase inhibitor) and relebactam (a novel ß-lactam inhibitor for treatment of HABP/VABP caused by susceptible Gram-negative bacteria.[30] RECARBIO™ is a QIDP for the treatment of HABP/VABP and received FDA approval for these indications on June 4, 2020. CMS agrees with the applicant that the drug meets the cost criterion.

CMS **finalizes approval** of RECARBIO™ for new technology add-on payments for FY 2022 when used for treatment of HABP and VABP. Cases eligible for new technology add-on payment will be identified by ICD-10-PCS codes XW033U5 and XW043U5. Based on information provided from the applicant the cost of the drug is $12,768,68 when used for the treatment of HABP and VABP. The maximum new technology add-on payment for a case involving RECARBIO™ for these indications will be $9,576.51 for FY 2022 (75 percent of the average cost of the technology).

Regulatory Impact. CMS approves ten alternative pathway applications for FY new technology add-on payments. CMS estimates that total payments will be approximately $151 million for FY 2022; QIDP payments will be approximately $50 million and payments for technologies part of the Breakthrough Device Program will be approximately $101 million (see table below reproduced from the final rule).

[29] FETROJA® also has a QIDP designation and is FDA approved for cUTI and was granted a new technology add- on payment under the alternative new technology add-on pathway for certain antimicrobials for cUTI for FY 2021(85 FR 58721).

[30] RECARBIO™ also has a QIDP designation and is FDA approved for cUTI and complicated intra-abdominal infections (cIAI) and was granted a new technology add-on payment under the alternative new technology add on pathway for these indications for FY 2021 (85 FR 58728).

FY 2022 Estimates for New Technologies Approved Under the Alternative Pathway				
Technology Name	**Estimated Cases**	**FY 2022 NTAP amount (65 % or 75 %)**	**Estimated Total FY 2022 Impact**	**Pathway (QIDP, LPAD, or Breakthrough Device)**
Ascope duodeno	3,750	$1,715.58	$6,433,425	Breakthrough Device
Aprevo	1,261	$40,950.00	$51,637,950	Breakthrough Device
Caption Guidance	2,592	$1,868.10	$4,842,115.20	Breakthrough Device
Contepo	17,320	$2,275.00	$39,403,000.00	QIDP
Exalt Model D	8,314	$1,715.58	$14,236,332.12	Breakthrough Device
Fetroja	379	$7,435.86	$2,818,190.94	QIDP
Harmony TPV	171	$26,975.00	$4,612,725.00	Breakthrough Device
PRCFC	2,296	$2,535.00	$5,820,360.00	Breakthrough Device
Recarbrio	928	$8,299.64	$7,702,065.92	QIDP
Shockwave Coronary IVL	3,760	$3,666.00	$13,784,160.00	Breakthrough Device

c. Other Comments

CMS summarizes the multiple comments regarding payments for QIDPs. CMS appreciates these comments and will consider them for future rulemaking.

7. Comment Solicitation on the New Technology Add-on Payment Newness Period for Products Available through an Emergency Use Authorization (EUA) for COVID-19

CMS states an EUA by the FDA allowing a product for emergency use would not be considered FDA marketing authorization for the purpose of new technology add-on payments, as it would not be considered to have FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with its longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, CMS believes a product available only through an EUA would not be eligible for new technology add-on payments.

CMS recognizes that data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance and that these products may eventually be available for new technology add-on payment.

CMS requested comments on the following:

- How data reflecting the costs of a product with an EUA should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with an EUA; and
- Whether the newness period should begin with the date of the EUA.

Commenters recommended that CMS use the date of FDA approval, and not the date of the EUA, as the beginning of the 2-to 3-year newness period. Commenters stated that a full FDA review process benefits patient safety and clinical efficacy. Commenters also believed that the data collected during the EUA period may reflect high variability in estimates of costs due to

challenges associated with variable treatment practices during the pandemic with a novel disease. The commenters also stated that the data collected may not reflect government price subsidies provided during the EUA period. Some commenters recommended that CMS allow EUAs as an appropriate form of FDA authorization as required under the new technology add-on payment process.

CMS appreciates these comments and will consider them for future rulemaking where applicable. In response to comments, CMS notes that there are distinct eligibility criteria for new technology add-on payments that are not satisfied by an EUA. CMS states that an EUA authorization is for emergency use of a product when it is determined that it is reasonable to believe that a product is effective in treating a condition and the known and potential benefits outweigh the known and potential risks for the product. The safety and effectiveness of therapies under an EUA continue to be evaluation and therefore CMS is unable to consider an EUA as FDA marketing authorization for the purposes of new technology add-on payments.

8. Extension of the New COVID-19 Treatments Add-on Payment (NCTAP) Through the End of the FY in which the PHE Ends

In response to the PHE, CMS established the NCTAP for COVID-19 cases that meet certain criteria.[31] Effective for discharges on or after November 2, 2020 and until the end of the PHE for COVID-19, the NCTAP pays hospitals the less of (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the claim exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the CARES Act, for certain cases that include the use of a drug or a biological product currently authorized for emergency use or approved for treating COVID-19.

CMS proposed to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends. CMS also proposed to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022.

Commenters overwhelmingly supported CMS' proposal to continue the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the FY in which the PHE ends. Many commenters recommended CMS remain flexible and continue extending NCTAP even after the PHE, until a data as the data used to establish payment for the applicable MS-DRGs reflects the cost of new COVID-19 treatments.

Some commenters supported CMS's proposal to discontinue the NCTAP for products that are approved for new technology add-on payments beginning FY 2022. A commenter, the applicant for Veklury, supported paying NCTAP until it expired and then pay the new technology add-on payment once the NCTAP ends. The commenter provided information discussed in the rule supporting this recommendation. Another commenter noted that in many cases, the NCTAP results in higher payment than the new technology add-on payment for the same product and recommended CMS provide the add-on payment or the NCTAP, whichever resulted in the highest Medicare payment.

[31] 85 FD 71157 through 71558

After consideration of comments, CMS finalizes its proposal to extend the NCTAP through the end of the FY in which the PHE ends, including products that are approved for new technology add-on payments for FY 2022. CMS also finalizes it will reduce the NCTAP for an eligible case by the amount of any new technology add-on payment. CMS states this will not create a financial distinction between technologies eligible for both the new technology add-on payment compared to technologies for NCTAP only.

Regulatory Impact. Because the cost and utilization of inpatient stays using these new treatments is unknow, CMS is not able to estimate the overall cost of the extension of the NCTAP. CMS notes that at the high extreme, if all of the new COVID-19 treatments result in a net cost of hospitalizations that exceed the outlier threshold for discharges during the NCTAP provision, the cost to the Medicare program will be the sum over all of these NCTAP cases of 0.65 times the outlier threshold for each case.

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. 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, 17-01 and 18-04. On March 6, 2020, OMB issued Bulletin No. 20-01. CMS notes that the updates from Bulletin No. 20-01 would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022.

CMS indicates that OMB Bulletin 18-04 used for determining the labor market areas and hospital wage index in FY 2021 had significant impact. As a result, CMS adopted a policy to place a 5 percent cap on any decrease in a hospital's wage index for FY 2021 only. Given the unprecedented nature of the ongoing COVID-19 PHE, CMS sought comment on whether to continue to limit the decrease in a hospital's wage resulting from use of OMB Bulletin 18-04 in FY 2022. The proposed rule indicated that such an extended transition could potentially take the form of continuing the FY 2021 wage index for those hospitals experiencing a continuing reduction in the wage index in FY 2022 from the adoption of OMB Bulletin 18-04. CMS further sought comment on making this transition budget neutral, as is its usual practice.

Comments/Responses: Many commenters indicated that it is not equitable to limit the transition adjustment only to the effects of the revised labor market delineations. The commenters requested the transition be implemented more broadly to all hospitals experiencing large declines in wage index values. Several commenters requested any adjustment be made non-budget neutral so it does not come at the expense of hospitals with an increased wage index.

CMS will limit reductions in the wage index to 5 percent in FY 2022 only for those hospitals that received a transition wage index in FY 2021 due to CBSA changes resulting from OMB Bulletin 18-04. In FY 2020 and FY 2021, CMS implemented two separate transition policies limiting any hospital to a 5 percent year-to-year reduction in wage index values. In FY 2020, the purpose of the transition was to address potential impacts due to implementation of the low wage policy. In FY 2021, the purpose was to address the impact of CMS's adoption of the revised OMB labor market delineations. There is no specific wage index policy finalized in FY 2022 that warrants a similar application of a transition cap to all hospitals.

For FY 2022, similar to FY 2021, CMS is applying a budget neutrality adjustment consistent with past practice. CMS has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment only to transition wage index policies that benefit a hospital (e.g., the hospital with the declining wage index).

B. Worksheet S-3 Wage Data

The final rule wage index values are based on data from FY 2018 submitted cost reports. Categories of included and excluded costs from prior years are unchanged for FY 2022. CMS calculates the FY 2022 wage index based on wage data of 3,182 hospitals. The data file used to construct the final wage index includes FY 2018 data submitted to CMS as of June 30, 2021. General wage index policies are unchanged from prior years.

CMS notes that it proposed to exclude 86 providers due to aberrant data. For the final FY 2022 wage index, CMS restored 28 hospitals to the wage index because their data was either verified or improved, but also removed the data of 5 hospitals for the first time after the proposed rule due to their data being aberrant or conversion to CAH status. Thus, 63 hospitals with aberrant data remain excluded from the FY 2022 wage index.

One commenter objected to the exclusion of hospital data from the wage index with a high average hourly wage that was justified with supporting documentation. This commenter indicates that CMS' decision is without statutory authority, arbitrary and capricious and abuse of discretion without any definable standards. The commenter objected to CMS "improperly" substituting its judgment of reasonable wage levels for actual, free-market data.

CMS believes the commenter is referring to a hospital in Fresno, California. The hospital documented the accuracy of its wages but has an average hourly wage that is significantly higher than the next highest average hourly wage of any other hospital in its CBSA and surrounding areas. CMS believes this hospital's data, while accurate, is the result of a unique salary structure and business model. The hospital's average hourly wage according to CMS does not accurately reflect the economic conditions of its area. CMS, therefore, believes the hospital's wage data

does not reflect "the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level as required under the statute.

C. Method for Computing the Unadjusted Wage Index

For the FY 2022 wage index, CMS did not propose any changes to the steps for computing the unadjusted wage index. The final rule includes a detailed listing of these steps. CMS calculates an unadjusted national average hourly wage of $46.52.

D. Occupational Mix Adjustment

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 Medicare Administrative Contractors by September 3, 2020. CMS reports having occupational mix data for 95 percent of hospitals (3,028 of 3,182) used to determine the FY 2022 wage index. Consistent with the statute, CMS will apply the 2019 occupational mix survey data to the FY 2022 wage index. The FY 2022 national average hourly wage, adjusted for occupational mix, is $46.47.

E. Analysis of New Occupational Mix Survey Data

CMS compares the impact of using the 2019 occupational mix survey to the 2016 occupational mix survey on the wage index. These results indicate that the wage indexes of 51.9 percent of urban areas (214) and 61.7 percent of rural areas (29) will decrease. Wage indexes will increase for 48.1 percent of urban areas (198) and 38.3 percent of rural areas (18) from the use of the 2019 occupational mix survey data compared to the 2016 occupational mix survey data.

F. Rural, 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 2022 wage index for 269 urban hospitals requiring a budget neutrality adjustment factor of 0.992868 (-0.71 percent) applied to hospital wage indexes.

CMS is also continuing a policy adopted in FY 2020 to exclude the wage data of a hospital that is reclassifying from urban to rural in calculating the rural floor for a state. Such a hospital's wage data will be used to calculate the rural wage index but not the rural floor wage index that applies to hospitals that are not treated as rural for IPPS payment purposes. In response to a comment, CMS clarifies that this policy does not apply to hospitals that reclassify as rural through the Medicare Geographic Classification Review Board (MGCRB).

Some commenters objected to nationwide application of budget neutrality for a policy that benefits a small minority of urban hospitals in a few states. However, CMS responds that section 3141 of the Affordable Care Act requires CMS to apply a "uniform, national adjustment to the area wage index" beginning with FY 2011." This nationwide budget neutrality adjustment replaced the state-specific one CMS applied previously.

Imputed Floor. The rural floor cannot apply in all urban states as there is no rural area wage index upon which to determine the floor. CMS adopted an imputed floor for all urban states beginning in FY 2005. The original methodology for computing the imputed floor benefited only New Jersey hospitals. Beginning in FY 2013, CMS adopted an alternative methodology for hospitals in other all urban states (Delaware and Rhode Island). CMS applied the imputed floor in a budget neutral manner necessitating a reduction in payment to all hospitals to offset its cost. CMS allowed the imputed floor—both the original and alternative methodologies—to expire after FY 2018.

The imputed floor was reestablished by section 9831 of the American Rescue Plan Act (ARPA) enacted by Congress on March 11, 2021. However, the imputed floor provision was enacted with an exemption from IPPS budget neutrality obviating the need for a reduction in payment to all hospitals to offset its cost. In addition, the ARPA provision will apply in Washington DC, Puerto Rico and in states that have rural areas but no hospitals that are being paid using a rural wage index (only hospitals in Connecticut meet this last criterion).

The ARPA was enacted too late for CMS to incorporate the imputed floor wage index into the proposed rule. Following the proposed rule, CMS posted a separate data file on its website that showed the imputed floor wage index.[32] The imputed floor values are shown below:

CBSA	State Name	Imputed Floor
07	Connecticut	1.1606
08	Delaware	0.9998
09	Washington DC	1.1108
31	New Jersey	1.1625
40	Puerto Rico	0.3497
41	Rhode Island	1.1313

The final rule wage index reflects the calculation of the imputed floor but does not provide a comparable table to the one above.

Commenters supported and opposed the imputed floor policy but opponents conceded that CMS does not have any discretion on this policy. All commenters were pleased that reinstatement of the imputed floor is being done non-budget neutral. CMS is modifying the regulations consistent with the statute to reflect the current imputed floor policy.

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

[32] (FY 2022 IPPS Proposed Rule Home Page | CMS, file #12 under data files).

Wyoming. CMS indicates that 44 hospitals will receive the frontier floor value of 1.0000 for FY 2022. As all hospitals in Nevada have a wage index of over 1.0, the provision will have no effect on Nevada hospitals. This provision is not budget neutral, and CMS estimates an increase of approximately $64 million in IPPS operating payments due to the frontier floor.

Low Wage Index Hospital Policy. CMS proposed to continue the policy to increase wage indexes below the 25th percentile by one-half the difference between the hospital's otherwise applicable wage index and the 25th percentile wage index value for FY 2022. For FY 2022, the 25th percentile wage index value across all hospitals is 0.8437. CMS is finalizing this policy without change. The final rule budget neutrality adjustment is -0.20 percent.

In response to comments opposing the policy, CMS reiterates responses from prior rule making (84 FR 42327-42328). Some commenters opposing the policy reference an Office of Inspector General (OIG) report that states that Medicare payment is only one factor contributing to hospitals' low wages. Consistent with the OIG Report, the commenters suggested that the low wage index policy be suspended pending further study. CMS responded that it has been studying the wage index for several years and the low wage index policy was already in place by the time of the OIG report. CMS felt that action was needed immediately and many commenters support CMS' policy.

G. Wage Index Tables

Final rule wage index tables 2, 3 and 4 can be found at: FY 2022 IPPS Final Rule Home Page | CMS. Select #2 under FY 2022 Final Rule Tables.

H. Geographic Reclassification

Geographic reclassification is 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 (15 miles for urban hospitals and 35 miles for rural hospitals) and have wages that are different than its own area and comparable to the wages of the requested area:

- Urban Hospitals: Average hourly wage that is at least 108 percent of other hospitals in its geographic area and 84 percent of the requested area.
- Rural Hospitals: Average hourly wage that is at least 106 percent of other hospitals in its own geographic area and 82 percent of the requested area.

The MGCRB decides whether hospitals meet the criteria to receive the wage index of another hospital.

Under a separate process that does not involve the MGCRB, hospitals that meet specific criteria in statute may request that a CMS Regional Office treat an urban hospital as rural for purposes of IPPS payment. Under the statute, hospitals that reclassify from urban to rural are treated as rural for all IPPS purposes. Such hospitals may also apply for geographic reclassification under the MGCRB process using the more favorable rural reclassification rules. However, CMS' policy has been that when applying the 106 percent criterion to an urban hospital that has reclassified as

rural, the comparison is made to other hospitals in the urban area where the hospital is geographically located, not other hospitals in the rural area of its state.

While CMS did not propose any changes to the geographic reclassification rules, it did simultaneously release a separate interim final rule with comment that changes reclassification policy for urban hospitals that have reclassified to rural areas beginning in FY 2022. In response to adverse litigation against the agency in *Bates County Memorial Hospital v. Azar*, an urban hospital that has reclassified as rural may qualify for a subsequent MGCRB reclassification if its average hourly wage is 106 percent of the average hourly wage of hospitals located in the rural area of its state rather than other urban hospitals located in its same (or home) geographic area.

CMS indicates that this revised policy is effective for MGCRB reclassifications beginning on October 1, 2022. If a hospital applied for and was rejected for an MGCRB reclassification beginning on October 1, 2021 but would have qualified were this rule in effect, CMS allowed the denial of the hospital's geographic reclassification to be reversed for FY 2022.

Comments/Responses. Public commenters supported CMS' proposal and asked a variety of clarifying questions. In response, CMS stated:

- In the *Three Year MGCRB Reclassification Data File* used for MGCRB reclassification, an urban to rural reclassified hospital's geographic urban CBSA will continue to be listed. The hospital will not be listed as being rural.
- Consistent with the above, a hospital applying for MGCRB reclassification would not include other urban to rural reclassified hospitals in the rural average hourly wage for the 106 percent criterion.
- To meet the 106 percent criterion, CMS will allow the comparison to be done to the average hourly wage in either the hospital's geographic home area or the rural area to where it is reclassified.

Geographic Reclassifications. There are 406 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2022. There are 243 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2020 that will continue for FY 2022, and 291 hospitals approved for wage index reclassification in FY 2021 that may continue for FY 2022. Nine hundred and forty hospitals are in an MGCRB reclassification status for FY 2022 (with 140 of these hospitals reclassified back to their home area).

The deadline for withdrawing or terminating a wage index reclassification for FY 2022 approved by the MGCRB was 45 days from publication of the FY 2022 proposed rule in the *Federal Register* (June 24, 2021). 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 2022 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.

Allowing Electronic Appeals of MGCRB Decisions. In the FY 2021 IPPS final rule, CMS revised the regulations to allow electronic submissions of appeals of MGCRB decisions and require

electronic copies to CMS' Hospital and Ambulatory Policy Group. In the FY 2022 IPPS proposed rule, CMS proposed to further revise the regulation to specify that the hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. This policy is intended to allow requests for review to the Office of the Attorney Advisor to also be submitted electronically. There were no public comments on this change that CMS finalizing without change.

Tolling the Administrator's Review for Good Cause. Currently the CMS Administrator has 90 calendar days following a party's request for review of an MGCRB decision to issue a decision. She has 105 days from the date of the MGCRB's decision to issue her own decision if she initiates a review under her own discretion. The 90-day timeframe to issue a decision can be tolled for good cause, but there is no comparable provision that allows the 105-day timeframe to be tolled. CMS proposed that the Administrator can also toll the 105-day deadline for good cause. There were no comments on this proposal that CMS is finalizing without change.

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 a hospital located in a Lugar County. A Lugar hospital is treated as reclassified to the urban area where the highest number of its workers commute. This process is automatic and will occur with no action on the part of the hospital.

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. As a Lugar reclassification occurs automatically, a Lugar hospital must decline its reclassification using the same process as other hospitals to receive the outmigration adjustment (e.g., notify CMS within 45 days of proposed rule publication that it is declining its Lugar reclassification).

CMS restates the following policies with respect to how Lugar hospitals may decline their urban status to receive the outmigration adjustment:

- Waiving deemed urban status results in the Lugar hospital being treated as rural for all IPPS purposes.
- Waiving deemed urban status can be done once for the 3-year period that the outmigration adjustment is effective.
- If a Lugar hospital waives its reclassification for 3 years, it must notify CMS to reinstate its Lugar status within 45 days of the IPPS proposed rule publication for the following fiscal year.
- In some circumstances, a Lugar hospital may decline its urban reclassification to receive an outmigration adjustment that it would no longer qualify for once it is reclassified as rural. In these circumstances, CMS will decline the Lugar hospital's request and continue to assign it a higher urban wage index (which itself could result in the county requalifying for the outmigration adjustment based on data in the final rule).

I. Out-Migration Adjustment

CMS will apply the same policies for the FY 2022 out-migration adjustment that it has been using since FY 2012. Estimates of increased payments are $55 million in FY 2022 to 245 hospitals. This provision is not budget neutral.

J. Urban to Rural Reclassification

As noted earlier, 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.

Changes to Urban to Rural Cancellation Requirements. In the FY 2020 IPPS/LTCH PPS final rule, CMS noted concerns about relatively low wage hospitals timing an urban to rural reclassification to become effective after the lock-in date to avoid reducing their state's rural wage index. These hospitals then cancel their rural reclassifications effective for the next fiscal year and then reapply to become rural again after the lock-in date. For FY 2020, at least twenty-one hospitals in one state and five hospitals in another state engaged in this practice.

CMS notes that this form of manipulation (hospitals canceling rural status to remove their wage data from the rural wage index calculation) resulted in the rural wage index for one state increasing by over 4 percent between the FY 2020 proposed rule and the FY 2020 final rule. The figure could have been significantly greater (as high as 10 percent) in certain states according to CMS' proposed rule analysis. CMS believes this practice of applying for and cancelling rural reclassification to manipulate a state's rural wage index is detrimental to the stability and the accuracy of the Medicare wage index system.

In the past, CMS had a rule that required an urban hospital reclassifying as rural to maintain that status for at least one year. The rule was designed to prevent hospitals that qualify for rural referral center (RRC) status from briefly reclassifying as rural in order to obtain the permanent benefit of special provisions that favor RRCs when they apply for MGCRB reclassification.

These rules made sense when a hospital could not both have an urban to rural reclassification and an MGCRB reclassification at the same time. CMS eliminated that rule when it became possible for an urban hospital to reclassify as rural and then further apply for an MGCRB reclassification under the more favorable rural reclassification rules. However, CMS now believes it is necessary

and appropriate to adopt a similar measure to prevent rural reclassifications from being used purely as a mechanism for statewide wage index manipulation.

CMS proposed that requests to cancel rural reclassifications must be submitted to the CMS Regional Office not earlier than one calendar year after the reclassification effective date. For example, a hospital that was approved to receive a rural reclassification effective October 1, 2021 would not be eligible to request cancellation until October 1, 2022. That reclassification would then be canceled one year later effective October 1, 2023.

Further, CMS proposed to make cancellation requests effective for the Federal fiscal year that begins in the calendar year after the calendar year in which the cancellation request is submitted. For example, CMS proposed that a cancellation request submitted on December 31, 2021 would be effective October 1, 2022. But a cancellation request submitted one day later on January 1, 2022 would not become effective until October 1, 2023. CMS' proposed policy was intended to ensure that a hospital approved for rural reclassification (and that does not receive an additional reclassification) would have its data included in the calculation of the rural wage index for at least one Federal fiscal year before the rural reclassification status could be canceled. The policy would apply to all written requests submitted by hospitals on or after October, 1, 2021 to cancel rural reclassifications.

CMS does not believe the proposed changes would have an undue impact on hospitals that are reclassified as rural for reasons other than manipulating the rural wage index. In the FY 2021 final rule, 81 percent of hospitals with rural reclassifications were assigned a wage index based on an MGCRB or "Lugar" reclassification, and would not receive a wage index based on their rural reclassification. Another 11 percent received a rural wage index value that was greater than or equal to their geographically urban area. Since these hospitals are typically benefiting by maintaining rural reclassification status, CMS does not believe they would be negatively affected by these proposals. More than half of the remaining 9 percent of hospitals with rural reclassifications do so to maintain MDH or SCH status. These special statuses convey additional financial benefits to hospitals and are not typically or routinely canceled by hospitals.

Comments/Responses: Public commenters were supportive of CMS taking action to limit urban to rural reclassification that manipulate the rural wage index. Commenters suggested a variety of alternatives to CMS' proposals. These alternatives would exempt a hospital from these policies if the purpose in reclassifying as rural or cancelling a rural reclassification is for other than wage index manipulation. For example, a hospital would be exempt from the proposed policies if it was canceling a long-maintained urban to rural reclassification or the cancelation is related to a hospital's SCH or MDH status or for purposes Medicare DSH.

Some commenters suggested limiting a hospital from being able to reapply to acquire rural status after canceling rural status rather than having to maintain rural status for a minimum period of time. CMS indicated concerns that these suggestions are not consistent with the statute as the statute requires CMS to treat a hospital as rural if the hospital meets the statutory requirements to be considered rural.

Other commenters expressed concern about the lengthy timeframe required to cancel a rural reclassification (e.g., December 31 effective on October 1 of the following year) without being able to review wage index data from the proposed rule. CMS acknowledged this policy would add a significant amount of time to the current requirement for an urban to rural cancellation but felt the timeframe was needed to avoid the potential for wage index manipulation by timing cancellation requests and new applications around the lock-in date.

Despite this latter concern, CMS is not finalizing the proposal to require an urban to rural cancellation to be made in the calendar year that precedes the fiscal year that the cancellation would become effective (e.g., by December 31, 2021 for a cancellation that would be effective October 1, 2022). CMS indicates a hospital that cancels an urban to rural reclassification for FY 2022 under the current rules (e.g., by June 2, 2021) and reacquires rural status on October 1, 2021 for FY 2022 would be required to retain that rural status until at least FY 2024 (as it could not request cancellation of that status until at least October 1, 2023 effective at the beginning of the following fiscal year on October 1, 2024). CMS believes this policy significantly reduces the urgency to finalize the policy that requires an urban to rural cancellation to be made in the calendar year that precedes the fiscal year that the cancellation would become effective. That is, the first policy (requiring urban to rural status to be maintained for at least one year before cancellation could be requested) achieves the intended goal of the second policy (ensuring that an urban to rural reclassified hospital's wage data is used in calculating the rural wage index for at least one year). For this reason, CMS does not see an urgent need to finalize that policy at this time.

While CMS will continue to allow urban to rural cancellation requests to be made 120 days in advance of the fiscal year start date, it will finalize the policy that require an urban to rural reclassification to be maintained for a minimum of one year before a request to cancel may be made. CMS will continue to monitor rural reclassification applications and cancellation requests for potential manipulation of the wage index. It will take into consideration the comments so far received and, if necessary, make additional proposals to address this issue further in future fiscal years.

K. Requests for Wage Index Data Corrections

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. CMS posts the wage index timetable on its website including all of the public use files made available during the wage index development process. All deadlines are eastern standard time. The FY 2022 wage index process is complete. For the FY 2023 wage index timetable go to: FY2023-Wage-Index-Home-Page | CMS

L. 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. However, application of the 62 percent labor-related share is not subject to wage index budget neutrality

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. As a result of its proposal to rebase and revise the hospital market from 2014 to 2018 (discussed in the next section), CMS proposed to use a revised national labor-related share of 67.6 percent for FY 2022. One commenter asked that CMS phase-in the reduction in the labor-related share over 3 years without applying budget neutrality due to the COVID-19 PHE. CMS does not believe it is necessary or appropriate to phase-in the change to the labor-related share. The policy is being finalized without change.

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 of 67.6 percent. Consistent with the statute, CMS is applying budget neutrality for the change to the labor-related share from 68.3 to 67.6 percent but not for the lower 62 percent labor share when a hospital has a wage index less than 1.0.

IV. Rebasing and Revising of Hospital Market Baskets

CMS proposed to rebase and revise the hospital market basket that is used in the annual update to IPPS operating costs and the update to target amounts for facilities excluded from the IPPS (religious non-medical health care institutions, cancer hospitals and short-term acute care hospitals located in the U.S. territories of the Virgin Islands, Guam, Northern Mariana Islands and American Samoa). CMS also proposed to update the capital input price index (CIPI) used to annually update the capital IPPS. Currently, the hospital market basket and the CIPI use 2014 data for the base year. CMS proposed to move the base year from 2014 to 2018.

Operating Market Basket. The below table shows the impact from changing to a 2018-based IPPS market basket. In no year would the change be more than 0.1 percentage point, and the average for the historical and projected period is unchanged.

FY	2014-Based IPPS Market Basket % Change	2018-Based IPPS Market Basket % Change
Historical Data		
FY 2017	2.6	2.5

FY	2014-Based IPPS Market Basket % Change	2018-Based IPPS Market Basket % Change
FY 2018	2.5	2.5
FY 2019	2.4	2.4
FY 2020	2.0	2.0
Average: FY 2017 – FY 2020	**2.4**	**2.4**
Forecast		
FY 2021	2.7	2.7
FY 2022	2.7	2.7
FY 2023	2.8	2.8
FY 2024	2.9	2.9
Average FY 2021 – FY 2024	**2.8**	**2.8**

The below table shows how the labor-related share would decline from 68.3 percent to 67.6 percent from moving to a 2018-based IPPS market basket.

FY	2014-Based IPPS Market Basket Cost Weight	2018-Based IPPS Market Basket Cost Weight
Wages and Salaries	43.4	41.2
Employee Benefits	12.4	11.7
Professional Fees: Labor-Related	6.8	8.6
Administrative and Facilities Support Services	1.0	1.1
Installation, Maintenance and Repair Services	2.4	2.4
All Other: Labor-Related Services	2.3	2.6
Total Labor-Related Share	**68.3**	**67.6**

Comments/Responses: CMS received comments opposing the change in the labor-related share. One set of comments objected to CMS only including 64 percent of the "Professional Fee: Labor-Related" category in the labor-related share. These commenters acknowledge that hospitals may obtain some professional services in a national market (the remaining 36 percent of the category weight), but the rates for those services result from a variety of factors, including those that are dictated by local labor costs. Similar comments were made regarding home office costs when the home office is located outside of the hospital's geographic wage area (e.g., home office costs vary by local market area and a portion of them—40 percent—should not be excluded from the labor-related share).

CMS disagrees stating that services purchased from firms outside the local labor market may differ from those that would be purchased in the local labor market for any number of reasons including but not limited to, the skill level of the contracted personnel, higher capital costs, etc. Similarly, home office labor costs outside the geographic wage area of the hospital are excluded from the wage index because they will not vary based on local economic factors.

Several other commenters asked CMS to delay changing the labor share arguing that a 2018-based market basket will not be representative of hospital labor costs during the PHE. CMS responded that it does not have data that would allow it to evaluate the impact of the PHE on the share of hospital costs that are labor-related. However, once it does, it will evaluate this comment further. CMS is finalizing the change to the labor share as proposed.

CIPI. The below table shows the impact from changing to a 2018-based CIPI. In no year would the change be more than 0.1 percentage point, and the average for the historical and projected period is unchanged. CMS did not receive any comments on the proposed rebasing and revising of the CIPI. The rebasing and revising of the CIPI is being finalized without change.

FY	2014-Based IPPS Market Basket % Change	2018-Based IPPS Market Basket % Change
Historical Data		
FY 2017	1.1	1.0
FY 2018	1.2	1.1
FY 2019	1.4	1.3
FY 2020	1.2	1.2
Average: FY 2017 – FY 2020	**1.2**	**1.2**
Forecast		
FY 2021	1.0	0.9
FY 2022	1.0	1.0
FY 2023	1.2	1.1
FY 2024	1.3	1.2
Average FY 2021 – FY 2024	**1.1**	**1.1**

V. Other Decisions and Changes to the IPPS

A. Rural Referral Centers (RRCs)

Rural Referral Centers (RRC) are hospitals that are either geographically rural or treated as rural for IPPS purposes that are subject to special rules for the DSH payment adjustment and geographic reclassification. To qualify as an RRC, a hospital must have more than 275 beds or meet case-mix, discharge and other criteria for the federal fiscal year that ends at least one year prior to the beginning of the cost reporting period for which the hospital seeks RRC status.

CMS annually revises case mix index (CMI) and discharge criteria to qualify for RRC status. While the latest data used for these purposes would normally be FY 2020 CMI values and FY 2019 Medicare cost reports for FY 2022, CMS proposed to continue using FY 2019 CMI values and FY 2018 cost reports to avoid using atypical utilization that spans the period of the COVID-19 PHE. Public comments agreed with this proposal. CMS is finalizing the proposal without change.

To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, a hospital may qualify as an RRC if the hospital is rural or treated as rural and has:

- 275 beds or more; or
- More than 5,000 discharges (3,000 for an osteopathic hospital) in its cost reporting period that began during FY 2018 and
    - A CMI greater than or equal to the lower of 1.70449 (national urban hospital CMI excluding teaching hospitals) or the CMI for the hospital's region shown in the below table.

Census Region	CMI Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4447
2. Middle Atlantic (PA, NJ, NY)	1.5005
3. East North Central (IL, IN, MI, OH, WI	1.60875
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.62455
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5777
6. East South Central (AL, KY, MS, TN	1.54085
7. West South Central (AR, LA, OK, TX	1.74375
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7833
9. Pacific (AK, CA, HI, OR, WA)	1.6913

The median regional CMIs in the final rule reflect the March update of the FY 2019 MedPAR 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.

B. Low-Volume Hospitals

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. The below table shows the statutory and regulatory criteria to be a low-volume hospital and how the additional payment is calculated.

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%

CMS is not making any changes to the low-volume hospital program for FY 2022. Absent statutory intervention, only hospitals with less than 200 total discharges will be eligible for the low volume hospital adjustment beginning in FY 2023.

C. Disproportionate Share and Uncompensated Care

1. Background

Medicare makes DSH and uncompensated care payments (UCP) 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 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 2022 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 2021 Medicare DSH estimates, which were based on the March 31, 2021 update of the HCRIS and the FY 2021 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 2021 Medicare estimate of DSH is $13.985 billion (about 1 percent less than the estimate in proposed rule). **The Factor 1 amount is seventy-five percent of this amount or $10.49 billion.** Factor 1 for 2022 is about $889 million less than the final Factor 1 for FY 2021. OACT's estimates for FY 2022 began with a baseline of $13.882 billion in Medicare DSH expenditures for FY 2018. The table below shows the factors applied to update this baseline to the current estimate for FY 2022.

Factors Applied for FY 2019 through FY 2022 to Estimate Medicare DSH Expenditures Using 2018 Baseline

FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2019	1.0185	0.97	1.009	1.0176	1.0144	14.082
2020	1.031	0.857	1.038	0.9912	0.9091	12.801
2021	1.029	1.013	1.029	0.9662	1.0364	13.267
2022	1.025	1.059	0.9675	1.00375	1.0541	13.985

- 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). Note this figure is total discharges inclusive of IPPS exempt hospitals and units (inpatient psychiatric facility, inpatient rehabilitation facility, children's hospitals, cancer hospitals and hospitals in U.S. territories) that are then netted out through the "other" column adjustment.

- The case-mix column shows the estimated change in case-mix for IPPS hospitals.
- The "other" column shows the changes 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 and the 20 percent add-on for COVID-19 discharges).

CMS states that the discharge factors for FY 2020 to FY 2022 reflect the estimated impact of the COVID-19 pandemic. It also adjusted the case-mix factor figures for FY 2020 and FY 2021 for the pandemic. The FY 2022 case-mix increase is an estimate based on the recommendation of the 2010-2011 Medicare Technical Review Panel. For the "other" category, CMS notes that this includes a factor for Medicaid expansion due to the ACA developed using public information and statements for each State regarding its intent to implement the expansion. Specifically, CMS assumes approximately 55 percent of all individuals who were potentially newly eligible Medicaid beneficiaries in 2018, 2019, and 2020 resided in States that elected to expand Medicaid eligibility; assumes 60 percent for 2021 and thereafter. For more detail CMS refers readers to OACT's Memorandum on Factor 1.[33]

The table below shows the factors that CMS includes in the "update" column of the table above.

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2019	2.9	-0.75	-0.8	0.5	1.85
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.7	0	-0.7	0.5	2.5

Comment/Responses: Many commenters requested that CMS calculate estimated DSH payments for purposes of Factor 1 without adjusting for the impact of COVID-19 PHE. Other commenters cited additional data on why CMS' estimates for Factor 1 were too low: this included a higher 2020-2021 Medicaid enrollment during the pandemic than CMS estimated, and that more recent data alone may not fully account for the increase in discharges during the second half of FY 2021. Others requested more clarity regarding the estimate of the "Other" factor used to calculate Medicare DSH payments. In its response, CMS notes that its estimates incorporate the latest information from OACT of the impact of the COVID-19 PHE on the Medicare program. CMS also states that it does not believe that excluding and/or mitigating the impact of the pandemic through adjustments to the Factor 1 calculation would be consistent with the statute.

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.

[33] Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh

3. FY 2022 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's (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 minus 0.2 percentage points for each of fiscal years 2018 and 2019. 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.[34]

For FY 2022, CMS estimated in the proposed rule that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2021 and 2022 was 10.2 percent and 10.1 percent, respectively. For the final rule, CMS updates the calculation of Factor 2 for FY 2022 to incorporate more recent data.

Using these estimates, CMS calculates Factor 2 for FY 2022 (weighting the portion of calendar years 2021 and 2022 included in FY 2022) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2021: 9.8 percent.
- Percent of individuals without insurance for CY 2022: 9.5 percent.
- Percent of individuals without insurance for FY 2022 (0.25 times 0.098) +(0.75 times 0.095): 9.6 percent

Factor 2 = 1-|((0.096-0.14)/0.14)| = 1- 0.3143 = 0.6857 (68.57 percent)

CMS calculated Factor 2 for the FY 2022 final rule to be 0.6857 or 68.57 percent, and the uncompensated care amount for FY 2022 to be $10.489 billion x 0.6857 = $7.192 billion which is $1.098 billion less than the FY 2021 UCP total of about $8.290 billion; the percentage decrease is -13.24 percent. The final rule estimate is about -5.72 percent lower than uncompensated care estimate in the FY 2022 proposed rule of $7.628 billion. The below tables show the Factor 1 and Factor 2 estimates for FY 2021 and the final factors for FY 2022:

[34]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

FY 2022 Change in UCP

	FY 2021	FY 2022	$ Change ($ in billions)	% Change
Factor 1	$11.378	$10.489	-$0.889	-7.8%
Factor 2	0.7286	0.6857	-.0429	-5.9%
UCP	$8.290	$7.192	$-1.098	-13.24%

Comment/Responses: Citing the pandemic, many commenters requested that for FY 2022 CMS maintain total uncompensated care payments at the current level for FY 2021. Commenters noted that it seems counterintuitive that the percentage of uninsured decreased given the significant increase in unemployment due to the pandemic. In response, CMS provides additional detail in its response about how it incorporated employment changes on insurance coverage. It notes that its approach takes into account faster than anticipated employment growth, an improving economic outlook based on a consensus of the Blue Chip forecasters, and substantial recent and anticipated, temporary increases in Medicaid enrollment. CMS also states that its statutory authority at section 1886(r)(2)(B)(i) require use of the most recent data on the uninsured and that its use of NHEA data is consistent with the statute.

4. Factor 3 for FY 2022

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 determines the total pool available for uncompensated care payments. This result multiplied by Factor 3 determines the amount of the uncompensated care payment that each eligible hospital 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 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 as CMS improved the instructions for use of Worksheet S-10 and began auditing its reporting.

In FY 2018, CMS began transitioning to use of Worksheet S-10 by using two years of low-income patient days and one year of Worksheet S-10 data (FY 2014).[35] In FY 2019, CMS continued that transition by using one year of low-income patient days and two years of Worksheet S-10 data (FY 2014 and FY 2015).[36]

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.

In FY 2021, CMS finalized its proposal to use the most recent available single year of audited Worksheet S-10 data to determine Factor 3 for FY 2021 and subsequent years. For FY 2021, CMS used FY 2017 data to determine Factor 3. It did not finalize a methodology to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals for FY 2022 using Worksheet S-10 data as it believed further consideration and review was needed. It also finalized the definition "uncompensated care" for FY 2021 and subsequent fiscal years that it had initially adopted in FY 2018. Specifically, "uncompensated care" is 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).

b. Use of Audited FY 2018 Data to Calculate Factor 3 for FY 2022

CMS will use a single year of Worksheet S-10 data from FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology for all eligible hospitals except for 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 2018 cost reports reflect improvements to the Worksheet S-10 instructions that were effective on October 1, 2017.

CMS notes that uncompensated care payments to hospitals whose FY 2018 Worksheet S-10 data have been audited represent about 99.6 percent of the proposed total uncompensated care payments for FY 2022. CMS states that it used the June 30 HCRIS extract to calculate Factor 3.
IHS and Tribal Hospitals and Subsection(d) Puerto Rico hospitals that have a FY 2013 cost report.

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. CMS states that it is continuing to consider the feedback it received through consultation with IHS and Tribal hospitals for future rulemaking.

[35] 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).
[36] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

Comment/Responses: Many commenters supported the use of a single year of FY 2018 Worksheet S-10 data for the calculation of Factor 3 for FY 2022. They cited that these are the most recent reports which have been subject to audit and that these audits have continued to improve the accuracy and reliability of Worksheet S-10 data over time. Other commenters expressed opposition to using a single year of data as that there is significant variation in year-to-year uncompensated care payments for some hospitals. CMS notes that it will consider in future years using multiple years of data when almost all providers have been audited for more than one fiscal year under the revised reporting instructions.

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

As in previous years, CMS notes that the auditing process for the FY 2018 Worksheet S-10 was a common topic among many commenters. Commenters recommended that CMS consider:

- A comprehensive audit process and expand the Worksheet S-10 audits to include all DSH-eligible hospitals receiving uncompensated care payments;
- The provider burden associated with the audits;
- Ensuring transparency and consistency by making audit materials and protocols publicly available;
- The need for a timely review and appeals process for any adverse findings or inconsistent audit disallowances; and
- Inconsistent and different sampling and extrapolation techniques employed by MACs during Worksheet S-10 audits.

In its response, CMS notes that based on its limited audit resources it is not feasible to commit to audit all hospitals every year or to implement a timely review and appeals process but anticipates expanding the number of hospitals subject to audit. CMS also notes that hospitals whose FY 2018 Worksheet S-10 data that have been audited represent about 99.6 percent of total uncompensated care payments for FY 2022. CMS reiterates as it has in the past that it does not make review protocols public as CMS desk review and audit protocols are confidential and for CMS and MAC use only but that it will continue to work with the MACs each year to ensure a consistent audit process across providers and MACs.

CMS also received suggestions for clarification of the Worksheet S-10 instructions, as well suggestions for form revisions to improve reporting. CMS reiterates its efforts to refine and improve the instructions and to improve the accuracy and consistency of the information reported on Worksheet S-10. Regarding specific structural changes to Worksheet S-10, CMS notes that these comments fall outside of the scope of this final rule. It refers commenters, however, to the

forthcoming Paper Reduction Act (PRA) package comment period for the Worksheet S-10 for specific questions about or suggestions for modifications and clarifications to Worksheet S-10 including reporting instructions.

c. Methodological Considerations for Calculating Factor 3

New Hospital for Purposes of Factor 3

CMS will continue to determine Factor 3 for new hospitals that do not have an FY 2018 cost report to use in the Factor 3 calculation (that is, hospitals with CCNs established on or after October 1, 2018). Because these hospitals will have not FY 2018 uncompensated care data, new hospitals will not receive interim uncompensated care payments during FY 2022. The MAC will make a final determination about whether the hospital is eligible on settlement of its FY 2022 cost report and then determine the amount of the uncompensated care payment using the Factor 3 calculation.

Newly Merged Hospitals

CMS continues to determine each newly merged hospital's final uncompensated care payment 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 will be based only on the data for the surviving hospital's CCN available the time of the development of the final rule. For FY 2022, this data will be the FY 2018 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 2022 cost report.

CCR Trim Methodology

Consistent with its process for trimming CCRs in FY 2021, CMS will apply the following steps (shown in table below) for trimming CCRs in FY 2022.

Methodology for Trimming CCRs	
Step 1	Remove Maryland hospitals and all-inclusive rate providers
Step 2	For FY 2018 cost reports, CMS calculates 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. CMS calculates the ceiling as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. 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 2018 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, CMS applied the statewide average CCR to 10 hospitals, of which 3 have FY 2018 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 re-calculates 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

If the hospital's uncompensated care costs for FY 2018 are an extremely high ratio (greater than 50 percent) of its total operating costs, then CMS will use data from the FY 2019 cost report for the ratio calculation. Thus, CMS will trim the hospital's uncompensated care costs for FY 2018 by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2022. For hospitals whose FY 2018 cost report has been audited, CMS will not apply the trim methodology.

In addition to the existing UCC trim methodology, CMS finalizes its proposal to apply a new trim specific to certain hospitals that are not projected to be DSH eligible and do not have audited FY 2018 Worksheet S-10 data. It notes that in rare cases hospitals that are not currently projected to be DSH eligible and that do not have audited data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). Thus, for FY 2022, in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent (rounded from 58 percent), it would exclude the hospital from the prospective Factor 3 calculation. This trim will only impact hospitals that are not currently projected to be DSH eligible. If the hospital is determined to be DSH eligible at cost report settlement, then the MAC will calculate the Factor 3 after reviewing the reported uncompensated care information.

d. 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. CMS then uses this per discharge payment amount to make interim uncompensated care payments to each projected DSH eligible hospital. These interim payments are reconciled following the end of the year.

CMS finalizes its proposal to modify this calculation for FY 2022 to be based on the average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that includes data from FYs 2018, 2019, and 2020. It believes that using a 3-year average would underestimate discharges, due the decrease in discharges during the pandemic.

To reduce the risk of overpayments of interim uncompensated care payments and the potential for unstable cash flows for hospitals and MA plans, CMS continues its voluntary process through which a hospital may submit a request to its MAC for a lower per 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 will 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. This does not change how CMS reconciles the total uncompensated care payment amount at cost report settlement.

Comments/Response: Commenters supported this change because of the COVID-19 PHE.

e. 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 2022, CMS finalizes its proposal that after the publication of the FY 2022 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, including with respect to mergers and/or report upload discrepancies.

Comments/Response: CMS notes that commenters informed them of discrepancies with respect to mergers and notes that it resolved these issues. It referred a specific question related to Worksheet S-10 adjustment back to the respective MAC.

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 2022 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,366 hospitals that it projects to be eligible for DSH in FY 2022. CMS presents estimates based on using FY 2018 Worksheet S-10 data to determine Factor 3.

The total amount of UCP is estimated at $7.192 billion, a -13.24 percent decrease from FY 2021 UCP ($1.098 billion). Changes in FY 2022 uncompensated care payments are driven by a decrease in Factor 1 and Factor 2 as well as by a small decrease in the number of projected eligible DSH hospitals. The payment change for any individual hospital will vary as payment impacts solely from Factor 3 are redistributive. A percent change in UCP payments lower than negative 13.24 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 13.24 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 2021-FY 2022 ($ in millions)	Percent Change
All Hospitals	-$1,098	-13.24%
Urban	-1,014	-13.00
Large Urban	-686	-14.21
Other Urban	-328	-11.03
Rural	-84	-17.22
Beds: 0-99 (Urban)	-45	-15.43
Beds: 250+ (Urban)	-674	-12.01
New England (Urban)	-40	-17.73
Middle Atlantic (Urban)	-163	-16.55
West North Central (Urban)	-59	-11.85
West South Central (Urban)	-204	-12.49
Pacific (Urban)	-115	-15.93
Major Teaching	-399	-13.39
Non-Teaching	-326	-13.34
Voluntary	-575	-12.62
Proprietary	-140	-11.5
Government	-383	-15.22

Rural hospitals are projected to receive a larger percentage decrease in UCP (17.22%) than urban hospitals (13.00%) in FY 2022 compared to FY 2021. Urban hospitals in the New England, the Middle Atlantic, and Pacific regions are expected to receive larger than average decreases. The variation by teaching status is minimal and the percent change in payments is similar to the overall average payment decrease of 13.24 percent. Government hospitals are projected to receive larger than average decreases of 15.22 percent, whereas voluntary and proprietary hospitals are projected to receive a payment decrease of 12.62 and 11.5 percent, respectively.

D. Hospital Readmissions Reduction Program (HRRP)

CMS finalizes as proposed all regulatory and subregulatory changes to the Hospital Readmissions Reduction Program (HRRP) described in the proposed rule: 1) adoption of a measure suppression policy to account for the effects of the COVID-19 public health emergency (PHE); 2) application of the measure suppression policy to the pneumonia readmission measure beginning with program year FY 2023;[37] 3) updating the technical specification updates of the remaining five program measures to exclude patients with COVID-19 secondary diagnoses; 4) continuing alignment of HRRP performance periods with MedPAR file updates and 5) making minor changes to regulation text. Details of the proposals, along with comments received and the

[37] Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506)

agency's responses to comments, are provided in the rule and summarized below. No changes were proposed to the methodologies for calculating payments or payment adjustments factors.

Using the FY 2022 HRRP payment adjustment factors, in the regulatory impact analysis section of the rule CMS estimates that 2,500 hospitals, or 85 percent of those eligible, will be penalized under the HRRP in FY 2022, with aggregate penalties representing 0.63 percent of payments to hospitals. (An estimated dollar total of penalties is not provided.) A table in that section shows the variation in these impacts by hospital characteristics. Hospitals with the smallest penalty payment percentages are large urban (500 or more beds), teaching hospitals with large numbers of residents (100 or more), have high DSH percentages (65 and over), or are located in the West North Central or Pacific regions.

1. HRRP Background and the FY 2022 Measure Set

The Hospital Readmissions Reduction Program (HRRP) reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level for diseases or after procedures as defined in the HRRP's measure specifications. The program's requirements are found at §§ 412.152 through 412.154. Detailed information about the HRRP is available on the CMS website https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program and the CMS QualityNet website https://qualitynet.cms.gov/inpatient/hrrp.

A hospital subject to the HRRP receives an adjustment factor that is between 1.0 (no reduction) and 0.9700 (or a maximum possible reduction of 3 percent) of base operating DRG payments based upon its readmissions' performance compared to hospitals with similar proportions of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligible beneficiaries. The payment adjustment (P) is calculated using the formula shown below where NM=budget neutrality modifier; dx=diagnosis and ERR=expected readmission rate. An outline of the steps of the calculation process is available for download at https://qualitynet.cms.gov/files/5f294e391e13dc0021eea933?filename=HRRP_Pymt_ReducMthdlgy_Infogr.pdf.

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

The final measure set for the FY 2022 HRRP is unchanged from FY 2021 and consists of the following:

- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506),
- Hospital 30-Day All-Cause RSRR Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505),
- Hospital 30-Day, All-Cause, Unplanned, RSRR Following Coronary Artery Bypass Graft (CABG) Surgery (NQF#2515),

- Hospital 30-Day, All-Cause, RSRR Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891),
- Hospital 30-Day, All-Cause, RSRR Following Heart Failure (HF) Hospitalization (NQF #0330), and
- Hospital-Level 30-Day, All-Cause RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

In the proposed rule, CMS requested comments on future reporting of HRRP measure results stratified by demographic and social risk factors other than dual eligibility. Responses to that request are discussed later in the rule and in section V.G.5 of this summary. Also, part of the proposed rule was two broader RFIs related to the agency's quality measure portfolio, including the HRRP. These RFIs addressed transitioning the CMS quality enterprise to a fully digital platform by 2025 and identifying health equity gaps in the agency's quality programs through methodological and data collection changes. CMS provides summaries of comments received in response to the digital transformation and health equity RFIs in sections IX.A and IX.B of the rule respectively.

2. Measure Suppression Policy for CMS Value-Based Programs Including the HRRP

CMS finalizes as proposed a "cross-program measure suppression policy" for its value-based programs, including the HRRP, beginning with FY 2022 and extending for the duration of the COVID-19 PHE. Under this policy, one or more quality measures may be suppressed in the agency's value-based programs,[38] if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and performance scores based on those data. Suppression would involve measure reporting and/or scoring methodology adjustments. CMS plans to provide facilities with confidential feedback reports showing their performances on suppressed measures to illustrate how the PHE has affected them as well as to follow established policies for public reporting of HRRP results.

To guide its decision making, CMS finalizes adoption of the following Measure Suppression Factors for use with the HRRP and other value-based programs:

1) Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or worse compared to historical performance during the immediately preceding program years;
2) Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE;
3) Rapid or unprecedented changes in
    i. Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
    ii. The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin;
4) Significant national shortages or rapid or unprecedented changes in
    i. Healthcare personnel;

[38] CMS lists the following as its value-based programs: HRRP, Hospital Value-Based Purchasing Program, Hospital Acquired Condition Program, Skilled Nursing Facility Value-Based Purchasing Program and End-Stage Renal Disease Quality Incentive Program.

ii. Medical supplies, equipment, or diagnostic tools or materials; or
iii. Patient case volumes or facility-level case mix.

CMS requested input on the proposed policy and suppression factors. Commenters were generally supportive of the measure suppression policy and the associated suppression factors. Concerns were raised about public reporting of hospital performance on measures that had been suppressed and stated that comparisons between suppressed and unsuppressed scores would be unfair. CMS emphasizes that publicly reported data will be accompanied by explanatory information about the suppressed measures and their implications. The agency commits to ongoing monitoring of the PHE's impacts and the effects of the policy as adopted, with policy revision proposals to be made as indicated.

CMS also requested input on adoption of a measure suppression policy for future PHEs. Commenters voiced concerns that such a policy would allow implementation of scoring adjustments and payment changes outside of rulemaking and recommended stakeholder involvement prior to any future policy and suppression factor adoption. CMS states that any scoring adjustments or payment changes that might address a future fiscal year of the program due to the COVID-19 PHE or another type of PHE would be proposed through rulemaking.

3. Application of the Measure Suppression Policy to the HRRP for the COVID-19 PHE

a. Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506)

CMS finalizes its proposal to suppress the HRRP's pneumonia readmission measure for the FY 2023 program year, citing Measure Suppression Factor 2 -- clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE. CMS notes that the SARS-CoV-2 virus is primarily a respiratory pathogen and often causes pneumonia, and the suppressed measure focuses on readmissions for pneumonia. CMS reprises the data analyses it conducted that led to proposing measure suppression and notes receiving supportive comments.

b. *All Other HRRP Measures*

CMS confirms its plan, as stated in the proposed rule, to update the measures for readmissions related to AMI; HF; THA/TKA; COPD; and CABG. Through its HRRP subregulatory process, CMS will update the denominators of these five measures by excluding cases in which COVID-19 is a secondary diagnosis. CMS adds that the same update will be applied to exclude cases in which COVID-19 is a primary diagnosis, as the procedure-specific readmission measures (CABG and THA/TKA) could include such patients in their measure cohorts.

CMS mostly received supportive comments on its measure update plan. CMS clarifies that any patients having primary or secondary diagnoses of COVID-19 will be removed from both their index admission and readmission cohorts, thereby excluding those who are readmitted due to COVID-19 within the 30-day readmission window. CMS also clarifies that exclusions will be based on the COVID-19 specific ICD-10 code: U07.1. The agency will explore the feasibility of providing measure-specific confidential reports to hospitals on actual performance on the

measures prior to exclusions being made. CMS concludes by stating that its data analyses do not support suppressing the five non-pneumonia readmission measures.

c. Applicable Periods and Use of MEDPAR Data

CMS finalizes the following proposals without modifications: 1) continue to exclude admissions of Medicare Advantage patients as identified in the Medicare Enrollment Database; 2) determine aggregate payments for excess readmissions and for all discharges by using data from MedPAR claims with discharge dates that align with the FY 2022 applicable (performance) period; 3) continue to use MedPAR claims data from the applicable period to identify the discharges to be used in aggregate payment calculations; 4) define the data source as the MedPAR file update for each Federal FY, which is updated six months after the end of each FY within the applicable period; and 5) automatically adopt use of MedPAR data corresponding to the applicable period for FY 2023 and all subsequent program years (i.e., data that are one year advanced from the previous program FY). Commenters were supportive of these policies.

4. HRRP Extraordinary Circumstances Exception Policy (ECE Policy)

CMS finalizes the provisions of the September 2020 IFC that extended the exclusion of all Q1 and Q2 claims data from HRRP calculations to include not only the FY 2022 applicable period but also FYs 2023 and 2024. CMS notes that comments received in response to the IFC were generally supportive.

CMS emphasizes that the data use exceptions issued in 2020 under the ECE are specific to claims data usage in HRRP calculations. Hospitals are not exempted from submitting claims for care delivered during the excepted periods and they remain subject to payment reductions made based on nonexcepted data.

CMS outlines the temporary policy consequences of the data exceptions granted under the HRRP ECE policy in combination with Secretarial authority to utilize his own criteria in selecting measures for use in HRRP calculations (section 1886(q)(5)(A)(i) of the Act).

- The FY 2022 applicable period is adjusted to be July 1, 2017, through December 1, 2019.
- The associated period for calculating DRG payments is also adjusted to be July 1, 2017, through December 1, 2019.
- The HRRP ERR formula's budget neutrality modifier (NM in the formula shown above) will be calculated using 2019 data.
- The HRRP measures will use less than 12 months of data for risk adjustment for admissions between July 1,2020, and June 30, 2021 (i.e., shorter lookback period). Index admission comorbidities will continue to be used as part of risk adjustment.

CMS notes that while these temporary changes are themselves substantive, their impacts on the HRRP's previously finalized policies are not substantive and, therefore, the changes fall under the program's subregulatory process. As further support for non-substantive impacts of the temporary policy changes, CMS restates its analysis from the proposed rule that demonstrated

minimal effects on payments to hospitals by removal of the six months of data (Q1 and Q2 2020) from HRRP calculations (86 FR 25468).

5. Request for Comment: Stratifying Future Results for Condition-Specific Readmission Measures by Race and Ethnicity

In support of its initiative to close the health equity gap through changes to Medicare's quality programs, in the proposed rule CMS requested comment on the following:

- Confidential reporting to hospitals of HRRP measure results stratified using indirectly estimated race and ethnicity in addition to the currently reported results stratified using dual eligibility;
- Future expansion of stratified reporting using additional social factors, such as language preference and disability status, to be collected by hospitals;
- Public reporting on Care Compare of results stratified using both indirectly estimated race and ethnicity, and dual eligibility, after at least one year of confidential reporting and further rulemaking; and
- Mechanisms to incorporate other demographic characteristics into HRRP data analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

Many commenters voiced general support of stratified reporting of HRRP results to identify and understand health disparities. Multiple commenters expressed concerns related to reporting of the stratified data including privacy issues, confusion generated by using indirectly estimated race and ethnicity data, and actionability of indirectly estimated data. Several recommended that results stratified using indirectly estimated demographic data should only be reported confidentially and not publicly. CMS reprises its discussion from the proposed rule about techniques of indirect estimation and states that specific HRRP changes including proposals for public reporting of stratified data would be made through rulemaking.

6. Regulatory Text Update

CMS finalizes amendments to § 412.154(f)(4) to update the name of its site used to publicly report hospital data, including HRRP results.

E. Hospital Value-Based Purchasing Program

CMS finalizes as proposed the adoption of a measure suppression policy to account for the effects of the COVID-19 PHE and to apply the policy for the duration of the PHE. Based on the suppression policy, CMS makes changes to various HVBP program measures for FYs 2022 and 2023. In accordance with the policy, CMS also updates as feasible the program's measure performance standards for FYs 2024 through 2027. Separate from the suppression policy, the agency finalizes removal of the CMS PSI 90 measure from the HVBP's measure set beginning with program year FY 2023.

CMS also finalizes as proposed adoption of a special scoring rule for FY 2022 under which no Total Performance Scores (TPSs) would be calculated. The agency further finalizes that, absent TPS availability, it will adjust hospitals' incentive payment percentages for FY 2022 to equal the statutory 2 percent reductions made to their base operating DRG payments in that FY. Because the special scoring rule is being finalized as proposed, all HVBP program adjustment factors for all hospitals will reflect a net-neutral payment adjustment for hospitals in accordance with the finalized special rule as found at § 412.168.

CMS additionally finalizes updates to the HVBP program's ECE policy, makes minor regulatory text changes, and refers readers to RFIs concerning digital quality measurement and health disparities reporting across the agency's quality enterprise including the HVBP program. (The RFIs with responses received are described by CMS in the rule at section IX.A – digital quality measurement – and section IX.B – health disparities reporting.) No changes were proposed regarding domain weighting or minimum case numbers for measures required to assign domain scores.[39]

1. HVBP Program Background

CMS calculates a VBP incentive payment percentage for each hospital based on its TPS for a specified performance period. The payment adjustment reflects 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 based on the hospital's TPS. An HVBP Program measure set is specified by CMS through rulemaking for each payment year.[40] Each hospital's TPS is calculated by summing the greater of the hospital's achievement or improvement points for each measure then creating domain scores that themselves are summed as the TPS. Finally, CMS converts the hospital TPS into a value-based incentive payment percentage through a linear exchange function, under which the sum of all hospitals' payments will equal the total amount of dollars contributed to the VBP funding pool.

HVBP program requirements are codified at §§ 412.160 through 412.168. Tables V.H-4 through V.H-6 in the rule list the program measures as finalized for program yeas FY 2022 through 2025, A summary table of program measures is provided below in section V.G.10 of this summary. Additional information on the program is available on the CMS HVBP website https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing and the CMS QualityNet website https://qualitynet.cms.gov/inpatient/hvbp.

2. Measure Suppression Policy

CMS finalizes as proposed a "cross-program measure suppression policy" for its value-based programs, including the HVBP program, beginning with FY 2022 and extending for the duration of the COVID-19 PHE. Under this policy, one or more quality measures may be suppressed in

[39] The established minimum case numbers for program year FY 2024 and future years are shown in Table V.H-16.
[40] Measures available for inclusion in the program are those included in the Hospital IQR Program that have also been included on the Hospital Compare (now Care Compare) website for at least one year prior to the start of the relevant performance period.

the agency's value-based programs, if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and performance scores based on those data. Suppression would involve measure reporting and/or scoring methodology adjustments. To guide its decision making when considering measure suppression, CMS finalizes adoption of several Measure Suppression Factors; these factors are identical to those listed above in section V.G.1 of this summary.

CMS plans to provide facilities with confidential feedback reports showing their performance on suppressed measures to illustrate how the PHE has affected them as well as to follow established policies for public reporting of HVBP program results. Public reporting of the actual suppressed measure data is also planned according to established HVBP program policy.

CMS requested input on the proposed policy and suppression factors and on adoption of a measure suppression policy for future PHEs. Comments echoed those made for the HRRP (see summary section V.G.2 above). CMS again responds that any scoring adjustments or payment changes that might address a future fiscal year of the HVBP program due to the COVID-19 PHE or another type of PHE would be proposed through rulemaking.

3. Application of the Measure Suppression Policy to the HVBP Program

Suppression is finalized for seven measures, listed below, including all five related to hospital-associated infections (HAIs). For each suppressed measure, CMS will calculate the rate for the relevant program year(s) but then suppress use of those rates for making hospital payment changes during those years.[41] CMS analyzed data for all HVBP program measures to detect COVID-19 PHE effects, except CMS PSI 90 for which removal was separately proposed. Analyses of the five HAI measures were conducted in concert with the Centers for Disease Control and Prevention (CDC). Data analyses and suppression rationales are reprised in the rule.

For FY 2022, the following measures will be suppressed:

1) Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166);
2) Medicare Spending Per Beneficiary (MSPB) – Hospital (NQF #2158);
3) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138);
4) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139);
5) American College of Surgeons – CDC Harmonized Procedure Specific Site Surgical Site Infection (SSI) Outcome Measure (NQF # 0753) (Colon Surgery and Abdominal Hysterectomy);
6) NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716); and
7) NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).

For FY 2023, the following changes will be made:

[41] Calculations for the HCAHPS measures are calculated by the survey vendors and reported to CMS.

- The pneumonia mortality measure will be suppressed;[42]
- The CMS PSI 90 measure is removed from the program's measure set beginning with this year and for subsequent years; and
- The technical specifications of five program measures will be updated through the program's existing subregulatory process for non-substantive change to exclude patients with COVID-19 primary or secondary diagnoses.
    - Mortality rate measures for AMI, CABG, COPD, and HF, and
    - Complication rate after primary elective THA and/or TKA.

Where relevant, the agency combines the effects of removing CMS PSI 90 on HVBP program performance standards, measure scoring, and payment adjustments with those of applying measure suppression.

CMS invited input on the suppression proposals for both FYs; changes in HVBP program scoring given the inability to reliably calculate TPSs for FY 2022 and resulting special payment adjustments for that FY; and the removal of CMS PSI 90 starting with FY 2023. Most commenters were supportive of suppressing the HCAHPS, HAI, and MSPB for FY 2022 and the pneumonia mortality measure for FY 2023. Concerns were voiced about public reporting of the actual performance rates of the suppressed measures. Support for the special scoring and payment changes was divided, as was support for removing CMS PSI 90.

CMS reiterates that the transparency of reporting actual performance data publicly has great value and that explanatory information will be provided to aid the public in properly interpreting the results. CMS also notes that the CMS PSI 90 measure will remain in the Hospital Acquired Condition Reduction Program (HACRP) and included in Overall Hospital Star Ratings.

CMS notes having received comments about updating the technical specifications of five program measures to exclude patients with COVID-19 primary or secondary diagnoses, even though this will occur under the program's existing subregulatory process for non-substantive changes. Commenters were divided between support and concerns. CMS clarifies that exclusions will be based on the COVID-19 specific ICD-10 code: U07.1. and that – for the AMI, CABG, COPD, and HF measures – patients readmitted due to COVID-19 within the readmission window of the index admission will also be excluded. Also, CMS responds that patients without a COVID-19 diagnosis present on admission who die during their admissions will be included in the four measure cohorts. CMS agrees to explore the feasibility of providing measure-specific confidential reports to hospitals on actual performance on the measures prior to exclusions being made and to monitor performance rates frequently to detect if further policy changes are needed.

4. Baseline and Performance Periods

CMS finalizes as proposed revisions to the baseline periods of seven measures: the HCAHPS, MSPB, and all five HAI measures for FY 2024. CMS had previously established baseline and performance periods for HVBP measures for FYs 2023 through 2027, but reassessed these periods for potential effects resulting from the nationwide exception granted in response to

[42] Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468)

COVID-19 that excludes Q1 and Q2 2020 data from use in HVBP scoring. CMS notes having received comments in support of the proposed revisions. Tables V.H-6 through V.H-10 in the rule list the baseline and performance periods for these measures as finalized for FYs 2023 through 2027.

5. Performance Standards

CMS finalizes revisions to the performance standards for multiple measures and multiple FYs as proposed, taking into account the now finalized suppressed measures and baseline and performance periods described above. The finalized standards are provided in Tables V.H-11 and V.H-12 in the rule. These tables reflect the converging suppressed measures and revised baseline and performance periods with previously established standards as follows:

- Proposals for suppression of measures for FYs 2022 and 2023 will not change the established performance standards for those program years.
- Performance standards are not being provided for the CMS PSI 90 measure for any FY, since the measure is being removed from the program before its reporting is required.
- MSPB measure standards are set based on performance year data and are not available in advance for any FY.
- For FY 2024, for measures in the Safety, Person and Community Engagement and Efficiency and Cost Reduction domains, performance standards will be based on CY 2019 data. Previously established Clinical Outcome domain measure standards for FY 2024 are unchanged.
- For FY 2025 and FY 2026, previously established standards for measures in the Clinical Outcome domain as previously established are unchanged.
- For FY 2027, newly established standards are being provided for the Clinical Outcomes Domain measures.

6. Scoring Methodology

CMS finalizes the following changes as proposed for FY 2022:

- Rates will be calculated for all HVBP program measures;
- Achievement or improvement points and domain scores will be calculated only for the measures in the Clinical Outcomes Domain, as these have not been suppressed;
- Measure rates and domain outcome scores will not be used to calculate TPSs.
- Each hospital's base-operating DRG payment amount will be reduced by 2 percent as required in statute;
- CMS will assign to each hospital a value-based incentive payment amount that matches the 2 percent reduction;
- Confidential hospital-specific reports of measure rates for all measures (whether or not suppressed) will be provided to hospitals; and
- Measure results from all measures will be displayed publicly according to established HVBP program policy, with explanations about measure suppression and COVID-19 PHE effects on performance.

CMS requested input on the special rules and scoring methodology for FY 2022. The majority of commenters were supportive. CMS clarifies that eligible clinicians who normally report as facility-based clinicians to the Merit-based Incentive Payment System (MIPS) – and whose scoring is based on the TPSs of their associated facilities – will have to use another MIPS reporting mechanism for MIPS performance year CY 2021/payment year CY 2023.

7. HVBP program Extraordinary Circumstances Exception (ECE) Policy Updates

CMS reaffirms the modified HVBP program ECE policy finalized in the May 20 COVID-19 IFC: CMS may grant exceptions to hospitals who have not requested them when a qualifying event beyond hospitals' control affects an entire region or locale (e.g., the COVID-19 PHE). CMS also reaffirms its decision announced in the September 2020 COVID-19 IFC: the agency will not use any voluntarily-submitted CY 2020 HVBP program measure data from Q1 and/or Q2 2020 for HVBP program scoring purposes.

CMS also acknowledges and responds to comments from the September 2020 COVID-19 IFC. Comments were generally supportive. CMS specifically clarifies that HAI measure data submitted to CDC in accordance with requirements of the states in which they are located will not impact HVBP scoring or payment for those hospitals as a result of suppression of those measures and application of the FY 2022 special scoring rule and related payment adjustment changes.

8. Regulatory Impact

As a result of the special scoring rule for FY 2022, all HVBP program adjustment factors for all hospitals will reflect a net-neutral payment adjustment. This adjustment policy is fixed for FY 2022, and HVBP program adjustments will not change as a result of subsequent availability of newer MedPAR data after the publication of this final rule. Thus, CMS has no reason to publish the usual table updates (Table 16A – updated proxy adjustment factors -- and Table 16B – actual incentive payment adjustment factors) to reflect newer data.

9. Regulations Text

CMS finalizes minor regulation text changes regarding the term QualityNet system administrator and renaming of the Hospital Compare website and its associated URL.

10. HVBP Program Summary Table

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**NQF #**	**2021**	**2022**	**2023/ 2024**	**2025**
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

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**NQF #**	**2021**	**2022**	**2023/ 2024**	**2025**
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate	1893	X	X	X	X
CABG 30-day mortality rate	2558		X	X	X
Safety Domain					
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)*	0531			Removed	
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 (SSI)	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	Removed			
Person and Community Engagement Domain					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Communication with Nurses Communication with Doctors Responsiveness of Hospital Staff Communication About Medicines Cleanliness and Quietness of Hospital Environment Discharge Information Overall Rating of Hospital 3-Item Care Transition measure (CTM)	0166 0228	X	X	X	X
Efficiency and Cost Reduction Domain					
Medicare Spending per Beneficiary	2158	X	X	X	X
*The predecessor measure, the AHRQ PSI–90 patient safety composite, was removed beginning with FY 2019. Reporting of the updated successor measure CMS PSI 90 was to start with FY 2023 but instead measure removal has been finalized in this rule beginning with FY 2023.					

F. Hospital-Acquired Condition Reduction Program

For the Hospital Acquired Condition Reduction Program (HACRP), CMS finalizes as proposed 1) adoption of a measure suppression policy to account for the effects of the COVID-19 PHE and to apply the policy for the duration of the PHE; and 2) suppression of Q3 and Q4 CY 2020 data for the CMS PSI 90 measure and all five of the CDC-NHSN Hospital Associated Infection (HAI) measures. CMS confirms HACRP ECE policy updates made through the May, 2020 and September, 2020 COVID-19 IFCs and clarifies some applications of the ECE policy. Minor changes to regulation text also are finalized. Lastly, readers are referred to RFIs concerning the potential for continued movement of CMS quality programs, including the HACRP, to digital platforms and about closing the health equity gap in those programs (see sections IX.A and IX.B, of the rule, respectively, for further information.)

A table in the regulatory impact analysis section of the rule shows the estimated impact of the HACRP on hospitals for FY 2022. Overall, 766 hospitals are in the worst-performing quartile and will be penalized. The percentage of facilities penalized is somewhat higher for the largest urban, largest teaching (by number of residents), highest DSH percentage, and New England region hospitals. The percentage is somewhat lower for the smallest urban, privately-owned, and West South-Central hospitals.

Earlier in the rule, while discussing application of the finalized suppression policy to the HACRP, CMS estimates that worst-quartile performance status will change from FY 2021 to FY 2022 for 17.2 percent of hospitals; 8.6 percent will move into the quartile and 8.6 percent will move out of the quartile. CMS states that these changes are consistent with those of prior years and offers further support for the propriety of the finalized measure suppression.

1. HACRP Background

Under the HACRP, a 1-percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile based on a specified set of measures. No changes to the HAC program's measure set were proposed for FY 2022, and performance will continue to be assessed on six measures: five HAI measures and the CMS PSI 90 patient safety measure.

Beginning with FY 2017 CMS has utilized the "Winsorized Z-Score Method" for determining HACRP measure performance scores. The Total HACRP Score for a hospital is calculated by giving each measure for which the hospital has a measure score an equal weight and then summing the weighted measure Winsorized z-scores. The distribution of Total HAC Scores for all hospitals is used to define the top quartile of hospitals (i.e., worst performers), members of which are subject to the HACRP's payment reduction penalty. An ECE was adopted for the program in FY 2016.

A summary table of HAC Program measures is provided below in section V.I.6 of this summary. Requirements of the HAC Program are codified at §§412.170 through 412.172. More information on the HAC Program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program and at https://qualitynet.cms.gov/inpatient/hac. An overview of the Total HAC Score calculation process is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/HAC-Reduction-Program-Fact-Sheet.pdf.

2. Measure Suppression Policy

CMS finalizes as proposed a "cross-program measure suppression policy" for its value-based programs, including the HACRP, beginning with FY 2022 and extending for the duration of the COVID-19 PHE. Under this policy, one or more quality measures may be suppressed in the agency's value-based programs, if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and performance scores based on those data. Suppression would involve measure reporting and/or scoring methodology adjustments. To guide

its decision making when considering measure suppression, CMS finalizes adoption of several Measure Suppression Factors; these factors are identical to those listed above in section V.G.1 of this summary.

CMS plans to provide facilities with confidential feedback reports showing their performance on suppressed measures to illustrate how the PHE has affected them. Public reporting of the actual suppressed measure data is also planned according to established HACRP program policy.

CMS requested input on the proposed policy and suppression factors and on adoption of a measure suppression policy for future PHEs. Comments echoed those made about the HRRP and the HVBP programs, and included concerns about the downstream effects of the COVID-19 PHE in FY 2024 (see summary section V.G.2 above). CMS again responds that any scoring adjustments or payment changes that might address a future fiscal year of the HACRP program due to the COVID-19 PHE or another type of PHE would be proposed through rulemaking.

3. Application of the Measure Suppression Policy to the HACRP

Suppression of Q3 and Q4 2020 data is finalized for all six HACRP measures for FYs 2022, 2023, and 2024. The cross-program measure suppression policy is triggered when CMS determines that a measure has been compromised by the COVID-19-PHE. For the HACRP, a suppressed measure's rate will be calculated but suppressed from use during calculations of Total HAC scores. Specifically, a zero percent weight will be assigned to each suppressed measure. CMS analyzed data for all of the program's measures to detect COVID-19 PHE effects. Analyses of the five HAI measures were conducted in concert with the CDC. Data analyses and suppression rationales are reprised in the rule.

CMS has determined that the Q3 and Q4 2020 data for all HACRP measures have been compromised by COVID-19 PHE effects. This determination is separate from the nationwide blanket quality reporting exception granted under the ECE policy for Q1 and Q2 2020 data, but the consequences for HACRP scoring are additive with respect to several measures (e.g., revised applicable periods). CMS notes that hospitals are still required to submit their Q3 and Q4 2020 data, even though the associated measures will be suppressed.

As a result of the finalized data suppression, the applicable periods for calculating Total HAC scores for FYs 2022, 2023, and 2024 will be revised as listed below.

<u>CMS PSI 90</u>

FY 2022: July 1, 2018 through December 31, 2019
FY 2023: July 1, 2019 through December 31,2019, and January 1, 2021 through December 31, 2021
FY 2024: January 1, 2021 through June 30, 2022

<u>HAI measures (n=5)</u>

FY 2022: January 1, 2019 through December 31, 2019
FY 2023: January 1, 2021 through December 31, 2021
FY 2024: per established policy, January 1, 2021 through December 31, 2022

CMS explicitly identified a measure suppression policy for FYs 2022 and 2023 in the proposed rule. Based on public comments, CMS will apply the policy to the HACRP for FY 2024 as well.

CMS invited input on its measure suppression proposals. Most commenters were supportive. Concerns were voiced about public reporting of the actual performance rates of the suppressed measures. CMS reiterates that the transparency of reporting actual performance data publicly has great value and that explanatory information will be provided to aid the public in properly interpreting the results. CMS specifically clarifies that HAI measure data submitted to the CDC's NHSN in accordance with requirements of the states in which they are located will not impact HACRP scoring or payment for those hospitals as a result of suppression of those measures.

4. HACRP ECE Policy

CMS finalizes the provisions of the September 2020 IFC that extended the exclusion of all Q1 and Q2 claims data such that any CDC NHSN data submitted for care during Q1 and Q2 2020, even if voluntarily submitted, will be excluded from HACRP performance calculations for FY 2022 and FY 2023. CMS notes that comments received in response to the IFC were generally supportive. CMS clarifies that application of the ECE and measure suppression policies do not relieve hospitals of payment reductions under the HACRP, if applicable.

5. Regulatory Text Update

CMS makes a technical change to finalize amendments to § 412.172(f)(4) to update the name of its site used to publicly report hospital data, including HACRP results.

6. HACRP Measure Summary Table

Table HAC-1: HACRP Measures and Performance Periods for FYs 2020-2024						
	NQF #	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**FY 2024***
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531	X	X	X	X	X
Applicable (Performance) Period		*7/1/16-6/30/18*	*7/1/17-6/30/19*	*7/1/18 - 12/31/19**	*7/1/19 - 12/31/19 plus 1/1/21 - 6/30/21**	*1/1/21 – 6/30/22**
CDC NSHN Measures						
Central Line-associated Blood Stream Infection (CLABSI)	0139	X	X	X	X	X
Catheter-associated Urinary Tract Infection (CAUTI)	0138	X	X	X	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections	0753	X	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)	1716	X	X	X	X	X
Clostridium difficile (CDI)	1717	X	X	X	X	X
Applicable (Performance) Period CDC NHSN Measures		*1/1/17-12/31/18*	*1/1/18-12/31/19*	*1/1/19-12/31/19*	*1/1/21 - 12/31/21*	*1/1/21 – 12/31/22*
*** Adjustments Made to Applicable Periods due to COVID-19 Impacts**						

G. Payments for Indirect and Direct Graduate Medical Education Costs

1. Background

Medicare pays hospitals for DGME and IME based on the number of full-time equivalent (FTE) residents they train. Since 1997, the law has limited the number of residents a hospital may count for DGME and IME (other than dental and podiatric residents) to the amount they counted in 1996. The law also provides that Medicare's payment for DGME and IME is based on a 3-year rolling average count of residents.

2. Provisions of the Consolidated Appropriations Act (CAA), 2021

CAA 2021, division CC, contained 3 provisions affecting Medicare DGME and IME payments to teaching hospitals.

- Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year) to be distributed beginning in FY 2023, with priority given to hospitals in 4 statutorily-specified categories.
- Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for DGME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average count of residents. Section 127 is effective for cost reporting periods beginning on or after October 1, 2022.
- Section 131 of the CAA makes statutory changes to the determination of DGME per resident amounts and DGME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. Section 131 is effective on December 27, 2020—date of enactment of the CAA.

CMS provided detailed proposals to implement each of these policies in the proposed rule. In the final rule, CMS does not restate those proposals or summarize the public comments. Rather, CMS says that due to the number and nature of the comments it received, it will address the public comments and its final decisions in a separate document.

3. Intern and Resident Information System (IRIS)

IRIS is an audit tool that is used to determine whether hospitals that jointly train residents are not counting any single resident as more than 1.0 FTE. The regulations currently require an IRIS "diskette" to be provided to the hospital's MAC with its cost report. As "diskettes" are no longer used to furnish these data, CMS proposed to change the regulation such that it only requires IRIS "data." CMS is currently in the process of upgrading IRIS to an XML format. Providers will be required to use the new XML IRIS format for all cost reports with cost reporting periods beginning on or after October 1, 2021. CMS does not have a free download of the new IRIS XML format; the providers should use their vendors' software to file their IRIS report with the MAC.

Further, in response to reviews by the Office of Inspector General, CMS proposed that the FTE count on IRIS must match the counts the hospital claims on its cost report worksheets. If the total counts of DGME FTE residents (unweighted and weighted) and of IME FTE residents on IRIS do not match the counts on the hospital's cost report, CMS proposed to reject the cost report for lack of supporting documentation.

Comments/Responses: One commenter raised concerns that some IRIS vendors have not made the suggested changes from commenters and/or have not released new versions of their software. This commenter further said teaching hospitals should be able to work with the new software format for a full cost reporting year and work through any system concerns and issues before being subject to a regulatory requirement that might result in the rejection of a hospital's Medicare cost report. The commenter also requested that CMS explain in more detail the process and timeframe for resolving duplicate counts of residents.

To address concerns in the comments about the availability of IRIS software, CMS indicates that it is validating vendor IRIS software to ensure that it meets the IRIS XML specifications and will release the list of all approved IRIS software vendors. The timeline for review and resolution of duplicates would be based on the MACs' schedule for reviewing affected cost reports. Also, the MACs would follow their established process for resolving duplicates.

In response to this comment and other comments, CMS acknowledges the possibility of duplicates being identified by IRIS that are not reported on the cost report and the potential for duplicates not to be identified by IRIS but reflected on the cost report. For this reason, CMS will not reject cost reports for mismatched counts between IRIS and the cost report for cost reporting periods beginning on or after October 1, 2021 and before October 1, 2022. Further, CMS will establish a tolerance level of difference between the IRIS count and the count of residents on hospital cost reports that will trigger a rejection of the cost report.

H. 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 three times, most recently by section 128 of the CAA 2021). 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.

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. Policies for Implementing CAA 2021 Extension

CAA 2021, division CC section 128 extends the demonstration for another five years for all hospitals participating in the demonstration as of December 30, 2019. CMS proposed to retain the policy used for previous extensions and apply the cost-based reimbursement methodology beginning on the date following the last day of the previous period for each hospital that elects to continue participating in the demonstration. Similarly, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 will be eligible to elect to participate for an additional 5-year period after its end date under the CURES Act extension. CMS also proposed to permit the hospitals that withdrew from the demonstration in February 2020 to elect to participate for an additional 5-year period starting from the day after its end date. The period of participation for the last hospital under the CAA 2021 authority would extend until June 30, 2028.

3. FY 2022 Budget Neutrality Adjustment

The final rule indicates that 26 hospitals that will participate in the program in FY 2022. The agency estimates that the demonstration program will cost $65,779,803 in FY 2022. After reconciling FY 2016 Medicare cost reports, CMS estimates additional costs of $3,577,797 for FY 2016 not previously accounted for in the budget neutrality adjustment. The total budget neutrality adjustment being made is based on $69,595,797.

CMS received three comments on the rule: one related to nurse practitioner services that was outside the scope of the rule and another one where CMS explains that each subsequent five-year extension of the demonstration project results in a "rebasing" of reasonable cost payment to the first year of the five-year extension. Subsequent year reasonable cost payment imposes reasonable cost payment from the first year of the demonstration project as a limitation factor on payment.

The last comment related to providing long-term financial sustainability needed to maintain access to care in rural areas. CMS responded to this comment advising of the Rural Emergency Hospital (REH) provision in the CAA 2021. This provision allows CAHs and small rural hospitals meeting specific conditions to receive special outpatient hospital payments without needing to maintain inpatient beds. CMS advises reviewing the request for information regarding this provision in the 2022 hospital outpatient rule.

I. Market-Based MS-DRG Relative Weights

In the FY 2021 IPPS/LTCH PPS final rule, CMS finalized a requirement for hospitals to report the median Medicare Advantage (MA) payer-specific negotiated charge by MS-DRG on their Medicare cost report effective for cost reporting periods ending on or after January 1, 2021. CMS also finalized a policy to use the median MA payer-specific negotiated charge in the MS-DRG relative weight methodology beginning with FY 2024.

Public commenters on the change to the Medicare cost report made as part of the Paperwork Reduction Act process raised questions about the usefulness of this data. CMS also further

considered the many contract arrangements hospitals use to negotiate rates with MA plans. For these reasons, CMS proposed to repeal the reporting requirement and its plan to use payer-specific MA negotiated rates in the MS-DRG relative weight methodology for FY 2024 and subsequent fiscal years. CMS also requested comment on alternative approaches or data sources that could be used in setting IPPS rates.

Comments/Responses: Many commenters, including MedPAC, supported repealing the requirement for hospitals to report MA-specific negotiated rates and using this information to set the MS-DRG relative weights beginning in FY 2024. The commenters reiterated the same points they made opposing this requirement in response to the FY 2021 IPPS/LTCH PPS proposed rule:

- Concerns about the accuracy of this data to represent hospital relative resource use;
- Circularity in the data if MA rates are based on Medicare fee-for-service rates;
- Lack of impact on market-based pricing;
- Burdensome reporting;
- Does not inform price transparency; and
- Data should be reported by MA plans, not hospitals.

Other commenters urged CMS not to repeal the policy stating that it would:

- Help lower costs, improve competition and empower patients;
- Reduce CMS' reliance on the hospital chargemaster to set rates;
- Not result is significant additional reporting burden; and
- Show a strong commitment to price transparency.

CMS agreed with the commenters supporting repeal of the policy and responded to those disagreeing with the proposal that the policy was not intended to lower costs. In response to CMS' commitment to price transparency, the rule lists all of the price transparency requirements that remain in place:

- The Hospital Transparency Final Rule (where CMS recently proposed increasing penalties for non-compliance);
- Transparency in Coverage Final Rule (where CMS imposes price transparency requirements on MA plans);
- President's Executive Order on Promoting Competition in the American Economy; and
- Recent publication of the Requirements Related to Surprise Billing; Part I. interim final rule with comment that establishes new protections from surprise billing and excessive cost-sharing for consumers receiving health care items and services.

In response to CMS' request for comment on alternative approaches or data sources, public commenters suggested:

- Using data that incents value-based care, reduced costs, and improving quality of care;
- Accounting for various risk-based contracting arrangements;
- Countering the practice of charge compression;

- Not unduly burdening hospitals;
- Reducing reliance on the hospital chargemaster;
- Working closely with the stakeholder community; and
- Not exposing confidential negotiations with competing payers.

CMS is finalizing all of its proposal without change. The agency will consider the many comments received on this issue as it contemplates future policy.

J. Payment Adjustment for CAR-T Clinical Trial Cases

CMS created MS-DRG 018 (CAR-T cell Immunotherapy) beginning in FY 2021. To calculate the relative weight, CMS does not use clinical trial cases where the hospital does not have a cost for the CAR-T cell therapy product. Similarly, CMS adjusts payment for clinical trial cases to avoid paying the hospital for the high cost of the CAR-T cell therapy product not incurred. The FY 2021 payment adjustment is 0.15 (e.g., the full IPPS payment is reduced by 85 percent).

As indicated earlier, CMS proposed not to use FY 2020 MedPAR data to set FY 2022 IPPS rates because of the COVID-19 PHE. For this reason, CMS' analysis of the payment adjustment is based on an update of FY 2019 MedPAR data. CMS proposed a revised adjustment of 0.17. The payment adjustment would be 0.25 if CMS used FY 2020 data.

Some commenters requested that CMS adopt a payment adjustment of 0.25 using the FY 2020 data. CMS declined to do so indicating that it is using the FY 2019 claims to set the MS-DRG relative weights. For consistency, CMS also calculated the payment adjustment based on non-CAR-T costs using the FY 2019 data. CMS is finalizing its proposed payment adjustment of 0.17 for FY 2022.

VI. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2022. For FY 2021, CMS established a national capital Federal rate of $466.21. CMS proposed a national capital Federal rate of $471.89 for FY 2022. The final national capital Federal rate is $472.60.

Update Factor:

For FY 2022, CMS will increase the national capital Federal rate by 0.8 percent based on the capital input price index (CIPI) of 1.1 percent and other factors shown in Table 1 below.

CMS is not adopting any change to the capital update for intensity. For FY 2022, CMS projects a 0.5 percent increase in total case-mix index. CMS estimates that the real case-mix increase will equal 0.5 percent for FY 2022. 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 (e.g., increases in case mix due to improved coding are removed from the capital update). Therefore, CMS is applying an adjustment for case mix change in FY 2022 of 0.0 percentage points as all of the increase in case mix is real.

Due to the COVID-19 PHE on the FY 2020 MedPAR claims data, CMS is using 2019 claims

data to set the MS-DRG relative weights. For this reason, CMS proposed not to evaluate the effect of FY 2020 reclassification and recalibration for FY 2022 capital update. CMS is adopting a 0.0 percent adjustment for this factor in FY 2022.

The forecast error correction is -0.3 percent.

Table 1

CMS FY 2022 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2018-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
Effect of FY 2020 Reclassification and Recalibration		0.0
Forecast Error Correction		-0.3
Total Update		0.8

Other Adjustments:

For FY 2021, CMS estimated that outlier payments would be 5.34 percent total capital IPPS payments. For FY 2022, CMS is taking outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.31 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.02 percentage points for outlier payments refunded to hospitals. This makes the estimate of FY 2022 capital outlier payments 5.29 percent of total capital payments. Therefore, the FY 2022 outlier adjustment factor is 0.9471 (-5.29 percent), compared to 0.9466 (-5.34 percent) in FY 2021. The net change is +0.01 percent (0.9471/0.9466). Thus, the outlier adjustment increases the FY 2022 capital federal rate by 0.05 percentage points.

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS has been 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 providing a 5 percent cap on reductions to certain wage indexes) in the budget neutrality adjustment.

CMS has determined a net GAF budget neutrality adjustment in two steps:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index).
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases.

The first step in the GAF budget neutrality adjustment is retained on the capital rate from year-to-year. As explained in the FY 2021 IPPS final rule, CMS believes it would be technically more appropriate to remove the past year's budget neutrality adjustment determined in step 2 before applying the new payment year adjustment.

To remove the prior year budget neutrality adjustment for the increase in the lowest quartile wage index and the 5 percent cap on the wage index, CMS will divide the capital Federal rate by 0.9927 which is the cumulative effect of these policy adjustments over 2 years.

CMS then proposes to continue with its 2-step approach to determining GAF budget neutrality as follows:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index). CMS determined a budget neutrality adjustment of 1.0003 for this factor.
- Isolate the impact of the increase in the lowest quartile wage indexes and the 5 percent cap on reductions to the wage index (referred to by CMS as the Quartile/Cap adjustment factor). CMS determined a GAF budget neutrality factor of 0.9974 for FY 2022.

CMS also incorporates an adjustment for FY 2022 MS-DRG changes and recalibration of the relative weights of 1.0001 into the capital rate. This combined adjustment for GAFs due to changes in the wage index in step 1 above and changes for MS-DRGs and recalibration is 1.0004 (1.0003 x 1.0001 or 0.04 percent). The Quartile/Cap adjustment of 0.9974 (-0.026 percent) is then applied.

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 2022 national capital Federal rate compared to the FY 2021 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2021 and FY 2022 Capital Federal Rate

	FY 2021	FY 2022	Change	Percentage Change
Update Factor*	N/A	1.0080	1.0080	0.8
GAF/DRG Adjustment Factor*	N/A	1.0004	1.0004	0.04
Quartile/Cap Adjustment Factor**	0.9927	0.9974	1.0047	0.47
Outlier Adjustment Factor**	0.9466	0.9471	1.0005	0.05
Capital Federal Rate	$466.21	$472.60	1.0137	1.37

* 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 2021 to FY 2022 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2022 is a net change of 1.0004 (or 0.04 percent).
** The outlier adjustment factor and the lowest quartile adjustment factors are 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 2022 outlier adjustment factor is 0.9471/0.9466, or 1.0005 (or 0.05 percent). The net change to the Quartile/Cap adjustment is 0.9974/0.9927 or 0.47 percent.

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2022 of $472.60, a 1.37 percent increase over the FY 2021 rate of $466.21

VII. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase

Most hospitals are paid under prospective payment systems. Some hospitals, however, 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 2021 2nd quarter forecast of the hospital market basket for FY 2022 and is 2.0 percent.

B. Report on Adjustment 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 2020 were $5,088,002 as shown by hospital type in the below table.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	2	$10,677,342	$1,462,829
Children's Hospitals	6	$4,413,902	3,018,578
RNHCIs*	6	$920,503	$606,595
Total	14	$16,011,747	$5,088,002

*Religious Non-Medical Health Care Institutions (previously known as Christian Science Sanatoria)

C. Frontier Community Health Integration Project Demonstration

The Frontier Community Health Integration Project (FCHIP) Demonstration[43] 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.

CMS presents a detailed analysis of how it determined whether the FCHIP was budget neutral. In

[43] The FCHIP Demonstration was authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275).

summary, CMS states that there were no statistically significant findings that the FCHIP Demonstration resulted in additional expenditures. CAHs' episode of care expenditures during the initial period of the demonstration were lower than expenditures would have been absent the demonstration. Sensitivity analysis (using a 95 percent confidence interval) showed that total expenditures for the 10 participating CAHs in the demonstration would need to cumulatively increase cost by more than 18 percent (which translated to $3,120 per episode, or a total of $3,529,039 for the three interventions combined) to exceed expenditures absent the demonstration. As a result of these findings, CMS did not propose to apply a budget neutrality offset to CAH payments for FY 2022. CMS is finalizing this proposal and not applying any budget neutrality adjustment to CAH payments for FCHIP.

The original period of the demonstration was August 1, 2016 through July 31, 2019. Section 129 of the CAA, 2021 extended the FCHIP for another five years beginning July 1, 2021. However, eligible CAH participants have elected to change the number of interventions and payment waivers they would participate in during the extension period. As a result, CMS is delaying the start of the extension period until January 1, 2022 to make arrangements for these changes. The CAHs have not expressed concerns about the revised effective date of the extension period.

VIII. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

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 are paid an IPPS comparable amount. The criteria for exclusion from the site neutral payment remain the same for FY 2022:

- 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 LTCH payments 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 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.

With respect to data used for FY 2022 LTCH PPS rate setting, CMS finalizes its proposal to use FY 2019 data where utilization patterns reflected in the FY 2020 data are significantly impacted by the COVID-19 PHE. It uses the FY 2019 MedPAR claims data and the FY 2018 HCRIS file in lieu of the FY 2020 MedPAR claims data and the FY 2019 HCRIS file, respectively. This is consistent with the data use policy for IPPS rate setting, described in section I.F of this summary.

Summary of Final Changes to LTCH PPS Rates for FY 2022*	
Standard Federal Rate, FY 2021	$43,755.34
Update factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+1.9%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+1.9% (1.019)
Net update LTCHs not reporting quality data	-0.1% (0.999)
Adjustments	
Average wage index budget neutrality adjustment	1.002848
Standard Federal Rate, FY 2022	
LTCHs reporting quality data ($43,755.34*1.019*1.002848)	$44,713.67
LTCHs not reporting quality data ($43,755.34*0.999*1.002848)	$43,836.08
Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$33,015
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$30,988
Impact of Policy Changes on LTCH Payments in 2022	
Total estimated impact	1.1% ($42 million)
LTCH standard federal payment rate cases (75% of LTCH cases)	0.9% ($31 million)
Site neutral payment rate cases (25% of LTCH cases)**	3.0% ($11 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 2022". Table IV does not include the impact of site neutral payment rate cases. **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.	

A. MS-DRGs and Relative Weights

1. Background

Similar to FY 2021, the annual recalibration of the MS-LTC-DRG relative weights for FY 2022 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. CMS also excludes data from all-inclusive rate providers, Medicare Advantage claims, and LTCHS paid under demonstration projects from the MS-LTC-DRG relative weight calculations.

2. Patient Classification into MS-LTC-DRGs

CMS applies 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 incorporated into the MS-LTC-DRG system for FY 2022 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.F. of the preamble of the final rule. Other changes to the MS-DRG that affect assignments under GROUPER Version 39 (discussed in section II.E of the final rule), including changes to the Medicare Code Editor and the ICD-10-CM/PCS coding system, apply to the LTCH PPS.

3. Development of the MS-LTC-DRG Relative Weights

In developing the FY 2022 relative weights, CMS uses its current methodology and established policies related to the hospital-specific relative-value methodology, volume-related adjustments, 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 2022 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 39 of the GROUPER to calculate the FY 2022 MS-LTC-DRG relative weights.

5. Hospital-Specific Relative-Value Methodology (HSRV)

CMS uses its HSRV methodology in FY 2022, unchanged from FY 2021, 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. It standardizes charges for each applicable LTCH case by dividing the adjusted charge for the case (adjusted for short stay outlier (SSO) cases) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

6. Volume-related Adjustments

As it has in done for previous fiscal years, 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. (See 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 proposed 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. (See 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 continues for FY 2022 its approach of combining severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained.

8. Selected Steps for Determining the MS-LTC-DRG Relative Weights

CMS continues to use its methodology for 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 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 case 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 2022 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; CMS applies a normalization factor of 1.25815 for FY 2022. Second, a budget neutrality factor is applied to each normalized relative weight; CMS finalizes a budget neutrality factor of 1.0002384 for FY 2022.

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the final rule (pages 1,479 to 1,493 of the display copy).

B. Payment Rates and Other Changes

1. Overview LTCH PPS Payment Rate Adjustments

As noted earlier, 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

The update to the LTCH PPS standard federal payment rate for FY 2022 is equal to 1.9 percent; this is derived from an LTCH PPS market basket increase of 2.6 percent less the multifactor productivity adjustment of 0.7 percentage point. The estimates for the market basket increase and the productivity adjustment (which have significantly increased from the proposed rule) are based on IGI's second quarter 2021 forecasts. For FY 2021, CMS rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year, and it uses the 2017-based LTCH market basket to update the LTCH PPS standard federal payment rate for FY 2022. For LTCHs that fail to submit data to the LTCH Quality Reporting Program (QRP), the annual update would be 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 2022. The final LTCH update for FY 2022 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	2.6%	2.6%
Multifactor Productivity	-0.7 PP	-0.7 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	1.9%	-0.1%

As noted above, CMS rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year beginning with FY 2021. It notes that one of the price proxies adopted for the 2017-based LTCH market basket (i.e., Moody's AAA Corporate Bond Yield Index for the "For-profit Interest" cost category) is no longer available for use under license to IGI; CMS substitutes the iBoxx AAA Corporate Bond Yield index for this purpose because it captures the same technical concept as the Moody's index and tracks similarly to it.

3. Area Wage Levels and Wage-Index

CMS adopts the revised labor market area delineations announced in OMB Bulletin No. 20-01[44] (issued on March 6, 2020) effective for FY 2022 under the LTCH PPS. However, the agency determined that the changes in this OMB Bulletin do not affect the CBSA-based labor market area delineations used under the LTCH PPS. Thus, no changes to the specific wage index updates are necessary as a result of its decision to adopt the updates in OMB Bulletin 20-01.

[44] See https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf

CMS adopted a policy for FY 2021 to 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 by reason of the changes resulting from the adoption of revised labor market area delineations announced in OMB Bulletin 18-04. CMS clarifies that the policy expires at the end of FY 2021.

CMS finalizes an FY 2022 labor-related share of 67.9 percent based on IGI's second quarter 2021 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (63.6%) and capital costs (4.3%). 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 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. 20-01. It finalizes an area wage level budget neutrality adjustment of 1.002848.

4. LTCH Standard Federal Payment Rate Calculation

CMS finalizes the following LTCH PPS standard federal payment rates for FY 2022:

- $44,713.67 for LTCHs reporting quality data, calculated as follows: $43,755.34 (FY 2021 payment rate) * 1.019 (statutory update factor) * 1.002848 (area wage budget neutrality factor) = $44,713.67

- $43,836.08 for LTCHs not reporting data to the LTCH QRP, calculated as follows: $43,755.34 (FY 2021 payment rate) * 0.999 (statutory update factor less quality adjustment) * 1.002848 (area wage budget neutrality factor) = $43,836.08

5. Cost-of-Living (COLA) Adjustment

CMS continues to update the COLA factors for Alaska and Hawaii in the same manner 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 that is applied to the nonlabor-related portion of the standard Federal payment rate. The COLA is determined by comparing Consumer Price Index (CPI) growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city published by the Bureau of Labor Statistics (BLS). The COLA is capped at 25 percent and updated every 4 years.

CMS updates the COLA factors using its historical methodology to create reweighted CPIs for each area to reflect the underlying composition of the IPPS market basket nonlabor-related share. Specifically, it uses the respective CPI commodities index and CPI services index to create reweighted indexes for Urban Alaska, Urban Hawaii and the average U.S. city using the approximate 57 percent commodities/43 percent services shares obtained from the 2018-based IPPS market basket. CMS used data for 2009 through 2020. The COLA continues to be capped at 25 percent. The table below shows the current COLAs and those finalized effective for FY 2022.

Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2022		
Area	**FY 2018 – FY 2021**	**FY 2022 – FY 2025**
Alaska		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
All other areas of Alaska	1.25	1.24
Hawaii		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

6. 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).

CMS had proposed to modify its methodology for calculating the applicable fixed-loss amount for FY 2022 for LTCH standard federal payment cases while maintaining estimated HCO payments at 7.975 percent of total estimated LTCH PPS payments for standard federal payment rate cases. CMS described the modifications as technical changes to the methodology for determining the charge inflation factor it applies to charges on MedPAR claims and to the methodology for determining the CCRs to use when determining the fixed-loss amount. Commenters' reactions were mixed; one objected to the changes because they resulted in a higher fixed-loss threshold. CMS finalizes the changes (described in more detail below) which apply for FY 2022 and subsequent fiscal years.

a. Charge Inflation Factor

Due to a significant difference between estimated and actual charge inflation, for FY 2022 and subsequent fiscal years, CMS will determine the charge inflation factor based on the historical growth in charges for the LTCH PPS standard federal payment rate cases; it calculates the inflation factor using historical MedPAR claims data instead of using estimates calculated from quarterly market basket update values determined by the CMS Actuary. It finalizes a three-step methodology:

- Identify standard federal payment rate cases for the two most recently available fiscal years, removing any Medicare Advantage or all-inclusive rate provider claims.
- Remove statistical outliers, by calculating a provider's average charge in both fiscal years; dividing the average charge for the more recent fiscal year by the average charge for the prior fiscal year; and trimming claims for providers whose calculated charge growth factor is outside 3 standard deviations from the mean provider charge growth factor.

- Using remaining claims, calculate a national charge inflation factor by dividing the national average charge for the more recent fiscal year by the average charge for the prior fiscal year.

For FY 2022, due to COVID-19 PHE data concerns, CMS uses data from the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR file. CMS calculates a one-year rate of change of 6.0723 percent ($207,224 / $195,362). It then calculates a two-year charge inflation factor of 1.125133 (calculated by squaring the one-year factor), and a three-year charge inflation factor of 1.193455 (calculated by cubing the one-year factor). CMS inflates the billed charges obtained from the FY 2019 MedPAR file by the 3-year charge inflation factor of 1.193455 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022.

b. CCRs

Historically, CMS has used CCRs from the most recently available PSF file without any adjustment. It proposed to adjust CCRs used to calculate the fixed-loss amount by a factor calculated based on historical changes in the average case weighted CCR for LTCHs. It proposed the following four-step methodology:

- Identify providers with standard federal payment rate cases from the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims) and identify for each of these providers the CCR from the most recently available PSF.
- Trim providers with insufficient CCR data in the most recent PSF or the prior year PSF (i.e., providers whose CCR was missing; providers assigned the statewide average CCR for their state; and providers whose CCR was not updated between the most recent PSF and the prior year PSF).
- Remove statistical outliers. Calculate a provider's CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year PSF; and remove providers whose CCR growth factor is outside 3 standard deviations from the mean provider CCR factor.
- Using remaining providers, calculate a national CCR adjustment factor by determining the average case-weighted CCR from both the most recent PSF and the prior year PSF and dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

CMS finalizes the proposed changes. For FY 2022, due to COVID-19 PHE data concerns, CMS uses the March 2020 PSF and the March 2019 PSF. CMS also uses claims from the March 2020 update of the FY 2019 MedPAR file in calculating the average case-weighted CCRs in step 4.

CMS calculated a national average case-weighted CCR of 0.256374 for March 2019 and 0.246517 for March 2020, resulting in a one-year national CCR adjustment factor of 0.961554 and a 2-year national CCR adjustment factor of 0.924586 (calculated by squaring the 1-year factor). CMS notes that in calculating the fixed-loss amount for FY 2022, it assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the

statewide average in the March 2020 PSF or whose CCR was missing in the March 2020 PSF. For all other providers, it multiplied their CCR from the March 2020 PSF by the 2-year national CCR adjustment factor.

c. Fixed-loss Amount for LTCH PPS Standard Federal Payment Rate Cases

CMS did not propose any other changes to its methodology to calculate the applicable fixed-loss amount for standard federal rate cases. It calculates a fixed-loss amount of $33,015 for FY 2022 which CMS estimates will result in 7.975 percent 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).

d. HCO Payments for Site Neutral Payment Rate Cases

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 2022, CMS finalizes a fixed-loss amount for site neutral payment rate cases of $30,988. CMS also finalizes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2022. Consistent with the policy adopted in FY 2019, the HCO budget neutrality adjustment is not 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.

7. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS continues to include an applicable operating Medicare DSH and uncompensated care payment amount in the calculations of the "IPPS comparable amount" (under the SSO policy at §412.529) and the "IPPS equivalent amount" (under the site neutral payment rate at §412.522). For FY 2022, the DSH/uncompensated care amount equals 76.43 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA and adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

C. Impacts

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2021 to FY 2022, will result in an increase of 1.1 percent or $42 million in aggregate payments for the 363 LTCHs included in this impact analysis. This impact results from increases in payment of $11 million for site neutral cases and $31 million for LTCH standard federal payment rate cases.

CMS estimates that high-cost outliers in FY 2020 will be about 8.5 percent of estimated total LTCH PPS standard federal payment rate payments. As it does annually, CMS sets the high-cost

outlier threshold for LTCH standard federal payment rate cases so that 8 percent of total payments are made as high-cost outliers. The difference between the 8.8 percent figure for FY 2021 and the estimate of 8.0 percent for FY 2022 accounts for the approximately 0.83 percent reduction in payment for high-cost outliers.

CMS notes that there will not be any transitional payment for site-neutral cases in FY 2022 like there was in FY 2020 based on the start date of the LTCH's cost reporting period.

Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2022" 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; it 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 2022		
	Number of LTCHs	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	360	0.9%
By Location:		
Rural	19	1.2%
Urban	341	0.9%
By Ownership Type:		
Voluntary	60	0.6%
Proprietary	290	1.0%
Government	10	1.1%
By Region		
New England	10	0.5%
Middle Atlantic	23	0.4%
South Atlantic	62	1.2%
East North Central	55	0.8%
East South Central	31	0.9%
West North Central	22	0.8%
West South Central	105	0.8%
Mountain	29	1.5%
Pacific	23	1.2%
*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 2022" on pages 2255-2256 of the display copy.		

Tables. The complete set of tables providing detail on the LTCH PPS for FY 2022 is accessible at: https://www.cms.gov/medicaremedicare-fee-service-paymentlongtermcarehospitalppsltchpps-regulations-and-notices/cms-1752-f

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Advancing to Digital Quality Measurement -RFI

CMS requested input into the agency's planning for transformation to a fully digital quality enterprise by 2025, posing questions grouped into three categories: definition of digital quality

measures (dQMs); use of FHIR for current eCQMs; and changes under consideration to advance digital quality measures. CMS provides a synopsis of comments received and initial agency reactions, some of which is further condensed below.

CMS states there was widespread support for a transition to digital quality management but that most commenters were skeptical that the changes would be completed by the target date of 2025. Additional positive general comments included the potential for simplified reporting processes and faster information exchange. High-level concerns voiced included that the transformation would be resource intensive for providers. Others noted that despite the ambitious timeline, no measures have yet been selected, and further noted that putative measures would need to be vetted by stakeholders, field tested, and validated prior to any implementation. Phased implementation incorporating pilot opportunities, program incentives, and reporting flexibility was recommended.

Opinion was divided about the definition of dQM under consideration by CMS: a software that processes digital data to produce a measure score or scores. Some respondents applauded the breadth and flexibility of the definition while others found it too broad and vague. Some worried that dQMs if not well-designed would reflect vendor capabilities rather than care quality.

CMS states that there was general support for the incorporation of FHIR-based APIs into the new digital quality system. However, some commenters voiced concerns that transitioning to such a system will be resource-intensive and impose considerable burden on providers; they strongly recommended a timeline that is sensitive to provider readiness and available resources. Data aggregation was also supported conceptually by several respondents.

Alignment of measurement areas, specifications, data elements, and tools across reporting programs to produce a common dQM portfolio was strongly supported. Also supported was that CMS and ONC work to ensure that data elements of the new dQMs align with the United States Core Data for Interoperability (USCDI) standards. Some noted the need for standardization of social risk factor reporting requirements.

CMS closes by stating that the input received will be taken into account as the agency develops regulatory proposals or other guidance.

B. Closing the Health Equity Gap in CMS Hospital Quality Programs - RFI

Through this RFI CMS requested comment on revisions to CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, other providers, and patients. Input was sought on the following:

- expanding the agency's current disparities methods to include reporting by race and ethnicity using indirect estimation statistical techniques;
- hospital collection of standardized demographic information for the purposes of potential incorporation into measure specifications as a step towards more robust equity measurement; and

- the design of a *Hospital Equity Score* (HES) for calculating results across multiple social risk factors and measures, including race/ethnicity and dual eligibility.

CMS provides a synopsis of comments received and initial agency reactions, some of which is further condensed below.

CMS reports strong support for the collection of data to enable quality measure stratification by race, ethnicity, and dual status. The need for data collection standards was emphasized and CMS agrees. Opinions were divided on support for using indirect estimation techniques to impute missing data. CMS responds by describing the potential uses of the Medicare Bayesian Improved Surname Geocoding Version 2.1 (MBISG) algorithm, developed under contract to CMS.

CMS notes the extensive list of demographic and social risk factor variables recommended for collection by commenters, including back pain and preoperative narcotic use. Other commenters noted the added burden that would be imposed on providers to collect additional information from patients. CMS states that the agency is sensitive to the issue of added burden. Opinions on the timing and setting for extended data collection from patients varied.

CMS also reports diverging commenter views on the creation of a *Hospital Equity Score*. Support was often phrased in conditional terms, such as evidence that better demographic and social risk factor data collection is in fact occurring and that the data are proven to be accurate before the score is tested for use. Some respondents stated that the score could hold providers accountable for factors outside of their control.

Support was nearly universal of the agency's goal to advance health equity in its quality programs. Alignment of CMS initiatives with other governmental and private initiatives was strongly supported. Utilization of existing systems where feasible and the production of actionable data were also emphasized along with continuous attention to provider burden. Opinions were also varied about the value and propriety of public reporting of equity-related data though support for confidential reports to providers was strong.

CMS closes by stating that the input received will be considered during policy development.

C. Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting program. Hospitals that do not submit specified quality data or fail to meet all program requirements are subject to a one-fourth reduction in their annual payment update. Certain provisions of the IQR Program are found at § 412.140. More information on the measures themselves and reporting processes is available at https://qualitynet.cms.gov/inpatient/iqr. A summary table of Hospital IQR Program measures for payment years FY 2022 through FY 2026 is provided at the end of this summary section (see below IX.C.5).

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that for FY 2022, 68 hospitals will not receive the full market basket rate update factor 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 68 hospitals are projected receive an update factor of 1.325 percent. Another 24 hospitals are estimated to receive a combined payment increase of -0.7 percent because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.[45]

1. Additions to the Hospital IQR Program Measure Set[46]

CMS finalizes the addition of four new measures to the IQR program's measure set as proposed and one new measure as proposed but with modified public data reporting.

a. Maternal Morbidity Structural Measure ("Maternal Morbidity Measure")

CMS adopts this structural measure as proposed. The measure determines, by hospital attestation, the number of hospitals currently participating in a structured State or national Perinatal Quality Improvement (QI) Collaborative and whether participating hospitals are implementing the safety practices or bundles embedded in these QI initiatives research cited by CMS suggests that participation in maternal care QI collaboratives results in effective management of morbidities that might otherwise lead to death. The measure addresses a maternal morbidity measure gap in CMS' quality measure inventory.

After several revisions during the pre-rulemaking process, this measure was conditionally supported for rulemaking by the Measures Application Partnership (MAP), contingent on measure endorsement by the National Quality Forum (NQF). CMS chose to proceed with measure adoption prior to NQF review because of the public health importance of the problem being addressed, and in accordance with section 1886(b)(3)(B)(viii)(IX)(bb) of the Act. This section provides discretion to the Secretary to specify a measure for quality program inclusion that is not NQF-endorsed in the absence of a currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Reporting of the new measure will begin with a shortened reporting period of October 1, 2021, through December 31, 2021, and data would be used in making FY 2023 payment determinations. For FY 2024 and subsequent payment years, the reporting period will be the 12-month calendar year occurring two years prior to the applicable payment year (e.g., calendar year 2022 reporting for FY 2024 payment). Data submission will be through CMS' Hospital Quality Reporting (HQR) System, a web-based data collection tool (formerly known as the QualityNet Secure Portal).

CMS reviews comments received on the measure proposal. Some commenters were supportive of measure adoption as proposed. Others suggested measure changes and urged CMS to obtain NQF endorsement of this measure, and a few opposed measure adoption. Concerns were raised about the short interval available prior to the initial required data reporting period during which

[45] The 0.7 percent reduction reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction for being identified as not being a meaningful EHR user.
[46] CMS notes parenthetically that a Hospital IQR Program measure must first be adopted into the program and be publicly reported on the Care Compare website for at least one year before that measure can be added to the Hospital Value-Based Purchasing Program.

hospitals need to identify and choose a participating collaborative and to prepare their data systems for reporting this measure. In response, CMS emphasizes the importance of the public health problem and measure inventory gap to be addressed as reasons for rapid adoption of the measure and its reporting. CMS clarifies that information about participating perinatal QI collaboratives will be available through the HQR system.

b. Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) ("Hybrid HWM Measure")

CMS adopts this hybrid measure (based on both claims and electronically submitted clinical data) as proposed. It is designed to more comprehensively measure mortality rates among hospitals and to more accurately assess mortality rates in smaller-volume hospitals than existing mortality measures. Mortality data are subdivided into 15 mutually exclusive service line divisions, 6 surgical (e.g., orthopedic) and 9 non-surgical (e.g., pulmonary) and the measure is expressed as a ratio: the number of deaths within 30 days of admission as predicted by the hospital's observed case mix and service mix divided by deaths expected using nationwide data for hospitals with similar case and service mixes. The measure includes Medicare FFS beneficiaries aged 65-94 years, and excludes some high-risk major trauma diagnoses (e.g., burns).

The measure's core clinical elements are intended to reflect patient clinical status at admission through linked clinical (e.g., vital signs) and laboratory data that are typically collected by hospitals at or soon after patient admission. The elements will be used for risk-adjustment purposes. CMS will perform the actual measure calculations and transmit the results back to the data submitters. Measure reliability depends on vital sign data element submission for at least 90 percent of the hospital's Medicare FFS aged beneficiary discharges and submission of the laboratory test element results for at least 90 percent of non-surgical patients. Hospitals will be required to submit the six clinical linking variables for 95 percent or more of eligible discharges.

After several revisions during the pre-rulemaking process, this measure was conditionally supported for rulemaking by the MAP, contingent on measure endorsement by the NQF, which subsequently occurred as NQF #3502 in October, 2019. Adjustments for social risk factors were not included as their use was found to mask hospital-level effects that may represent lower quality care. More detailed information about this measure's methodology and specifications is found in the Core Clinical Data Elements and Hybrid Measures folder, available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology. CMS will update the measure specifications annually for changes in diagnosis codes and clinical laboratory value sets.

CMS finalizes an initial voluntary reporting period for the Hybrid HWM measure to run from July 1, 2022 through June 30, 2023. Mandatory reporting will begin July 1, 2023. through June 30, 2024. to be used for FY 2026 payment determinations, with a similar timeline for subsequent payment years. Hospitals will be required to submit the clinical data elements and their associated linking variables no later than the first business day 3 months following the end of the

reporting period.[47] Data must be submitted to CMS using Quality Reporting Data Architecture Category I (QRDA I) files; this file type is the current electronic health record (EHR) data and measure reporting standard adopted for electronic clinical quality measures (eCQMs) within the IQR program.

Hospitals that submit data during the voluntary period will receive confidential hospital-specific reports and data will not be publicly reported. Beginning with the mandatory period, hospitals will receive confidential reports and data will be publicly displayed according to extant IQR program policies; the latter include a 30-day review and correction period before public display.

CMS reviews comments received on the measure proposal. Many commenters were supportive of measure adoption as proposed, and several offered suggestions for revisions. CMS clarifies that hospitals must report vital signs for 90 percent or more of eligible discharges and laboratory results for 90 percent or more of eligible discharges to comply with IQR requirements. A few commenters opposed measure adoption, stating that other existing mortality measures in the CMS measure inventory produce more actionable data. CMS disagrees.

c. COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

CMS finalizes adding this measure as proposed, except for modification to the data that will be publicly reported. The measure is designed to track the percentage of a facility's healthcare personnel (HCP) who receive a complete COVID-19 vaccination course. CMS regards HCP vaccination rates as being of interest to beneficiaries and caregivers during healthcare decision-making and as an aid to facilities in tracking their efforts to reduce COVID-19 transmission. Full specifications are available on the CDC website: https://www.cdc.gov/nhsn/nqf/index.html.

The MAP conditionally supported the measure contingent upon clarification of measure specifications, and CMS has returned to the MAP with results from further measure testing and updated specifications. CMS chose to proceed with measure adoption prior to receiving full MAP support for rulemaking and before NQF review because of the public health importance of the problem being addressed in accordance with section 1886(b)(3)(B)(viii)(IX)(bb) of the Act. This section provides discretion to the Secretary to specify a measure for quality program inclusion that is not NQF-endorsed in the absence of a currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

CMS finalizes as proposed an initial data reporting period of October 1, 2021, through December 31, 2021, for use in the FY 2023 Hospital IQR Program payment year. For FY 2024 and subsequently, CMS also finalizes as proposed a full calendar year reporting period (e.g., all 12 months of CY 2022 data would be reported for use in the FY 2024 IQR program). Further, CMS finalizes its proposal to publicly report this measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible. CMS does not finalize its proposal to add one additional quarter of data to each refresh to reach a total of four quarters followed by ongoing display of four quarters refreshed on a rolling basis. Instead, CMS will display only the most recent quarter of data.

[47] Linking variables such as hospital CMS Certification Number and patient date of birth are used by CMS to match a patient's EHR clinical data to the associated claims data.

Data submission by hospitals will be required quarterly through CDC's National Health Safety Network (NHSN) web-based surveillance system. Hospitals will report data for at least one self-selected week per month. Hospitals are familiar with NHSN reporting, which they already use for the existing HCP Influenza Vaccination measure. The CDC will report data quarterly to CMS. CMS will use the CDC-calculated vaccination coverage rates for reporting on Care Compare.

CMS reviews comments received on the measure proposal. Many commenters were supportive of measure adoption as proposed. Some objected citing reasons including:

- Available vaccines have not yet received full FDA approval;
- CMS should delay tracking until the need for vaccine booster doses becomes known;
- Vaccination of HCP should not be required for compliance with the IQR program;
- HCP is defined too broadly; and
- The measure is operationally and logistically burdensome.

CMS responds that:

- The EUA granted to the vaccines by the FDA was the result of a rigorous process;
- The measure does not require HCP to be vaccinated for IQR compliance and the measure specifications provide for removal from counting of HCP with contraindications to vaccination; and
- All hospital personnel can be exposed through their work and could become disease-spreaders so all should be counted.

CMS notes that hospitals are familiar with reporting through the NHSN and that the burden is justified by the ongoing COVID-19 PHE.

CMS emphasizes that the EEOC released technical assistance stating that Federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19, so long as the employer complies with applicable provisions of the Americans with Disabilities Act and Title VII of the Civil Rights Act and other similar EEO considerations.[48]

Many commenters opposed public reporting as proposed and recommended reconsideration. Concerns included the short initial reporting period and short interval until required reporting starts; the potentially confusing nature of rolling reporting to the public; and the dilution of the most recent data by rolling display, obscuring the information of greatest interest to the public. CMS states that reporting must start as soon as possible because the PHE is ongoing, but concurs with the potential for dilution of the information of greatest public interest. CMS, therefore, modifies public data display to show only the most recent quarter's results.

[48] U.S. Equal Opportunity Employment Commission. What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws. https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

d. Hospital Harm – Severe Hypoglycemia Electronic Clinical Quality Measure (eCQM) (NQF # 3503e)

CMS finalizes the addition of this new eCQM to the IQR Program beginning with payment year FY 2025 to track the rate at which severe hypoglycemia events occur after administration of antihyperglycemic medications to inpatients. CMS notes that rates vary considerably across facilities. CMS emphasizes that these events are associated with worse outcomes (e.g., increased requirement for post-acute care) and higher costs, and evidence suggests that most such events are avoidable with appropriate glucose monitoring. Measure specifications are available at https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms816v1.

The MAP voiced concern about the feasibility of rapid, repeated, reliable glucose testing as required by the measure. CMS responded by testing the measure in multiple hospitals and with differing EHR systems. The results were found to be reliable, valid, and acceptable. The measure received NQF endorsement in early 2019 (NQF # 3503e).

CMS reviews comments received on the measure proposal. Many commenters were supportive. Several voiced concern about the repeated glucose testing requirements over a short time to which CMS reiterated its measure testing data that supported feasibility. Some recommended that continuous glucose monitoring be incorporated into the measure as an option for glucose measurement; CMS believes the measure as specified can accommodate continuous glucose monitoring as an option but indicates the agency will consider adding clarifying language to the specification's guidance section.

e. Hospital Harm – Severe Hyperglycemia Electronic Clinical Quality measure (eCQM) (NQF # 3533e)

CMS finalizes the addition of this new eCQM to the IQR Program beginning with payment year FY 2025 to track the rate at which severe hyperglycemia events occur among hospitalized diabetic patients. CMS notes that rates vary considerably across facilities; these events are associated with worse outcomes (e.g., increased infection rates) and higher costs; and evidence suggests that most such events are avoidable with proper glycemic management. Measure specifications are available at https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms816v1.

The MAP gave conditional support for rulemaking continent on NQF endorsement. The measure received NQF endorsement in July 2020 (NQF # 3533e).

CMS reviews comments received on the measure proposal. Many commenters were supportive. Concerns were voiced about the measure's complexity to which CMS responds that testing has demonstrated measure implementation feasibility. Some recommended that continuous glucose monitoring be incorporated into the measure as an option for glucose measurement; CMS believes the measure as specified can accommodate continuous glucose monitoring as an option but indicates the agency will consider adding clarifying language to the specification's guidance section. CMS clarifies that the public reporting timeline will follow the established policy for display of eCQM data (85 FR 58959).

2. Removing Measures from the Hospital IQR Measure Set

CMS finalizes the removal of three measures from the IQR program's measure set as proposed. However, CMS does not finalize the proposed removal of two measures and retains them without modifications.

a. Deaths Among Surgical Inpatients with Serious Treatable Complications (CMS PSI-04)

CMS does not finalize its proposed removal of this measure and the measure will remain in the IQR program's measure set. The proposal for removal cited IQR program Removal Factor 3: availability of a more broadly applicable measure, referring to the newly finalized Hybrid HWM measure (described earlier in the rule and above in this summary).

Commenters noted that CMS PSI-04 offers more granular and more directly actionable results than the Hybrid HWM measure. They suggested that CMS PSI-04 has potential value as a safety measure focused on surgical patients and that the measure could be improved by refining its specifications. CMS agrees with commenters, does not finalize measure removal, and plans to explore refining the measure with the agency's measure development contractor and through stakeholder outreach.

b. Exclusive Breast Milk Feeding (eCQM) (PC-05)

CMS finalizes the removal of this measure from the IQR program's measure set beginning with the CY 2024 reporting period/FY 2026 payment year, citing Removal Factor 5: Availability of a measure that is more strongly associated with desired patient outcomes for the measure's topic. CMS notes the newly finalized Maternal Morbidity Structural Measure (described earlier in the rule and above in this summary) that is more strongly aligned with the agency's current focus on maternal health.

Many commenters supported measure removal, although several observed the paucity of measures in the CMS inventory that address maternal health. CMS notes that because reporting of the new Maternal Morbidity measure will begin October 1, 2021, while removal of PC-05 will not occur until the CY 2024 reporting year, there will be a period of overlap in which reporting of both measures will be required; CMS says the overlap period cannot be shortened due to operational considerations within the agency.

c. Admit Decision Time to Emergency Department Departure (eCQM) (ED-2)

CMS finalizes the removal of this measure from the IQR program's measure set beginning with the CY 2024 reporting period/FY 2026 payment year, citing Removal Factor 8: costs associated with the measure outweigh the benefit of its continued use. Recent studies have shown that this measure of ED boarding time is inconsistently reported and not strongly associated with adverse outcomes.

Many commenters supported removal of the ED-2 eCQM. Some questioned whether the cost-benefit relationship of measure removal is clear; eCQM measure reporting involves considerable

time and resource investment to establish the necessary clinical workflows and return on that investment is lost by measure removal. CMS acknowledges eCQM-related investment but believes that measure removal creates a streamlined measure set and reduces hospital burden and thereby costs. CMS also notes that ED boarding time is tracked through a Hospital Outpatient Quality Reporting Program (Hospital OQR program) measure (OP-18).

d. Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK-03) (eCQM)

CMS does not finalize its proposed removal of this measure and the measure will remain in the IQR program's measure set. The proposal for removal cited IQR program Removal Factor 8: costs associated with the measure outweigh the benefit of its continued use. CMS notes the presence of multiple stroke-related eCQMs in its measure set, and identified STK-03 for removal to streamline the measure set, because few hospitals have chosen to report this measure and the measure's patient population is also captured in STK-02 eCQM.

While some commenters supported measure removal, others argued for retention. Retention was recommended because STK-02, unlike STK-03 does not specifically target prescribing of anticoagulation therapy. Commenters stated STK-02 is associated with more general antithrombotic therapy while STK-03 relates to the specific anticoagulation therapy that is indicated for stroke patients who also have atrial fibrillation/flutter. Commenters were concerned that removal of STK-03 would lead to an inappropriate reduction in use of anticoagulation therapy. CMS was persuaded by the arguments for retention and decided not to finalize removal of the STK-03 measure.

e. Discharged on Statin Medication eCQM. (STK-06) (eCQM)

CMS finalizes the removal of this measure from the IQR program's measure set beginning with the CY 2024 reporting period/FY 2026 payment year, citing Removal Factor 8: costs associated with the measure outweigh the benefit of its continued use. Current guidelines emphasize the use of antiplatelet therapy over use of statins and other existing measures capture whether patients are discharged on antithrombotic therapy.

Many commenters supported measure removal. Concern was raised that this eCQM was easier for small hospitals to report than many other eCQMs and that measure removal reduces alignment of IQR program and Joint Commission requirements. CMS notes that small hospitals can use the zero-denominator declaration and case threshold exemption processes to comply with eCQM reporting requirements. The agency also notes that while alignment of requirements across standards-setting organizations is desirable, it is not always feasible.

3. Future Measure Considerations

a. 30-Day All-Cause Mortality Measure for Patients Admitted With COVID-19 Infection (COVID-19 mortality measure)

CMS requested comments about the potential development of a hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID-19 infection to assess how the

burden of the PHE impacts hospitals' abilities to care for patients. CMS indicates that the claims-based measure would likely resemble those for other condition-specific mortality measures already in the IQR and VBP programs (e.g., Pneumonia 30-day Mortality measure). The agency notes that public reporting of results would not be operationally feasible before FY 2023. Measure proposal would be done through rulemaking.

Commenters were generally supportive. Specifically suggested were having an initial period of confidential reporting only to hospitals before public reporting and seeking NQF endorsement. Concerns were voiced that measure construction issues were likely to arise related to cohort overlap with the recently finalized Hybrid HWM measure and to risk adjustment. Also expressed was a concern about devoting resources to developing this measure since deaths due to COVID-19 are declining.

b. Hospital-Level, Risk-Standardized Patient Reported Outcomes (PRO) Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) Performance Measure (THA/TKA PRO-PM)

CMS is considering the future inclusion of the THA/TKA PRO-PM in the Hospital IQR Program. The prevalence of pain and disability attributed to hip and knee osteoarthritis is substantial in the Medicare population, and THA and TKA are two of the Medicare program's most commonly performed procedures. Functional status and pain as perceived by the patient are important postoperative outcomes and best measured through PRO-PMs, and standardized postoperative assessment tools exist for these two procedures. (HOOS, JR and KOOS, JR). This measure has been available for voluntary reporting by hospitals participating in the Comprehensive Care for Joint Replacement (CJR) episode payment model since the model began in April 2016, with assessments completed 90 or fewer days preoperatively and at roughly one year postoperatively.

Commenters were supportive of PRO-PMs generally and following total joint arthroplasty specifically. Suggestions were offered for additional measure exclusions and for public data reporting, as well as reporting across settings (e.g., inpatient versus outpatient). Commenters requested release of data about the measure's performance in the CJR model before measure adoption into the IQR program. Risk adjustment for social risk factors was recommended. Concerns were raised about hospital and physician burden.

c. Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

CMS already provides feedback to hospitals on HRRP readmission measures with results stratified by patients' dual eligibility status. CMS sought input about providing reports to hospitals about their performances on the Hybrid Hospital Wide Readmissions measure (Hybrid HWR) measure) stratified by race and ethnicity as well as dual eligibility. Public reporting would follow a period pf confidential reporting to hospitals. Specific proposals would be made through rulemaking.

Commenters expressed interest in receiving confidential stratified reports, but were less enthused about public reporting of their results. Concerns were expressed about reliability and actionability of imputed race and ethnicity data and about the added imposed burden of collection of social risk factor information from patients.

d. Potential Future Reporting of a Structural Measure to Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

CMS invited comments about collecting one or more attestation-based structural measure(s) to assess priority domains related to organizational commitment to health equity. Commenters supported the intent of the measure but found it to be too broadly defined for actionability. They suggested that the measure must be linked to improved patient outcomes and the importance of testing any provisional measure for feasibility and data integrity.

4. Form, Manner, and Timing of Data Submission

a. Procedural Requirement Updates § 412.140

CMS finalizes as proposed to update two references in this section to the QualityNet website to the current URL (QualityNet.cms.gov) and to replace the terms QualityNet Administrator and QualityNet System Administrator with QualityNet security official to align with other CMS quality programs. The identified individual's responsibilities will not change. CMS notes receiving only supportive comments.

b. Updates to Requirements for eCQM Reporting

CMS finalizes requiring hospitals to use only certified technology consistent with the 2015 Edition Cures Update beginning with CY 2023 reporting/FY 2025 payment determinations. All available eCQMs used in the Hospital IQR Program for CY 2023 reporting/FY 2025 payment and subsequent years will need to be reported using technology certified to the 2015 Edition Cures Update.

Commenters were divided about support for this proposal. Concerns about timing were expressed. CMS believes that sufficient transition time is being allotted. CMS clarifies that hospitals are being required to use only 2015 Edition Cures Update CEHRT for IQR program data submission beginning with the CY 2023 reporting period, they are not being required to implement Cures Update certified health IT by December 31, 2022. CMS plans to work with the Office of the National Coordinator for Health IT (ONC) to monitor the timely availability of EHR technology certified to the 2015 Edition Cures Update. CMS also points out that hospitals experiencing unusual difficulties related to 2015 Edition Cure Update adoption may apply for a hardship exception from eCQM reporting under the IQR program's ECE policy.

CMS also clarifies that beginning with the CY 2021 reporting period/FY 2023 payment determination, hospitals must report the same set of self-selected eCQMs across all quarters of a given reporting year.

c. Updates to Requirements for Hybrid Measure Reporting

CMS finalizes the proposed requirement for hospitals to use only certified technology consistent with the 2015 Edition Cures Update for hybrid measure reporting beginning with CY 2023 reporting/FY 2025 payment determinations. Most commenters were supportive. Timeline concerns were raised by some and CMS restates that it plans to work with ONC to monitor the timely availability to hospitals from vendors of EHR technology certified to the 2015 Edition Cures Update.

d. Reporting and Submission Period Updates for New Structural and NHSN Measures

CMS restates the finalized reporting and submission periods for the newly adopted Maternal Morbidity Structural measure and the COVID-19 Vaccine Coverage Among HCP measure described earlier in the rule and this summary. Both measures will have initial reporting periods of October 1, 2021, through December 31, 2021 for FY 2023 payment determinations.

For the Maternal Morbidity measure, for FY 2024 and subsequent payment years, the reporting period will be as proposed: the 12-month calendar year occurring two years prior to the payment year (e.g., calendar year 2022 reporting for FY 2024 payment). The measure's submission period will follow the current structural measure submission policy: April 1, 2022 through May 16, 2022 for the first year, and April 1 through the deadline as for Q4 chart-abstracted measures in subsequent years.

For the COVID-19 NHSN-submitted measure, for FY 2024 and subsequently, CMS finalizes a full calendar year reporting period (e.g., all 12 months of CY 2022 data will be reported for use in the FY 2024 IQR program) for each facility's CMS Certification Number. CMS originally proposed public display of a rolling four quarters of results but modifies its proposal, such that public data display on Care Compare will show only the most recent quarter's results.

e. IQR Program Data Validation Educational Review Process

For chart-abstracted measures, CMS finalizes as proposed to use the corrected scores that result from educational reviews for all four quarters of data validation beginning with FY 2024; if an error is identified during the fourth quarter, the corrected quarterly score would be used to compute the final confidence interval used in making payment determinations. Previously the agency could only make hospital score corrections for chart-abstracted measures after data validation education reviews for the first three quarters of the data validation period due to operational inability to calculate the necessary confidence interval in a timely manner for the fourth quarter.

No changes were proposed to the educational review process for eCQMs. Tables listing the quarters required for data validation of chart-abstracted measures and eCQMs for FY 2023 and FY 2024 payment determinations are provided in the rule (section IX.C.10.b(1)(b)).

5. Previously Finalized and Proposed Hospital IQR Program Measures

CMS provides tables showing the Hospital IQR Program measure set for each of the FY 2023 through FY 2026 payment determinations and subsequent years. Selected information from those tables is consolidated into the table below.

Summary Table HPA IQR-1: IQR Program Measures by Payment Determination Year X= Mandatory Measure , V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
Chart-Abstracted Process of Care Measures						
Severe sepsis and septic shock: management bundle (NQF #500)	X	X	X	X	X	X
PC-01 Elective delivery < 39 weeks gestation (NQF#0469)	X	X	X	X	X	X
ED-1 Time from ED arrival to departure for admitted patients (NQF#0495)	Removed					
ED-2 Time from admit decision to departure for admitted patients (NQF#0495)[a]	X	Removed				
IMM-2 Immunization for influenza (NQF #1659)	Removed					
VTE-6 Incidence of potentially preventable VTE	Removed					
Electronic Clinical Quality Measures						
AMI-8a Primary PCI w/in 90 minutes arrival CAC-3 Home Mgmt Plan Document to Caregiver STK-2 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)**** STK-8 Stroke education STK-10 Assessed for rehabilitation services (NQF #0441) VTE-1 VTE prophylaxis (NQF #0371) VTE-2 ICU VTE prophylaxis (NQF #0372) ED-1 Time from ED arrival to departure for admitted patients (NQF#0495) ED-2 Time from admit decision to ED departure for admitted patients (NQF #0497)**** EDHI-1a Hearing Screening Pre-Hospital Discharge PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469) PC-05 Exclusive breast milk feeding (NQF #0480) **** Safe Use of Opioids – Concurrent Prescribing (NQF #3316c) Hospital Harm-Severe Hypoglycemia (NQF #3503e)* Hospital Harm-Severe Hyperglycemia (NQF #3533e)*	Report 4 of the following 15 eCQMs: AMI-8a CAC-3 ED-1 ED-2 EHDI-1a PC-01 PC-05 STK-02 STK-03 STK-05 STK-06 STK-08 STK-10 VTE-1 VTE-2	Report 4 of the following 8 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2	Report 4 of the following 9 eCQMs: ED-2 PC-05 STK-02 STK-03*** STK-05 STK-06 VTE-1 VTE-2 Safe Use of Opioids	Report Safe Use of Opioids AND 3 of the following 6 eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2	Report Safe Use of Opioids AND 3 of the following 7 eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02	Report Safe Use of Opioids AND 3 of the following 7 eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02
Healthcare-Associated Infection (HAI) Measures						
Central Line Associated Bloodstream Infection (CLABSI)	X	Removed				

Summary Table HPA IQR-1: IQR Program Measures by Payment Determination Year X= Mandatory Measure , V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	Removed				
Catheter-Associated Urinary Tract Infection (CAUTI)	X	Removed				
MRSA Bacteremia	X	Removed				
Clostridium Difficile Infection (CDI)	X	Removed				
Healthcare Personnel Influenza Vaccination (NQF #0431)	X	X	X	x	X	X
Healthcare Personnel COVID-19 Vaccination*			X	X	X	X
Claims-Based Measures						
Mortality						
Pneumonia 30-day mortality rate	Removed					
Stroke 30-day mortality rate	X	X	X	X	X	X
COPD 30-day mortality rate	Removed					
CABG 30-day mortality rate	X	Removed				
Readmission/Coordination of Care						
Hospital-wide all-cause unplanned readmission (NQF #1789)**	X	X	X	X	X	Removed
Excess days in acute care after hospitalization for AMI (NQF #2881)	X	X	X	X	X	X
Excess days in acute care after hospitalization for HF (NQF #2880)	X	X	X	X	X	X
Excess days in acute care after hospitalization for PN (NQF #2882)	X	X	X	X	X	X
Claims and Electronic Data Measures (Hybrid)						
Hybrid HWR (all-cause readmission) (NQF #2879)				V		X
Hybrid HWM (all-cause mortality)*					V	**X**
Patient Safety						
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)***	X	X	X ***	X	X	X
THA/TKA complications	X	X	Removed			
Efficiency/Payment						
AMI payment per 30-day episode of care (NQF #2431)	X	X	X	X	X	X
Heart Failure payment per 30-day episode of care (NQF # 2436)	X	X	X	X	X	X
Pneumonia payment per 30-day episode of care (NQF #2579)	X	X	X	X	X	X
THA/TKA payment per 30-day episode of care	X	X	X	X	X	X
Patient Experience of Care						
HCAHPS survey (NQF #0166)	X	X	X	X	X	X
Structural Measures						
Maternal Morbidity*			X	X	X	X

*Measure finalized for adoption in FY 22 rule
** Will be replaced for FY 2026 by Hybrid HWR.
*** Proposed for removal in this rule but removal not finalized
**** Proposed for removal and removal finalized
[a] A similar measure remains in the hospital outpatient quality program, (OP-18)

D. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The PCHQR Program requires quality reporting by PPS-Exempt Cancer Hospitals (PCHs); the program's measure results are publicly available but the results have no associated payment consequences. In this rule CMS finalizes one measure removal, one measure addition, and several minor administrative updates. The program's requirements have not been previously collated and codified, and CMS finalizes doing so in this rule.

CMS also refers readers to an RFI earlier in the rule about closing health equity gaps in CMS quality programs (see section IX.B of the rule and this summary), addressing the potential stratification of quality measures and creation of a health equity score, including applicability to the PCHQR Program. Similarly, CMS refers readers to an RFI earlier in the rule about expanding the use of the FHIR® standard to move CMS quality programs, including the PCHQR program, towards a fully digital measure portfolio (see section IX.A of the rule and this summary).

1. Measure Updates

a. Removal of the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology Measure (PCH-15) (NQF # 0383)

CMS finalizes without modification its proposal to remove PCH-15 from the PCHQR program's measure set beginning with the FY 2024 program year based on Removal Factor 7: it is not feasible to implement the measure specifications.[49] CMS notes that the measure steward is reverting to a prior measure version and will no longer maintain the specifications for the PCHQR program's measure version. The steward also has emphasized that its reinstated prior version is designed to be paired with a measure that CMS notes has previously been removed from the PCHQR program's measure set (PCH-16). Removal of the chart-abstracted, topped out, PCH-15 measure will reduce provider reporting burden.

CMS reviews comments received. Several commenters recommended retention of the PCH-15 measure, along with reverting to the measure's prior version and reintroducing its companion measure PCH-16 into the program. CMS declines the recommendation and indicates interest in developing new oncology pain management measures that are eCQMs and outcomes-focused.

b. Adoption of the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

CMS finalizes adding this measure as proposed, except for modification to the extent of data that will be publicly reported. The measure is designed to track the percentage of a PCH's healthcare personnel (HCP) who receive a complete COVID-19 vaccination course. CMS regards HCP vaccination rates as being of interest to beneficiaries and caregivers during healthcare decision-making and as an aid to PCH's in tracking their efforts to reduce COVID-19 transmission. Full specifications are available on the CDC website: https://www.cdc.gov/nhsn/nqf/index.html.

[49] The PCHQR Program considers the same eight measure removal factors as those used in the Hospital IQR Program.

The pre-rulemaking process for this measure is as described for the same measure being adopting into the IQR program, and is excerpted in section IX.C.1.c of this summary. The MAP conditionally supported the measure contingent upon clarification of measure specifications, and CMS has returned to the MAP with results from further measure testing and updated specifications. CMS is proceeding with measure adoption without full MAP support or NQF endorsement, using Secretarial discretion found in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act.

CMS finalizes as proposed an initial data reporting period of October 1, 2021, through December 31, 2021, for measure use in the FY 2023 PCHQR Program payment year. For FY 2024 and subsequently, CMS also finalizes as proposed a full calendar year reporting period (e.g., all 12 months of CY 2022 data would be reported for use in the FY 2024 IQR program). Further, CMS finalizes its proposal to publicly report this measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible. CMS does not finalize its proposal to add one additional quarter of data to each refresh to reach a total of four quarters followed by ongoing display of four quarters refreshed on a rolling basis. Instead, CMS will report only the most recent quarter of data (as discussed in section IX.C.1.c of this summary for the IQR program).

Data submission requirements parallel those for this measure as adopted into the Hospital IQR program: quarterly reporting through CDC's NHSN web-based surveillance system and data submission for at least one self-selected week per month. The CDC will report data quarterly to CMS; PCH quarterly vaccination rates as calculated by the CDC will appear on Care Compare.

CMS reviews comments received on the COVID-19 HCP Vaccination Coverage measure proposal. Most comments were duplicates of those submitted concerning adopting this same measure into the IQR program. Those comments and the agency's responses are excerpted above in section IX.C.1.c of this summary. No substantive concerns specific to the PCH care setting were raised. CMS notes that for FY 2022, PCHs achieved a vaccination rate of 89 percent on a similar influenza vaccine measure.

2. Regulation Text Updates

a. QualityNet Administrator

CMS finalizes as proposed technical changes to update references to replace the term QualityNet Administrator with QualityNet security official to align with other CMS quality programs.

b. Codification of PCHQR Program Requirements

CMS finalizes its proposal without modification to codify PCHQR Program requirements in new § 412.24 entitled "Requirements under the PPS-Exempt Caner Hospital Quality Reporting (PCHQR) Program". Also finalized as proposed is a new paragraph § 412.23(f) that would require cancer hospitals that participate in the PCHQR Program to follow all of the requirements of § 412.24 as listed below:

- Program participation requirements (adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) including the PCHQR Program registration process;

- Data submission requirements for quality measures adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) that are selected by CMS under section 1866(k) of the Act and must be submitted in a form and manner, and at a time, specified by CMS;
- Quality measure removal and retention factors adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183) and expanded in FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611));
- Public reporting requirements for quality measure data reported by PCHs, with measure information displayed on the CMS website adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191)), and
- The ECE policy (adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848) and updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425)) detailing the process for CMS to grant an extension or exception to quality measure reporting requirements under the PCHQR Program.

3. PCHQR Program Measures for the FY 2023 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in two tables in section IX.D.6 of the rule combined and reproduced below with modifications.

Table HPA PCHQR-1: PCHQR Program Measures for FY 2023 and Subsequent Years		
Measure	**NQF #**	**Public Display Start Date**
Safety and Healthcare Associated Infection (HAI)		
Catheter-associated Urinary Tract Infection (CAUTI)	0138	Deferred to CY 2022
Central Line-associated Blood Stream Infection (CLABSI)	0139	Deferred to CY 2022
HCP Influenza Vaccination Coverage	0431	2019
Colon and Abdominal Hysterectomy Surgical Site Infections	0753	2019
Methicillin-resistant staphylococcus aureus (MRSA)	1716	2019
Clostridium difficile (CDI)	1717	2019
COVID-19 HCP Vaccination*	N/A	October, 2022
Clinical Process/Oncology Care		
Patients Dying from Cancer Given Chemotherapy last 14 days of life (EOL-Chemo)	0210	Not displayed
Patients Dying from Cancer not admitted to hospice (EOL-Hospice)	0215	Not displayed
Oncology: Plan of Care for Pain**	0383	2016
Intermediate Clinical Outcomes		
Patients Dying from Cancer ICU Admission in the ICU last 30 Days of Life (EOL-ICU)	0213	Not displayed
Patients Dying from Cancer admitted to hospice <3 days (EOL-3DH)	0216	Not displayed
Patient Experience of Care		
HCAHPS	0166	2016
Claims-Based Outcomes		

Table HPA PCHQR-1: PCHQR Program Measures for FY 2023 and Subsequent Years		
Measure	**NQF #**	**Public Display Start Date**
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	N/A	April 2020
30-Day Unplanned Readmissions for Cancer Patients	3188	Not displayed
Surgical Treatment Complications for Localized Prostate Cancer	N/A	Not displayed

* Finalized for addition to the PCHQR program for FY 2023

** Finalized for removal from the PCHQR program beginning with FY 2024

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP is a pay-for-reporting quality program under which LTCHs submit data to CMS on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument. An LTCH that fails to meet the program's quality data reporting requirements is subject to a 2.0 percentage point reduction in its annual update factor. Information about many aspects of the program is available through the LTCH QRP website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting.

In this rule, CMS finalizes adding one measure to the LTCH QRP measure set and updating another; finalizes increasing by two the number of publicly reported measures; and finalizes updates of the policy for public reporting of LTCH QRP data to account for COVID-19 PHE effects. A summary table of LTCH QRP measures is provided in section IX.E.6 of this summary.

CMS also responds to an RFI about future LTCH QRP measures and refers to other RFIs that deal with strategies 1) to move CMS quality programs onto digital platforms, including use of the FHIR standard, and 2) to close the health equity gap in the LTCH QRP and other CMS quality programs.

1. LTCH QRP Measure Changes

a. COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

CMS finalizes as proposed the adoption of this measure into the LTCH QRP measure set beginning with FY 2023. This process measure tracks the rate of vaccination among LTCH HCP.

CMS finalizes as proposed an initial data reporting period of October 1, 2021 through December 31, 2021, to support use of this measure beginning with the FY 2023 LTCH QRP. For FY 2024 and subsequently, CMS finalizes as proposed a full calendar year reporting period (e.g., all 12 months of CY 2022 data would be reported for use in the FY 2024 LTCH QRP). Further, CMS finalizes its proposal to publicly report this measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible. CMS does not finalize its proposal to add one additional quarter of data to each refresh to reach a total of four quarters followed by ongoing display of four quarters refreshed on a rolling basis. Instead, CMS will report only the most recent quarter of data.

Data submission by LTCHs will be required quarterly through CDC's NHSN, reporting data for at least one self-selected week per month. The CDC will report vaccination rates quarterly to CMS, and those rates will be publicly reported on Care Compare.

This measure went through the standard pre-rulemaking process. The MAP awarded conditional support for rulemaking, requesting clarification of the measure's specifications, which CMS provided to the MAP in March, 2021. The measure is not NQF-endorsed, but CMS adopts the measure into the LTCH QRP under the exception at section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, which allows the Secretary to select non-NQF-endorsed measures when the Secretary is unable to identify a suitable NQF-endorsed measure that is available, feasible, and practical.

CMS reviews comments received on the proposed measure. Support from commenters was mixed. Concerns were similar to those voiced about adoption of this measure into the Hospital IQR Program (see summary section IX.C.1.c above).

Related to LTCHs, commenters did note the disproportionate and devastating impact of the SARS-CoV-2 virus on older adults in congregate care settings, with which CMS agrees and emphasizes the excess risk of viral exposure and transmission in LTCHs. Commenters described challenges of health data collection from LTCH employees and CMS indicates that facilities may apply for hardship exceptions to measure reporting under the LTCH QRP ECE policy as needed.

CMS highlights the interplay of state laws and regulations, Equal Employment Opportunity Commission policies, contraindications to vaccination, and other factors affecting willingness of facility staff members to be vaccinated. CMS notes that LTCHs are familiar with NHSN reporting so that the measure's imposed added burden is minimal.

CMS clarifies that any HCP eligible to work one day in the LTCH during the measure's reporting period is counted, regardless of whether they also work in another facility that is reporting the same measure. CMS also clarifies that the LTCH QRP COVID-19 HCP measure is separate and distinct from the SARS-CoV-2 Vaccination by Clinician measure proposed for inclusion in the Merit-based Incentive Payment System (MIPS) in the CY 2022 Physician Fee Schedule proposed rule.

b. Transfer of Health Information to the Patient-Post-Acute Care (TOH-Patient-PAC)

CMS finalizes as proposed revising the denominator of the TOH-PAC-Patient measure by excluding patients discharged to home health or hospice care, as these patients are already included in the denominator of a companion measure (TOH-PAC-Provider). Commenters were overwhelmingly supportive; a suggestion was made to exclude short stay patients from the measure which CMS declines to accept.

Of note, in the CY 2022 Home Health PPS proposed rule (86 FR 35983), CMS proposes to require LTCHs to begin reporting two measures -- Transfer of Health (TOH) Information to Provider-PAC and TOH Information to Patient-PAC – and the elements in the six Standardized Patient Assessment Element (SPADE) data categories dealing with social determinants of health (SDOH) beginning October 1, 2022. In the May 8, 2020, COVID-19 IFC (85 FR 27550), CMS

had – in response to the COVID-19 PHE -- delayed the compliance date for reporting these measures to January 1st of the year that is at least one full CY after the end of the PHE.

c. LTCH QRP Measures for Future Years

CMS excerpts comments received in response to the proposed rule's RFI concerning future LTCH QRP measures. Frailty and malnutrition were mentioned as important concerns but also as ones that may not be reversible during an LTCH stay. CMS indicates that the input received will be considered for future rulemaking.

2. Request for Information on Support of Digital Quality Measurement Using Fast Healthcare Interoperability Resources (FHIR®)

CMS requested input into the agency's planning for transformation to a fully digital quality enterprise by 2025, to include the LTCH QRP, with special emphasis on the potential role of FHIR-based standards for efficient exchange of clinical information across clinical settings by clinicians through APIs. CMS acknowledges comment receipt and states that any updates to the LTCH QRP's requirements related to digital transformation will be addressed through rulemaking.

3. Request for Information on Closing the Health Equity Gap

CMS requested information on potential revisions to the LTCH QRP to facilitate comprehensive and actionable reporting of health disparities; this could include adding measures and SPADEs as well as providing performance results stratified by one or more social risk factors (e.g., race and ethnicity). CMS acknowledges receiving comments demonstrating strong stakeholder interest in this topic and states its desire to provide reports stratified by race and ethnicity to LTCHs if feasible. CMS notes that any updates to the LTCH QRP requirements related to health equity would be addressed through rulemaking.

4. Public Reporting of Certain LTCH QRP Measures

a. Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Measure

CMS finalizes public reporting of the LTCH SBT Day 2 measure beginning with the March 2022 Care Compare refresh, or as soon as technically feasible, as proposed. Data reporting to CMS for this measure by LTCH providers began on July 1, 2018. The inaugural data publicly displayed on Care Compare will be from July 1, 2020 through June 30, 2021, while the Provider Data Catalog will contain data from July 1, 2018 through December 31, 2019.

Comments received were few and support for the proposal was mixed. Some raised measure specification concerns; CMS notes that the specifications have not changed since the adoption of this measure into the LTCH QRP. In response to a concern about the potential for public reporting to pressure providers' clinical decisions, the agency responds that the measure requires an assessment to be made but does not dictate the outcome of the assessment and subsequent clinical decision-making.

b. Ventilator Liberation Rate for the PAC LTCH QRP Measure

CMS finalizes public reporting of the LTCH Ventilator Liberation Rate beginning with the March 2022 Care Compare refresh, or as soon as technically feasible. Data collection for this measure uses the LCDS patient assessment instrument and reporting began with patients admitted or discharged on or after July 1, 2018. The inaugural data publicly displayed on Care Compare will be from July 1, 2020, through June 30, 2021, while the Provider Data Catalog will contain data from July 1, 2018 through December 31, 2019.

Comments received were few and mostly supportive. CMS disagrees with a commenter who advocates removal of data collected during the COVID-19 PHE from public reporting.

c. COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

CMS finalizes public reporting of the COVID-19 Vaccination HCP Coverage measure beginning with the September 2022 Care Compare refresh, or as soon as technically feasible. Based on commenter concerns about the proposed reporting of four quarters of data on a rolling basis – public confusion, dilution of the most recent and actionable data – CMS modifies the proposal for rolling four-quarter public reporting to instead display only the most recent quarter of data (see also summary section IX.E.1.a above).

5. Public Reporting of Measures with Fewer than Standard Numbers of Quarters Due to COVID-19 Effects ("Exempted Quarters")

CMS finalizes as proposed temporary changes to the data collection quarters specified in prior rulemaking for LTCH QRP measure results that are publicly displayed on Care Compare. CMS will implement the COVID-19 Affected Reporting (CAR) Scenario for public reporting of measure results for the LTCH QRP Care Compare data refreshes for December 2021 through June 2023. The finalized changes are designed to account for incomplete data reporting during the COVID-19 pandemic ("exempted quarters") and to return to pre-pandemic public reporting timelines as rapidly as feasible, while preserving the usefulness and accuracy of the displayed results. Tables FF4, FF5, FF8 and FF9 in the rule show the revised refresh schedules by measure data source.

Refreshes on Care Compare for the LTCH QRP measures are specific to each measure's source data: the LTCH Care Data Set (LCDS); Medicare claims; or the CDC NHSN. Normally, four contiguous quarters of data are used for LCDS-derived and NHSN measures while eight quarters are used for claims-based measures.

In response to the COVID-19 PHE, CMS granted a nationwide exemption to the LTCH QRP reporting requirements for Q4 2019 and Q1 and Q2 2020, although facilities were able to report data voluntarily. CMS subsequently determined that the Q4 2019 data were suitable for use in Care Compare refreshes as previously scheduled but that Q1 and Q2 2020 data were not suitable. Based on its data analysis, CMS decided that freezing the publicly displayed results beginning with the December 2020 refresh would be appropriate until such time as the data to be added were no longer affected by the Q1 and Q2 2020 nationwide data reporting exemption. The CAR

scenario allows more rapid return to pre-pandemic refresh schedules by reducing the number of quarters of data collected for each refresh and was extensively tested and analyzed by CMS as described in the proposed rule.

CMS reviews the comments received, most of which opposed the agency's proposal. Concerns centered on the inclusion of Q3 and Q4 2020 data in refreshes, as commenters view these data as flawed and unsuitable for public display. Commenters further stated that disclaimers explaining the data flaws must be included with the displayed data on Care Compare. CMS responds that excluding use of the Q3 and Q4 2020 data would create an unacceptable gap in data reporting. CMS declines the addition of disclaimers to the website about the CAR scenario data as implying that the data being reported are not credible for use by the public in decision-making; CMS finds this implication to be unjustified based on the extensive testing done of the CAR scenario. CMS clarifies that the previously established review and correction periods will apply to the LCDS-derived and claims-based measures and that a similar preview opportunity is available through the CDC for the NHSN-based measures.

6. Summary Table of LTCH QRP Measure Set

Table HPA LTCH QRP-1: LTCH QRP Measure Set, by Year					
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	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	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	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	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	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	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	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X	X	X
NHSN Ventilator Associated Event Outcome Measure	X	X	Removed		
Medicare spending per beneficiary MSPB-PAC LTCH	X	X	X	X	X

Table HPA LTCH QRP-1: LTCH QRP Measure Set, by Year					
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Discharge to Community PAC LTCH*	X	X	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X	X	X
Drug Regimen Review Conducted with Follow-up		X	X	X	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay		X	X	X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate		X	X	X	X
Transfer of Health Information to the Provider – PAC Measure**				X	X
Transfer of Health Information to the Patient – PAC Measure**				X	X
COVID-19 Vaccination Coverage among Healthcare Personnel					X
* Measure updated to remove baseline nursing facility patients beginning in FY 2020.					
** Compliance date for the collection and reporting of these measures has been proposed for October 1, 2022 in the Home Health PPS proposed rule (86 FR 35983) after being delayed for at least one full FY after the end of the COVID-19 PHE (85 FR 27597 through 27597).					

F. Medicare and Promoting Interoperability Program

A hospital that is not identified as a meaningful user of certified electronic health record technology (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 the final rule, 97 hospitals are estimated to fail to meet the meaningful use requirements for FY 2022 payment and would receive an update factor of 0.025 percent. An additional 24 hospitals are estimated to fail to meet both the meaningful use and IQR Program requirements and under the final rule would receive an update factor of -0.7 percent.

1. Reporting Periods in 2023 and 2024

A continuous 90-day reporting period was previously adopted for the Medicare and Medicaid Promoting Interoperability Program reporting in 2022 for new and returning participants. CMS had proposed to extend continuous 90-day reporting for new and returning participants for the Medicare Promoting Interoperability Program EHR reporting periods in 2023 and to establish a 180-day reporting period for new and returning participants for the Medicare Promoting Interoperability Program EHR reporting periods in 2024. CMS finalizes these proposals.

Commenters supported the extension of the 90-day reporting period policy for 2023 while some expressed concerns about the 180-day period for 2024. Those concerns relate to the 2015 Edition Cures update and the need for extended testing periods until the updates are fully implemented as well as the impact of the COVID-19 PHE. While noting the issues, CMS nonetheless believes that the two-year advance notice will afford vendors and eligible hospitals and CAHs adequate time to meet the requirement.

Reporting periods for these programs are codified in the definition of *EHR reporting period* at §495.4.

CMS reminds readers that under the statute, the Medicaid Promoting Interoperability Program will end in 2021; thus, absent a successful appeal related to 2021 or a prior year, December 31, 2021 is the last date states may make payments under this program.

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, 2020 and 2021 and eligible for 5 bonus points. 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 as prohibited and in accordance with applicable law.

Stakeholders continue to express concern to CMS that making this measure mandatory for reporting in 2022 is premature. PDMPs themselves are still maturing, and they are not yet consistently integrated into EHR workflow.

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.

CMS finalizes its proposal to continue the Query of PDMP measure as a voluntary measure for EHR reporting periods in 2022. It believes that at least one more year is needed before potentially requiring the Query of PDMP measure. CMS will also increase the bonus points for this optional measure from 5 to 10 which results in an increase to 20 in the maximum total points available for the Electronic Prescribing Objective for 2022. It notes that the increase to 10 bonus points for this measure is consistent with the policy finalized for MIPS eligible clinicians in the 2021 PFS final rule and aligns with the MIPS Promoting Interoperability performance category.

CMS believes reporting the Query of PDMP measure should be mandatory in the near future. Commenters reiterated concerns expressed in the past regarding implementation challenges due to different state law requirements and urged the agency to continue its policy of voluntary reporting of the measure for years after 2022.

3. Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

CMS had proposed to modify the Provide Patients Electronic Access to Their Health Information measure to require eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. Under the proposal, this would have applied beginning with the EHR reporting period in 2022, and would have included all patient health information from encounters on or after January 1, 2016.

Commenters sought clarification on a number of key issues regarding the measure; specifically, stakeholders queried how CMS would define an "indefinite" timeline and what specific data would be included in "all patient health information" under the proposed changes. Commenters also noted potential conflicts with state law. Due to these concerns, CMS does not finalize its proposal at this time and will seek more feedback from eligible hospitals and CAHs should it seek to propose changes to the measure in the future.

4. Health Information Exchange Objective: Engagement in Bi-directional Exchange Through Health Information Exchange (HIE)

CMS believes that incentivizing participation in HIEs that support bi-directional exchange will contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. It proposed a new optional measure for the Health Information Exchange objective: Health Information Exchange (HIE) Bi-Directional Exchange measure (at §495.24(e)(6)(ii)(C)) that would be worth 40 points. CMS finalizes the proposal.

The new measure is an alternative to the two existing measures: Support Electronic Referral Loops by Sending Health Information measure (at §495.24(e)(6)(ii)(A)) and Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (at §495.24(e)(6)(ii)(B)). CMS believes the new measure will incentivize eligible hospitals and CAHs to engage in health information exchange for care coordination that includes additional transitions and referrals as well as other potential scenarios such as where the recipient of the transition of care may be unknown; where the eligible hospital or CAH may not be the referring health care provider; or where the transition of care may happen outside the scope of the EHR reporting period.

Eligible hospitals or CAHs may either report the existing two measures and associated exclusions or report the new HIE Bi-Directional Exchange measure. In no case may more than 40 points be earned for the HIE objective. The new measure is reported by attestation and requires a yes/no response. Eligible hospitals or CAHs must attest to the following:

- Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Using the functions of CEHRT to support bi-directional exchange with an HIE.

CMS notes the new measure is broader than the existing measures. The Support Electronic Referral Loops by Sending Health Information measure includes only new patients and known transitions or referrals received that occur during the EHR reporting period. The Support Electronic Referral Loops by Receiving and Reconciling Health Information measure includes only known transitions of care or referrals made that occur during the EHR reporting period. The

bi-directional engagement under the new measure must be enabled for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department and all unique patient records stored or maintained in the EHR for those departments during the EHR reporting period. There would be no exclusions, exceptions or allowances made for partial credit.

To successfully attest to the new measure, the eligible hospital or CAH must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes capabilities which support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). CMS clarifies that an eligible hospital or CAH attesting to the three statements is not required to use all of the relevant certified health IT modules to support their connection with an HIE, nor must a connection with an HIE be solely based on certified health IT modules. For instance, a provider's EHR could generate a C-CDA using a certified health IT module, and subsequently transmit that document to an HIE using technology that is not part of a certified health IT module. CMS notes that none of the actions required to attest to the new measure are intended to conflict with a patient's rights or a covered entity's requirements and responsibilities under the HIPAA Privacy Rule.

Most commenters supported the addition of the new measure. Many comments sought clarification on various aspects of the measure, and CMS provided the following responses:

- Enabling bi-directional exchange under the first attestation statement does not mean that an eligible hospital or CAH is required to conduct information transactions that are not clinically necessary. Rather, it means that an eligible hospital or CAH has established the capabilities necessary to complete exchanges of information for their patients at the appropriate time.
- The term "HIE" broadly refers to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange "frameworks," "networks," or other terms.
- With respect to audit evidence for the measure, CMS suggests a dated report or screenshot that documents successful receipt and transmission of patient data via the entity providing health information exchange services. That documentation should include evidence to support that it was generated for that eligible hospital or CAH's system (e.g., identified by NPI, CMS certification identification number, hospital name, etc.) and/or letter, email, or other documentation from the entity providing health information exchange services that confirm participation of the eligible hospital or CAH, the date of on-boarding, a description of services provided, and a description of exchange network participants (for example, number/type of participating providers).

5. Modifications to the Public Health and Clinical Data Exchange Objective

a. Background

CMS previously established a policy for this objective that eligible hospitals and CAHs must report on any two of six finalized measures.[50] A yes/no response must be submitted for two measures to earn 10 points for the objective; failure to report or reporting a "no" answer for a measure earns a zero score. Exclusions are available for each measure; if an exclusion is claimed for one measure and a "yes" answer is provided for the second, the eligible hospital or CAH receives 10 points. If exclusions are claimed for both measures, the 10 points are redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

b. Modifications to the Public Health and Clinical Data Exchange Objective

Beginning with the EHR reporting period in 2022, CMS had proposed to require reporting on the following four measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. CMS finalizes its proposals. The agency believes this will put public health agencies (PHAs) on better footing for future health threats and a long-term COVID-19 pandemic recovery.

Syndromic Surveillance Reporting. Beginning with the EHR reporting period in 2022, CMS changes the setting for which data is required to be submitted from urgent care to the emergency department (POS 23). It makes a technical change to the first exclusion to the measure by eliminating a reference to urgent care. The other two exclusions are not changed.

Some commenters objected to the change in setting. While the long-term goal is to expand syndromic surveillance capabilities to a broader array of clinical settings, CMS believes that hospital emergency departments remain a core focus and offer a broad representation of patients with severe or acute illness. The agency also notes that PHAs can receive syndromic data from urgent care facilities.

CMS believes requiring this measure will expand coverage of syndromic surveillance to every region in the United States, help healthcare facilities and PHAs better prepare for emerging health events, and provide critical national early warning capabilities necessary for swift response and control of COVID-19 outbreaks. It does not believe this requirement would pose a significant burden on hospitals as 49 states already participate in the National Syndromic Surveillance Program.

Immunization Registry Reporting. CMS did not propose any changes to the description of the measure, and it states that all of the exclusions previously finalized remain available. It believes

[50] The six measures are Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting.

that making this measure a required measure is critical for the COVID-19 vaccination response and to understanding vaccine coverage nationwide as well as at the jurisdictional level.

Electronic Case Reporting. CMS did not propose any changes to the description of the measure, and it states that all of the exclusions previously finalized remain available. CMS is concerned by the uneven adoption of electronic case reporting. It believes requiring this measure will accelerate the development of electronic case reporting capabilities in EHR systems; reduce healthcare administrative burden of complying with State-mandated disease reporting requirements; provide regulatory clarity for EHR vendors; and improve the timeliness, completeness, and utility of case report data for PHAs.

Electronic Reportable Laboratory Result Reporting. CMS did not propose any changes to the description of the measure, and it states that all of the exclusions previously finalized remain available. It notes that electronic laboratory reporting by hospitals lags in comparison to larger commercial and clinical laboratories. The agency believes that requiring this measure will spur hospital laboratories to adopt this capability, increase the timeliness and completeness of laboratory reporting to PHAs, strengthen the effectiveness of prevention and control measures, and reduce the burden of reporting by laboratory staff.

6. Scoring of the Public Health and Clinical Data Exchange Objective

CMS finalizes its proposed changes to the scoring for this objective. Beginning with the EHR reporting period in 2022, eligible hospitals and CAHs will receive 10 points for the objective if they report a "yes" response for each of the four required measures. If an exclusion is claimed for three or fewer of the required measures, they will receive 10 points for the objective if they report a "yes" response for one or more of these measures and claim applicable exclusions for which they qualify for the remaining measures. Failure to report on any of the four measures, or reporting a "no" response for one or more of those measures, will result in a score of zero for the objective and a total score of zero for the Medicare PIP. If applicable exclusions are claimed for all four measures, CMS will redistribute the points for the objective to the Provider to Patient Exchange objective.

The remaining two measures (Public Health Registry Reporting and Clinical Data Registry Reporting) are optional and available for a total of 5 bonus points if a "yes" response is reported for either of the two optional measures. Because CMS makes these two measures optional, it eliminates the three exclusions previously available for each of them.

7. SAFER Guides

ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014 (updated in 2016). Three of these Guides (i.e., the Foundational, Infrastructure, and Clinical Process Guides) support the ability of health care providers and organizations to address EHR safety by conducting self-assessments to optimize the safety and safe use of EHRs. CMS notes that the SAFER Guides provide recommended safety practices during planned or unplanned EHR unavailability, due to events like system disruptions, systems failures, or natural disasters.

CMS finalizes its proposal to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the 2022 EHR reporting period. Following the completion of an initial self-assessment, an eligible hospital or CAH must attest to having conducted an annual self-assessment of all nine SAFER Guides (available at https://www.healthit.gov/topic/safety/saferguides) at any point during the calendar year in which the EHR reporting period occurs. Attestation is a single "yes/no" attestation statement accounting for a complete self-assessment using all nine guides. CMS expects providers to revisit the assessments to determine whether any changes have occurred for their organization.

While the measure is required, it will not be scored. Reporting a "yes" or "no" will not affect the total PIP score. In response to concerns from commenters, CMS underscores that a "no" answer is acceptable and will not result in a penalty. CMS expects that the eligible hospital or CAH will complete a checklist of recommended practices at the beginning of each SAFER Guide. CMS notes that a self-assessment does not require an organization to confirm that it has implemented "fully in all areas" each practice described in a particular SAFER Guide; the organization is not scored on how many of the practices it has fully implemented.

8. Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

CMS established attestation requirements for hospitals in order to implement section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which requires that hospitals not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. As part of the PIP, eligible hospitals and CAHs must attest to the following three statements:

- Statement 1: Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified HER technology.
- Statement 2: Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR Part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bidirectional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.
- Statement 3: Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

In the ONC 21ST Century Cures Act final rule (published on May 1, 2020), ONC finalized the following definition of information blocking for health care providers: Information blocking means a practice that, except as required by law or covered by an exception […], is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. (See 45 CFR 171.103.)

The Cures Act also provided for "appropriate disincentives" for health care providers that the HHS IG determines have committed information blocking. CMS emphasizes that while there may be overlap between the MACRA and Cures Act provisions, the two authorities are separate and distinct. For example, the information blocking regulations establish exceptions that are not reflected in the previously finalized attestation statements.

After review of the attestation statements and taking into account the information blocking regulations, CMS finalizes its proposal to eliminate the second and third attestation statements. Commenters universally applauded this proposal. CMS believes that the similarities between practices described in statements 2 and 3, and the practices that could constitute information blocking under ONC's information blocking regulations will create confusion for stakeholders. CMS also makes wording changes to the heading of the regulation text at §495.40(b)(2)(i)(I) and the definition of meaningful EHR user at §495.4 to refer to "Actions to limit or restrict the compatibility or interoperability of CEHRT".

9. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program in 2022

Table IX.F.-02 in the final rule lists the objectives and measures for the Medicare PIP for the EHR reporting period in 2022 as revised to reflect the policies finalized in the rule. Table IX.F.-03 lists the 2015 Edition certification criteria required to meet the objectives and measures.

10. Changes to the Scoring Methodology for the EHR Reporting Period in 2022

In order to be considered a meaningful user for the EHR reporting period in 2021, 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.

CMS notes that performance results for 2019 showed that 3,776 of 3,828 participating eligible hospitals and CAHs met the minimum threshold score (or total score) of 50 points.

For the EHR reporting period in 2022, CMS finalizes its proposal to raise the minimum threshold score to 60 points.

The scoring methodology for 2022 is shown in the following table.

Performance-Based Scoring Methodology for EHR Reporting Periods in 2022

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	10 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
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures: * Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following 2 measures: * Public Health Registry Reporting Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

* Signifies a final policy adopted in the FY 2022 IPPS/LTCH final rule.

11. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. 2022 EHR Reporting Period

- As part of being a meaningful user under the Medicare PIP, eligible hospitals and CAHs must report on eCQMs selected by CMS. For the 2022 reporting period eligible hospitals and CAHs must report the Safe Use of Opioids measure and must report on three of the eight available eCQMs for three self-selected quarters of data during the calendar year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program. The eCQMs available for 2022 reporting are as follows:

- ED-2 Admit Decision Time to ED Departure Time for Admitted Patients (NQF #0497)
- PC-05 Exclusive Breast Milk Feeding (NQF #0480)
- STK-02 Discharged on Antithrombotic Therapy (NQF #0435)
- STK-03 Anticoagulation Therapy for Atrial Fibrillation/Flutter (NQF #0436)
- STK-05 Antithrombotic Therapy by the End of Hospital Day Two (NQF #0438)

- STK-06 Discharged on Statin Medication (NQF #0439)
- VTE-1 Venous Thromboembolism Prophylaxis (NQF #0371)
- VTE-2 Intensive Care Unit Venous Thromboembolism Prophylaxis (NQF #0372)
- Safe Use of Opioids Safe Use of Opioids – Concurrent Prescribing (NQF #3316e) [required]

b. 2023 EHR Reporting Period

As it does for the hospital IQR program, CMS adopts the following two new eCQMs for the PIP program beginning with the 2023 reporting period/FY 2025 payment determination:

- Hospital Harm - Severe Hypoglycemia (NQF #3503e)
- Hospital Harm - Severe Hyperglycemia (NQF #3533e)

c. 2024 EHR Reporting Period

As it does for the hospital IQR program, CMS removes the following three eCQMs for the PIP program beginning with the 2024 reporting period/FY 2026 payment determination:

- STK-06 Discharged on Statin Medication (NQF #0439)
- PC-05 Exclusive Breast Milk Feeding (NQF #0480)
- ED-2 Admit Decision Time to ED Departure Time for Admitted Patients (NQF #0497)

CMS had proposed to also remove eCQM STK-03 Anticoagulation Therapy for Atrial Fibrillation/Flutter (NQF #0436). However, based on feedback from stakeholders, it declines to do so in the final rule. The agency explains its rationale for retaining the eCQM in the IQR program provisions in section IX.C of the preamble to the final rule, and finalizes the same policy under the PIP program to maintain alignment between the two programs.

d. Updates to Certification Requirements for eCQM Reporting – 2015 Edition Cures Update

CMS finalizes its proposal to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25667) to submit data for eCQMs, beginning with the reporting period in 2023. CMS is not persuaded by some commenters who expressed concerns about inadequate time to prepare and test the 2015 Edition Cures Update before reporting.

X. Changes for Hospitals and Other Providers

A. Medicaid Enrollment of Medicare Providers and Suppliers

Under existing Medicare and Medicaid law and regulations, state Medicaid programs are required to pay providers for Medicare cost-sharing on behalf of certain Medicare enrollees who are also enrolled in Medicaid (“dual eligibles”). Medicare cost sharing includes Medicare Part A

and B premiums, coinsurance, and deductibles and includes the costs associated with Medicare items and services whether or not those items and services are also covered under the Medicaid state plan.

Medicaid programs may, however, limit their payments for Medicare cost sharing such that the total amount paid for the item or service to the provider is equal to the amount the state would have paid for that item or service under the Medicaid program (the "lesser-of" policy). The provider is prohibited from charging the beneficiary the difference between the Medicaid payment amount and their Medicare payment amount, but may include those amounts as Medicare "bad debt" subject to 42 §CFR 413.89.

In order for a provider to claim that such unpaid amounts are bad debt, they need to receive documentation from the state that the claim processing has been completed and that identifies the state's cost sharing liability (the "remittance advice" (RA)). In some states where the Medicaid program does not recognize a particular service or provider type, the providers have been unable to enroll in the Medicaid program nor receive an RA from the state program and therefore are unable to incorporate those costs as bad debt.

CMS proposed to address this problem by clarifying states' obligations to providers of services for dual eligible beneficiaries. Specifically, CMS proposed to add new paragraph (d) to 42 CFR §455.410 – a section that describes Medicaid requirements with respect to the enrollment and screening of providers. Under the proposal, a state Medicaid agency would be required to enroll all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing if the providers or suppliers meet all Medicaid enrollment requirements, even if the Medicare-enrolled provider or supplier is of a type not recognized by the state Medicaid agency.

CMS noted that the change is not intended to require states to recognize or enroll additional provider types for any other purpose than the adjudication and issuance of a Medicaid RA. In addition, the systems' changes that would be required by this provision are likely to be eligible for a federal matching share of 90 percent of costs – the matching share applicable to state Medicaid Management Information Systems.

Comments/Responses: Most commenters supported the proposal although a few expressed concerns about legality and burden. Some commenters suggested additional modifications or requested technical clarifications as provided below:

- State Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers, including out-of-state providers and suppliers, that otherwise meet the requirements for being enrolled.
- Providers or suppliers must apply to be enrolled. CMS will not penalize states for non-enrollment of providers or suppliers who do not apply to enroll.
- Claims from unenrolled providers and suppliers do not have to be processed.
- CMS will work with states to streamline enrollment and notes that states can rely on screening performed by Medicare if certain requirements are met.
- The alternative documentation policy to the Medicaid RA that CMS adopted in the FY

2021 IPPS final rule will remain in effect for the foreseeable future.

Comments and responses from opponents of the proposal are provided below:

- CMS should allow ineligibility to enroll in Medicaid as documentation of Medicare bad debt in place of the Medicaid RA. While CMS acknowledges that there are providers who never receive state payment of cost-sharing for the services they furnish, cost-sharing policy differs by state, service, and provider type, and changes over time. CMS states that it is necessary for providers nationally to provide evidence of state liability when claiming Medicare bad debt.
- CMS exceeded its authority by requiring enrollment of providers and suppliers who would otherwise be excluded from Medicaid enrollment such as for violations of various state criminal laws. The response indicates that states do not need to enroll eligible Medicare-enrolled providers and suppliers for all purposes on par with Medicaid providers and suppliers that get paid by the state for furnishing state plan services. CMS denies and revokes a provider or supplier's Medicare-enrollment based upon certain state or federal felony convictions.

CMS is finalizing its proposal effective January 1, 2023.

In the proposed rule, CMS indicated that it considered addressing a related concern in future rulemaking. Some Medicare providers have been unable to get states to make cost-sharing payments for items or services that would not be covered under the Medicaid state plan. For example, Medicaid may deny payment for an item or service that exceeds Medicaid day limits or other conditions for payment but does not exceed Medicare day limits or conditions**.** CMS requested feedback from stakeholders on this practice and asked for specific examples. Several commenters support requiring states to process claims for Medicare cost-sharing without requiring that the claim meet the Medicaid state plan coverage and payment rules for that service. None commented in opposition. CMS will continue to consider this issue for future rulemaking.

Regulatory Impact Analysis. CMS is unable to estimate the impact of the proposal because of the variation in state policies, but provides some contextual information for each of the three areas where this provision would have impact. Based on this context, it expects that the savings to providers, CMS, and other federal agencies in avoiding bad debt appeals would far exceed the costs to providers and suppliers and Medicaid agencies of enrolling new providers into states' systems.

- Updating State Medicaid systems with other provider types and cost-sharing logic. CMS has no sound basis upon to determine how many states would need to make system updates to implement this policy. CMS estimates it would take a maximum of 6 months and 960 hours at a rate of $44.53 per hour to make the necessary system changes or $42,749 (960 x $44.853). As this policy is effective January 1, 2023, states will have 17 months from the release of the final rule until the effective date to make the necessary changes.

- New providers and suppliers enrolling in state Medicaid systems. CMS is uncertain how many providers and suppliers will need to enroll as a result of this policy. CMS estimates enrollment will take an average of three hours of an office manager's time at $28.91 per hour. For every 100 providers and suppliers that apply to enroll in Medicaid, the estimated cost would be $8,673 ($28.91 x 3 x 100). CMS estimates the same costs to the state for processing enrollment applications.
- Reducing Medicare bad debt appeals. The policy would reduce the costs of bad debt appeals for both providers and CMS by ensuring that more providers are able to claim Medicare bad debt. While CMS cannot predict the outcome of future appeals and litigation, "Select Specialty Hospital – Denver, et al v. Azar" involved 77 providers in 26 states where CMS paid a total of $23.6 million for bad debt claims that were denied from 2005 to 2010. There are currently 20 open cases on the same issue with the amount in controversy of $17.2 million.

B. Medicare Shared Savings Program

CMS finalizes its proposal that a Shared Savings Program ACO, prior to advancing along the program's BASIC track "glide path" towards increased risk bearing for performance year (PY) 2022, may elect to remain at its PY 2021 glide path level for PY 2022. An ACO electing to "freeze" for PY 2022 will automatically be advanced for PY 2023 to the glide path level at which the ACO would have participated during PY 2023, absent the option to freeze for PY 2022 (i.e., the ACO will advance one step towards increased risk assumption). ACOs also have the option to advance more quickly along the glide path to assume increased risk for PY 2022, as they do for all PYs under established policy (i.e., skip ahead one or more levels).

The automatic advancement will be cumulative for ACOs that also elected to freeze for PY 2021 when that option was offered through the May 2020 COVID IFC. An ACO electing to freeze for PYs 2021 and 2022, will be advanced two steps along the glide path for PY 2023. An ACO who elects to freeze at a level that does not require two-sided risk bearing will not be required to establish a repayment mechanism for the PY corresponding to that freeze.

CMS also finalizes as proposed several regulation text changes to accommodate the freeze option for PY 2022 and to correct a cross-reference error.

CMS reviews comments received. Commenters were nearly universally supportive of the second freeze option. Many, however, opposed any automatic advancement upon return to the glide path for PY 2023, regardless of having chosen to freeze in place for one or two years, wishing to return at only a single step advancement from their PY 2022 levels. Commenters cited ongoing financial challenges related to continued ACO disruptions by the COVID-19 PHE and its downstream effects on their assigned beneficiaries, stating that more time was needed for ACOs to recover financially before being required to accept a higher level of risk bearing.

CMS disagrees and declines to modify the policy as proposed and finalized. CMS notes that 75 percent of all ACOs participating on the BASIC track for PY 2021 (combining all five BASIC track levels) are in a second or subsequent Shared Savings Program agreement period and have multiple years of operational experience. The agency believes that such ACOs should be able to

handle automatic advancement for PY 2023. CMS estimates a net $90 million reduction in federal spending due to the PY 2022 freeze option, related to retention of ACOs in the program and the decrease in the amount of shared savings that will be earned by ACOs participating at lower risk/reward levels.

XI. MedPAC Recommendations

In its March 2021 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by 2.0 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)." CMS responded that consistent with the statute, it is establishing an applicable percentage increase for FY 2022 of 2.0 percent (before application of the documentation and coding and other adjustments), provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. CMS does not have the authority to establish HVIP.

TABLE I
CHANGES TO IPPS OPERATING COSTS FOR FY 2022

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights & DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
All Hospitals	3,195	2.5	0.0	0.0	0.0	0.0	0.2	0.1	2.6
By Geographic Location:									
Urban hospitals	2,459	2.5	0.0	0.0	-0.1	0.0	0.2	0.1	2.6
Rural hospitals	736	2.2	0.1	0.2	1.3	-0.2	0.0	0.1	2.8
Bed Size (Urban):									
0-99 beds	634	2.4	0.0	0.1	-0.6	0.1	0.2	0.3	2.7
100-199 beds	754	2.5	0.0	0.0	-0.2	0.2	0.2	0.2	2.6
200-299 beds	427	2.5	0.0	0.1	0.2	0.0	0.2	0.1	2.4
300-499 beds	421	2.5	0.0	0.0	0.1	0.0	0.1	0.1	2.6
500 or more beds	223	2.5	0.0	-0.1	-0.3	0.0	0.2	0.0	2.6
Bed Size (Rural):									
0-49 beds	311	2.1	0.1	0.3	0.7	-0.1	0.0	0.2	4.3
50-99 beds	253	2.1	0.1	0.2	0.8	-0.1	0.0	0.2	2.4
100-149 beds	94	2.2	0.1	0.2	1.3	-0.2	0.0	0.0	2.5
150-199 beds	39	2.3	0.0	0.2	1.6	-0.2	0.0	0.1	2.6
200 or more beds	39	2.3	0.0	0.3	2.0	-0.3	0.0	0.0	2.8
Urban by Region:									
New England	112	2.5	0.0	-1.0	0.8	3.7	0.6	0.1	2.7
Middle Atlantic	304	2.5	0.0	-0.2	0.3	-0.4	0.5	0.2	2.5
East North Central	381	2.5	0.0	-0.2	-0.2	-0.4	0.0	0.0	2.4
West North Central	160	2.4	-0.1	0.2	-0.6	-0.3	0.0	0.6	2.7
South Atlantic	402	2.5	0.0	0.3	-0.5	-0.3	0.2	0.0	2.9
East South Central	144	2.5	0.0	0.1	-0.3	-0.3	0.0	0.0	2.5
West South Central	364	2.5	0.0	-0.3	-0.5	-0.3	0.0	0.0	2.3
Mountain	172	2.4	0.0	0.2	0.1	-0.1	0.0	0.2	2.6
Pacific	370	2.4	-0.1	0.5	0.2	0.4	0.0	0.1	2.5
Puerto Rico	50	2.5	-0.5	-0.3	-1.0	0.2	0.0	0.1	1.7
Rural by Region:									
New England	19	2.3	0.0	-0.4	1.3	-0.3	0.2	0.0	3.4
Middle Atlantic	50	2.2	0.1	0.3	1.0	-0.2	0.0	0.0	2.6
East North Central	113	2.2	0.1	0.2	0.9	-0.1	0.0	0.0	2.2
West North Central	89	2.1	0.0	0.1	0.3	-0.1	0.0	0.2	2.8
South Atlantic	114	2.2	0.1	1.1	1.6	-0.2	0.0	0.0	3.0

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights & DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
East South Central	144	2.4	0.1	-0.1	1.8	-0.3	0.0	0.1	2.6
West South Central	135	2.2	0.1	0.0	2.8	-0.3	0.0	0.0	3.0
Mountain	48	1.9	0.0	0.6	-0.1	-0.1	0.0	0.8	1.9
Pacific	24	2.1	0.0	-0.1	1.1	-0.1	0.0	0.0	5.2
By Payment Classification:									
Urban hospitals	1,983	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6
Rural areas	1,212	2.4	0.0	0.0	0.9	-0.3	0.1	0.1	2.6
Teaching Status:									
Nonteaching	2,031	2.4	0.0	0.2	0.1	0.1	0.1	0.1	2.7
Fewer than 100 residents	907	2.5	0.0	0.0	0.1	-0.1	0.2	0.2	2.5
100 or more residents	257	2.4	0.0	-0.1	-0.2	0.0	0.2	0.0	2.6
Urban DSH:									
Non-DSH	502	2.5	0.0	0.0	-0.6	0.0	0.3	0.2	2.6
100 or more beds	1,227	2.5	0.0	0.0	-0.6	0.2	0.2	0.1	2.6
Less than 100 beds	348	2.5	0.0	0.1	-0.5	0.2	0.1	0.2	2.7
Rural DSH:									
SCH	265	2.0	0.0	0.1	0.2	0.0	0.0	0.1	2.5
RRC	608	2.4	0.0	0.0	1.0	-0.3	0.1	0.1	2.6
100 or more beds	30	2.5	0.1	-0.1	0.1	-0.4	0.0	0.0	1.5
Less than 100 beds	215	2.3	0.1	0.3	1.0	-0.3	0.0	0.2	3.2
Urban teaching and DSH:									
Both teaching and DSH	679	2.5	0.0	-0.1	-0.6	0.1	0.3	0.1	2.6
Teaching and no DSH	74	2.5	0.0	-0.1	-0.9	0.6	0.4	0.2	2.4
No teaching and DSH	896	2.5	0.0	0.2	-0.5	0.4	0.1	0.1	2.6
No teaching and no DSH	334	2.5	0.0	0.1	-0.6	-0.2	0.3	0.3	2.6
Special Hospital Types:									
RRC	523	2.5	0.0	0.0	1.0	-0.4	0.1	0.1	2.6
SCH	305	2.0	0.0	0.1	0.1	0.0	0.0	0.0	2.5
MDH	153	2.2	0.1	0.0	0.0	-0.2	0.1	0.1	2.6
SCH and RRC	154	2.1	0.0	0.1	0.5	-0.1	0.0	0.0	2.2
MDH and RRC	27	2.2	0.0	0.0	0.7	-0.2	0.1	0.0	2.2
Type of Ownership:									
Voluntary	1,881	2.5	0.0	-0.1	0.1	0.0	0.2	0.1	2.6
Proprietary	828	2.5	0.0	0.1	-0.1	0.1	0.1	0.1	2.6
Government	486	2.4	0.0	0.2	-0.3	-0.1	0.0	0.0	2.5
Medicare Utilization as a Percent of Inpatient Days:									

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2022 Weights & DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Imputed Floor Wage Index (6)[7]	Application of the Frontier State Wage Index and Outmigration Adjustment (7)[8]	All FY 2022 Changes (8)[9]
0-25	643	2.5	0.0	0.1	-0.6	-0.2	0.0	0.0	2.5
25-50	2,110	2.5	0.0	0.0	0.1	0.0	0.2	0.1	2.6
50-65	367	2.4	0.0	-0.1	0.2	0.3	0.3	0.2	2.2
Over 65	50	2.3	0.1	0.3	-0.7	-0.3	0.3	0.1	3.7
FY 2022 Reclassifications:									
All Reclassified Hospitals	934	2.4	0.0	0.0	1.2	-0.3	0.1	0.1	2.6
Non-Reclassified Hospitals	2,261	2.5	0.0	0.0	-0.9	0.2	0.2	0.2	2.6
Urban Hospitals Reclassified	749	2.4	0.0	0.0	1.1	-0.3	0.1	0.1	2.5
Urban Non-Reclassified Hospitals	1,723	2.5	0.0	0.0	-1.1	0.3	0.3	0.1	2.6
Rural Hospitals Reclassified Full Year	300	2.2	0.1	0.2	2.0	-0.2	0.0	0.0	2.5
Rural Non-Reclassified Hospitals Full Year	423	2.2	0.1	0.2	0.0	-0.2	0.0	0.2	3.3
All Section 401 Reclassified Hospitals	532	2.4	0.0	0.0	0.8	-0.3	0.1	0.1	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.3	0.1	0.0	2.4	-0.3	0.2	0.0	3.1

[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 2.0 percent update to the national standardized amount and the hospital-specific rate (the estimated 2.7 percent market basket update reduced by 0.7 percentage point for the productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required undersection 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 39 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data as the best available 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 1.000107 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2018 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 accordancewith section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000712.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2022 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2022. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.986737.

[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 0.992868.

[6] This column displays the effects of the imputed rural floor for all-urban states provided for under section 1886(d)(3)(E)(iv) of the Act. This is not a budget neutral policy.

[8] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section1886(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.

[9] This column shows the estimated change in payments from FY 2021 to FY 2022. This column includes the effects of the continued policy of increasing the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the lowest quartile wage index adjustment), the extended transition policy to place a 5-percent cap on any decrease in a hospital's wage index from itsfinal wage index in FY 2021 (that is, the 5-percent cap), and the associated budget neutrality factors. This column reflects the budget neutrality factor of 0.998035 for the lowest quartile wage index adjustment and the budget neutrality factor of 0.99987 for the 5-percent cap for FY 2022.