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SUMMARY
Fiscal Year 2022 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule

On April 27, 2021 the Centers for Medicare & Medicaid Services (CMS) released its proposed 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 proposed rule will be published in the *Federal Register* on May 10, 2021. **The public comment period ends at 5:00 PM on June 28, 2021**.

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1752-P) 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 proposed 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. There are also several requests for information (RFI) on quality measures, interoperability and health equities.

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

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

CMS estimates that policies and rates in the proposed rule would increase combined operating and capital payments to approximately 3,198 acute care hospitals paid under the IPPS by about $3.4 billion in FY 2022 or 2.8 percent. This increase accounts for the increase in operating and capital IPPS payments, increases in payment due to the imputed floor, new medical technology add-on payments and other proposed changes. CMS estimates that uncompensated care payments will decline by $0.9 billion reducing the overall increase to $2.5 billion.

A. Inpatient Hospital Operating Update

The proposed rule would increase IPPS operating payment *rates* by 2.8 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.8 percent rate increase is the net result of a market basket update of 2.5 percent less an annual multi-factor productivity (MFP) adjustment of 0.2 percentage points; and an adjustment of +0.5 percentage points required under section 414 of the 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 2.3 percent increase rather than a 2.8 percent increase.

Factor	Percent Change
FY 2022 Market Basket	2.5
Multifactor productivity adjustment	-0.2
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	2.8

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. For FY 2022, hospitals that choose not to participate in the IQR Program or do not successfully submit the required quality data are subject to a one-quarter reduction of the full market basket of 2.5 percent or -0.625 percentage points. The statute additionally requires that the update for any hospital that is not a meaningful EHR user be reduced by three-quarters of the market basket update or 1.875 percentage points. The update for hospitals that neither successfully participate in the IQR and are not meaningful EHR users is reduced by the full market basket increase or 2.5 percentage points.

CMS estimates that 65 hospitals will not receive the full market basket rate-of-increase because they failed the quality data submission process or chose not to participate in IQR; 105 hospitals because they are not meaningful EHR users; and 24 hospitals are estimated to be subject to both reductions.

The update for hospitals that have not successfully submitted quality data will be 1.675 percent for FY 2022. The reduction to the update is applied before application of the MACRA documentation and coding adjustment and equals the 2.3 percent market basket net of MFP less 0.625 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of 0.425 percent for FY 2022. This update is also applied before application of the MACRA documentation and coding adjustment and equals the 2.3 percent market basket net of MFP less 1.875 percentage points.

Hospitals that have neither successfully submitted quality data nor qualified as meaningful EHR users will receive an update of -0.2 percent or the 2.3 percent market basket net of MFP less 2.5 percentage points (the entire market basket).

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2022 payments increasing 2.7 percent. Not all policy changes are reflected in this total. For example, the total does not include decreases in uncompensated care payments. The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2022 increase in payment rates	+2.8[1]
Residual	-0.12[2]
Total	+2.7

[1]Weighted average of hospital-specific rate update of 2.3 and 2.8 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 proposed 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 proposed rule. The estimate may not have been particularly reliable anyway as CMS does not have any FY 2021 claims upon which to compare actual to targeted outlier payments.

Table I Impact Analysis

Detailed impact estimates are displayed in Table I of the proposed 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	2.7%
Urban	2.7%
Rural	2.9%
Major Teaching	2.7%

To the extent the impact on a given hospital category impact deviates from the national average of 2.7 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with all other hospitals. Typically, the impact would be redistributive from a policy that is budget neutral. The redistributive payment changes are reasonably modest. Nearly all of the changes are within a few tenths of a percentage point from the national average.

Other provisions having an impact include:

Rural Floor: The rural floor raises the wage index of 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 0.993988 (-0.6 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 2.7 percent increase in payments, primarily due to the application of the rural floor in Massachusetts.

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 $68 million to 44 hospitals and the out-migration adjustment that increases payments about $40 million to 184 hospitals.

New Technology Add-On Payments (NTAP). CMS is continuing NTAP payments for 23 technologies for which it estimates payments of just over $853 million in FY 2022. In addition, CMS is approving 14 (of 16) 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 $80 million in FY 2022. There are another 21 NTAP applications where CMS will make a decision in the final rule on whether the technology qualifies for NTAP payments.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 7.99 percent or about $662 million. 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 2,986 hospitals or 85 percent of all hospitals. The readmissions penalty is estimated to affect 0.68 percent of payments to the hospitals that are being penalized for excess readmissions. CMS includes an unnumbered table that illustrates the average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural, etc.) in FY 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. CMS provides an analysis by hospital category of how hospitals are affected by the HAC reduction program. By law, the penalty applies to 25 percent of all hospitals or 791 of 3,169 non-Maryland hospitals with a HAC score.

Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME). The Consolidated Appropriations Act (CAA), 2021 contained three provisions that will increase DGME and IME spending. The first one authorizes the Secretary to increase full time equivalent (FTE) resident caps by 1,000 FTEs over 5 years. The second one provides cap exemptions to

rural hospitals that participate in "rural training track" residencies that train residents to practice in rural areas. The third allows a hospital that trained a small number of residents for a short duration prior to December 27, 2020 to reset its DGME per resident amount and FTE cap. CMS provides 10-year cost estimates for each of these provisions than range from $30 million in FY 2022 to $530 million by FY 2031. More detail in these provisions is provided in section V. J.

Rural Community Hospital Demonstration Program. CMS is applying a budget neutrality adjustment for the Rural Community Hospital Demonstration Program based on $63.8 million in costs for FY 2022. For the final rule, the adjustment will be based on net costs of the demonstration in FY 2022 or total costs in FY 2022 less adjustments for updated cost estimates from prior years. Cost report information to determine the net adjustment is not available for the proposed rule. CMS is applying a budget neutrality adjustment to the IPPS standardized amounts.

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.

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. Based on the currently available data, CMS indicates that the FCHIP demonstration project was budget neutral and no adjustment to CAH payments is necessary.

Organ Acquisition Costs. CMS is proposing to only pay for organ acquisition costs on a reasonable cost basis when an organ is transplanted into a Medicare beneficiary. Cost savings of this proposal are estimated at $230 million in FY 2022 increasing to $1.74 billion over 5 years and $4.150 billion over 10 years. This estimate includes the acquisition costs for kidneys shifting from MA plans for MA beneficiaries to fee-for-service Medicare beginning January 1, 2021.

Shared Savings Program. CMS is proposing to extend the flexibility for certain ACOs to continue participating in the program without any downside risk in light of the uncertainties caused by the COVID-19 PHE. This policy is expected to retain participation among ACOs leery of taking on downside risk, or increasing levels of downside risk. The net effect of offering this flexibility is estimated to be a $90 million reduction in Federal spending. The estimated impact is roughly evenly split between net savings generated by ACOs that would have otherwise have terminated their participation in the program absent the flexibility and reduced shared savings payouts to ACOs that would elect to remain at the lower sharing rates despite the fact they would have ultimately earned – as a group - more shared savings had they transitioned to a risk arrangement.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2021:

- Hospital Submitted Quality Data and is a Meaningful EHR User (applicable percentage increase [i.e., before adjustments] = 2.3 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.675 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.425 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.2 percent)

The applicable percentage changes listed above are prior to budget neutrality factors applied to the standardized amount and other non-budget neutral adjustments pertaining to documentation and coding. The updated standardized amounts for the proposed rule were calculated applying the additional MACRA mandated documentation and coding adjustment of +0.5 percentage points for FY 2022. Additional budget neutrality adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 1.000098 (an increase of 0.01 percent);
- Wage index, 1.000277 (an increase of 0.03 percent);
- Geographic reclassification, 0.987018 (a reduction of 1.30 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.998108 or -0.19 percent;
- The outlier offset factor is 0.949 or -5.1 percent;
- The rural community hospital demonstration program adjustment is 0.999412 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, 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	2.3%
DRG Recalibration	0.01%
Wage index	0.00%
Geographic Reclassification	0.041%
25th Percentile	0.041%
Outlier	0.000%
Rural Community Hospital	-0.021%
Doc and Coding	0.500%
Net Change	3.00%

The proposed increase in the capital rate is 1.22 percent from $466.21 to $471.89. The combined proposed increase in the operating standardized amount and the capital rate will be 2.9 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).

FY 2022 PROPOSED RULE TABLES 1A-1D

TABLE 1A. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2022							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.425 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.675 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,150.84	$1,989.45	$4,074.76	$1,952.99	$4,125.48	$1,977.30	$4,049.40	$1,940.83

TABLE 1B. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX LESS THAN OR EQUAL TO 1)—FY 2022							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.425 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.675 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,806.98	$2,333.31	$3,737.21	2,290.54	$3,783.72	$2,319.06	$3,713.94	$2,276.29

TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE	
	Rate
National	$471.89

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 proposing to adopt an outlier threshold for FY 2022 of $30,967. 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 5.38 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.946676 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 December, 2020 update to the FY 2020 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data would be the December, 2020 update of the Provider-Specific File (PSF) for 2020 and 2019. However, as CMS explains elsewhere in the proposed 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.

If CMS followed its traditional methodology and used the latest data available, the FY 2022 proposed rule outlier threshold would be~~en~~ $36,483 or $5,516 higher. **CMS requests comment on whether to default to its traditional methodology of using the latest data to set the FY 2022 outlier threshold**. CMS is making the charge inflation factors, CCR adjustment factors and other information necessary to calculate the outlier threshold using the latest available data through the link provided at the beginning of this summary.

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 and uncompensated care payments but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program).

Charge Inflation. Consistent with the proposal to use data from prior to the PHE to determine the proposed 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:

FY 2018: $61,578.82 ($584,618,863,834 / 9,493,830 cases)
FY 2019: $65,522.10 ($604,209,834,327 / 9,221,466 cases)
Annual Rate of Increase: 6.4 percent (1.06404)

This charge inflation factor is multiplied by itself 3 times to determine a three-year rate of increase of 20.4 percent (1.20469).

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:
March 2019: 0.254027
March 2020: 0.247548.
% Change: -2.55 percent or 0.974495. This figure is used twice (0.974495 X 0.974495) to reflect the increase between 2020 and 2022.

Capital:
March 2019: 0.0207300
March 2020: 0.0019935.
% Change: -3.84 percent or 0.961165. This figure is used twice (0.961165 X 0.961165) to reflect the increase between 2020 and 2022.

For estimating the outlier threshold for FY 2022, CMS's calculation will reflect application of the floor on the wage index of eligible hospitals in frontier states and adjustments to the wage index for outmigration as well as increasing the wage index for hospitals with a wage index below the 25th percentile wage index value across all hospitals. Section 9831 of Public Law 117-2 enacted on March 11, 2021 restored the imputed floor adjustments to the wage index effective for FY 2022. This provision was enacted too late for CMS to reflect the new policy in modeling the outlier threshold. However, the imputed floor will be applied to determine the outlier threshold in the FY 2022 final rule.

Reconciliation. Over the course of the year, Medicare makes outlier payments based on hospital data from a prior year. Outlier reconciliation occurs when the hospital's actual CCR for the period changes from the CCR used to make outlier payments by more than 10 percentage points or the hospital receives more than $0.5 million in outlier payments. Continuing a practice began in FY 2020, CMS will reflect the potential for reconciliation in the determination of the FY 2022 outlier threshold.

For the FY 2022 outlier threshold, CMS is proposing to 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 indicated these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC for the proposed rule. For the FY 2022 proposed rule, CMS is using the December 2020 extract of the Hospital Cost Report Information System (HCRIS).

CMS is proposing to determine reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2016 for FY 2022). It is then proposing to subtract 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 proposed rule, CMS estimates that reconciliation in FY 2016 resulted in 12 hospitals being owed $12.140 million or -0.013 percent of total operating IPPS payments. This figure rounds to -0.01 percent. Subtracting -0.01 percentage points from 5.10 percent is 5.11 percent. CMS will target 5.11 percent of operating payments as outliers assuming that -0.01 percentage points of that amount will be repaid to hospitals under the reconciliation process yielding the total 5.10 percent of total IPPS payments targeted as outliers. Reconciliation will have the effect of slightly decreasing the outlier threshold ($30,967 compared to $31,027) 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. CMS proposed to include reconciled capital outlier payments in the adjustment in the same way as the percentage was calculated for operating payments. For capital, CMS estimates the ratio of reconciled outlier payments to total payments is -0.01 percent based $915,421 in reconciled capital outlier payments owed to 12 hospitals.

FY 2020 Outlier Payments. CMS' current estimate, using available FY 2020 claims data, is that actual outlier payments for FY 2020 were approximately 5.42 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 section 414 of the Medicare Access and CHIP Reauthorization Act, CMS is implementing a positive 0.5 percentage point adjustment to the standardized amount.

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.

To allow the public to better analyze and understand the impacts of the proposals in this rule, CMS is posting a test version of the ICD-10 MS-DRG GROUPER Software, Version 39 on its website. This test software reflects the proposed GROUPER logic for FY 2022; it includes the new diagnosis and procedure codes effective for FY 2022 and does not include the diagnosis codes that are invalid beginning in FY 2022. CMS is also making available a supplemental file in Table 6P.1a that includes the mapped Version 39 FY 2022 ICD-10-CM codes and the deleted Version 38 FY 2021 ICD-10-CM codes for testing purposes with users' available claims data. All this information is 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 proposes to the MS-DRGs for FY 2021. CMS proposes to use claims data from the March 2020 update of the FY 2019 MedPAR file in its analysis of proposed MS-DRG classification changes for FY 2022. Alternatively, CMS is also providing the results of its analysis of proposed MS-DRG classification changes using claims data from the September 2020 update of the FY 2020 MedPAR file. As a result, for this proposed rule, the MS-DRG analysis was based on ICD-10 claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital bills received from October 1, 2018 through March31, 2020 for discharges occurring through September 30, 2019 (CMS refers to this claims data as the "March 2020 update of the FY 2019 MedPAR file"). CMS also analyzed ICD-10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital bills from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020 (CMS refers to this claims data as the "September 2020 update 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.

The table below, reproduced from the 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.

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

For analysis of requests to create a new MS-DRG, CMS evaluates the most recent year available of MedPAR claims data. For evaluation of requests to split an existing base MS-DRG into severity levels, CMS analyzes the most recent 2 years of data. Using 2 years of data reduces changes related to an isolated year's data fluctuation. CMS first evaluates if the creation of a new CC subgroup is warranted to determine if all criteria are satisfied in a three-way split. If the criteria fail, 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.

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 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 has concerns about the impact of implementing these MS-DRGs changes and **requests comments on the following proposals:**

- Delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023; and
- For FY 2022, maintain the current structure of the 32 MS-DRGs that currently have a three-way severity level split and would have been subject to the NonCC subgroup criteria.

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 proposes rule). CMS proposes to assign these services to MS-DRG 018. CMS also proposes to revise the title for MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect that cases reporting the administration of non-CAR T-cell therapies and other immunotherapies would be assigned to MS- DRG 018.

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

In the 2021 IPPS final rule, CMS finalized its proposal to create 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 requested asked CMS to review of the assignment of eight ICD-10-PCS codes (listed in the proposed rule). As discussed in the proposed 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 and proposes to reassign these three procedure codes to MS-DRGs 143, 144, and 145 for FY 2022. CMS also proposes reassignment of 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. CMS reviewed this request and proposes to maintain the current structure for these DRGs.

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 proposed 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. CMS reviewed this request and it proposes 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).

As a result of its review, CMS proposes to reassign 26 procedure codes listed in the proposed rule (nine procedure codes describe repair of pulmonary or thoracic structures and 17 procedure codes describe procedures performed on the sternum or ribs) from MS-DRGs 166, 167, and 168 to MS-DRGs 163, 164, and 165 in MDC 04. CMS notes that its data analysis for cases reporting any of these 26 procedure codes generally have an average length of stay and average costs that are more consistent with the cases in MS-DRGs 163, 164, and 165. CMS' clinical advisors agree with the reassignment of these procedures.

Based on the results of this revies, 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' analysis shows the cases in MS-DRG 215 reporting ICD-10-PCD codes 02HA0RJ, 02HA3RJ, or 02HA4RJ is summarized in the table below (reproduced from the proposed rule). 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.

MS-DRG		**Number of Cases**	**Average Length of Stay**	**Average Costs**
215	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catherization with MCC	161	6.5	$57,285
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catherization with CC	103	3	$47,996
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catherization without CC/MCC	67	1.7	$46,352

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 proposed rule, summarizes the results from the analyses using the March 2020 update of the FY 2019 MedPAR file. The results from based on the claims data from the September 2020 update of the FY 2020 MedPAR file are similar (see table in proposed 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
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 proposes to reassign ICD-10-PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MS-DRG 215 to MS-DRGs 216, 217, 218, 219, 220 and 221.

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 is not proposing to reassign diagnosis code I21.AI from MS-DRGs 280 through 285. CMS proposes 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.
CMS discusses how a diagnosis code may define the logic for a MS-DRG assignment. The diagnosis may be listed as a principal or secondary diagnosis, a secondary diagnosis, or only as a secondary diagnosis.

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 proposed tule lists the five ICD-10-CM diagnosis codes in subcategory B33.2. Based on its analysis of GROUPER logic and input from its clinical advisors, CMS proposes 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 proposed rule provides more information about the nine ICD-10-PCS procedure codes that describe LAAC procedures.

CMS' clinical advisors reviewed this request and continue to support the current assignments. CMS proposes 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. 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 proposed rule). CMS' clinical advisors reviewed the GROUPER logic and believe this request would be better addressed by revising the surgical hierarchy in MDC 05 instead of creating new MS-DRGs. CMS proposes 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.

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 proposed rule. Based on CMS' analysis and input from its clinical advisors, CMS proposes to maintain the current assignment of procedures describing percutaneous endoscopic surgical ablation.

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.

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 removing and replacements 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 proposed 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 proposes to add the three procedure code combinations (listed in the proposed 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.

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 believes 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 is 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.

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 do not support creating new MS-DRGs for CCRT without regard to principal diagnosis (see tables in the proposed rule).

CMS concludes that depending on the number of cases in each MS-DRG, it is difficult to detect patterns of complexity and resource intensity. CMS believes 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 is not proposing to create new MS-DRGs for cases reporting CCRT.

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

CMS discusses 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 proposed rule). CMS notes the claims data demonstrates 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 recognizes 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

[3]Although the 3-year anniversary of the market entry of ANDEXXA®, after consideration of comments CMS continued the new technology add-on payments for FY 2021 (85 FR 58614 through 58615).

states it needs additional time to explore options to address low volume high-cost drugs outside of the MS-DRG. CMS is not proposing any MS-DRG changes for cases involving the administration of ANDEXXA® for FY 2022. However, CMS proposes to continue 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 proposed 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
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

CMS discusses 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 proposes to revise the structure of MS-DRGS 814, 815, and 816 (Reticuloendothelial and Immunity Disorders) by updating the logic to reflect these new codes.

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 proposed rule). Based on its review and input from

its clinical advisors, CMS concludes the claims data do not support a three-way severity split for base MS-DRG 829. CMS' clinical advisors continue to believe that procedure code 06H03DZ does not require the resources of an operating room.

CMS proposes to maintain the current structure of MS-DRGs 829 and 830. CMS notes it continues to explore alternatives on how it may restructure the current O.R. and non-O.R. designations for procedures by using the additional detail that is available in the ICD-10 claims data (discussed below).

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

a. Adding Procedure and Diagnosis Codes

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

The reader is referred to the proposed rule for a discussion of 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:

- 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 are not discussed in the proposed rule; CMS will consider these requests as part of its comprehensive review of procedure codes. The reader is referred to the proposed rule for a discussion of the 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

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

- 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. Proposed 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).

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

- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

CMS plans to continue a comprehensive CC/MC analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. **CMS continues to invite comment regarding these principles, as well as other possible ways it can incorporate meaningful indicators of clinical severity**. CMS encourages commenters to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

CMS received several requests to change the severity level designations of specific ICD-10-CM diagnosis codes. CMS will consider these individual requests as it continues its comprehensive CC/MCC analysis. CMS will provide more details in future rulemaking.

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 proposes a potential change to the severity level designations for "unspecified" ICD-10-CM diagnosis codes. For FY 2022, CMS is considering 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 states 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.

The table below, reproduced from the proposed 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 proposed 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.21.

CMS solicits 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 is 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.

b. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2021[7]

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

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

c. Proposed CC Exclusions List for FY 2021

CMS created the CC Exclusions List to preclude coding of CCs for closely related conditions; to preclude duplicative or inconsistent coding from being treated as CC's; and to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.
CMS received three requests related to the CC Exclusions List logic. The reader is referred to the proposed 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 proposed additions and deletions to the CC Exclusion list:

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

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

13. Proposed Changes to the ICD-10-CM and ICD-10-PCS Coding Systems
The following tables identify new, revised and deleted diagnosis and procedure codes for FY 2021:

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

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

14. Proposed 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 compute software for the MCE Version 38 (and ICD-10 MS-DRGs) are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS discusses requests received by November 1, 2020 to examine specific code edit lists. The interested reader is referred to the proposed 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
- Unspecified codes

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. Proposed 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). As summarized in the table below, reproduced from the proposed rule, CMS proposes 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

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.

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.

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 proposed rule).

CMS notes that for FY 2021, there are 72,621 diagnosis codes and 78,136 procedure codes. At this time, there are 147 new diagnosis codes and 106 new procedure codes finalized for FY 2022.

17. Replaced Devices Offered without Cost or with a Credit. Page 259

In the FY 2008 final rule with comment period[8], 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,[9] 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 is not proposing to add any MS-DRGs to the policy for replaced devices offered without cost or with a credit. The table below, reproduced from the proposed rule, lists the existing MS-DRGs subject to this policy

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit

MDC	MS-DRG	MS-DRG Title
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with
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
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

[8] 72 FR 47246 through 47251
[9] 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**	**MS-DRG Title**
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
MDC 5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without
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
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
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

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
MDC 5	320	Other Endovascular Cardiac Valve Procedures without MCC
MDC 8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with
MDC 8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
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
MDC 8	470	Major Joint Replacement or Reattachment of Lower Extremity without
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

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 believes that FY 2020 inpatient utilization has been significantly affected by the COVID-19 PHE. CMS is proposing 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 for the following reasons:

- FY 2020 Utilization Data is Atypical: CMS' analysis shows 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 shows that FY 2020 utilization was significantly different compared to FY 2019 utilization. CMS concludes 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 presents 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 concludes 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 Hospital Cost Report Information System (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 notes

that many FY 2019 cost reporting periods actually end in FY 2020 during the period of the COVID-19 PHE. CMS is proposing to use cost report data from the FY 2018 HCRIS file in determining the proposed FY 2022 IPPS MS-DRG relative weights

While CMS is proposing to use the FY 2019 MedPAR and FY 2018 HCRIS to set the FY 2022 MS-DRG relative weights, it is also considering continuing with its historical practice of always using the latest available data for these purposes based the public comments. To facilitate comment on this alternative for FY 2022, CMS making available the FY 2020 MedPAR file and the FY 2019 HCRIS file that it would ordinarily have provided in conjunction with the proposed rule. These files can be accessed through the link provided at the beginning of this summary.

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 9,217,828 million Medicare discharges regrouped using the proposed 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.

CMS calculates the IPPS relative weights by reducing hospital charges to cost using CCRs for 19 distinct cost centers. For FY 2022, CMS is not proposing any changes to its methodology and will calculate MS-DRG weights using national averages for the 19 CCRs. Accompanying the proposed 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 Proposed Rule Data files (HCRIS Data File FY 2022 Proposed Rule).

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

Group	FY 2021 CCR	FY 2022 CCR
Routine Days	0.422	0.421
Intensive Days	0.347	0.344
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	0.107

Group	FY 2021 CCR	FY 2022 CCR
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	0.271
Other Services	0.350	0.346

The proposed rule cost-based relative weights were normalized by an adjustment factor of 1.820783 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

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

D. Add-On 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[10]; 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.[11] 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.[12] 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

[10] 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).
[11] 84 FR 42292 through 42297; regulations at § 412.87(c) and (d)
[12] 85 FR 58736

more than 2 or 3 years. CMS uses three criteria for evaluating whether a new technology is substantially similar to an existing technology[13]:

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.

Cost Criterion.

For purposes of the cost criterion, for FY 2022, CMS included the applicable MS-DRG thresholds in the data files associated with the FY 2020 annual IPPS rules. The proposed MS-DRG thresholds applicable to FY 2023 are included in the data files associated with the FY 2022 proposed rule on the CMS website.[14]

Because of the PHE, for FY 2022 ratesetting CMS proposes 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 proposed rule). Consistent with this proposal, for the FY 2023 threshold values, CMS proposes to use FY 2019 claims data to evaluate whether the charges of the cases involving a new medical service or technology will exceed the cost thresholds.[15]

As an alternative, CMS is also considering to use FY 2020 data for FY 2022 ratesetting. If CMS finalizes this alternative approach for FY 2022, it will use FY 2020 claims data for the final thresholds for applications for new technology add-on payments for FY 2023. The threshold values calculated using the FY 2020 claims data are available on the CMS website.
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:

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[13] 74 FR 43813 and 43814
[14] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[15] CMS proposes to use FY 2019 claims data to evaluate whether the new service or technology will exceed a threshold amount that is the lesser of 75 percent of the proposed FY 2022 standardized amount or 75 percent of one standard deviation beyond the geometric mean standardized charge (using FY 2019 claims data) for all cases in the MS-DRG (using FY 2019 claims data) to which the service or technology is assigned (or the case-weighted average of all relevant MS-DRGs).
[16] 84 FR 42288 through 42292

- The totality of circumstances is considered when making a determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries.
- A determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries means the new service or technology offers:
    - A treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
    - The ability to diagnose a medical condition in a patient population where that condition is currently undetectable; the ability to diagnose a medical condition earlier than methods currently available and the evidence supports that making a diagnosis affects the management of the patient; or
    - Significant improvement in clinical outcomes relative to services or technologies previously available as demonstrated by one of the following:
        - Reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
        - Decreased rate of at least one subsequent diagnostic or therapeutic intervention;
        - Decreased number of future hospitalizations or physician visits;
        - More rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
        - Improvement in one or more activities of daily living;
        - Improved quality of life; or
        - Demonstrated greater medication adherence or compliance; or
        - The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following sources: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- The service or technology may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

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

[17] 84 FR 42297 through 42300

[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.

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 proposal to provide 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.

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

[19] 85 FR 58739 through 58742

[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.

made at the town hall meeting and written comments received by December 28, 2020. Where applicable, CMS summarizes comments at the end of each discussion of the individual applications in this proposed rule. Comments that are unrelated to the "substantial clinical improvement" criterion are not summarized in this proposed rule. Commenters can resubmit their comments in response to proposals in this proposed rule.

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

Section "X" codes are ICD-10-PCS codes used to identify new medical services and technologies. Information regarding "X" codes can be found on the CMS web site at https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html. CMS notes that after Section "X" codes have served their purpose, proposals to delete them and create new codes in the body of ICD-10-PCS would be addressed at ICD-10 Coordination and Maintenance Committee meetings. CMS also notes that codes for new technologies that are consistent with the current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure.

4. Proposed 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.

The proposals for continuing nine new technology add-on payments for technologies still considered new for FY 2022 are listed in a table in the proposed rule and summarized below.

Proposed Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments (NTAP) 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
Jafafi®	5/24/2019	10/1/2019	$4,096.21
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

As previously discussed, the data in the FY2020 MedPAR claims file was significantly impacted by the PHE; utilization of inpatient services during the PHE is markedly different from what would have been expected in the absence of the PHE. Based on this analysis, CMS proposes to use the FY 2019 MedPAR claims data for FY 2022 ratesetting. CMS also proposes to use its authority to allow for a one-year extension of new technology add-on payments for technologies that would have otherwise had these new technology add-on payments discontinued beginning with FY 2022. If CMS finalizes its alternative approach of using FY 2020 data for FY 2022 ratesetting, it will also finalize to discontinue the new technology add-on payments for these expiring technologies beginning in FY 2022. The 14 technologies impacted by these proposals are listed in a table in the proposed rule and summarized below.

Proposed 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**
Azedra®	7/30/2018	10/1/2019	$98,150
Cablivi®	2/6/2019	10/1/2019	$33,215
Elzonris™	12/21/2018	10/1/2019	$125,448.05
AndexXA™	5/3/2018	10/1/2018	$18,281.25
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.			

CMS seeks comments on the following:

- The proposal to provide for a 1-year extension of new technology add-on payments for FY 2022 for those technologies the add-on payment would otherwise be discontinued beginning with FY 2022.
- The appropriate method to determine a cost per case for technologies sold on a subscription basis, such as ContaCT. Specifically, should 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 for which the technology may be eligible for the new technology add-on payment.

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

New Technology Applications. The summary below provides a high-level discussion of 22 new technology assessment; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether these technologies meet the newness, cost and substantial clinical improvement criteria.**

a. Aidoc Briefcase of 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. There are no approved ICD-10-PCS procedure codes to identify the use of this technology; a request for approval for a unique code was submitted.

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.

CMS is concerned that the technology might not meet the substantial similarity criteria as the applicant asserted that Briefcase for ICH and Briefcase for PE as identical in all aspects and differ only with respect of the training algorithm on PE and ICH. CMS does not believe the training of the algorithm on 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).

CMS continues to be interested in comments regarding issues related to determining newness for technologies that use AI, an algorithm, or software.[21] CMS requests comments on the following:

- How technologies that use AI, an algorithm, or software, including devices classified as radiological computer aided triage and notification software and radiologic computer-assisted diagnostic software, may be considered for identifying a unique mechanism of action;
- How updates to AI, an algorithm or software would add to already approved technology or a competing technology;
- Whether software changes for an already approved technology could be considered a new mechanism of action; and
- Whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome were the same as an already approved AI new technology.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS requests more information about the methodology the applicant used to select the diagnosis codes for its cost calculations. In addition, CMS is concerned the applicant might have used a single list price of Briefcase for PE per hospital although the cost per patient can vary based on the volume of cases. CMS requests more information about the applicant's cost per case calculation, including how additional information about the search for discharges from the Healthcare Cost and Utilization Project and the total cost of the technology was calculated for each subscribing provider. CMS requests comments on whether Briefcase for PE meets the cost criterion as a subscription model in which the number of subscribers and the estimated cost per case may change over time.

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. CMS summarizes this information in the proposed rule.

[21] Also discussed in the FY 2021 IPPS final rule, 85 FR 58626.

CMS is concerned 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 is also concerned that the studies do not account for other improvements in caring for patients with suspected PE. In addition, CMS notes 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 also provided responses to questions raised during the New Technology Town Hall meeting. CMS will consider these responses when deciding whether to approve the new technology add-on payments for Briefcase for PE.

b. Amivantamab

Johnson & Johnson submitted an application for Amivantamab, a bispecific monoclonal antibody for the treatment of metastatic non-small cell lung cancer (NSCLC). The applicant stated that amivantamab 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. Amivantamab 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. The applicant is seeking a Biologics License Application (BLA) for amivantamab for these indications. The applicant submitted a request for new ICD-10-PCS procedure codes.

For the first criterion (same or similar mechanism of action), the applicant stated that the mechanism of amivantamab 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 amivantamab to affect the DRG assignment. For the third criterion (treatment of the same or similar disease or patient population), the applicant stated that amivantamab 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS raises concerns about the methodology used to calculate the appropriate threshold

and case weighted threshold value. CMS also requests additional information on the population used for the sampling of cases for the cost determination.

Substantial Clinical Improvement. CMS discusses the information provided to support the applicant assertion that amivantamab represents a substantial clinical improvement over existing technologies. This includes 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 amivantamab results appear promising and based on available data with current therapies, amivantamab 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 discusses 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 is 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.

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.[22] The applicant states that DLBCL is the most common type of NHL in the US. First-line immune-chemotherapy results in long-lasting remission in more than 50% of patients. Approximately 10 to 15% of patients with 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® would be 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

[22] 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).

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. CMS is concerned that a different production and/or dosage does not represent a different mechanism of action as compared to FDA-approved CAR T-cell therapies. It is 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 notes that the FDA label for YESCARTA and KYMRIAH does not exclude patients with r/r DLBCL so it is not clear if Breyanzi® would treat a patient population different from these CAR T-cell therapies.

Cost. CMS summarizes 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 states 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.

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.

CMS is concerned that no published studies directly compare Breyanzi® with YESCARTA and KYMRIAH, the available CAR T-cell therapies for treatment of r/r DLBCL. CMS again reiterates that the FDA label for YESCARTA and KYMRIAH does not exclude treatment of patients with r/r DLBCL. It is 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 is concerned that there is 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.

d. Ciltacabtagene autoleucel

Janssen Biotech submitted an application for Ciltacabtagene autoleucel[23], an autologous chimeric-antigen receptor T cell (CAR-T) therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma (MM). Ciltacabtagene autoleucel is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.
MM is typically characterized by neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. Introduction of new treatment options have extended the median survival of patients but most patients will relapse after first-line treatment and require further treatment. Approximately 50% of relapsed patients survive after 5 years. The applicant stated that relapsed and refractory MM (RRMM) patients who have received at least 3 prior lines of therapy lack a standard treatment option.

Newness. Ciltacabtagene autoleucel was granted Breakthrough Therapy designation in December 2019 for the treatment of patients with RRMM who have previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 antibody. The applicant submitted a BLA for ciltacabtagene autoleucel in December 2020 and has not yet received FDA approval. Cases reporting the use of Ciltacabtagene autoleucel would be coded with ICD-10-PCS codes for CAR T-cells (XW033C3 and XW043C3); the applicant submitted a request for unique ICD-10-PCS codes.

For the first criterion (same or similar mechanism of action), the applicant stated that ciltacabtagene autoleucel has a unique mechanism of action because it has two distinct binding domains that confer avidity to the BCMA antigen, a 4-1BB co-stimulatory domain and a CD3z signaling domain. Other CAR T-cell products have only one target binding domain. The applicant also discussed how the CAR T-cell's mechanism of action is different from the BCMA-target agent, Blenrep, a monoclonal antibody linked to a toxic drug. For the second criterion (same or different MS-DRG), the applicant acknowledged that ciltacabtagene autoleucel 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 stated that ciltacabtagene autoleucel is indicated for a specific population of patients with MM having received three prior therapies.

CMS notes that ciltacabtagene autoleucel may have a similar mechanism of action and treat the same or similar patients as idecabtagene vieleucel another CAR T-cell therapy targeting BCMA for which an application for new technology add-on payments was also submitted for FY 2022 (discussed below). Idecabtagene vieleucel is indicated for patients with RRMM after four or more prior lines of therapy including PI, IMiD, and an anti-CD38 antibody. **CMS is interested in information on how these two technologies may differ with respect to the substantial similarity and newness criterion, to decide if these products are substantially similar and should be considered as a single application for new technology add-on payments.**

[23] Ciltacabtagene autoleucel refers to both JNJ-4528 and LCAR-B38M, the investigational product being studied in China.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS reiterates its concerns related to the variability in provider billing and charging practices for CAR-T cell therapy and it is not sure how representative this data is for calculating a CCR for CAR T-cell therapies.

Substantial Clinical Improvement. The applicant stated that ciltacabtagene autoleucel offers a treatment option for a patient population with limited options and provides a significantly improved outcome relative to other therapies for RRMM. CMS summarizes the information provided by the applicant, including results from the CARTITUDE-1 Study, a Phase 1b/2 open-label, multicenter, multi-national study (including the U.S.) to evaluate the safety and efficacy of ciltacabtagene autoleucel and the LEGEND-2 study, an ongoing Phase1, single-arm, open-label, multicenter trial in patients with RRMM (using LCAR-B38M in China). CMS notes there are no head-to-head comparisons of ciltacabtagene autoleucel and other CAR T-cell therapies and BCMA-targeted therapies. CMS also notes that the applicant used overall response rate (ORR) data instead of overall survival (OS) data as a measure of substantial clinical improvement.

e. COSELA (trilaciclib)

GI Therapeutics submitted an application for Trilaciclib, myelopreservation therapy that has the potential to mitigate chemotherapy induced myelosuppression (CIM). Trilaciclib 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. Trilaciclib received FDA's NDA approval on February 12, 2021. The applicant stated that Trilaciclib also received Breakthrough Therapy Designation in 2019 for the mitigation of clinically significant CIM in patients with SCLC. The applicant submitted a request for a new ICD-10-PCS code.

For the first criterion (same or similar mechanism of action), the applicant stated that Trilaciclib has a unique mechanism of action as a small molecule, 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 trilaciclib 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 Trilaciclib is the only preventive therapy given as a 30-minute infusion administered prior to chemotherapy to reduce chemotherapy related side effects.

CMS notes that it believes trilaciclib appears to treat the same patient population and disease as existing therapies.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS raises concerns about the ICD-10 codes used in the analysis. CMS also raises concerns about the applicant's selection of claims to use in the analysis; it is concerned that the use of a random sample may not be appropriate to obtain the cases used for the analysis.

Substantial Clinical Improvement. The applicant asserted that Trilaciclib offers a treatment option for patients unresponsive to or ineligible for currently available treatments and improves clinical outcomes as compared to current treatments. CMS summarizes the evidence presented by the applicant. CMS is 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.

f. 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 states 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. The applicant stated that two ICD-10-PCS codes (031B3ZF and 031C3ZF) identify procedures, including the WavelinQ; the applicant submitted a request for a unique ICD-10-PCS code. 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.

CMS is concerned 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 states it is not clear that the explicit addition of the balloon angioplasty in the IFU changes the mechanism of action of the device. CMS notes that balloon dilation was performed during the procedure using Ellipsys before the change in the IFU. If the current device is substantially similar to the original version of Ellipsys, CMS believes 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. CMS also notes the applicant did not discuss differences in the mechanism of action between Ellipsys and WavelinQ.[24]

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that the as a proxy for Ellipsys cases, in addition to radial lower arm fistulas, the applicant used claims with open subclavian artery bypass to open arm vein. CMS raises concerns that this is not the most approximate proxy for Ellipsys cases.

Substantial Clinical Improvement. The applicant outlined three comparators with Ellipsys and concluded that Ellipsys provides a substantial clinical improvement: (1) percutaneous AVF with the WavelinQ (4F) EndoAVF System; (2) pAVF with the prior version of Ellipsys; and sAVF. The applicant stated that no head-to-head clinical trial is available comparing Ellipsys and WavlinQ and discusses one retrospective study that provides a comparison. To compare the Ellipsys to the previous version, the applicant compared results from the pivotal trial (19% of patients had a balloon angioplasty) with the post-market registry that included the balloon angioplasty on all patients. The applicant stated there are no studies comparing Ellipsys with sAVF and it provided comparison information based on published results from studies using sAVFs.

CMS raises several concerns with the information provided in support of substantial clinical improvement, including limitations associated with retrospective comparisons and potential bias due to single operator and/or single site design. CMS also notes that the studies used physiologic endpoints as a surrogate outcome for fistula maturity instead of clinically functional fistulas as determined by a successful 2-needle cannulation. CMS is also concerned that studies done outside the U.S. might not be generalizable to the U.S. because of difference practice patterns between European countries and the U.S.

The applicant also provided responses to questions raised during the New Technology Town Hall meeting. Another comment was also submitted in response to this meeting. CMS will consider these responses when deciding whether to approve the new technology add-on payments for Ellipsys.

g. 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[25] which was approved in 2019 and UPLIZNA which was approved in 2020.

[24] In the FY 2021 IPPS final rule, CMS concluded that WavelinQ uses a unique mechanism of action (85 FR 58702).
[25] SOLIRIS was approved for new technology add-on payment in FY 2021.

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. The applicant submitted a request for a new ICD-10-PCS code.

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 IPLIZNA are IV administered and all patients might not want this treatment.

CMS notes that UPLINA may also be a treatment option for patients with meningococcal disease. CMS also questions whether patients unwilling to receive an IV infusion constitutes a new patient population for NMOSD.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is uncertain why the national other services average CCR was used to inflate costs to charges and whether another CCR, such as a CCR for drugs or blood and blood products, would be more appropriate. CMS also notes that when a MS-DRG has fewer than 11 cases, the analysis should impute a minimum case number of 11.

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.

CMS summarizes the two recent studies and additional information submitted by the applicant. CMS is concerned that data did not demonstrate improved outcomes over existing FDA approved treatments for NMOSD even without a study. CMS is interested in comparison of

outcomes such as time to first relapse and annual relapse rate. In addition, CMS is concerned the benefits are only related to the outpatient administration of the medication and the evidence does not support clinical improvement in the inpatient setting.

h. ABECMA® (idecabtagene vicleucel)

Celgene Corporation submitted an application of idecabtagene vicleucel, a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (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 (e.g., triple-class-exposed).

Newness. Idecabtagene vicleucel received FDA approval on March 26, 2021. A single dose of idecabtagene vicleucel contains a cell suspension of 300 to 460x 106 CAR T-cells. The applicant submitted a request for unique ICD-10-PCS codes for administration of idecabtagene vicleucel and they were approved and will be effective starting October 1, 2021 (XW033L7 and XW043L7).

For the first criterion (same or similar mechanism of action), the applicant stated that idecabtagene vicleucel 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 idecabtagene vicleucel 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 idecabtagene vicleucel; 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. The applicant stated that Blenrep's mechanism of action is cell destruction via microtubule inhibition where the microtubule inhibitor is conjugated to a BCMA-specific antibody (antibody-drug conjugate).

For the second criterion (same or different MS-DRG), the applicant acknowledged that idecabtagene vicleucel 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 idecabtagene vicleucel is indicated for a specific population of patients with MM having received four prior therapies.

CMS reiterates its concern that ciltacabtagene autoleucel may have a similar mechanism of action and treat the same or similar patients to that of idecabtagene vieleucel. CMS is interested in information on how these two technologies may differ with respect to the substantial similarity and newness criterion, to decide if these products are substantially similar and should be considered as a single application for new technology add-on payments.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS reiterates its concerns related to the variability in provider billing and charging

practices for CAR-T cell therapy and it is not sure how representative this data is for calculating a CCR for CAR T-cell therapies.

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

i. 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.

The applicant stated the 2020 American Society of Hematology Guidelines recommendations for the treatment of pulmonary embolism and deep vein thrombosis includes home care, systemic pharmacological thrombolysis and procedural care. Procedure care may include open procedures as well as catheter-directed thrombolysis and percutaneous mechanical thrombectomy. The applicant noted that mechanical thrombectomy may be performed with a variety of devices. 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. The applicant submitted a request for a unique ICD-10-PCS code to identify the technology.

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® - 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 notes that the applicant did not directly address the third criterion (same or similar disease or patient population), but based on the clinical uses described in the application, CMS believes the device is intended for a patient population that is similar to the patient population treated by existing thrombectomy devices.

CMS has several concerns about whether the technology meets the substantial similarity criteria and whether it should be considered new. CMS states 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.

CMS is also concerned that the mechanism of action for the overall system is substantially similar to the components of the system. CMS notes that if it determines that the catheter and tubing are substantially similar to the predicate devices cleared May 26, 2015 (K142870) and May 3, 2018 K180939, the newness date of the INDIGO® with Lightning would correspond to those dates and therefore may not be considered new.

Cost. CMS summarizes the analysis provided to demonstrate the technology 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. CMS discusses the information provided and is concerned that the applicant relies mostly on studies of INDIGO® without Lightning to substantiate its claims regarding INDIGO® with Lightning. CMS is also concerned that the applicant did not explicitly indicate the comparator for each of its claims in support for substantial clinical improvement. CMS is concerned whether there is enough evidence to support that INDIGO® with Lightning proves a substantial clinical improvement over existing aspiration catheters from INDIGO® and existing devices.

j. Ischemia Care Respiratory and Stroke Test Kit (ISC-REST)

Ischemia Care submitted an application for ISC-REST, a test kit composed of three tests to stratify the causes of ischemic stroke by differentiating those originating in the heart (cardioembolic (CE) stroke) and those that originate in the large arteries (large artery atherosclerotic (LA) strokes), in patients that have not suffered a hemorrhagic stroke. The ISC-REST contains three tests: (1) ISCDx, (2) the QIAstat-DX Respiratory SARS-CoV-2 Panel, and (3) the QIAGEN Access Anti-SARS-CoV-2 Total Test. According to the applicant, the ISCDx differentiates between CE and LA stroke based on analysis of RNA from whole blood. The QIAstat-DX Respiratory SARS-CoV-2 Panel used for the qualitative detection and differentiation of nucleic acid from 22 respiratory pathogens, including the SARS-CoV-2 virus, from nasopharyngeal swabs. The QIAGEN Access Anti-SARS-CoV-2 Total Test detects antibodies to SARS-COV-2 in blood.

The applicant stated the primary purpose of ISC-REST is to stratify ischemic stroke patients by cause, including COVID status, to simplify care pathways to prevent a secondary stroke which is often more severe, costly, and debilitating. ISC-REST targets strokes of "unknown cause" that are diagnosed as "cryptogenic"; these represent up to 40% of all ischemic strokes.

Newness. The ISC-REST and each of the three separate tests have varying FDA authorization statuses and indications. The applicant stated they are seeking Emergency Use Authorization (EUA) from the FDA for the ISC-REST test kit; the intended indication is to provide three critical diagnostic tests in the same kit for user convenience during the PHE. The ISCDX test is available as a Laboratory Developed Test. The QIAstat-DX Respiratory SARS-CoV-2 Panel was granted an EUA on March 30, 2020. The applicant stated it did not submit a EUA request for the QIAGEN Access Anti-SARS-CoV-2 Total Test. The applicant submitted a request for approval of a unique ICD-10-PCS code.

For the first criterion (same or similar mechanism of action), the applicant stated there are no blood tests for stroke or its causes and there is no blood testing combining COVID-19 screening and causes of stroke. For the second criterion (same or different MS-DRG), the applicant stated that the ISC-REST kit would map to existing MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant stated that there are no existing technologies to stratify stoke populations by the cause.

CMS summarizes its existing regulations for evaluating the newness criterion. For add-on payments, an application must have received FDA marketing authorization by July 1 prior to the particular fiscal year.[26] In the FY 2009 IPPS final rule, CMS codified its long standing practice of how it evaluates the eligibility criteria and stated that new technologies that have not yet received FDA approval do not meet the newness criterion.[27] CMS does not believe it is appropriate to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA has determined the technology is safe and effective. In the FY 2021 IPPS final rule CMS finalized a technical clarification to indicate that the new

[26] 42 CFR 412.87(e)(2)
[27] 73 FR 48561-48563

technology must have received FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year being considered.[28]
CMS states an EUA by the FDA to allow a product for emergency use would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as it would not be considered to have FDA approval or clearance. As discussed below (section F.7.) CMS seeks comments on how data reflecting the cost of a product with an EUA should be considered for a new technology add-on payment.

CMS discusses several concerns related to the newness criteria and requests comments addressing several issues. For the first criterion, CMS is concerned that the mechanism of action of ISC-REST cannot be considered new and discusses a variety of laboratory test, including blood tests, used to diagnose stroke and COVID-19. CMS requests comments whether ISC-REST has a unique mechanism of action even if all of its test components do not individually have a unique mechanism of action. For the second criterion, CMS believes that the technology would map to the same MS-DRGs as cases involving the standard of care for ischemic stroke and cerebral infarction. For the third criterion, request comments on whether the ISC-REST kit would be used as a diagnostic aid in the treatment of similar diseases and patient populations as the current standard-of-care ischemic stroke diagnosis evaluation.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is concerned that the applicants use of private data from three hospitals is not representative of the Medicare population and because this data is not publicly available, CMS cannot verify the information.

Substantial Clinical Improvement. The applicant discussed the reasons why ISC-REST represents a substantial clinical improvement over existing technologies. The applicant's information supporting these statements includes the BASE trial, a prospective, multicenter observational sample cohort study of patients to determine if the etiology of acute ischemic stroke could be objectively determined by RNA expression from patient's blood.
CMS notes that the BASE study provides information on the ISCDx test and not the entire ISC-REST kit. CMS cannot determine the test accuracy of the ISCDx test and it also cannot determine the impact of using this test on patient care and clinical outcomes. In addition, although the applicant made claims regarding how treatment decisions are impacted with the information provided by the ISC-REST kit, no information was provided to support these statements. CMS also discusses the limitations of the information in demonstrating the substantial clinical improvement of testing for COVID-19 at the same time as testing for the cause of ischemic stroke over existing technologies. CMS discusses the published literature that concluded additional information is needed to make a connection between COVID-19 and stroke and questions how this information would improve clinical outcomes.

k. Lifileucel

Iovance Biotherapeutics submitted an application for lifileucel, a one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for treatment of patients with unresectable or metastatic melanoma. TIL therapy with lifileucel involves the adoptive cell transfer of

[28] 85 FR 58742

autologous T-cells directly isolated from the tumor tissue and expanded *ex vivo* without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of lifileucel, the TIL migrates back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens.

Newness. The applicant submitted a BLA to FDA for lifileucel as an autologous TIL immunotherapy indicated for the treatment of patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD-1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. The applicant stated that lifileucel has been granted Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug and Fast Track designations. The applicant has submitted an application for a unique ICD-10-PCS code.

For the first criterion (same or similar mechanism of action), the applicant stated that lifileucel uses a novel and distinct mechanism of action which delivers a highly customized, personalized, and targeted treatment for unresectable or metastatic melanoma. The applicant discussed the difference between this therapy and current treatments, including CAR T-cell therapies. The applicant stated that CAR T-cell therapies mainly targets only single/surface tumor antigens and TIL cell therapy targets multiple tumor antigens. For the second criterion (same or different MS-DRG), the applicant stated that CMS has not yet determined the MS-DRG mapping for cellular therapies such as lifileucel. The applicant stated that although the mechanism of action for CAR-T cell therapy is different from TIL cell therapy, the resources for the treatments are similar. For the third criterion (same or similar disease or patient population), the applicant stated that upon FDA approval, lifileucel will be the first and only cell therapy indicated for patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy.

CMS acknowledges the applicant's discussion of the differences between CAR T-cell therapies and TIL therapies. **It seeks comments on whether these differences are sufficient to differentiate the mechanism of action of TIL from CAR T-cell therapies**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant provided two sensitivity cohorts and provided multiple analyses by first using the threshold from each MS-DRG included and two additional analyses using the MS-DRG 018 threshold. CMS notes that in addition to CAR T-cell therapies it is proposing to assign other immunotherapies such as lifileucel into MS-DRG 018. CMS reiterates its concerns related to the variability in provider billing and charging practices for CAR-T cell therapy and it is not sure how representative this data is for calculating a CCR for CAR T-cell therapies. CMS is also concerned that the applicant used ICD-10 codes that are not valid diagnosis codes.

Substantial Clinical Improvement. CMS discusses the information presented by the applicant which included data from an ongoing phase 2, multicenter study (NCT02360579); an article describing the TIL manufacturing process; a presentation; an abstract; and peer-reviewed post

summary meeting presentation. CMS is concerned that the primary evidence is based on an ongoing phase two trial and that it may not be able to make conclusions from these potentially partial results. CMS reiterates its concerns about a potential for overestimating treatment effects when trials stop early or report interim results. CMS also questions the use of ORR as the primary outcome and believes this measure may not be the most appropriate measure to evaluate substantial clinical improvement because it does not capture overall survival at some later time point. CMS is also concerned about the use of historical controls.

l. Narsoplimab

Omeros Corporation submitted an application for Narsoplimab, a fully human monoclonal antibody for the treatment of HSCT-TMA also known as transplant-associated thrombotic microangiopathy (TA-TMA). According to the applicant, narsoplimab inhibits mannan-binding lectin serine protease 2 (MASP-2), the effector enzyme of the lectin pathway of the complement system and inhibits activation of the lectin pathway. Narsoplimab prevents complement-mediated inflammation and exhibits anticoagulant effects, while leaving intact the respective functions of the classical and alternative pathways of innate immunity.
The applicant stated that HSCT-TMA is a lethal complication of hematopoietic stem cell transplantation (HSCT) that results in thrombosis in the small blood vessels, leading to organ failure. The applicant stated that there are currently no FDA-approved products indicated for the treatment of HSCT-TMA.

Newness. The applicant stated that it is in the process of completing a rolling submission of a BLA to the FDA for narsoplimab for the treatment of HSCT-TMA. Narsoplimab has received Orphan Drug designation and Breakthrough Therapy Designation for the treatment of patients with HSCT-TMA who have persistent thrombotic microangiopathy despite modification of immunosuppressive therapy. The applicant has submitted a request for a unique ICD-10-CM code for HSCT-TMA and an ICD-10-PCS code for the administration of narsoplimab.

For the first criterion (same or similar mechanism of action), the applicant stated that narsoplimab is the first therapeutic to target MASP-2 and the first treatment to inhibit the lectin pathway of the complement system. The applicant stated that narsoplimab is the only drug that addresses all the components of HSCT-TMA and is the only product that inhibits complement activation and has anticoagulant activity. The applicant asserted that the mechanism of action of narsoplimab differs from that of products occasionally used off-label for treatment of HSCT-TMA. For the second criterion (same or different MS-DRG), the applicant stated that patients will be assigned to the same MS-DRGs as patients who are diagnosed with HSCT-TMA/transplant-associated thrombotic microangiopathy (TA-TMA) regardless of treatment. For the third criterion (same or similar disease or patient population), the applicant states that upon FDA approval, narsoplimab will be the first technology specifically indicated to treat HSCT-TMA patients. The applicant also discussed the FDA indications for the existing products that are used off-labeled for treatment of HSCT-TMA and the differences between HSCT-TMA and other diseases, including hemolytic uremic syndrome (HUS) and thrombocytopenic purpura (TTP).

CMS requests comments on whether narsoplimab has a unique mechanism of action and whether HSCT-TMA is a similar disease to other forms of TMA.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that the applicant only provided the primary base analysis without sensitivity scenarios and it is unable to verify the analyses submitted in the application. CMS also is concerned that the applicant included many MS-DRGs which are defined by other factors which may not be related to the intended indication for narsoplimab and therefore might not have adequately identified potential cases eligible for treatment.

Substantial Clinical Improvement. The applicant discussed the reasons why narsoplimab represents a substantial clinical improvement over existing technologies. The applicant's information supporting these statements includes an abstract of the pivotal trial (a single arm trial of 28 adult HSCT-TMA patients); nine studies to provide a historical control to the pivotal trial; and four additional citations (three case studies and one case series). CMS discusses its concerns that the information is too limited to determine substantial clinical improvement, including its inability to verify the information as the applicant only provided evidence in the form of abstracts and presentations. CMS also discusses concerns about the study design of the pivotal trial including the trial was not designed for comparisons with other treatments.
A comment was also submitted in response to the New Technology Town Hall meeting. CMS will consider this comment when deciding whether to approve the new technology add-on payment.

m. NexoBrid™

Vericel Corporation submitted an application for NexoBrid™, a non-surgical, biologic option for removal of nonviable burn tissue, or eschar, in adult patients with deep partial-thickness and/or full-thickness thermal burns. According to the applicant NexoBrid™ has two components, the NexoBrid™ powder that contains the active pharmaceutical ingredient (API) which is a concentrate of proteolytic enzymes enriched in bromelain and a Gel Vehicle. The mechanism of action of NexoBrid™ is mediated by the proteolytic activity of its enzymes and is associated with selective debridement of eschar and denatured collagen while sparing healthy tissue.

Newness. The applicant submitted a BLA for NexoBrid™ and has submitted a request for an ICD-10 PCS code.

For the first criterion (same or similar mechanism of action), the applicant stated that NexoBrid™ is unique due to the bromelain active ingredient, which is extracted from the pineapple stem and a search of the FDA website did not yield any approved applications for the keywords' "bromelain" and "pineapple". For the second criterion (same or different MS-DRG), the applicant did not directly answer the question but the cost analysis included MS-DRGs that would capture burn patients. For the third criterion (same or similar disease or patient population), the applicant stated that NexoBrid™ treats the same patient population as existing approaches to eschar removal.

CMS states the applicant did not provide enough information about the composition of the proteolytic enzymes within NexoBrid™, its mechanism of action, and how the ingredients differ from other enzymatic debridement products on the market. Specifically, CMS is concerned whether the proteolytic enzyme is a type of collagenase similar to existing collagenase based enzymatic debridement products. CMS also believes that patients using NexoBrid™ would be assigned to the same MS-DRGs as patients treated for burns.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion.

Substantial Clinical Improvement. CMS summarizes the information presented by the applicant which includes information from two pivotal Phase 3 clinical trial (DETECT study). CMS has several concerns about its ability to determine substantial clinical improvement for NexoBrid™. These include the applicant's claims of superiority to standard of care debridement methods because the studies were not designed to compare NexoBrid™ to a specific surgical method or an enzymatic debridement product. CMS is also concerned that a comparison to a surgical treatment modality might not be the most appropriate comparator. CMS notes that it is unable to verify the results of the DETECT study as the data was not provided and it is not published.

n. Olumiant® (baricitinib)

Eli Lilly and Company submitted an application for Olumiant®, a Janus kinase (JAK) 1 and 2 inhibitor used in combination with remdesivir as a treatment option for COVID-19. The applicant stated that the cause of respiratory failure in COVID-19 is a hyperinflammatory state with upregulation of multiple cytokines that involve the JAK pathway which can be reversed with a JAK inhibitor. Olumiant® is FDA approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis, who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.
Newness. Olumiant® has not yet received marketing approval from FDA to treat COVID-19. It received an EUA by the FDA for treatment in combination with VEKLURY® (remdesivir) for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The applicant stated it intends to submit a supplemental new drug application (sNDA) for Olumiant®. Olumiant® is uniquely identified by ICD-10-PCS codes XW0DZM6, XW0G7M6, and XW0H7M6.

CMS reiterates its prior discussion of its existing regulations for evaluating the newness criterion (see discussion above for Ischemia Care Respiratory and Stroke Test Kit (ISC-REST)). CMS restates that an EUA by the FDA to allow a product for emergency use would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as it would not be considered to have FDA approval or clearance. As discussed below (section F.7.) CMS seeks comments on how data reflecting the cost of a product with an EUA should be considered for a new technology add-on payment. **With respect to Olumiant®, CMS requests comments on whether the newness period for this technology began on November 19, 2020, the date of its EUA and when the product became available on the market for this indication.**

In response to the PHE, CMS established the New COVID-19 Treatment Add-on Payments (NCTAP) under the IPPS for COVID-19 cases meeting certain requirements.[29] Effective for discharges occurring on or after November 2, 2020 and until the end of the PHE, CMS established the NCTAP to pay hospitals the lesser 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 case exceed the standard DRG payment, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID-19.[30] Qualifying inpatient cases using Olumiant® in combination with VEKLURY® are currently eligible for NCTAP beginning November 19, 2020 through the end of the PHE.

CMS acknowledges that there might be inpatient cases of COVID-19 beyond the end of the PHE, for which payments based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. CMS believes that the NCTAP should remain available for cases involving eligible treatments, including Olumiant® in combination with VEKLURY®, for the remainder of the fiscal year in which the PHE ends. As discussed below, CMS proposes to extend the NCTAP through the end of the fiscal year in which the PHE ends for certain products and discontinue the NCTAP for products approved for new technology add-on payments in FY 2022.

For the first criterion (same or similar mechanism of action), the applicant stated there are no JAK inhibitor therapies that have received an EUA or approval from the FDA to treat COVID-19. The applicant noted that the other therapies approved by FDA to treat COVID -19 in hospitalized patients, VEKLURY® and convalescent plasma have different mechanisms of action. For the second criterion (same or different MS-DRG), the applicant states Olumiant® would be the only JAK inhibitor therapy for patients with COVID-19 and therefore could not be assigned to the same MS-DRG as existing technologies. CMS notes that Olumiant® may map to the same MS-DRG as other existing COVID-19 treatments. For the third criterion (same or similar disease or patient population), the applicant discussed the unique characteristics of respiratory disease due to COVID-19. CMS states that Olumiant® involves the treatment of the same patient population and diseases as other treatments for COVID-19.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that Olumiant® in combination with VEKLURY® improves time to recovery, improves the odds of improvement in clinical status at Day 15 after enrollment, and reduces mortality in the treatment of COVID-19 compared to remdesivir alone. The applicant also claims that Olumiant® improves respiratory function is patients treated with corticosteroids for SARS CO-V-2 pneumonia when compared with corticosteroids alone.

[29] 85 FR 71155

[30] Additional Policy and Regulatory Revisions in Response to the COVID-19 PHE, 85 FR 71142, 71155 (November 6, 2020). https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf.

CMS summarizes the information provided which includes the results of the Adaptive COVID-19 Treatment Trial (ACTT-2), a randomized, double-blind, placebo-controlled trial sponsored by the NIH. The ACTT-2 trial included 1,033 hospitalized patients with COVIS-19 and assessed whether the combination of Olumiant® plus VEKLURY® was superior to VEKLURY® plus placebo. CMS discusses its concerns with the study including the finding of no statistically significant differences in time to recovery or odds of improvement in clinical status at Day 15 between the two patient groups for certain subgroups of patients. CMS is also concerned that the information provided in an observational study supporting improved pulmonary function in patients receiving Olumiant did not involve the treatment of Olumiant® with VEKLURY®, which is the authorized use per its EUA. CMS also discusses guidelines from the Infectious Diseases Society of America and from the NIH. The NIH guidelines state that the data is insufficient to recommend for or against Olumiant® in combination with VEKLURY®, where corticosteroids can be used instead, and there is insufficient data to recommend for or against the use of Olumiant®, in combinations with corticosteroids. CMS is interested in data regarding the use of Olumiant® in combination with VEKLURY® over corticosteroids.

CMS summarizes the applicant's responses to questions raised at the New Technology Town Hall meeting. CMS will consider this information when deciding whether to approve the new technology add-on payment.

o. 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.The applicant has submitted a request for a unique ICD-10-PCS code.
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.

CMS is concerned 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 is also concerned about what the applicant means about the ClearPath System market availability. If the ClearPath System and/or early versions of the Pure-Vu® System were considered to be available on the U.S. market and substantially similar to the current version, then the current version of the system would not be considered new. CMS is also concerned that the Pure-Vu® System is similar to other existing irrigation systems that irrigate the colon using water and gas.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes 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).

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, US-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. CMS notes 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.

p. 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[31] Regions of lnterest (ROIs). Rapid ASPECTS extracts image data for the 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

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

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. The applicant submitted a request for a unique ICD-10-PCS code.

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.

CMS is concerned that machine learning to assess CT scans and the synthesis of a single ASPECT score represented a unique mechanism of action or how the mechanism of action by which Rapid ASPECTS assesses stroke imaging is distinct from other automated imaging analysis tools, or the traditional hospital workforce.

CMS reiterates its interest in comments regarding issues related to determining newness for technologies that use AI, an algorithm, or software.[32] CMS requests comments on the following:

- How technologies that use AI, an algorithm, or software, including devices classified as radiological computer aided triage and notification software and radiologic computer-assisted diagnostic software, may be considered for identifying a unique mechanism of action;
- How updates to AI, an algorithm or software would add to already approved technology or a competing technology;
- Whether software changes for an already approved technology could be considered a new mechanism of action; and
- Whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome were the same as an already approved AI new technology.

[32] Also discussed in the FY 2021 IPPS final rule, 85 FR 58626.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that although the applicant stated it removed from its analysis cases and their assigned MS-DRGs where the assigned MS-DRG was for a body part other than the head, however the list of MS-DRGs included MS-DRGs which by definition describe procedures outside the head (MS-DRGs 37 and 38 for Extracranial Procedures).

CMS continues to request comments about the appropriate method to determine a cost per case for technologies sold on a subscription basis (as discussed above in section F.4). Specifically, should 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 for which the technology may be eligible for the new technology add-on payment.

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. CMS summarizes the information provided by the applicant which included three retrospective cohort studies (two peer-reviewed and one under review). CMS has several concerns that the information presented does not support that Rapid ASPECTS meets the substantial clinical improvement criterion. CMS is concerned 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 wonders whether individuals participating in these studies may have altered their behaviors by interacting with other computer-generated ratings. CMS is also concerned that the primary outcome is the correlation between the ASPECT scoring of experts and Rapid ASPECTS and it is not obvious how this high correlation is indicative of substantial clinical improvement. CMS also acknowledges 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.

CMS summarizes the applicant's responses to questions raised at the New Technology Town Hall meeting and comments received about the technology. CMS will consider this information when deciding whether to approve the new technology add-on payment.

q. 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. The applicant submitted a request for a new ICD-10-PCS procedure code.

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 blook volume, hypovolemic and hypotensive and patients from whom it is hard to obtain blood.

CMS is concerned that the Steripath®Micro™ ISDD® is substantially similar to the Steripath® Gen2 in that both devices utilize negative pressure and that the studies submitted to demonstrate substantial clinical improvement use the Steripath® Gen2. CMS believes the newness date for Steripath®Micro™ ISDD® would begin on February 28, 2020. CMS also requests comments on whether there are other FDA-cleared products designed to reduce blood culture contamination.
Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is concerned that the random sampling of claims that the applicant used for its analyses may be inappropriate because CMS does not agree with the applicant's assumption that Steripath®Micro™ ISDD® cases are randomly distributed across all cases identified. In addition, CMS discusses concerns about the methodology the applicant used to account for the savings from the use of Steripath®Micro™ ISDD® and it questions whether the applicant's approach accurately reflects the experience of providers and Medicare beneficiaries.

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). CMS summarizes the information provided by the applicant which included 5 peer-reviewed studies. CMS is concerned that much of the evidence supports the overall clinical value of reducing blood contamination by manual diversion over no diversion, but does 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 is concerned that the standard of care used in the studies (that is, no

diversion) is an appropriate comparator for this technology. CMS is interested in any clinical data that directly links the Steripath®Micro™ ISDD® to improved clinical outcomes. *q.*

r. 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. The applicant anticipates FDA approval for StrataGraft™ as the only skin substitute for treatment of STB classified by FDA as a biological that by promoting durable wound closure and regenerative healing. The applicant stated that the StrataGraft™ skin tissue is manufactured through organotypic culture under aseptic conditions in compliance with current Good Manufacturing Practices.

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.

CMS is 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 is interested in whether there are any dressings with a regenerative mechanism. CMS also seeks additional clarification about the population that

will be treated with StrataGraft™ skin tissue or is it intended for a subpopulation of burn patients or all patients with STB.

Cost. CMS summarizes the analysis provided to demonstrate the technology 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.

CMS is concerned about the lack of data comparing StrataGraft™ skin tissue to other biologic dressings and it again requests information about whether there are any dressings that may be approved for burns that demonstrates durable wound closure. It is also concerned that the sample size of 30 patients in STRATA2011 is sufficient to generalize the results to the Medicare population. CMS notes 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. CMS also observes that patients with 50 percent or greater TBS were excluded, but the applicant indicated the product could be especially useful for this population.

s. Tecartus™ (brexucabtagene autoleucel)(Tecartus)

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).[33] Tecartus is a single infusion product consisting of autologous T-cells engineered to express an anti-CD 19 chimeric antigen receptor. According to the applicant, this therapy targets the CD 19 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 Bruton's tyrosine kinase (BTK) inhibitor, ibrutinib, 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).

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

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 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.

CMS discusses several concerns about whether the technology meets the substantial similarity criteria and whether it should be considered new. CMS notes that both YESCARTA and KYMRIAH are CD19 directed CAR T-cell therapies used for treating patients an aggressive subtype of NHL. CMS also does not understand why the production process for Tecartus provides a unique mechanism of action. In addition, although the applicant describes differences between MCL and DLBCL, as the applicant acknowledged, patients present with similar clinical presentations and CMS is concerned that this therapy may involve treatment of a similar type of disease when compared to existing CAR T-cell therapies.
Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. As previous discussed, CMS reiterates that the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, it is uncertain how representative this data is for use in the applicant's cost analyses.

CMS requests comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS-DRG 018.

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. CMS summarizes this information in the proposed rule.

CMS discusses several concerns with the ZUMA-2 study. CMS remains concerned about the relatively small, combined sample size from the literature search and the ZUMA-2 study and remains concerned whether the sample size and research presented support extrapolating these results to the general Medicare population. CMS is 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 continues to raises issues about the lack of a direct study comparing outcomes of patients with r/r MCL treatment with Tecartus and BTK inhibitors.

t. TERLIVAZ® (terlipressin)

Mallinckrodt Pharmaceuticals submitted an application for TERLIVAZ®, a synthetic, systemic vasoconstrictor with selective activity at vasopressin-1 receptors used in the treatment of adults with hepatorenal syndrome type 1 (HRS-1). TERLIVAZ® is a pro-drug for the endogenous/natural porcine hormone lysine-vasopressin and a synthetic vasopressin analog derived from the natural/endogenous human hormone [Arg8]-vasopressin. According to the applicant, TERLIVAZ® has greater selectivity for the vasopressin receptors (v1) versus vasopressin receptors (v2) and inhibits portal hypertension with simultaneous reduction of blood circulation in portal vessels.

HRS-1 is a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced chronic liver disease (CLD). The applicant stated that there are currently no FDA-approved medications available in the U.S. indicated specifically for the treatment of HRS-1; several agents are used off-label.

Newness. The applicant stated that an NDA was filed for TERLIVAZ® in 2005 but a Complete Response Letter[34] (CRL) was issued by the FDA in November 2009. In April 2020, the applicant submitted the current NDA application as a Class 2 resubmission of the original NDA. On September 14, 2020, Mallinckrodt received a CRL from the FDA for this NDA and TERLIVAZ® has not received FDA marketing authorization. The applicant submitted a request for a unique ICD-10-PCS code for TERLIVAZ® infusion.

For the first criterion (same or similar mechanism of action), the applicant stated there are currently no FDA-approved treatment for HRS-1 that have a mechanism of action of selectivity for vasopressin V1 receptors. The applicant compared the characteristics of TERLIVAZ® with the other drugs used off-label for the treatment of HRS-1. For the second criterion (same or different MS-DRG), the applicant stated that TERLIVAZ® would be assigned to the same MS-DRG as existing technologies used to treat HRS-1. The applicant stated that the MS-DRG system does not differentiate between patients with HRS and non-HRS conditions and both TERLIVAZ® and existing technologies used to treat non-HRS conditions may be assigned to the same MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant stated TERLIVAZ® will treat the same type of disease but the applicant stated TERLIVAZ® will not treat the same or similar population when compared to existing technologies currently treating HRS-1. Although the FDA label will be indicated for patients

[34] A Complete Response Letter indicates that the review cycle for an application is complete and that the application is not ready for approval.

with HRS-1, the applicant claimed that TERLIVAZ® will offer a treatment option for HRS-1 patients that failed to respond to standard-of-care treatment options.

CMS is concerned that although TERLIVAZ® might be the first treatment specifically indicated for the treatment of HRS-1 that might not mean it is providing an unmet need for HRS-1 treatment.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is concerned that the analyses may include MS-DRGs that may not be related to the intended indication for TERLIVAZ®.

Substantial Clinical Improvement. The applicant asserted that TERLIVAZ® represents a substantial clinical improvement because the use of TERLIVAZ® is associated with a more rapid resolution of the HRS-1 disease process and a reduced rate of mortality compared to placebo, midodrine and octreotide, and norepinephrine. CMS summarizes the information provided by the applicant, including a PowerPoint presentation that discussed the results of the CONFIRM study. The CONFIRM study was a randomized, double-blind, placebo-controlled study comparing TERLIVAZ® to placebo.

CMS has several concerns with the information presented in support of substantial clinical improvement. CMS primary concern is that because no results from the CONFIRM trial have been published it lacks sufficient information to review this trial to support the applicant's assertions.

u. 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, Prior to its approval, on May 1, 202, VEKLURY® received an EUA for the treatment of suspected or laboratory confirmed COVID-19 is adults and children hospitalized with severe disease. VEKLURY® continues to have 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 has 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.

CMS notes that Olumiant® has received an EUA by the FDA for treatment in combination with VEKLURY® (remdesivir) for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients (new technology add-on payment application discussed above). In addition, CMS notes 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®. CMS reiterates its discussion about the application of new technology add-on payments for technology with EUA approval (see discussion above for Olumiant®).

Cost. CMS summarizes the analysis provided to demonstrate the technology 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. 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 notes that the articles submitted by the applicant used study design that may be subject to bias, such as the adaptive and open label design. CMS discusses several concerns with the ACTT-1 study and is concerned that VEKLURY® did not demonstrate superiority over the control. CMS summarizes the applicant's responses to questions raised at the New Technology Town Hall meeting. CMS will consider this information when deciding whether to approve the new technology add-on payment.

v. 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 states that initiation of treatment and possibly some additional infusions will be administered in the inpatient hospital setting. The applicant submitted a request for a unique 10-PCS code.

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.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that the analyses include many MS-DRGs that are defined by factors that may not be related to ZEPZELCA™ indication for metastatic SCLC.

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. CMS summarizes the information provided by the applicant which included four analyses, an epidemiology review, prescribing information, practice guidelines, a liter review inclusive of four articles, and one ZEPZELCA™ study.

CMS discusses several concerns with the information provided by the applicant. CMS is concerned the results in overall response and survival rates are 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 notes 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.

6. Proposed 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 provided for 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.[35] 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.

CMS provides background information on each application and proposes 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.

[35] 85 FR 58737 through 58742

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 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 approval for the additional indications is pending. CMS states that the newness date for the ALIF and LLIF indications would be December 3, 2020 and the TLIF indications depend on when market authorization is received. CMS agrees with the applicant that the device meets the cost criterion.

CMS proposes to approve the aprevo™ Intervertebral Body Fusion for the ALIF and LLIF, and also for the TLIF indication if the TLIF indication received FDA marketing authorization by July 1, 2021, for new technology payment for FY 2022. Based on preliminary information provided from the applicant the cost of the device is $31,500. CMS proposes the maximum new technology add-on payment for a case involving the aprevo™ Intervertebral Body Fusion would be $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. CMS agrees with the applicant that the device meets the cost criterion.

CMS proposes to approve the aScope™ Duodeno for new technology add-on payment for FY 2022. Based on preliminary information from the applicant the cost of the aScope™ Duodeno is $2,184.27 which includes the cost for the disposable sleeve, the aBox Duodno (a video process and light source) and other endoscopic accessories and equipment. Because 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 capital-related costs, CMS believes the operating cost of the aScope™ Duodeno is $1,995.

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 code. Because CMS would be unable to separately identify these cases to apply two separate payment amounts for these technologies, CMS proposes to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amounts for both technologies. For this calculation, CMS assumed the following case-weighted percentage: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. This resulted in a case-weighted average cost of $2,639.36 for both technologies. CMS proposes the maximum new technology add-on payment for a case involving these technologies would 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), so 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 described 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 item is a Class II medical device assigned to product code QJU with descriptor Image Acquistion and/or Optimization Guided by AI.

CMS agrees with the applicant that, using the cost per case provided by the applicant, the Caption Guidance™ system would meet the cost criterion for new technology add-on payments for FY 2022. Because the cost per case can vary based on utilization of the technology, CMS requests additional information on whether the Caption Guidance™ system would still meet the cost criterion, if, for instance, an increase in utilization resulted in a cost per case that is lower than the figure the applicant provided.

CMS proposes to approve the Caption Guidance™ system for new technology add-on payment for FY 2022. Based on preliminary information from the applicant the cost of the system is $2,874. CMS proposes the maximum new technology add-on payment for a case involving the Caption Guidance™ system would be $1,868.10 for FY 2022. As previously discussed, **CMS requests comments regarding its concerns about determining a cost per case for a technology subscription for its cost**. CMS may consider finalizing a different add-on payment amount after consideration of comments received.

(4) CERAMENT® G. BONESUPPORT Inc. submitted an application for CERAMENT® G. CERAMENT® G is designated as a Breakthrough Device for use as a bone-void filler as adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. CERAMENT® G has not yet received 510(k) clearance. CMS agrees that CERAMENT® G meets the cost criterion.

Subject to CERAMENT® G receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2021, CMS proposes to approve CERAMENT® G for new technology add-on payments for FY 2022. Based on preliminary information provided by the applicant the cost of CERAMENT® G is $6,020 per procedure. CMS proposes the maximum new technology add-on payment for a case involving the CERAMENT® G would be $3,913.

(5) 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 agrees with the applicant that the EXALT™ Model D meets the cost criterion.

CMS proposes to approve EXALT™ Model D Single-Use Duodenoscope for new technology add-on payments for FY 20200. As previously discussed, CMS believes that aScope™ Duodeno (discussed above) and EXALT™ Model D will share the same indication and will be identified by the same ICD-10-PCS code. Because CMS would be unable to separately identify these cases to apply two separate payment amounts for these technologies, CMS proposes to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amounts for both technologies. For this calculation, CMS assumed the following case-weighted percentage: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. This resulted in a case-weighted average cost of $2,639.36 for both technologies. CMS proposes the maximum new technology add-on payment for a case involving these technologies would 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 has not yet been granted FDA approval.

CMS discusses the cost analysis and notes that the costs of the FUJIFILM EP-7000X System do not include any operating costs. Therefore, even if the technology meets the cost criterion, it appears that 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. **CMS requests comments on whether the FUJIFILM EP-7000X System has any operating costs**. If the FUJIFILM EP-7000X System does have operating costs, since it appears to meet the cost criterion, CMS proposes to approve new technology add-on payments for only the operating costs of the FUJIFILM EP-7000X System for FY 2022, subject to the technology receiving FDA marketing authorization by July 1, 2021.

(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. The applicant noted that the proposed indication for the pending FDA marketing authorization is more expansive than the indication for the Breakthrough Device status to include patients who had a prior transcatheter intervention. CMS states that under the eligibility criteria for approval under the alternative pathway, only the Breakthrough Designation indication is eligible for the new technology add-on payment application.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is 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. Subject to the applicant adequately addressing this concern CMS agrees that the technology meets the cost criterion.

Subject to the Harmony™ System receives FDA clearance or approval for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract by July 1, 2021, CMS proposes to approve the Harmony™ System for new technology add-on payments for FY 2022. Based on preliminary information provided from the applicant the cost of the Harmony™ System is $41,500. CMS notes that the applicant indicated this cost is comprised of $33,000 for the Harmony™ TPV and $8,500 for the Harmony™ transcatheter pulmonary valve delivery and loading system. CMS requests clarification if any of these costs reflect capital equipment. If both components of the Harmony™ System are operating costs, CMS proposes the maximum new technology add-on payment for a case involving the Harmony™ System would be $26,975 for FY 2022.

(8) Neovasc Reducer™. Neovasc Inc, submitted an application for the Neovasc Reducer™ System, a permanent implant inserted percutaneously into the coronary sinus and indicated for relief of angina symptoms in patients with refractory angina. The Neovasc Reducer™ System was designated as a Breakthrough Device on October 10, 2018 for use in patients with refractory angina pectoris despite guideline-directed medical therapy who are unsuitable for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI). FDA Pre-Market Approval as a Class III medical device is pending. CMS agrees with the applicant that the Neovasc Reducer™ meets the cost criterion.

Subject to the Neovasc Reducer™ System receiving FDA marketing authorization for use in patients with refractory angina pectoris despite guideline-directed medical therapy who are unsuitable for revascularization by CABG or by PCI by July 1, 2021, CMS proposes to approve the Neovasc Reducer™ System for new technology add-on payments for FY 2022. Based on preliminary information from the applicant, the cost of the Neovasc Reducer™ is $15,000. CMS proposes that the maximum new technology add-on payment for a case involving the use of the Neovasc Reducer™ System would be $9,750 for FY 2022.

(9) Phagenyx® System. Phagenesis Ltd. Submitted an application for the Phagenyx® System, a neurostimulation device for the treatment of neurogenic dysphagia. The Phagenyx® System received Breakthrough Device designation on December 4, 2019 for use in treating neurogenic dysphagia in adult tracheotomized patients weaned from ventilation. The applicant noted the FDA De Novo application has a broader proposed indication to include the treatment of non-progressive neurogenic dysphagia in adult patients. CMS agrees with the applicant that Phagenyx® System meets the cost criterion.

Subject to the Phagenyx® System receiving FDA marketing authorization by July 1, 2020, CMS proposes to approve the Phagenyx® System for use in treating neurogenic dysphagia (the Breakthrough Designation) for new technology add-on payment for FY 2022. Based on preliminary information from the applicant, the cost of the Phagenyx® System is $5,000. CMS

proposes that the maximum new technology add-on payment for a case involving the use of the Phagenyx® System would be $3,250 for FY 2022.

(10) 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 PMA on November 24, 2020 for the Breakthrough Designation and additional indications. CMS agrees that PRCFC meets the cost criterion.

CMS proposes to approve PRCFC for new technology add-on payments for FY 2022 when used for control of massive bleeding associated with Fg deficiency. Based on preliminary information from the applicant, the cost of PRCFC is $3,900 per patient. CMS proposes that the maximum new technology add-on payment for a case involving the use of PRCFC would be $2,535 per patient for FY 2022.

(11) 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[36]) 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.

CMS believes 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 does not believe that the device is eligible for new technology add-on payments for FY 2022. CMS agrees that RECELL® meets the cost criterion.

CMS proposes to disapprove RECELL® for new technology add-on payments for FY 2022. CMS provides the following information if it receives updated information to establish that RECELL® meets the cost criterion. Based on preliminary information from the applicant, the cost per patient for RECELL® is $15,000 and the maximum new technology add-on payment for RECELL® would be $9,579 for FY 2022.

(12) 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.

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

Shockwave IVL System was designated as a Breakthrough Device in August 2019 for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. Approval by the FDA as a PMA for a Class III device is pending. CMS agrees that the Shockwave C2 IVL meets the cost criterion.

Subject to the Shockwave C2 IVL System receiving FDA marketing authorization by July 1, 2021, CMS proposes to approve the device for new technology add-on payments for FY 2022. Based on preliminary information provided by the applicant, the cost of the system for a case is $5,640. CMS proposes that the maximum new technology add-on payment for a case involving the Shockwave C2 IVL System would be $3,666 for FY 2022.

(13) Thoraflex™ Hybrid Device. Terumo Aortic submitted an application for the Thoraflex™, a single use medical device combining a gelatin-sealed woven polyester graft with a Nitinol self-expanding stent graft for the surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta. Thoraflex™ received Breakthrough Device designation March 20, 2020 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. Approval by the FDA as a PMA for a Class III device designation is pending. CMS agrees that Thoraflex™ meets the cost criterion.

Subject to Thoraflex™ receiving FDA marketing authorization by July 1, 2021, CMS proposes to approve the Thoraflex™ for new technology add-on payments for FY 2022.The applicant has not provided an estimate for the cost of the device. CMS notes that it expects the applicant to submit the cost information prior to the final rule.

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 anticipates 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.[37] If CONTEPO™ receives FDA marketing authorization before July 1, 2021, the new technology add-on payment for cases involving the use of this technology would be effective for discharges beginning after FDA marketing authorization is granted.

If CONTEPO™ receives FDA marketing authorization before July 1, 2021, the applicant indicated it would withdraw its FY 2022 application and would instead seek new technology add-on payments for CONTEPO™ for FY 2022 as a continuation of the conditional approval for FY 2021.

[37] 85 FR 58724

The applicant 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. If CONTEPO™ does not receive FDA approval by July 1, 2021, CMS proposes to conditionally approve CONTEPO™ for new technology add-on payments, subject to the technology receives FDA marketing authorization by July 1, 2022.

IF CONTEPO™ receives FDA marketing authorization before July 1, 2022, the new technology add-on payments for cases involving this technology would be effective for discharges beginning in the first quarter after FDA marketing authorization is granted. Based on preliminary information provided from the applicant the cost of the drug administered over 12.5 days is $3,500. CMS proposes a maximum new technology add-on payment for a case involving CONTEPO™ would be $2,625 for FY 2022.

(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.[38] CMS agrees that FETROJA® meets the cost criterion,
CMS proposes to approve FETROJA® for new technology add-on payments for FY 2022 when used for the treatment of HABP/VABP. Based on preliminary information provided from the applicant the cost of the drug is $11,439.79. CMS proposes a maximum new technology add-on payment for a case involving FETROJA® would be $8,579.84 for FY 2022.

(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.[39] 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 proposes to approve RECARBIO™ for new technology add-on payments for FY 2022 when used for treatment of HABP and VABP. Based on preliminary information provided from the applicant the cost of the drug is $12,768,68 when used for the treatment of HABP and VABP. CMS proposes a maximum new technology add-on payment for a case involving RECARBIO™ for these indications would be $9,576.51 for FY 2022.

[38] 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).
[39] 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).

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 allows a product for emergency use would not be considered an 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 seeks 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.

8. Proposal to Extend the New COVID-19 Treatments Add-on Payment (NCTAP) Through the End of the FY in which the PHE Ends for Certain Products and Discontinue NCTAP for Products Approved for New Technology Add-on Payments in FY 2022

In response to the PHE, CMS established the NCTAP for COVID-19 cases that meet certain criteria.[40] 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.

In order to continue to mitigate potential financial disincentives for hospitals to provide these treatments and to minimize any potential payment disruptions immediately following the end of the PHE, CMS believes that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (e.g., if the PHE were to end in FY 2022, until September 30, 2022.[41] CMS also believes that any new technology add-on payments that may be approved for a COVID-19 treatment would mitigate any potential financial issues and the NCAP would no longer be needed for that same product.

[40] 85 FD 71157 through 71558

[41] On January 22, 2021, former Acting HHS Secretary Cochran sent a letter to governors announcing that HHS has determined that the PHE will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.

CMS proposes 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 proposes 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.

Regulatory Impact. CMS proposes to continue new technology add-on payments for FY 2022 for 23 technologies. The estimated total payment would be approximately $853, 575 million for FY 2022 (a table in the proposed rule provides additional information for each technology.

CMS has not yet determined whether any of the technologies that applied under the traditional pathway discussed in this proposed rule will meet the criteria for new technology add-on payments for FY 2022 and has not estimated the potential payment of these technologies for FY 2022. Based on preliminary information from the applicants at the time of this proposed rule, CMS estimates that total payments for the 16 technologies that applied under the alternative pathway, if approved, would be approximately $80 million for FY 2022. Total estimated FY 2022 payments for new technologies that are designated as a QIDP would be approximately $58 million, and total estimated FY 2022 payments for new technologies that are part of the Breakthrough Device program would be approximately $22 million. CMS notes these estimated payments may be updated in the final rule based on revised or additional information it receives prior to the final rule.

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 proposes to incorporate the changes from Bulletin No. 20-01 into the FY 2022 labor market areas and wage indexes but notes that the updates 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 that it 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 seeks 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. 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 seeks comment on making this transition budget neutral, as is its usual practice.

B. Worksheet S-3 Wage Data

The proposed 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 2021. CMS calculates the FY 2022 wage index based on wage data of 3,159 hospitals. CMS states that the data file used to construct the final wage index includes FY 2018 data submitted to CMS as of February 5, 2021. General wage index policies are unchanged from prior years. However, CMS notes that it proposed to exclude 86 providers due to aberrant data. However, if data elements for some of these providers are corrected, CMS intends to include data from those providers in the final FY 2022 wage index.

C. Method for Computing the Unadjusted Wage Index

For the FY 2022 wage index, CMS is not proposing any changes to the steps for computing the unadjusted wage index. See 85 FR 58758 through 58761 or a detailed listing of these steps.

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 MACs (not directly to CMS), on the Excel hospital reporting form, by September 3, 2020. Data from the 2019 occupational mix survey will be used in the FY 2022 IPPS wage indexes.

CMS reports having occupational mix data for 94 percent of hospitals (2,955 of 3,159) used to determine the FY 2022 wage index. The FY 2022 national average hourly wage, unadjusted for occupational mix, is $46.42. The occupational mix adjusted national average hourly wage is $46.37.

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 49.3 percent of CBSAs overall will decrease due to application of the 2019 occupational mix survey data as

compared to the 2016 occupational mix survey data. Further, a larger percentage of urban areas (50.5 percent) than rural areas (40.4 percent) will benefit from the use of the 2019 occupational mix survey data as 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 287 urban hospitals requiring a budget neutrality adjustment factor of 0.993988 (-0.60 percent) applied to hospital wage indexes.

CMS is also continuing a policy adopted in FY 2020 not include 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.

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 that benefited hospitals in all urban states that did not benefit from the original methodology (Delaware and Rhode Island). CMS applied the imputed floor in 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 methodology—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 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 Connecticut at the time of the proposed rule).

The ARPA was enacted too late for CMS to incorporate the imputed floor wage index into the proposed rule. The final rule wage index will reflect the calculation of the imputed floor.

Frontier Floor Wage Index. The Affordable Care Act requires a wage index floor for hospitals in the low population density states of Montana, Nevada, North Dakota, South Dakota and Wyoming. CMS indicates that 44 hospitals will receive the frontier floor value of 1.0000 for FY 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 $40 million in IPPS operating payments due to the frontier floor.

Low Wage Index Hospital Policy. CMS is proposing 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 0.8418. CMS proposes to apply a budget neutrality adjustment of -0.19 percent for this policy.

G. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at: FY 2022 IPPS Proposed Rule Home Page | CMS. Select #2 under FY 2021 Proposed 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 as indicated below:

- 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 geographic area and 82 percent of the requested area.

The Medicare Geographic Classification Review Board (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, these 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 geographic area.

CMS indicates that this revised policy will be 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, the denial of the hospital's geographic reclassification may be reversed for FY 2022.

Geographic Reclassifications. There are 496 hospitals approved for wage index reclassifications

by the MGCRB starting in FY 2022. There are 245 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2020 that may continue for FY 2022, and 317 hospitals approved for wage index reclassification in FY 2021 that may continue for FY 2022. One thousand and fifty-eight hospitals are in an MGCRB reclassification status for FY 2022 (with 161 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 is 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 will be 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/LTCH 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/LTCH proposed rule, CMS is further revising 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.
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 is proposing that the Administrator can also toll the 105-day deadline for good cause.

Lugar Hospitals and Counties. A "Lugar" county is a rural county adjacent to one or more urban areas that is deemed to be part of the urban area where the highest number of its workers commute. A Lugar hospital is located in a Lugar county. 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 is 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 proposed 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 proposes to use the same policies for the FY 2022 out-migration adjustment that it has been using since FY 2012. Estimates of increased payments are $40 million in FY 2022 to 184 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.

Proposed 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 is proposing 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. Further, CMS is proposing 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 is proposing 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 will that 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 cancelled by hospitals.

K. Process for 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 at: FY 2022 Wage Index Home Page | CMS. Select file #1. This website also includes all of the public use files that CMS has made available during the wage index development process. All deadlines are eastern standard time.

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 is proposing to use a revised national labor-related share of 67.6 percent for FY 2022. 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 applying budget neutrality when applying the 62 percent labor share.

IV. Rebasing and Revising of Hospital Market Baskets

CMS is proposing 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 is also proposing 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 is proposing to move the base year from 2014 to 2018.

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 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	2.4	2.4
FY 2022	2.5	2.5
FY 2023	2.8	2.7
FY 2024	3.0	3.0
Average FY 2021 – FY 2024	**2.7**	**2.7**

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

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**

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.

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 rural hospitals that may geographically reclassify under special rules. To qualify as an RRC, a hospital must meet case-mix, discharge and other criteria. CMS annually revises 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, CMS proposes 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. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, a rural hospital with fewer than 275 beds available for use must meet the specific geographic criteria and:

- Have a CMI value for FY 2019 that is at least—
  - 1.70449 (national—all urban), or
  - The median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) for the census region in which the hospital is located. See below table.

Census Region	Proposed 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)	1.577
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

- Have at least 5,000 discharges (3,000 for an osteopathic hospital) for its cost reporting period that began during FY 2018.

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

The median regional CMIs and median regional discharges listed in the proposed rule reflect the March update of the FY 2019 MedPAR file containing data from bills received through March 2020. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its MAC.

B. Low-Volume Hospitals

1. Background

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

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

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

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

2. FY 2019 – FY 2022

Application Process. **A hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 to receive the low-volume adjustment for the federal fiscal year that begins October 1, 2021**. For a hospital whose request for low-volume hospital status is received after September 1, the MAC will apply the low-volume adjustment prospectively within 30 days of the date of a determination.

A hospital receiving the low-volume hospital payment adjustment for FY 2021 may continue to receive a low-volume hospital payment adjustment in FY 2022 by providing its MAC with a verification statement that it continues to meet the mileage criterion and provide information for the discharge criterion from its most recently submitted cost report.

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

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

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

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

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

C. Indirect Medical Education Payment Adjustment

For discharges occurring in FY 2021, CMS will continue to apply the IME adjustment factor of 5.5 percent for every approximately 10-percent increase in a hospital's resident-to-bed ratio.

D. 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 time period relative to uncompensated care costs for that same time period for all hospitals that receive Medicare DSH payments.

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

2. Proposed FY 2022 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. CMS used the Office of the Actuary's (OACT) January 2021 Medicare DSH estimates, which were based on the September 2020 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 September 2020 Medicare estimate of DSH is $14.098 billion. **The proposed Factor 1 amount is seventy-five percent of this amount or $10.573 billion.** The proposed Factor 1 for 2022 is about $805 million less than the final Factor 1 for FY 2021. OACT's estimates for FY 2022 began with a baseline of $13.931 billion in Medicare DSH expenditures for FY 2018. The table below shows the factors applied to update this baseline to the current proposed estimate for FY 2022.

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

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2019	1.0185	0.97	1.009	1.0179	1.0147	14.136
2020	1.031	0.853	1.038	1.0023	0.9150	12.933
2021	1.029	0.968	0.998	0.9754	0.9696	12.541
2022	1.028	1.075	1.005	1.0122	1.1242	14.098

- The discharge factor represents the increase in the number of Medicare FFS inpatient hospital discharges (based on Medicare claims data adjusted by a completion factor).
- The case-mix column shows the 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). The "other" column also includes a factor for Medicaid expansion due to the ACA.[42]

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.

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

[42] 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. The "Other" column also includes the estimated impacts on Medicaid enrollment; estimated increase of 2.9 percent in FY 2020 and projected to increase by an additional 1.2 percent in FY 2021.

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	2.5	0	-0.2	0.5	2.8

3. Proposed 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.[43]

For FY 2022, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2021 and 2022 is 10.2 percent and 10.1 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the proposed 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: 10.2 percent.
- Percent of individuals without insurance for CY 2021: 10.1 percent.
- Percent of individuals without insurance for FY 2022 (0.25 times 0.0102) +(0.75 times 0.0101): 10.1 percent

Proposed Factor 2 = 1-|((0.101-0.14)/0.14)| = 1- 0.2786 = 0.7214 (72.14 percent)

CMS calculated Factor 2 for the FY 2022 proposed rule to be 0.7214 or 72.14 percent, and the uncompensated care amount for FY 2022 to be $10.573 billion x 0.7214 = $7.628 billion which is about $662 million less than the FY 2021 UCP total of about $8.290 billion; the percentage decrease is 7.99 percent. The below tables show the Factor 1 and Factor 2 estimates for FY 2021 and the proposed factors for FY 2022:

[43]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 Proposed Change in UCP

	FY 2021	FY 2022	$ Change ($ in billions)	% Change
Factor 1	$11.378	$10.573	-$0.805	-7.1%
Factor 2	0.7286	0.7214	-.0072	-1.0%
UCP	$8.290	$7.628	-$0.662	-7.99%

4. Proposed 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. This policy was intended to limit year-to-year fluctuations in Factor 3 and the resulting uncompensated care payments. It also allowed CMS to transition from using low-income patient days to Worksheet S-10 to distribute uncompensated care payments.

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

Transmittal 11 issued in September, 2017[44] clarified effective October 1, 2013:

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

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

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).[45] 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).[46]

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

CMS again proposes to 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 Indian Health 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.

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

[45] 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).

[46] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

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 the revisions to the 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 uses data from the HCRIS extract updated through February 19, 2021. It intends to use the March 2021 HCRIS update for the FY 2022 final rule and the respective March updates for all future final years.

IHS and Tribal Hospitals and Subsection(d) Puerto Rico hospitals that have a FY 2013 cost report.

CMS proposes 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 proposes to 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.

c. Proposed Methodological Considerations for Calculating Factor 3

New Hospital for Purposes of Factor 3

CMS will continue to apply the new hospital policy that was initially adopted in FY 2020 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 proposes to continue its policy to treat hospitals that merge after the development of the final rule similar to new hospitals. Consistent with its policy adopted in the FY 2015 IPPS/LTCH PPS final rule, CMS proposes that the newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would 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 would annualize its data for purposes of the Factor 3 calculation. In addition, CMS continues its policy that the interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available the time of the development of the final rule. For FY 2022, this data would be the FY 2018 cost report available for the surviving CCN at the time the final rule is developed. At cost report settlement, CMS

would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2022 cost report.

Proposed CCR Trim Methodology

Consistent with its process for trimming CCRs in FY 2021, CMS proposes to 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 would calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. 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 proposed rule, the statewide average CCR would apply 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 proposes to re-calculate the hospitals uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable).

Uncompensated Care Data Trim Methodology

CMS proposes to continue the trim methodology for potentially aberrant UCC that it finalized in the FY 2019, FY 2020, and FY 2021 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2018 are an extremely high ratio (greater than 50 percent) of its total operating costs, CMS proposes that data from the FY 2019 cost report would be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2018 would be trimmed 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 proposes to apply a new trim specific to certain hospitals that 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, it proposes that 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 proposed trim would only impact hospitals that are not currently projected to be DSH eligible. If the hospital is ultimately determined to be DSH eligible at cost report settlement, then the MAC would calculate the Factor 3 after reviewing the reported uncompensated care information.

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

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

CMS proposes 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 would have to provide documentation to support a likely significant recoupment – for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000. The only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC. This does not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

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.[47]

For FY 2022, CMS is again proposing that after the publication of the FY 2022 IPPS/LTCH PPS final rule, hospitals would have 15 business days from the date of public display to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. CMS states that it currently expects to use data from the March 2021 HCRIS

[47] Comments on the list of mergers can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov.

extract for the FY 2022 final rule, which CMS states increases its confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period for this proposed rule.

Impact Analysis

The regulatory impact analysis presented in Appendix A of the proposed 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 2,378 hospitals that are projected to be eligible for DSH in FY 2022. CMS presents estimates based on its proposal to use to use FY 2018 Worksheet S-10 data to determine Factor 3.

The total amount of UCP is estimated at $7.628 billion, a 7.99 percent decrease from FY 2021 UCP (about $662 million). Changes in FY 2022 uncompensated care payments are driven by a proposed 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 7.99 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 7.99 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	-$662	-7.99%
Urban	-608	-7.79
Large Urban	-448	-9.27
Other Urban	-160	-5.37
Rural	-55	-11.27
Beds: 0-99 (Urban)	-28	-9.61
Beds: 250+ (Urban)	-382	-6.80
New England (Urban)	-28	-12.14
Middle Atlantic (Urban)	-115	-11.66
West North Central (Urban)	-34	-6.90
West South Central (Urban)	-108	-6.60
Pacific (Urban)	-81	-11.19
Major Teaching	-248	-8.33
Non-Teaching	-185	-7.55
Voluntary	-334	-7.34
Proprietary	-78	-6.40
Government	-250	-9.94

Under its proposal, rural hospitals are projected to receive a larger percentage decrease in UCP (11.27%) than urban hospitals (7.79%) in FY 2022 compared to FY 2021. Urban hospitals in the New England, the Middle Atlantic, Pacific, East South-Central regions and Puerto Rico are the most negatively affected. Rural hospitals in all regions are expected to receive larger than average decreases, except for rural hospitals in the East South Central and New England regions. The variation by teaching status is minimal and the percent change in payments is similar to the overall average payment decrease of 7.99 percent. Government hospitals are projected to receive larger than average decreases of 9.94 percent, whereas voluntary and proprietary hospitals are projected to receive a payment decrease of 7.34 and 6.40 percent, respectively.

E. 1115 Waiver Days in the Medicaid Fraction for Medicare Disproportionate Care

Some states extend medical coverage benefits under a section 1115(a) demonstration project (also referred to as a section 1115 waiver) to populations that could not have been made eligible for medical assistance under the Medicaid State plan. CMS reviews its history of when patient days of those expansion groups could be included in Medicaid inpatient days for calculating the Medicare DSH patient percentage. The proposed rule states that CMS' intent has been to include patient days of those populations who, under a demonstration project, receive benefits, including inpatient hospital coverage benefits, that are similar to the benefits provided to traditional Medicaid beneficiaries. This would not include circumstances where states extended coverage only for specific services (such as family planning) and that do not include insurance coverage for hospital care.

CMS also states that it does not believe that the uninsured patients whose costs are partially offset by uncompensated care pools can be "regarded" as being eligible for Medicaid and thus patient days paid from such pools and other similar sources should not be included in the calculation of the Medicare DSH adjustment. Likewise, CMS believes the days of patients, who under a section 115 expansion waiver, receive premium assistance (assistance used to purchase health insurance from a private entity) – should also be excluded from the calculation of the DSH calculation. CMS explains that because these individuals do not directly receive health insurance for inpatient hospital services and may have higher incomes than traditional Medicaid beneficiaries, it does not believe these days should be included in the numerator of the Medicaid fraction.

Recently, however, CMS notes that courts have decided in a series of cases (Bethesda Health, Inc. v. Azar, 980 F.3d 121 (D.C. Cir. 2020); Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019); HealthAlliance Hosps., Inc. v. Azar, 346 F. Supp. 3d 43 (D.D.C. 2018)) that, based on the current language of the regulations, CMS is required to count in the numerator of the Medicaid fraction patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration and the days of patients who receive premium assistance under a section 1115 demonstration program. These courts have concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is "eligible for inpatient hospital services" within the meaning of the current regulation.

Considering these court decisions, CMS proposes to modify its regulation to ensure that the only section 1115 days that may be counted in the numerator of the Medicaid fraction are the days of patients for whom a section 1115 waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day. Specifically, CMS proposes to revise the regulation at §412.106(b)(4)(i) to state explicitly that a patient is deemed eligible for Medicaid for the purposes of the DSH calculation on a given day, and the corresponding patient day is included in the numerator of the Medicaid fraction, only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan that includes coverage for inpatient hospital care on that day or the patient directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act. CMS proposes to remove §412.106(b)(4)(ii) in its entirety as this provision would no longer be needed.

CMS states that to the extent that this proposal has an impact on expenditures, it cannot be estimated because CMS does not have information on the number of section 1115 days by hospital.

F. Hospital Readmissions Reduction Program

In response to the impact of the COVID-19 PHE on hospitals subject to the Hospital Readmissions Reduction Program (HRRP), CMS first proposes to adopt a measure suppression policy and then apply that policy to the pneumonia readmission measure beginning with program year FY 2023.[48] CMS also makes technical specification updates to the other five program measures to exclude patients with COVID-19 secondary diagnoses. Other proposals would continue to align HRRP performance periods with MedPAR file updates and would make minor changes to regulation text.

Clarifications are provided regarding several aspects of the HRRP's Extraordinary Circumstances Exception (ECE) policy. No changes are made to the established "applicable periods" (i.e., performance periods) for FY 2023 and subsequent years or to the methodology or calculations used to determine payment adjustment factors. RFIs concerning health equity gap closure and advancement towards quality programs based on digital quality measures are presented. CMS noes that it will continue to include HRRP data in the calculations of its Overall Hospital Star Ratings.

Using the FY 2021 HRRP payment adjustment factors, in the regulatory impact analysis section of the proposed rule CMS estimates that 2,545 hospitals, or 85 percent of those eligible, will be penalized under the HRRP in FY 2022, with aggregate penalties representing 0.68 percent of payments to hospitals. (An estimated dollar total of penalties is not provided.) A table shows the variation in these impacts by hospital characteristics.

CMS provides sources for the legislative and regulatory histories of the HRRP and refers readers to the program's requirements 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-

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

Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program and the CMS QualityNet website https://qualitynet.cms.gov/inpatient/hrrp.

1. Background

The Hospital Readmissions Reduction Program (HRRP) reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level. The list of conditions to which the HRRP applies in FY 2022 is: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective total hip arthroplasty (THA)/total knee arthroplasty (TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass surgery (CABG).

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. Using the March update to the MedPAR file for a 3-year applicable period, hospitals are grouped by quintiles (five "peer groups") based on their proportions of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligible beneficiaries. Each hospital's payment adjustment is calculated using the formula shown below that compares the hospital's excess readmissions ratio (ERR)[49] to the median ERR of the hospital's peer group.
In the formula, "payment" refers to base operating DRG payments, dx refers to an HRRP condition (e.g., pneumonia, THA/TKA), and NM_M is a budget neutrality factor (neutrality modifier)[50] that is the same across all hospitals and all conditions.

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

2. Current HRRP Measures

No changes are proposed to the HRRP measure set for FY 2022 or subsequent years, shown below:

- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506),
- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505),
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF#2515),
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891),
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330), and

[49] An Excess Readmissions Ratio (ERR) is calculated for each HRRP condition as the ratio of predicted-to-expected readmissions. Predicted readmissions are the number of unplanned readmissions predicted for a hospital based on the hospital's performance and its case mix. Expected readmissions are the number of unplanned readmissions anticipated for an average hospital with a similar case mix.
[50] Using the most recently available full year of MedPAR data, CMS will compare total Medicare savings from the HRRP across all hospitals and then calculate a multiplicative factor to produce the same savings as would have occurred under the previous method (without peer grouping).

- Hospital-Level 30-Day, All-Cause Risk-960Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

Regarding the future of the HRRP and other quality programs, CMS refers readers to IX.A of this rule where the agency requests information on actions and priorities, such as incorporation of application programming interfaces (APIs) based on the Fast Healthcare Interoperability Resources (FHIR) standard, to transform the CMS quality enterprise into one that leverages digital measures and electronic information exchange. (More information about this RFI also is found in section IX.A of this summary.) A second RFI appears in section IX.B of this rule concerning approaches to closing the health equity gap in CMS quality programs, for example through methodological changes such as the use of indirectly estimated race and ethnicity data.

3. HRRP Policy Flexibility in Response to the COVID-19 PHE: Measure Suppression Policy

CMS describes the many ways in the ongoing COVID-19 pandemic continues to impact healthcare delivery and interfere with reliable quality measurement. CMS expresses particular concern that the payments and penalties of value-based programs such as the HRRP may become inequitable, especially for hospitals treating large numbers of COVID-19 patients. In response, CMS proposes to adopt a policy for the duration of the COVID-19 PHE permitting suppression of one or more quality measures in its value-based programs, to be accomplished through scoring methodology adjustments. (CMS identifies the value-based programs as follows: the HRRP, Hospital Value-Based Purchasing Program, Hospital Acquired Condition Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and ESRD Quality Incentive Program.) For a suppressed HRRP measure, CMS proposes to calculate the measure's rate for the relevant program year but then suppress the use of that rate to make hospital payment changes by weighting the suppressed measure at zero percent in the HRRP scoring methodology. Hospitals would receive confidential reports of their rates as calculated without suppression.

The policy would be invoked if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and performance scores based on those data. To guide its decision making, CMS proposes to adopt 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;

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

As an alternative to the proposed suppression policy, CMS contemplated extending the national ECE for quality data reporting during Q1 and Q2 2020 to include Q3 and Q4. CMS rejected this alternative for reasons including the downstream effects of the large data gap thus created. The alternative of making no further changes (beyond the Q1 and Q2 2020 reporting waiver already issued) and proceeding with scoring and payment adjustments as usual was also considered. CMS rejected this alternative since it would require use of flawed data would be likely to favor hospitals who treated fewer COVID-19 patients.

CMS invites comment on the following:

- **Adoption of the proposed measure suppression policy for the HRRP for the duration of the COVID-19 PHE;**
- **The proposed Measure Suppression Factors;**
- **Development of a measure suppression policy for future PHEs under which measure suppression could be activated without notice-and-comment rulemaking;**
- **Regional adjustment of measure suppression for factors such as population density; and**
- **Partial rather than total suppression of measure data.**

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

CMS proposes 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 – since the SARS-CoV-2 virus is primarily a respiratory pathogen and often causes pneumonia, and this measure focuses on readmissions for pneumonia. CMS notes that much of the applicable period for this measure for FY 2023 falls within the timeframe of the declared PHE. CMS also describes data analyses that show patients with COVID-19 readmitted for pneumonia are a distinct, severely ill subset for whom appropriate risk adjustment may not be readily accomplished. Primary diagnoses of sepsis were common and mortality rates were extremely high. Finally, CMS also conducted simulations of suppressing the pneumonia readmission measure for FY 2023 and found minimal impact on program participants -- the number of hospitals whose payments would fall due to their HRRP performances was reduced by about 5 percent.

CMS does not propose to suppress the pneumonia readmission measure for the FY 2022 program year. The agency notes that, after accounting for the nationwide ECE excluding all Q1 and Q2 2020 claims data from quality reporting and subsequent calculations, the entirety of the applicable period falls outside of the declared PHE.

4. Measure Suppression: All Other HRRP Measures

CMS' data analyses for the five remaining readmission measure conditions (AMI, CABG, COPD, HF, and THA/TKA) showed a less severe impact of COVID-19 on data validity than the pneumonia readmission measure. Further, the impact on the five could be lessened by excluding patients having secondary diagnoses of COVID-19 from their measure cohorts. CMS, therefore, will use its established subregulatory

process for HRRP technical measure specification updates to remove patients having secondary diagnoses of COVID-19 from the denominators of these five readmission measures.

5. Use of MedPAR files in the HRRP

In this rule, CMS proposes for FY 2022 to again use MedPAR claims data corresponding to the HRRP applicable period in the calculation of aggregate payments made to hospitals for excess readmissions. Specifically, the annual March MedPAR file update would be used as the data source. Until now, nearly identical policies for MedPAR data usage have been adopted annually during HRRP rulemaking; in this rule CMS proposes to make adoption of MedPAR file use for the applicable period automatic beginning with FY 2023 with subsequent automatic advancements of one year each as is done for the HRRP applicable periods.

6. ECE Policy Clarifications

CMS reprises the history of the HRRP's ECE policy, including the exceptions granted due to the COVID-19 PHE per policy to participants in Medicare's quality reporting and value-based programs through the agency's March 2020 guidance memorandum[51] and September 2020 COVID IFC (85 FR 54832 through 54833). The exceptions recognize the variations (e.g., geographic) in COVID19 PHE impacts and their potential effects on the reported data. In this proposed rule, CMS provides clarifications about operational considerations related to the exceptions as granted.

In General. CMS states that the nationwide exceptions will result in the exclusion from HRRP calculations of hospitals' performances on readmission measures for FY 2022, FY 2023, and FY 2024 of CY Q1 and Q2 2020 data. CMS notes that the exceptions are specific to claims data usage in HRRP calculations and that participating hospitals are not exempted from submitting claims for care delivered during the excepted periods. The agency clarifies that the exceptions granted relate only to claims data usage by the program and not to payment reductions under the program resulting based on nonexcepted data.

Specific for FY 2022. CMS reports simulating the exclusion of 6 months of data from HRRP calculations from the applicable period for program year FY 22 to identify changes in patterns of hospital payment and found minimal impact. CMS notes that the applicable period for calculation ERRs for that program year as adjusted for the exceptions granted and for a 30-day claims runout period would be July 1, 2017 through December 1, 2019. This period also would apply to DRG payment calculations as used in the HRRP formula. Calculation of the formula's neutrality modifier would be based on CY 2019, the most recent full year for which data are available. The usual 12-month lookback period used for risk adjustment, July 2, 2019 through June 30, 2020, would be shortened to 6 months (July 2, 2019 through December 31, 2019). CMS states that the described modifications to payment adjustment factor components for program year FY 2022 will be adopted through the existing HRRP subregulatory process for nonsubstantive updates, given the minimal impact of excepting 6 months of data as identified in the agency's simulation of data exclusion.

[51] The guidance (85 FR is found at https://www.cms.gov/files/document/guidance-memo-exceptions-and extensions-quality-reporting-and-value-based-purchasing-programs.pdf.

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

CMS requests comments on the following related to the HRRP's current measure set:

- **the possibility of confidentially reporting stratified results using indirectly estimated race and ethnicity, in addition to the currently reported results stratified using dual eligibility, and--by expansion of standardized data collection -- to additional social factors, such as language preference and disability status;**
- **the possibility of publicly reporting stratified results using both indirectly estimated race and ethnicity, and dual eligibility, on Care Compare, after at least one year of confidential reporting and further rulemaking; and**
- **possible mechanisms of incorporating other demographic characteristics into analyses that address and advance health equity, such as measuring disability status using administrative and self-reported data.**
-

By way of background, CMS first refers readers to Section IX.B of this rule for a comprehensive RFI dealing with potential strategic approaches to closing the health equity gap in the agency's quality programs before addressing potential interventions specific to the HRRP in the above comment request. CMS further describes having created the complementary Within-Hospital and Across-Hospital methods to assess disparities related to the HRRP's condition-specific readmission measures and having used the two methods to provide confidential hospital-specific reports to HRRP participants.

8. Regulation Text Update

CMS proposes to update the reference to the Hospital Compare website at §412.154 to read "Hospital Compare website or successor website" to reflect the renaming of that website as Care Compare.

G. Hospital Value-Based Purchasing Program

In response to the impact of the COVID-19 PHE on hospitals subject to the Hospital Value-Based Purchasing Program (HVBP), CMS first proposes to adopt a measure suppression policy and then apply that policy to many of the HVBP's measures for the FY 2022 program year and to one measure for FY 2023. Also proposed are a special rule for FY 2022 scoring, removal of the CMS PSI 90 measure effective with the FY 2023 program year, and minor changes to regulation text.

CMS describes technical specification updates for five measures for the FY 2023 program year and estimated measure performance standards for FY 2024 through FY 2027. Updates made to the HVBP ECE policy and exceptions granted due to the COVID-19 PHE are reprised. Tables of previously established and newly proposed baseline and performance periods for FYs 2023 through 2027 are provided. References to RFIs concerning transforming the CMS quality

programs onto digital platforms and about health equity gap closure in those same programs are provided.

No changes are made to established policies for retention and removal of HVBP measures, measure and case number minimums, or domain weights Administrative overlap areas of the HVBP with the HIQR and HAC RP are reaffirmed without change (e.g., relationship between HIQR and HVBP measures). An updated measure list for the HVBP is provided at section V.H.12 of this summary. CMS notes that HVBP measure performance data are included in the calculation of CMS' Overall Hospital Star Ratings.

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.

1. Background

Under the Hospital VBP Program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score (TPS) for a specified performance period. A hospital's VBP incentive payment adjustment factor for a fiscal year combines a uniform 2 percent contribution to the VBP incentive payment funding pool (a reduction to each hospital's base operating DRG payments) and a hospital-specific incentive payment percentage based on the hospital's TPS. The adjustment factor may be positive, negative or result in no change in the payment rate that would apply absent the program.

A VBP Program measure set is specified by CMS through rulemaking for each payment year. 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. 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.

2. HVBP Policy Flexibility in Response to the COVID-19 PHE: Measure Suppression Policy

CMS provides a discussion of its proposed measure suppression policy for its VBP programs very similar to that provided for the HRRP (see Section V.G of the rule and section V.G.3 of this summary). In response to concerns that VBP payments may become inequitable due to COVID-19 impacts, especially for hospitals treating large numbers of COVID-19 patients, CMS is proposing to adopt a policy for the duration of the PHE permitting suppression of one or more quality measures in its value-based programs, to be accomplished through scoring methodology adjustments. For a suppressed VBP measure, CMS proposes to calculate the rate for the relevant program year but then suppress use of those rates for making hospital payment changes.

Operational details of the proposed policy as applied to the HVBP are described in subsequent sections of the rule (and of this summary).

The policy would be invoked if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and performance scores based on those data. To make its determinations, CMS proposes to use the same Measure Suppression Factors as proposed for use above for the HRRP and other value-based programs, repeated below:

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

To apply the proposed measure suppression policy to the HVBP, CMS proposes for the FY 2022 payment year to suppress all of the measures in three of the four program domains -- Person and Community Engagement, Safety, and Efficiency and Cost -- and to adopt a special scoring and payment rule. Under the special rule CMS would calculate a domain score for the remaining Clinical Outcomes Domain, whose measures CMS proposes not to suppress. However, since that domain score would be the only one available and as that domain's weight is only 25 percent, CMS would not calculate TPSs for HVBP hospitals. CMS would, as usual, make the statutory 2 percent reduction to each hospital's base operating DRG payment amount. However, absent the availability of TPSs, each hospital would be assigned a value-based incentive payment percentage, application of which would be budget-neutral: returning to the hospital the amount lost through the DRG payment rate reduction (i.e., the hospital's base operating DRG payment would remain unchanged for FY 2022). Details of the proposed special scoring rule for FY 22 are reprised later in section V.H.6.a. of the rule.

CMS would still provide confidential reports to hospitals that contain performance results as if no measures had been suppressed. Operational constraints may cause those reports not to be available as early as usual but CMS anticipates to deliver the reports before CY 2021 ends. CMS proposes to publicly display Q3 and Q4 2020 hospital data accompanied by information about performance impairment due to COVID-19 effects.

In addition, CMS proposes to suppress the HVBP's pneumonia mortality measure for FY 2023 payment.[52] The rationale and operational details for suppressing this measure are discussed separately further below.

As an alternative to the proposed suppression policy, CMS contemplated extending the national ECE for quality data reporting during Q1 and Q2 2020 to include Q3 and Q4. CMS rejected this alternative for reasons including the downstream effects of the large data gap thus created. The alternative of making no further changes (beyond the Q1 and Q2 2020 reporting waiver already issued) and proceeding with scoring and payment adjustments as usual was also considered. CMS rejected this alternative since it would require use of flawed data would be likely to favor hospitals who treated fewer COVID-19 patients.

CMS ends this section of the rule by inviting comment on the following topics:

- **Adoption of the proposed measure suppression policy for the HVBP for the duration of the COVID-19 PHE;**
- **The proposed Measure Suppression Factors;**
- **Development of a measure suppression policy for future PHEs under which measure suppression could be activated without notice-and-comment rulemaking;**
- **Regional adjustment of measure suppression for factors such as population density; and**
- **Partial rather than total suppression of measure data.**

3. Proposals for Suppression of Specific HVBP Measures

CMS presents a series of proposals to suppress 7 HVBP measures for the FY 2022 payment year, listed below. The proposals are based upon analyses conducted by CMS and CDC designed to determine how measure validity has been affected by the COVID-19 PHE, excerpted below. Full details are available in section V.L.1.b of the rule.

Measure. Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166)
Domain. Person and Community Engagement Domain
Analysis. Significant top-box score declines limited to COVID-impacted quarters
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

Measure. Medicare Spending Per Beneficiary – Hospital (NQF #2158)
Domain. Efficiency and Cost Reduction
Analysis. Rapid case-mix changes, COVID-19 hospitalizations higher mortality, longer stays
Proposal. Satisfies Measure Suppression Factor 4: significant national shortages, rapid changes

Measure. National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

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

Domain. Safety
Analysis. Significant rate increases during COVID-impacted quarters
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

Measure. National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0138 (NQF #0139)
Domain. Safety
Analysis. Significant rate increases during COVID-impacted quarters
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

Measure. American College of Surgeons – Centers for Disease Control and Prevention Harmonized Procedure Specific Site Surgical Site Infection (SSI) Outcome Measure (NQF # 0753) (Colon Surgery and Abdominal Hysterectomy)
Domain. Safety
Analysis. Fall in reporting volume, most other domain measures significantly impacted
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

Measure. National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)
Domain. Safety
Analysis. Significant rate increases during COVID-impacted quarters
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

Measure. National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)
Domain. Safety
Analysis. Low reporting volume, most other domain measures significantly impacted
Proposal. Satisfies Measure Suppression Factor 1: significant deviation in national performance

CMS presents a proposal to suppress 1 HVBP measure for the FY 2023 payment year, shown below. The proposal reflects data analysis conducted by CMS designed to determine how measure validity has been affected by the COVID-19 PHE, excerpted below. Full details are available in section V.L.1.b(5) of the rule.

Measure. Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization (NQF #0468)
Domain. Clinical Outcome
Analysis. Many in measure cohort with COVID-19 as secondary diagnoses and had higher mortality. Much of performance period impacted by COVID PHE; performance period for FY 2022 without COVID-impacted quarters. Suppression with minimal hospital payment consequences (number of hospitals with payment increases falls by 1 percentage point).
Decision. Satisfies Measure Suppression Factor 2: Clinical proximity of measure's focus (mortality from pneumonia) to the COVID-19 disease's pathogen (respiratory virus)

4. Suppression-Contingent Payment Details for FY 2022

CMS reiterates that if the proposed HVBP measure suppressions are finalized, a payment reduction would be made for each HVBP hospital as required by statute but that each hospital would ultimately receive a value-based incentive payment that matches the payment reduction amount. However, if the suppression proposals are not finalized, CMS would follow the established HVBP methodology using the available data Q1 and Q2 2020 data are excepted per the ECE policy declaration for that time period.

A table in the regulatory impact analysis section shows the estimated adjustments to base operating DRG payments resulting from the FY 2022 HVBP if the suppression policy and associated proposals are not finalized. The majority of all hospitals would receive a decrease, and, on average, urban hospitals located in the New England region and rural hospitals located in the East South-Central region would have the highest positive payment changes.

CMS emphasizes the following payment details for FY 2022 should the suppression policies not be finalized:

- CMS estimates that the total amount available for FY 2022 incentive payments approximates $1.9 billion (based on December 2020 MedPAR file update data).
    - The estimate will be updated for the final rule (March 2021 data).
- Proxy value-based incentive payment adjustment factors appear in Table 16 on the website of tables associated with this proposed rule.
    - Factors are based on pre-COVID-19 PHE TPSs.
- The linear exchange function slope used for payment calculations also appears in Table 16 and is 2.6527024687.
- Table 16 will be updated as Table 16A for the IPPS/LTCH FY 2022 final rule and the linear exchange function slope will also be updated therein based pm March 2021 MedPAR file data and FY 2021 TPSs.
    - Table 16A will be updated to Table 16B after the hospitals' data review and correction period has closed.

CMS notes that if the suppression policy proposals are finalized, Table 16 will not be updated to Table 16A for the final rule nor will Table 16B be posted.

5. Removal of the CMS PSI 90 Measure

CMS proposes to remove CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531) from the HVBP measure set beginning with the FY 2023 payment year, citing removal Factor 8: the costs associated with the measure outweigh the benefits of its use. CMS notes that this measure was adopted in the FY 2018 IPPS/LTCH final rule but reporting for the measure is not required until FY 2023 (i.e., has not yet begun). This same measure is already in use in the HAC RP and including the measure in both programs appears to have little added value while consuming additional hospital and CMS resources. Measure removal from the HVBP rather than the HAC RP would be operationally easier and less confusing since required reporting has not yet started under the HVBP. CMS notes that there are 5 other measures that are

duplicated in the HBVP and HAC RP (e.g., CLABSI and CAUTI) and reaffirms its commitment to monitoring the cost-benefit ratio of each duplication, but finds no reason to propose removal of any of those 5 measures at this time.

6. Updated Technical Specifications

CMS has previously established an HVBP policy for making nonsubstantive updates to measures' technical specifications through a subregulatory process. Employing that process, in this rule CMS describes updates to be made beginning with payment year FY 2023 to exclude admissions with COVID-19 principal or secondary diagnoses from the denominators of 5 non-pneumonia HVBP Clinical Outcomes Domain measures:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230),
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558),
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893),
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229), and
- Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

When analyzing the pneumonia mortality measure for COVID-19 impacts (which led to a proposal for measure suppression for FY2023), CMS found that the cohorts for these 5 measures included some though fewer admissions with concurrent COVID-19 diagnoses than the pneumonia mortality measure cohort. Since the performance periods for these 5 measures do include all of CY 2020 and several months of CY 2021, measure results may still be subject to some COVID-19 effects. Through data simulations, CMS was able to show that these 5 measures were fairly resistant to COVID-19 impacts, leading CMS to select a strategy of continued use of the measures after excluding admissions with concurrent COVID-19 diagnoses from the measure cohorts, rather than selecting total measure suppression.

7. Baseline and Performance Periods

CMS has previously established baseline and performance periods for HVBP measures for FYs 2023 through 2027. The periods vary in length by measure, ranging from one to three years. CMS describes having reassessed these periods for potential effects resulting from the nationwide exception granted under the HVBP ECE policy in response to COVID-19 that excludes Q1 and Q2 2020 data from use in HVBP scoring due. CMS has determined changes should be made for measures having one-year baseline or performance periods that would otherwise include data from the excepted quarters. Revisions are proposed only for FY 2024 performance periods and only for certain measures, namely replacing CY 2020 baseline periods with CY 2019 baseline periods for the HCAHPS and MSPB measures as well as all 5 Patient Safety Domain measures. Although baseline periods for some measures for FY 2027 will be

shortened by the excepted months, the periods remain 30 or more months in length which CMS judges as sufficient for data reliability.

Readers are referred to Tables V.H-6 through V.H-10 in the rule that list the baseline and performance periods by measure for FYs 2023 through 2027 as previously established and without change by this rule or as previously established but having revisions proposed in this rule.

8. Performance Standards

CMS notes having previously established performance standards for HVBP payment years FYs 2022 through 2026 in prior IPPS/LTCH final rules. Several proposals made in this rule, if finalized, would change those standards (e.g., changes to measurement baseline periods). CMS provides additional information about performance standards changes 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 proposed for removal before reporting for the measure is required.
- MSPB measure standards are set based on performance year data and are not available in advance for any FY.
- For FY 2024, if the baseline period changes for measures in the Safety, Person and Community Engagement and Efficiency and Cost Reduction domains are finalized, performance standards will be based on CY 2019 data, and estimated standards are provided in Tables V.H-11 and V.H-12 of this proposed rule for these measures. Clinical Outcome domain measure standards for FY 2024 are unchanged.
- For FY 2025 and FY 2026, baseline periods for measures in the Safety and Person and Community Engagement domains for this FY have not yet been completed and benchmarks cannot be estimated. Previously established standards for Clinical Outcomes Domain measures are unchanged.
- For FY 2027, baseline periods for measures in the Safety and Person and Community Engagement for this FY have not yet been completed and benchmarks cannot be estimated. CMS provides newly established performance standards for the Clinical Outcomes Domain measures that reflect the exclusion of Q1 and Q2 2020 excepted data.

Readers are referred to Tables V.H-11 through V.H-15 in the rule and their accompanying narrative material for further details and the numerical values of the standards.

9. HVBP Extraordinary Circumstances Exception Policy Implementation During the COVID-19 PHE

CMS reprises the history of the HVBP's ECE policy and describes how the policy has been implemented thus far during the COVID-19 PHE:

- In its May 2020 IFC, CMS modified the extant ECE policy to allow exceptions to be granted 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 published supplemental guidance on March 27, 2020, wherein the agency stated that qualifying claims will be excluded form HVBP measure calculations for Q1 and Q2 2020 for the Clinical Outcomes Domain measures and the CMS PSI 90 measure.; and providers and facilities were relieved of their reporting obligations under the HVBP for HCAHPS survey measure data and the 5 NHSN safety measures data (e.g., CAUTI) for Q4 2019, Q1 2020, and Q2 2020.
- In its September 2020 IFC, CMS stipulated that the agency will not use voluntarily-submitted CY 2020 HVBP measure data from Q1 and/or Q2 2020 for HVBP scoring purposes.

CMS indicates that it will provide responses in the IPPS/LTCH FY 2022 final rule to comments received on the September 2020 IFC.

10. Regulation Text Updates

CMS proposes to replace the term QualityNet System Administrator with QualityNet security official in § 412.167(b)(5). CMS also proposes to update references to the Hospital Compare website to its successor, the Care Compare site (https://www.medicare.gov/care-compare) (§§ 412.163 through 412.164). Finally, CMS proposes to update the URL for its QualityNet website to QualityNet.cms.gov. (§ 412.165).

11. Requests for Information (RFIs)

CMS refers readers to sections IX.A and IX.B of this rule, respectively, for RFIs concerning transforming CMS' quality programs to digital platforms incorporating the Fast Healthcare Interoperability Resources (FHIR) standard and about improving data collection to better measure and analyze healthcare disparities across CMS programs such as the HVBP.

12. HVBP Measure Summary Tables

Readers are referred to Tables V.H-4 and V.H-5 of the rule hat display the HVBP measures for the FY 2022 payment year and FYs 2023-2025, respectively, if the measure proposals in this rule are finalized. This information is provided in the table below with modifications.

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**NQF #**	**2021**	**2022**	**2023/ 2024**	**2025 2026**
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 2026**
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 successor measure is to start with FY 2023 but is instead proposed for removal in FY 2023 in this rule.					

H. Hospital-Acquired Condition Reduction Program

In response to the COVID-19 PHE effects on Hospital-Acquired Condition Reduction (HAC) Program data, CMS proposes to adopt a measure suppression policy similar to that proposed for the HRRP and HVBP. CMS further proposes to suppress Q3 and Q4 CY 2020 data for the CMS PSI 90 measure and all of the National Health Safety Network (NHSN) Hospital Associated Infection (HAI) measures (CAUTI, CLABSI, SSI, MRSA bacteremia and CDI). In addition, CMS provides clarification to the HAC Program's extraordinary circumstances exception (ECE) policy as implemented to date during the PHE and describes nonsubstantive technical measure specification updates. Minor changes to regulation text are proposed. Finally, readers are referred to requests for information (RFI) concerning the potential for continued movement of CMS quality programs (including the HAC Program) to digital platforms and about closing the health equity gap in those programs (see sections IX.A and IX.B V of the rule and of this summary, respectively, for further information about the RFIs).

No changes are proposed for FY 2022 to the HAC program's measure set; program policies for measure removal and retention, review and correction periods and processes, or data validation; or the Equal Measure Weights scoring methodology. CMS notes that Overall Hospital Star Ratings include data collected on HAC performance.

Certain 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. A table of HAC Program measures is provided below in section V.I.8 of this summary.

1. Background

The HAC Reduction Program was implemented beginning in FY 2015. Under the program, a 1-percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile based on a set of HAC measures. Currently, performance is assessed on six measures: five CDC NHSN Healthcare Associated Infection (HAI) measures and the CMS PSI 90 patient safety measure.

Beginning with FY 2017 CMS has utilized the "Winsorized Z-Score Method" for determining a HAC program measure performance scores. The Total HAC Score for a hospital is calculated by giving each measure an equal weight and then summing its weighted measure Winsorized z-scores. 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 will be subject to the HAC program's penalty. An (ECE) policy was adopted in FY 2016.

2. Current HAC Program Measure Set

The measures for use in FY 2022 are unchanged from FY 2021 and are listed below.

- CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531).
- NHSN Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138).
- NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) (NQF #1717).
- NHSN Central Line-Associated Bloodstream Infection (CLABSI)(NQF #0139).
- American College of Surgeons – CDC Harmonized Procedure Specific Surgical Site Infection (Colon and Abdominal Hysterectomy SSI) (NQF #0753).
- NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia (MRSA Bacteremia) (NQF #1716)

3. HAC Program Policy Flexibility in Response to the COVID-19 PHE Measure Suppression

CMS provides a discussion of its proposed measure suppression policy for the HAC program very similar to that provided for the HRRP and HVBP (see Sections V.G.3 and V.H.1.a of the rule and sections V.G.3 and V.H.2 of this summary). In response to concerns that HAC Program payments may become inequitable due to COVID-19 impacts, especially for hospitals treating

large numbers of COVID-19 patients, CMS is proposing to adopt a policy for the duration of the PHE permitting suppression of one or more quality measures in its value-based programs, to be accomplished through scoring methodology adjustments.

For a suppressed measure, CMS proposes to calculate the measure's rate for the relevant program year but then suppress use of that rate for making hospital payment changes. A weight of zero percent would be assigned by CMS to each suppressed measure for use in the total HAC score calculation. Confidential feedback reports using the suppressed measure data would be provided to hospitals. Suppressed measure data would be publicly reported accompanied by material explaining the limitations of the measure results and total HAC scores due to suppression. Additional operational details are discussed later in the rule and in this summary.

The policy would be invoked if the agency were to determine that circumstances related to the PHE have significantly compromised measure data and the resultant total HAC score. To make its determinations, CMS proposes to use the same measure suppression factors as proposed for use for the HRRP and other value-based programs, repeated below:

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

As an alternative to the proposed suppression policy, CMS contemplated extending the national ECE for quality data reporting during Q1 and Q2 2020 to include Q3 and Q4. CMS rejected this alternative for reasons including the downstream effects of the large data gap thus created. The alternative of making no further changes (beyond the Q1 and Q2 2020 reporting waiver already issued) and proceeding with scoring and payment adjustments as usual was also considered. CMS rejected this alternative since it would require use of flawed data and would be likely to favor hospitals who treated fewer COVID-19 patients in Q3 and Q4.

CMS ends this section of the rule by inviting comment on adoption of the measure suppression policy for the HAC Program and on the proposed measure suppression factors. CMS also asks for input about options including development of a measure suppression policy for future PHEs under which measure suppression could be activated without notice and comment rulemaking; regional adjustment of measure suppression for factors such as population density; and partial rather than total suppression of measure data.

4. Proposal for Q3 and Q4 2020 Data Suppression for All HAC Program Measures

CMS proposes to apply the measure suppression policy to each of the six HAC Program measures for the FY 2022 and FY 2023 payment years. Measure data from Q3 and Q4 2020 would not be used in performance calculations for those years (nor would the Q1 and Q2 2020 data for which a nationwide ECE exception was granted in March 2020). To support the proposed suppression of all HAC Program measures, CMS cites measure suppression factor 1 -- significant deviation in national performance on the measure from preceding years—and factor 4 -- significant national or regional shortages or rapid or unprecedented patient volume or case mix changes.

CMS discusses results of Q3 and Q4 data analyses performed by the agency and by the CDC that showed numerous COVID-19 PHE impacts, including 1) significant national measure rate increases for CAUTI, CLABSI, and MRSA bacteremia; 2) low case reporting volumes for the SSI and CDI measures; 3) volume decreases for all of the component CMS PSI 90 composite measures; and 4) increased risk-adjusted rates for PSI component measures that include non-surgical patients (e.g., pressure ulcer rate). CMS indicates that the numerous and wide-ranging impacts found justify suppression of multiple measures for FYs 2022 and 2023 since some or all of the suppressed measure data would normally be used in the performance periods for those payment years.

CMS provides the performance periods that would be applicable if the proposed data suppression is implemented (see below) and states that the proposed periods would generate sufficiently reliable data to allow valid assessment of hospital performance for HAC Program payment reduction determinations.

- CMS PSI 90 for FY 2022: July 1, 2018 through December 31, 2019 (18 months);
- CMS PSI 90 for FY 2023: July 1, 2019 through December 31, 2019 plus January 1, 2021 through June 30, 2021 (12 months)
- All other measures for FY 2022: January 1, 2019 through December 31, 2019 (12 months); and
- All other measures for FY 2022: January 1, 2021 through December 31, 2021 (12 months).

CMS describes an alternative of using the CMS PSI 90 data as usual but suppressing the remaining 5 NHSN measures as proposed but has ongoing concerns about the national comparability of the CMS PSI 90 data. Another alternative considered, not to suppress Q3 and Q4 2020 data for any measure would require utilization of flawed data and disadvantage hospitals whose peak periods of providing COVID-19 patient care occurred later in CY 2020.

5. HAC Program ECE Policy Related to the COVID-19 PHE

After reviewing the regulatory history of the HAC Program, CMS reprises the nationwide blanket ECE policy exception granted in March 2020 for CMS quality programs, which provided that qualifying claims would be excluded from CMS PSI 90 measure calculations for Q1 and Q2 2020. In its September 2020 IFC, the agency extended this exception to cover all chart-abstracted data for the same quarters for all of the remaining five HAC Program measures.

CMS notes that some states and other entities may require hospitals to report to CDC the NHSN measures of the HAC Program for purposes other than the HAC Program, such as epidemiologic

surveillance. In response to queries, the agency states that a hospital required to submit data for such purposes may request an individual ECE for exclusion of these data from any total HAC score calculations. Also, in response to queries, CMS clarifies that exceptions granted under the ECE policy apply to data collection, reporting, and usage and do not directly exempt hospitals from HAC Program payment reductions.

CMS provides results from its analysis of the HAC Program impacts of the ECE nationwide granted in March 2020. Simulated removal of 6 months of data (e.g., Q1 and Q2 2020) from HAC scoring moved 6 percent of hospitals into the worst performing quartile (and subject to penalty) and 6 percent out of that quartile (not subject to penalty). The total -- changes for 12 percent of hospitals – is less than the 18% typically seen year-to-year.

6. Technical Specification Changes Related to COVID-19

CMS uses a subregulatory process for making nonsubstantive changes to the technical specifications of HAC Program measures. CMS indicates that updates to measure inclusion criteria created by measure developers in response to the PHE are nonsubstantive and do not substantially impact any HAC Program's finalized policies.

7. Regulation Text Update

CMS proposes to update references in HAC Program regulations to the CMS Hospital Compare website to the renamed site – Care Compare (https://www.medicare.gov/care-compare).

8. Summary Table Measures and Performance Periods

The table below summarizes the performance periods for the six HAC Program measures through the FY 2023 payment year (created from preamble section V.I.3.d).

HAC Reduction Program Measures and Performance Periods for Payment Years 2020-2023					
	NQF #	**FY 2020**	**FY 2021**	**FY 2022***	**FY 2023***
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531	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*
CDC NSHN Measures					
Central Line-associated Blood Stream Infection (CLABSI)	0139	X	X	X	X
Catheter-associated Urinary Tract Infection (CAUTI)	0138	X	X	X	XX
Colon and Abdominal Hysterectomy Surgical Site Infections	0753	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)	1716	X	X	X	X
Clostridium difficile (CDI)	1717	X	X	X	X

HAC Reduction Program Measures and Performance Periods for Payment Years 2020-2023					
	NQF #	**FY 2020**	**FY 2021**	**FY 2022***	**FY 2023***
Applicable (Performance) Period CDC NHSN Measures		*1/1/17-12/31/18*	*1/1/18-12/31/19*	*1/1/2019-12/31/19*	*1/1/21 - 12/31/21*
*** Proposed Adjustments to Applicable Periods Due to COVID-19 Impacts**					

I. 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. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive. 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 provided incentives to reduce the number of residents and disincentives to increase the number of residents by basing DGME and IME payment on a 3-year rolling average count of residents (e.g., the hospital would only gain or lose 1/3 of each FTE resident for each resident added or subtracted from the training program).

One component of the IME payment formula considers the hospital's ratio of residents to beds (known as the IRB). A higher IRB will result in higher IME payments. The law also caps a hospital's IRB ratio used for payment at its actual IRB from the prior year. The provision also provides disincentives to increase the number of residents as a hospital will not receive the higher payments from a higher IRB until the following year.

There are also rules that allow hospitals that are affiliated to jointly train residents to apply the FTE caps on an aggregate basis. These rules allow flexibility among these hospitals to continue those training relationships and allow increases in resident training above the cap at one hospital to be offset by lower resident training in another hospital. However, there are limitations on new teaching hospitals that participate in resident training in newly established residency training programs from participating in affiliation agreements for their first five years as a teaching hospital. These rules are designed to prevent arrangements that will circumvent the statutory goal of limiting the number of Medicare subsidized residents nationally to the number counted in 1996.

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

The Consolidated Appropriations Act, 2021 (CAA), 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 set out at section 1886(h)(4)(G)(i) of the Act used to calculate payments for these hospitals.
- Section 131 of the CAA makes statutory changes to the determination of DGME per resident amounts (PRA) and DGME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration.

3. Distribution of Additional Residency Positions

Section 126 of the CAA authorizes the Secretary to distribute 1,000 new FTE slots over 5 years (limited to 200 per year) to applicant hospitals beginning in FY 2023. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase, and the increase is effective beginning July 1 of that fiscal year.

In determining the qualifying hospitals for which an increase is provided, the law requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first five training years from the date the increase would be effective. The Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals:

1. Hospitals located in rural areas or treated as rural for IPPS purposes;
2. Hospitals that are training more residents than their FTE cap;
3. Hospitals in states with new medical schools or additional locations and branches of existing medical schools; and
4. Hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs).

Hospitals are limited to receiving no more 25 additional FTE residency positions and must agree to use all of the slots made available to them.

a. Application Deadline. CMS proposes that the application deadline will be January 31 of the fiscal year prior to the fiscal year the increase in FTEs becomes effective (i.e., for increases that are effective July 1, 2023, the application deadline is January 31, 2022). CMS will provide an online application that must include all of the requested information to be considered complete. The application and instructions will be included on the CMS DGME website at: Direct Graduate Medical Education (DGME) | CMS.

b. Demonstrated Likelihood. CMS proposes that this criterion will be met by the hospital showing that it cannot accommodate a planned new program or expansion of an existing program under its current FTE resident cap(s) using Worksheets E, Part A and E-4 from the Medicare cost report CMS-Form-2552-10.

For a new program, the hospital's application would attest to the following:

- The hospital has submitted an application for approval of the new residency program has been submitted to the Accreditation Council on Graduate Medical Education (ACGME)

or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

- The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval by the application deadline for that year.
- The hospital has received either:
    - Written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or
    - Other types of communication by the application deadline for that year from the accrediting bodies concerning the new program approval process (such as notification of site visit).

For an expansion of an existing program, the hospital's application would attest:

- The hospital has approval by the application deadline from the ACGME or ABMS to expand the number of FTE residents in the program.
- The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

c. Located in a Rural Area or Treated Rural. CMS proposes that a hospital will be considered located in a rural area if it is outside of a MSA or metropolitan division as defined by the Executive Office of Management and Budget. A hospital that is treated as rural is a hospital that is located in an MSA or metropolitan division that qualifies to be treated as rural and has applied and been granted that designation under section 1886(d)(8)(E) of the Act. To qualify under this criterion, the hospital must be treated as rural by the application deadline for additional resident slots.

d. Training more Residents than the FTE Cap. CMS proposes that this criterion will be met if a hospital's unweighted[53] count of residents for a cost reporting period ending on or before the date of enactment of CAA, 2021 (December 27, 2020) is higher than its applicable resident cap as adjusted for participating in affiliated group arrangements, hospital mergers, emergency affiliation arrangements, establishing new medical residency training programs, participating in rural training tracks (RTTs) and receiving additional slots under residency redistribution provisions and from closed hospitals.

e. Hospitals Located in States with New Medical Schools, Additional Locations or Branch Campuses. To meet this criterion, the hospital must be in a state where the Liaison Committee on Medical Education or Commission on Osteopathic College Accreditation has accredited a new medical school or additional location on or after January 1, 2000. CMS' proposal lists 35 states and one territory where this criterion is met: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana,

[53] Residents are counted as 1.0 FTE during an "initial residency period" or the period time required to become board certified in the initial specialty that the resident begins training. Beyond this period (generally for subspecialty training), the resident is counted as 0.5 FTE.

Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

f. Hospitals Serving HPSAs. CMS is proposing to consider hospitals that are located in geographic primary care and mental health HPSAs for purposes of determining hospitals that serve areas designated as HPSAs. For primary care HPSAs, CMS proposes no limitation on the physician specialty for additional resident slots. For mental health HPSAs, CMS proposes to limit the additional resident slots to psychiatry residents. CMS further proposes that at least 50 percent of the resident's training time over the duration of the program must occur within the HPSA. Hospitals will be able document they meet this criterion under CMS' proposal through an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report.

g. Limiting and a Prioritizing Number of Residents Available to Each Hospital. CMS is limited by statute to making 200 new residency slots available each year for 5 years. Given this limitation and the number of hospitals that are expected to qualify under each of the four criteria listed above, CMS is proposing to limit an award of an additional residency slot to 1.0 per hospital per year.
CMS would further prioritize among hospitals receiving residents based on the following criteria:

- *Residency Programs that Treat Underserved Populations*. CMS proposes to give priority to hospitals with residency programs that provide services to medically underserved populations in a population-based HPSA[54] (with the same requirements that apply to geographic HPSAs).
- *Use of HPSA Scores*. The Health Resources and Services Administration assigns HPSA scores on a scale of 0 to 25 as a measure of the severity of a primary care or mental health provider shortage in a geographic area, with higher scores indicating a more severe health professional shortage. CMS proposes to prioritize awarding of resident slots based on HPSA score.

CMS would prorate residents in the above prioritization categories only in the event that the number of qualifying hospitals under the first category or the highest HPSA score under the second category exceed the number of residency positions available. Hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

Alternatively, CMS considered prioritizing hospitals that qualify in more than one of the four statutory eligibility categories. Hospitals that qualify under all four categories would receive top priority, hospitals that qualify under any three of the four categories would receive the next highest priority, then any two of the four categories, and finally hospitals that qualify under only one category. Again, CMS would only prorate if the number of qualifying hospitals exceeds the

[54] In a geographic HPSA, the entire population of that HPSA is designated as underserved for a particular type of service. In a population-based HPSA, a particular population (low-income populations, Medicaid-eligible, Native American, homeless, migrant farmworker, etc.) are designated as medically underserved.

number of available residents with each hospital being awarded a maximum of 1.0 FTE.

h. Distributing At Least 10 Percent of Positions to Each of the Four Categories. The statute requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions within each of the qualifying four categories. CMS believes this will occur through prioritizing applications by HPSA score as hospitals may qualify for additional residents through more than a single category. CMS proposes to collect information regarding qualification categories to track progress in meeting the statutory requirement that at least 10 percent of residents be allocated to each of the qualifying categories.

i. Hospital Attestation to National CLAS Standards. CMS proposes that all applicant hospitals would be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).

j. Payment for and Aggregation of Additional FTE Residency Positions. There are different DGME PRAs for primary care residents and residents that train in obstetrics and gynecology than for residents training in all other specialties. CMS proposes to pay for the additional residents using the PRA that correlates to the specialty the resident is training in.

k. Use of Residents in DGME and IME Affiliation Agreements. Medicare statute and regulations allow hospitals that jointly train residents to affiliate and apply their FTE caps on an aggregate basis. CMS is proposing that additional resident slots awarded under this program may be used in affiliation agreements beginning in the 5th year after the effective date of those FTE resident cap positions.

l. Conforming DGME and IME Regulations. CMS would make the same changes to the DGME and IME regulations with respect to application of the DGME and IME resident caps.

m. Prohibition on Administrative and Judicial Review. Consistent with statute, CMS is proposing to prohibit administrative or judicial review of the determinations and distribution of additional residency positions.

4. Rural Training Tracks (RTT)

RTTs are graduate medical education programs that are specifically designed to train residents to practice in rural areas. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 allowed urban hospitals to count residents training in RTTs above their caps effective in 2000. CMS regulations allowed payment for FTE residents in these programs above the hospital caps for 5 years. In the sixth year, additional residents in these programs were incorporated into hospital FTE DGME and IME caps.

While the BBRA exempted the additional RTT residents from an urban hospital's FTE cap for 5 years, it did not exempt those additional residents from the 3-year rolling average count of residents to determine DGME and IME payment in existing teaching hospitals that already had established DGME and IME caps. For newly established teaching hospitals, the 3-year rolling average would apply to the RTT residents after 5 years.

Similarly, the BBRA provisions did not exempt the additional RTT residents from the annual cap on the IRB ratio in existing teaching hospitals that already had established DGME and IME caps. For newly established teaching hospitals, the IRB cap applies to RTT residents after 5 years. Finally, while the BBRA provisions exempted the urban teaching hospital participating in the RTT programs from the FTE caps, the law did not provide an analogous adjustment for a rural hospital for training a resident in an RTT.

Section 127 of the CAA addresses these and other concerns that stakeholders have raised about RTT provisions of the law.

a. Cap Adjustment for Urban and Rural Hospitals Participating in Rural Training Track Programs. Section 1886(h)(4)(H)(iv) of the Act (as modified by section 127 of the CAA) provides for adjustments to FTE caps for both a rural and an urban hospital that "established or establishes" an RTT effective for cost reporting periods beginning on or after October 1, 2022. CMS describes RTTs as "hub and spoke" programs. The urban hospital is the "hub" and each rural hospital participating in the RTT is the "spoke." Under current policy, an urban hub may be an existing medical residency training program and neither the urban nor rural hospital would qualify for a cap adjustment when a new spoke is added. CMS is proposing that each time an urban hospital adds a new spoke, the urban and rural hospital would qualify for a cap adjustment.

While CMS proposes allowing cap adjustments when new spokes are added to an existing RTT, CMS is not proposing to allow expansion of existing RTT programs when a new spoke is not added. CMS justifies this limitation as being consistent with the statute's direction that allows it to prescribe rules for adjustments to FTE caps while considering that Congress established caps to limit the number of residents subsidized by Medicare in the aggregate nationally. Further, CMS notes that the statute authorizes the Secretary to "adjust in an appropriate manner" the FTE cap for hospitals participating in RTTs.

CMS notes that the slots associated with the RTT FTE limitation are fungible. Urban and rural hospitals with multiple RTT "spokes" may reduce the number of FTE residents training between the hub and spokes in order to accommodate an increase in training at the hub or another spoke subject to the proviso that 50 percent of the training must continue to occur in rural areas. Further, urban and rural hospitals can receive cap adjustments for new RTT programs in different specialties.

b. Removal of Requirement that Rural Track Must Be "Separately Accredited". Section 127 of the CAA removes the requirement that the rural track be "separately accredited." Specifically, section 1886(h)(4)(H)(iv)(II) now states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, or establishes an accredited program where more than 50 percent of the training takes place in a rural area, the Secretary may adjust the resident cap. CMS proposes that effective for cost reporting periods beginning on or after October 1, 2022, so long as the program in its entirety is accredited by the ACGME, regardless of the specialty, it may qualify as a RTT and urban and/or rural hospitals receive rural track FTE cap adjustments assuming all other requirements are met. CMS further notes that the statute adopts a requirement that was previously only regulations that

at least 50 percent of the training occur in a rural area for a residency program to qualify as an RTT. Consistent with this requirement, CMS proposes to allow any specialty program where more than 50 percent of the training occurs in a rural area to qualify as an RTT.

c. Exemption from the 3-Year Rolling Average During the 5-Year Rural Track FTE Limitation Window. Section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to provide for an exemption from the 3-year rolling average of the urban and rural hospital during the 5-year growth window for FTE residents participating in rural tracks. CMS is proposing that during the 5-year cap growth window for RTTs, the FTE residents participating in the RTT either at the urban hospital or a rural hospital would not be included in a hospital's 3-year rolling average calculation effective for RTTs started in cost reporting periods beginning on or after October 1, 2022.

d. Documentation Required for Medicare Administrative Contractor (MAC). In order to facilitate the implementation of increases to RTT FTE limitations, either via interim payments or cost report adjustments, an urban hospital "hub" that adds one or more rural "spokes" in one or more specialties, CMS proposes that the urban and rural hospitals must show its MAC the following:

- The accreditation for the "spoke", information whether the "spoke" is in the same specialty as a RTT that the urban hospital already has, or whether the "spoke" is a newly created RTT in a different specialty;
- Intern and resident rotation schedules (or similar documentation) showing that residents in each particular RTT program (both hub and spokes overall) spend greater than 50 percent of their training in the program in a geographically rural area; and
- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of the particular "spoke", so that the MAC may be able to verify the RTT cap limitation.

5. Hospitals that Hosted a Small Number of Residents for a Short Duration

Section 131 of the CAA provides CMS with the opportunity to reset the low or zero DGME PRA and to reset the low DGME and IME FTE resident caps of hospitals that hosted a small number of residents for a short duration. Hospitals with a low PRA may have first served as a training site for a small number of residents on rotation from an existing training program at some point in the past. In this circumstance, the resident salaries and other costs may have been predominantly incurred at the other hospitals where the resident was training. As a result, the hospital that served as a training site may have had no or very low per resident costs to set the PRA in the first year of training residents.

Hospitals with a very low DGME and IME FTE cap may have served as a training site for a small number of residents in a new medical residency training program on rotation from another hospital. As a result, the cap was established at the hospital based only on residents that rotated in for a short duration of time. These hospitals may have later decided to engage in establishing their own new medical residency training programs and found they already had DGME and IME FTE caps that would not have accommodated the number of residents in a new program. Section 131(a) and (b) of the CAA address concerns of these hospitals by allowing the Secretary

to recalculate the PRA and redetermine the FTE caps if the hospital trains resident(s) in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025. The statute classifies two categories of hospitals that CMS refers to as "category A" and "category B":

- Category A. A hospital that, as of December 27, 2020, has a PRA that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997.
- Category B. A hospital that, as of December 27, 2020, has a PRA that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020.

a. Hospitals Qualifying to Reset their PRAs. The law allows the PRA to be reset if the hospital trains at least 1.0 FTE (in the case of a category A hospital) or more than 3.0 FTEs (in the case of a category B hospital). CMS will not round up to determine whether a hospital qualifies for a recalculated PRA. The recalculation period begins on December 27, 2020, and ends 5 years later. CMS is proposing that to redetermine the PRA, the training occurring at a category A hospital or a category B hospital need not necessarily be in a new program; the residents may be in either an approved program that is "new" for Medicare DGME and IME purposes, or may be in an existing approved program.

Further, CMS indicates that it is not relevant whether these hospitals may have trained at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period or periods prior to December 27, 2020. The relevant factor in determining when to reset PRAs is if and when the hospital trains the requisite amount of FTE residents in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years from enactment). Once reset, in the absence of additional legislation, the PRAs for either a Category A hospital or a Category B hospital are permanent, subject to annual inflation updates.

b. Calculating the Revised PRA and Cost Reporting Requirements. CMS will calculate the revised PRA under the normal existing rules as the lower of:

- The hospital's actual cost per resident incurred in connection with the GME program(s) in the first cost reporting period beginning on or after December 27, 2020 and before December 27, 2025 in which the hospital trained more than 1.0 or 3.0 FTE residents depending on whether the hospital qualifies under category A or category B; or
- The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area (or, if there are fewer than three PRAs for this calculation with base periods beginning on or after October 1, 1997, the updated weighted mean value of per resident amounts of all hospitals located in the same census region).

CMS notes that the law specifies that the Secretary shall not establish a PRA until such time as a hospital that is not in an affiliation agreement with another hospital for training residents has trained as least 1.0 FTE resident in a cost reporting period. The law is silent on hospitals that are in affiliation agreements. Thus, effective for a cost reporting period beginning on or after December 27, 2020, CMS proposes to establish a PRA in the instance where a hospital trains less

than 1.0 FTE and that hospital has entered into a Medicare GME affiliation agreement for that training. Otherwise, a hospital must have more than 1.0 FTE resident (or more than 3.0 FTE residents in the case of a category B hospital) in a cost reporting period for CMS to determine a PRA.

The statute requires a hospital that trains at least 1.0 FTE in an approved program on or after December 27, 2020 to report the number of FTEs it trains on its cost report. Effective for a cost reporting period beginning on or after December 27, 2020, CMS proposes that a hospital must report FTE residents on its Medicare cost report for a cost reporting period if:

1. In the absence of a Medicare GME affiliation agreement, a hospital trains at least 1.0 FTE in an approved program or programs; or
2. If there is a Medicare GME affiliation agreement, a hospital trains less than 1.0 FTE in an approved program or programs.

This proposal is intended to put hospitals on notice that CMS will establish a PRA when FTE residents are reported on a Medicare cost report beginning on or after December 27, 2020. CMS notes that newly added clause 1886(h)(2)(F)(v) of the Act states that "as appropriate, the Secretary may consider information from any cost reporting period necessary to establish a [new PRA]." CMS then discusses its "predicate facts" rule. The predicate facts rule allows CMS to use information from a prior cost reporting period—even if that cost reporting period has been settled for more than 3 years and is not subject to reopening—to determine payments in a subsequent or future cost reporting period (provided that cost reporting period remains subject to reopening). The predicate facts rule does not substantively change any of CMS' proposals regarding calculating a revised PRA if a hospital qualifies as result of having a PRA based on less than 1.0 FTE (category A hospital) or less than 3.0 FTE (category B hospital).

c. Hospitals Qualifying to Reset their FTE Resident Caps. CMS explains that to qualify for resetting the FTE cap, the statute states the Secretary shall adjust the FTE resident caps in the manner applicable to a new program if the hospital "begins training" the requisite number of FTE residents (1.0 or 3.0 depending on whether the hospital is category A or B). To reset a PRA, a training program does not necessarily need to be new. However, the statute requires a training program to be new for the hospital to qualify to have its FTE cap reset.

CMS proposes that "begins training" means future training in a new program for the first time on or after December 27, 2020. For both category A and B hospitals, CMS says that the relevant factor in determining the timing of resetting their FTE resident caps is if the hospital first begins training the requisite amount of FTE residents at some point in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years from enactment).

Based on the examples that CMS provides, the relevant considerations to make a determination if a hospital with an FTE cap qualifies to have its cap reset are:

- Did the hospital FIRST begin training residents before 12/27/2020 in a new program? If yes

- Did the hospital train less than the requisite number of residents (e.g., less than 1.0 FTE (category A) or less than 3.0 FTE (category B)?)

If the answer to the first and second question is "YES", the hospital qualifies to have its cap reset. If the answer to the first question is "YES" and to the second question is "NO", then the hospital does not qualify to have its cap reset. If the answer to the first question is "NO", the 2nd question is moot. Either the hospital has not participated in GME training before and would qualify under the normal rules to have its cap set in the 6th year after beginning to train residents in new programs or the hospital has an established cap based on training residents in established programs and does not qualify to have its cap reset.

d. Calculating Replacement FTE Resident Caps. CMS proposes to use its existing regulations to calculate each qualifying hospital's FTE cap (e.g., the cap would be determined in the 5th year of the new program based on the number of residents in training at that time).

The proposed rule further indicates that CMS proposes not to set an FTE cap for any hospital that has trained few than 1.0 FTE residents in a cost reporting period beginning on or after December 27, 2020. For all hospitals that do not yet have caps triggered, CMS proposes that a cap will only be triggered in a GME naïve hospital as of December 27, 2020 when the hospital trains at least 1.0 FTE in a new medical residency training program.

CMS further reiterates its "predicate facts" rule applies to FTE caps as it does to the determination of the PRA. That is, CMS proposes to not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation it would need to establish the FTE resident caps from that period to determine future payments.

6. 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 proposes to change the regulations 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 Medicare Administrative Contractor.

Further, in response to reviews by the Office of Inspector General, CMS is proposing that the FTE count on IRIS must match the counts the hospital claims on its cost report worksheets. CMS is proposing that the IRIS data must contain the same total counts of DGME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of DGME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

J. 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 Consolidated Appropriations Act, 2021 (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. Proposed Policies for Implementing CAA 2021 Extension

Section 128 of the CAA 2021 extends the demonstration for another five years and provides for the continued participation for all hospitals participating in the demonstration as of December 30, 2019. CMS interprets the statute as providing for an additional 5-year period for hospitals participating as of that date.

Four hospitals ended the 5-year extension authorized by the CURES Act during FY 2020; CMS proposes to retain the policy used for previous extensions and apply the cost-based reimbursement methodology to 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 proposes 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. Proposed FY 2022 Budget Neutrality Adjustment

CMS identifies 27 hospitals that will participate in the program in FY 2022. The agency estimates that the demonstration program will cost $63,829,479 in FY 2022. As of the date of publication of the proposed rule, CMS has not finalized the completed cost reports for the 18 hospitals participating in FY 2016; thus, it does not propose to include in the offset amount the difference between estimated and actual expenses of the demonstration program for FY 2016. It

will include that difference in the budget neutrality offset amount for the final rule if the entire set of finalized cost reports become available. The total budget neutrality adjustment would be based on $63,829,479. CMS will update this figure for the final rule.

K. 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 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 is proposing 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.

L. Payment Adjustment for CAR-T Clinical Trial Cases

CMS created new MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Immunotherapy for CAR-T cell therapy cases. 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 not pay for the cost of the CAR-T cell therapy product that the hospital did not incur. The FY 2021 payment adjustment is 0.15 (e.g., the full IPPS payment is reduced by 85 percent to account for hospital not incurring the very high cost of the CAR-T cell therapy product).

As indicated earlier, CMS is proposing 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 for this proposal is based on an update of FY 2019 MedPAR data. Based on the later FY 2019 MedPAR data, CMS proposes a revised adjustment of 0.17. CMS notes that the payment adjustment would be 0.25 if it used the latest FY 2020 data.

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 is proposing a national capital Federal rate of $471.89 for FY 2022.

Update Factor:

For FY 2022, CMS will increase the national capital Federal rate by 0.7 percent based on the capital input price index (CIPI) of 1.0 percent and other factors shown in Table 1 below.

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. Therefore, CMS is applying an adjustment for case-mix change in FY 2022 of 0.0 percentage points.

Due to the COVID-19 PHE on the FY 2020 MedPAR claims data, CMS is proposing not to evaluate the effect of FY 2020 reclassification and recalibration and is proposing a 0.0 percent adjustment for this factor in FY 2022.

CMS proposes a forecast error correction of -0.3 percent.

Table 1

CMS FY 2022 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE	
FY 2018-based CIPI	1.0
Intensity	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-0.5
Real Across DRG Change	0.5
Net Case-Mix Adjustment (Projected - Real)	0.0
Subtotal	1.0
Effect of FY 2018 Reclassification and Recalibration	0.0
Forecast Error Correction	-0.3
Total Proposed Update	0.7

Other Adjustments:

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) 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—the latter of which applied in FY 2021 only).
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases (FY 2021 only).

While CMS calculated these adjustments in two steps, it applied a single uniform adjustment to the capital rate. In past years, CMS did not remove the past year's budget neutrality adjustment before applying the adjustment for the proposed rule year. However, 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 proposed rule year adjustment. There is a detailed and complex explanation of CMS' reasoning. In summary, CMS believes the two adjustments need to be separated because the second step adjustment has incorporated the outmigration and frontier floor adjustments that are not subject to budget neutrality. The first step adjustment can be

retained on the rate while the second step adjustment must be removed from the rate before applying the proposed year budget neutrality adjustment.

To remove the prior years' budget neutrality adjustment for the increase in the lowest quartile wage index and the 5 percent cap on the wage index (FY 2021 only), CMS proposes to 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). CMS determined a budget neutrality adjustment of 1.00 for this factor.
- Isolate the impact of the increase in the lowest quartile wage indexes. CMS determined a GAF budget neutrality factor of 0.9976 for FY 2022.

The budget neutrality adjustment for changes in the GAFs will be 1.000. CMS also proposed to incorporate an adjustment for MS-DRG changes and recalibration of the relative weights of 1.0001 into the capital rate. This combined adjustment for GAFs due to wage index and changes for MS-DRGs and recalibration is 1.0001 (1.000 x 1.0001 or 0.01 percent).

For FY 2022, CMS is taking outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.34 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.01 percentage points for outlier payments refunded to hospitals. This makes the estimate of FY 2022 capital outlier payments 5.33 percent of total capital payments. Therefore, the FY 2022 outlier adjustment factor is 0.9467 (-5.33 percent), compared to 0.9466 (-5.34 percent) in FY 2021. The net change is +0.01 percent (0.9467/0.9466). Thus, the outlier adjustment increases the FY 2021 capital federal rate by 0.01 percentage points.

Proposed Rule Calculation:

The proposed 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	1.007	1.0070	0.7
GAF/DRG Adjustment Factor*	N/A	1.0001	1.0001	0.01
Lowest Quartile Adjustment Factor**	0.9927	0.9976	1.0049	0.49
Outlier Adjustment Factor**	0.9466	0.9467	1.0001	0.01
Capital Federal Rate	$466.21	$471.89	1.012	1.22

* 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 1.0001 (or 0.01 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 0.9467/0.9466, or 1.0001 (or 0.01 percent). The net change to the lowest quartile adjustment is 0.9976/0.9927 or 0.49 percent.

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2022 of $471.89, a 1.22 percent increase over the FY 2021 rate of $466.21

Exception Payments. The proposed rule continues exception payments if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control.

New Hospitals. Medicare defines a "new hospital" as a hospital that has operated for less than 2 years. CMS notes that a new hospital is paid 85 percent of its Medicare allowable capital-related reasonable costs through the first 2 years of operation unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate.

VII. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase

Most hospitals are paid under prospective payment systems. However, some hospitals continue to be paid based on reasonable costs subject to a per discharge limit updated annually under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. Hospitals that continue to be paid reasonable costs subject to a limit include 11 cancer hospitals, children's hospitals, and hospitals located in the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Religious non-medical health care institutions are also paid reasonable costs subject to a limit.

The annual update to the TEFRA limit is based on IGI's 2020 4th quarter forecast of the hospital market basket for FY 2021 and is estimated at 2.5 percent.

B. Frontier Community Health Integration Project Demonstration

The Frontier Community Health Integration Project (FCHIP) Demonstration[55] 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

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

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 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 is not proposing to apply a budget neutrality offset to CAH payments for FY 2022.

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.

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 proposes updates for LTCHs using a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment 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 proposes to use FY 2019 data where utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID-19 PHE. It proposes to use 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 proposal is consistent with the data use policy proposed for IPPS rate setting, described in section I.F of this summary.

Summary of Proposed Changes to LTCH PPS Rates for FY 2022*	
Standard Federal Rate, FY 2021	$43,755.34
Proposed Rule Update factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.2%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.2% (1.022)
Net update LTCHs not reporting quality data	+0.2% (1.002)
Proposed Rule Adjustments	
Proposed average wage index budget neutrality adjustment	1.002458
Proposed Standard Federal Rate, FY 2022	
LTCHs reporting quality data ($43,755.34*1.022*1.002458)	$44,827.87
LTCHs not reporting quality data ($43,755.34*1.002*1.002458)	$43,950.62
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$32,680
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$30,967
Impact of Proposed Policy Changes on LTCH Payments in 2022	
Total estimated impact	1.4% ($52 million)
LTCH standard federal payment rate cases (75% of LTCH cases)	1.2% ($41 million)
Site neutral payment rate cases (25% of LTCH cases)**	3.0% ($11 million)
*More detail is available in Table IV, "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for Standard 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.

2. Patient Classification into MS-LTC-DRGs

CMS proposes to continue to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates also

would be incorporated into the MS-LTC-DRG system for FY 2022 since the two systems share an identical base. Proposed MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble of the proposed rule. Other proposed changes to the MS-DRG that affect assignments under the proposed GROUPER Version 39 discussed in section II.E of the proposed 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 proposes to use its current methodology and established policies related to the hospital-specific relative-value methodology, volume-related and monotonicity adjustments, and the steps for calculating the relative weights with a budget neutrality factor (described in more detail below).

4. Relative Weights Source Data

FY 2022 proposed 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 proposed relative weights.

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

CMS proposes to continue to use 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.

6. Volume-related adjustments

CMS proposes to continue 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 proposed 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 proposes to continue 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 proposes to continue its methodology of calculating the relative weights by first removing cases with a length of stay of 7 days or less (Step 1) and then removing statistical outliers (Step 2). The effect of short stay outlier (SSO) cases (those with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) is adjusted for by counting an SSO 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 proposes to apply 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 proposes to apply a normalization factor of 1.25811 for FY 2022. Second, a budget neutrality factor is applied to each normalized relative weight; CMS proposes a factor of 1.000275 for FY 2022.

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 1,191 to 1,214 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. Proposed Annual Update for LTCHs

The proposed annual update to the LTCH PPS standard federal payment rate is equal to 2.4 percent. For FY 2021, CMS rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year. Thus, CMS proposes an update equal to the 2017-based LTCH market basket of 2.4 percent less 0.2 percentage points (PP) for multifactor productivity. For LTCHs failing 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 proposed LTCH update for FY 2022 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	2.4%	2.4%
Multifactor Productivity	-0.2 PP	-0.2 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.2%	0.2%

3. Area Wage Levels and Wage-Index

CMS proposes to adopt the revised labor market area delineations announced in OMB Bulletin No. 20-01[56] (issued on March 6, 2020) effective for FY 2022 under the LTCH PPS. However, the agency determined that the changes in this OMB Bulletin would 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 proposal to adopt the updates in OMB Bulletin 20-01.

CMS notes that the policy it adopted 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 expires at the end of FY 2021.

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 proposes to substitute 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.

CMS proposes an FY 2022 labor-related share of 68.0 percent based on IGI's fourth quarter 2020 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (63.7%) and capital costs (4.3%). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related;

[56] See https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf

administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services.

CMS proposes to compute the wage index in a manner that is consistent with prior years, taking into account the proposed revised labor market area delineations announced in OMB Bulletin No. 20-01. It proposes an area wage level budget neutrality adjustment of 1.002458.

4. Proposed LTCH Standard Federal Payment Rate Calculation

CMS proposes the following LTCH PPS standard federal payment rates for FY 2022:

- $44,827.87 for LTCHs reporting quality data, calculated as follows: $43,755.34 (FY 2021 payment rate) * 1.025 (statutory update factor) * 1.002458 (area wage budget neutrality factor) = $44,827.87

- $43,950.62 for LTCHs not reporting data to the LTCH QRP, calculated as follows: $43,755.34 (FY 2021 payment rate) * 1.002 (statutory update factor less quality adjustment) * 1.002458 (area wage budget neutrality factor) = $43,950.62

5. Cost-of-Living (COLA) Adjustment

CMS proposes to continue updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states 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 proposes to update 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 proposes to use 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 proposed 2018-based market basket. CMS used data for 2009 through 2020. The COLA would continue to be capped at 25 percent. The table below shows the current COLAs and those proposed for FY 2022.

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2022

Area	FY 2018 – FY 2021	Proposed FY 2022
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

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2022		
Area	**FY 2018 – FY 2021**	**Proposed FY 2022**
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 proposes to adjust 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 would make what it describes 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. The changes, if finalized, would apply for FY 2022 and subsequent fiscal years.

a. Proposed Charge Inflation Factor

Due to a significant difference between estimated and actual charge inflation, CMS proposes to determine the charge inflation factor based on the historical growth in charges for the LTCH PPS standard federal payment rate cases; it would calculate 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 proposes 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 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 year.

For FY 2022, due to COVID-19 PHE data concerns, CMS would use the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR file. CMS calculated a proposed one-year rate of change of 6.0723 percent ($207,224 / $195,362). It then proposes a two-year charge inflation factor of 1.125133 (calculated by squaring the proposed one-year factor), and a proposed three-year charge inflation factor of 1.193455 (calculated by cubing the proposed one-year factor). CMS proposes to inflate the billed charges obtained from

the FY 2019 MedPAR file by the 3-year charge inflation factor of 1.193455 when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022.

b. Proposed CCRs

Historically, CMS has used CCRs from the most recently available PSF file without any adjustment. It proposes 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 proposes a four-step methodology:

- Identify providers with standard federal payment rate cases from the most recent Med PAR 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.

For FY 2022, due to COVID-19 PHE data concerns, CMS would use the March 2020 PSF and the March 2019 PSF. CMS would also use claims from the March 2020 update of the FY 2019 MedPAR file in calculating the average case-weighted CCRs in step 4.

CMS calculated proposed national average case-weighted CCRs of 0.256374 for March 2019 and 0.2465170 for March 2020, resulting in a proposed one-year national CCR adjustment factor of 0.961555 and a proposed 2-year national CCR adjustment factor of 0.924588 (calculated by squaring the proposed 1-year factor). CMS notes that in calculating the proposed 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 proposed 2-year national CCR adjustment factor.

c. Proposed 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 proposes a fixed-loss amount of $32,680 for FY 2022 which CMS estimates will result in 7.975 of LTCH standard federal payment rate cases being paid as HCOs. The HCO payment continues to equal 80 percent of the estimated care cost and

the outlier threshold (adjusted standard rate payment plus fixed-loss amount). If an HCO case is also an SSO case, the HCO payment will equal 80 percent of the estimated case cost and the outlier threshold (SSO payment plus fixed-loss amount). Consistent with historical practice, CMS will use the most recent available LTCH claims data and CCR data for the final rule.

d. Proposed 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 proposes a fixed-loss amount for site neutral payment rate cases of $30,967. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2022. Consistent with the policy adopted in FY 2019, CMS proposes that the HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments.

7. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS proposes to continue its policy that 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) include an applicable operating Medicare DSH and uncompensated care payment amount. For FY 2022, the DSH/uncompensated care amount equals 79.11 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

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 1.4 percent or $52 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 $41 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 proposes to set 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 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 2021" in the proposed rule shows the detailed impact by location, participation date, ownership type, region, and bed size for only LTCH PPS standard federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases. CMS reports that regional differences in impacts are largely due to updates to the wage index. Also of note is that the number of LTCHs shown in Table IV (360) differs from the figure CMS indicates in the narrative of the impact analysis (363).

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	1.2%
By Location:		
Rural	19	1.5%
Urban	341	1.2%
By Ownership Type:		
Voluntary	60	1.0%
Proprietary	290	1.2%
Government	10	1.4%
By Region		
New England	10	0.8%
Middle Atlantic	23	0.7%
South Atlantic	62	1.5%
East North Central	55	1.2%
East South Central	31	0.7%
West North Central	22	1.3%
West South Central	105	1.0%
Mountain	29	1.7%
Pacific	23	1.6%
*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 1877-1878 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-p

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, CMS requests information about adopting a digital measurement approach for its hospital quality and value-based purchasing programs and about strategies to close the health equity gap in those programs. Specific changes are proposed for the quality reporting programs that apply to acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. Finally, changes to the Medicare Promoting Interoperability Program are also proposed.

A. Advancing to Digital Quality Measurement-RFI

CMS requests input into the agency's planning for transformation to a fully digital quality enterprise by 2025, posing numerous questions grouped into three categories: definition of

digital quality measures; use of FHIR for current eCQMs; and changes under consideration to advance digital quality measures. Examples of questions from each category are presented at the end of this section; readers are referred to the rule for the full question list. CMS indicates that it will not respond to comments received about this RFI through the FY 2022 IPPS/LTCH final rule, but will consider the input received when drafting future regulations and policies.

By way of background, CMS offers a definition for digital quality measures (dQMs): quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. CMS notes that a dQM's score includes a calculation that processes digital data; the agency also lists multiple examples of dQM data sources (e.g., electronic health records - EHRs, wearable medical devices). Also discussed by the agency is the potential role of FHIR-based standards for efficient exchange of clinical information across clinical settings through APIs. CMS is actively studying the use of FHIR-based APIs to access quality data it already collects as well as transitioning to FHIR-based quality reporting through APIs for eCQMs already adopted into several of the agency's quality reporting and value-based purchasing programs.

CMS concludes the discussion of this RFI with a commitment to using policy levers and collaborating with stakeholders to transition to fully digital quality measurement across the agency, with staged implementation of a cohesive portfolio of dQMs and incorporation of principles from the HHS National Health Quality Roadmap.

- Definition of Digital Quality Measures
    - Do you have feedback on CMS' dQM definition?

- Use of FHIR for Current eCQMs
    - Would the transition to FHIR-based quality reporting reduce burden on health IT vendors and providers?
    - Would access to near real-time quality measure scores benefit your practice?

- Changes Under Consideration to Advance Digital Quality Measurement
    - Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements?
    - How important is inclusion of patient generated health data and other non-standardized data within a FHIR-based standard framework?
    - What role should data aggregators play in CMS quality reporting in collaboration with providers?
    - What are initial priority areas for the agency's dQM portfolio (e.g., measurement requirements, tools)?

B. Closing the Health Equity Gap in CMS Hospital Quality Programs - RFI

Through this RFI CMS seeks comment on revision to CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients. To this end, CMS explores three potential major, near-term

initiatives and poses multiple questions specifically applicable to each initiative. The initiatives and examples of specific questions for each initiative are listed below:

- The possibility of expanding the agency's current disparities methods to include reporting by race and ethnicity using indirect estimation;
    - What would be appropriate privacy safeguards for the data produced through indirect estimation?
    - What are data elements beyond race and ethnicity that would be feasible to collect and be useful for stratification within quality measures?
- The possibility of hospital collection of standardized demographic information for the purposes of potentially incorporating into measure specifications to permit more robust equity measurement;
    - What are the feasibility and utility for collection by hospitals, at the time of admissions, of a minimum set of demographic data elements using electronic data definitions that permit nationwide, interoperable health information exchange?
- The design of a Hospital Equity Score (HES) for calculating results across multiple social risk factors and measures, including race/ethnicity and dual eligibility;
    - What are potential interventions by hospitals to improve low equity scores?

As background for this RFI, CMS cites evidence for worse health outcomes that could stem from disparate care across patient populations (e.g., higher COVID-19 complication rates for black, Latino, and Indigenous and Native Americans relative to whites). The agency focuses the ensuing discussion on the potential for expanding use of CMS Disparity Within-Hospital and Across-Hospital methods beyond their current for race and ethnicity boundaries. CMS notes that confidential reporting to hospitals of disparity analyses for their performances on the Pneumonia Readmission Measure (NQF #0506) and Pneumonia Mortality (NQF # 068) was trialed n 2019, and that many commenters supported continuing such field trials. CMS further notes the availability of several tools for capturing race and ethnicity and compares them to the gold-standard of self-reported data. Relatedly, the agency reports its work on indirect estimation methods applicable to race and ethnicity and its experience using those methods, citing the very high reliability of the Medicare Bayesian Improved Surname Geocoding (MBISG) model for white, black, and Hispanic data prediction.

CMS also reviews collection and standardization of a minimum demographic data set, using electronic definitions, and related aspects of the Certified Electronic Health Record Technology (CEHRT) currently required for use by hospitals under the Medicare Promoting Interoperability (PI) Program to improve the robustness of disparity method results. CMS concludes discussion of this RFI by exploring the potential for creating a Health Equity Score (HES) for hospitals based on prior work from which a Health Equity Summary Score (HESS) was developed for use in Medicare Advantage contracts and plans. HES scores would be provided confidentially to hospitals and any public reporting of scores would be subject to rulemaking.

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. CMS provides a list of references for readers interested in details of the legislative and regulatory history of the IQR Program. Additional information on the measures themselves and reporting processes is available at https://qualitynet.cms.gov/inpatient/iqr.

As further described below, CMS proposes changes to the IQR program that would add 5 new quality measures, remove 5 existing measures, and revise the current electronic health record (EHR) certification requirements. The agency also requests comment on several future measures under consideration and introducing data stratification into an existing measure. 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.6). No changes are proposed to IQR program measures or policies regarding the retention, removal, addition, or updating of measures.[57]

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the changes to the Hospital IQR Program proposed in this rule will add 2,475 hours annually to hospital burden at an annual cost of $101,475 across a 4-year period from payment year FY 2022 through payment year FY 2027.

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that for FY 2022, 65 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 proposed rule, these hospitals would receive an update factor of 1.675 percent. Another 24 hospitals are estimated to receive a combined payment increase of -0.2 percent because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.[58]

1. Proposals to Adopt New Measures into the Hospital IQR Measure Set

a. Maternal Morbidity Structural Measure ("Maternal Morbidity Measure")

Measure Details. CMS proposes to adopt one new structural measure to determine the number of hospitals currently participating in a structured State or national Perinatal QI Collaborative and whether participating hospitals are implementing the safety practices or bundles embedded in these QI initiatives beginning with IQR program payment year FY 2021. CMS also proposes to define a state or national Perinatal Quality Improvement Collaborative as a statewide or a multi-State network working to improve women's health and maternal health outcomes by addressing the quality and safety of maternity care. The measure would require attestation in response to a two-part question; full specifications are available at https://www.cms.gov/files/document/maternal-morbidity-structural-measure-specifications.pdf.

Question. "Does your hospital or health system participate in a Statewide and/or National

[57] Relatedly, CMS notes 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.
[58] The 0.2 percent reduction reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user.

Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care (part 1), and has implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis (part 2)?"

Responses. (A) "Yes"; (B) "No"; or (C) "N/A (our hospital does not provide inpatient labor/delivery care)".

Clarifying Information. Material would be provided to clarify that a "Yes" response requires an affirmative answer to both parts of the measure's question.

Measure Rationale. In discussing the proposed measure CMS describes the large increase in maternal morbidity and mortality rates since 1990 in the U.S. despite high rates of spending on maternity care. CMS reviews the strong association between maternal morbidity (e.g., hypertension) and mortality and notes that maternal morbidity and mortality are considered highly preventable. CMS states that a major factor contributing to the observed morbidity and mortality increases is inconsistent obstetric practice, such as the absence of standardized emergency protocols in hospitals providing inpatient labor/delivery care. CMS cites evidence that hospital participation in maternal care QI collaboratives results in effective management of morbidities that may lead to death. The proposed measure is designed to allow CMS to assess hospital participation in QI collaborative programs in the inpatient setting and their implementation of safety practices or bundles.

Pre-rulemaking. CMS describes in detail the progress of the measure through the standard pre-rulemaking process for quality measure addition. The measure was placed on the December 2019 Measures Under Consideration (MUC) list. The measure underwent several language modifications in response to recommendations from the Measures Application Partnership (MAP), ending with conditional support for rulemaking by the MAP, contingent on measure endorsement by the National Quality Forum (NQF). However, CMS proposes to implement the Maternal Mortality measure for the FY 2023 payment year rather than await NQF endorsement because of the public health importance of the problem being addressed, and having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Data Reporting and Submission. To accelerate attention to maternal morbidity and mortality, CMS proposes to 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 would be the 12-month calendar year occurring two years prior to the payment year (e.g., calendar year 2022 reporting for FY 2024 payment).

Hospitals would submit data using a CMS-approved web-based data collection tool available on the CMS Quality Net website (https://qualitynet.cms.gov/).

b. Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) ("Hybrid HWM Measure")

Measure Details. CMS proposes to adopt one new hybrid measure (based on both claims and electronically submitted clinical data) to more comprehensively measure the mortality rates of hospitals and to improve its ability to measure mortality rates in smaller volume hospitals beginning with IQR program payment year FY 2026. The measure's core clinical data elements are intended to reflect patient clinical status at admission. 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 similar case and service mixes. The measure includes Medicare FFS beneficiaries aged 65-94 years, and some high-risk major trauma diagnoses (e.g., burns) are excluded.

For this and other hybrid measures combining clinical (EHR) data with claims data, CMS performs the measure calculations and reports results back to data submitters. Calculation of reliable results for the Hybrid HWM measure would require hospitals to report the core clinical data element vital signs for at least 90 percent of the Medicare FFS aged beneficiary discharges and the laboratory test results for at least 90 percent of non-surgical patients. (Lab results are not used in risk adjustment of the surgical service divisions' cohort.) CMS notes that the clinical elements and lab tests were chosen from those nearly universally collected by hospitals at or soon after admissions.

More detailed information about this measure 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 would update the measure specifications annually for changes in diagnosis codes and clinical laboratory value sets.

Measure Rationale. In discussing the proposed Hybrid HWM measure, CMS reviews data about hospital deaths from preventable harm and the associated costs. CMS considers hospital mortality to be a quality indicator that is meaningful to patients and informative for hospital quality improvement efforts. CMS notes that the proposed measure would provide beneficiaries and caregivers with a single overall point of comparison across hospitals; the measure also would address the current information gap about small hospital mortality, as smaller facilities often do not meet case reporting thresholds for the hospital IQR program's existing condition-specific mortality measures that are displayed on Care Compare. The measure aligns with the agency's goal to move towards digital quality measures (dQMs).

Pre-rulemaking. CMS describes in detail the progress of the measure through the standard pre-rulemaking process for quality measure addition. The measure was placed on the December 2017 MUC list. The measure was modified by CMS in response to input from stakeholders and the

MAP as follows: 1) exclusion of patients enrolled in hospice; 2) analysis for the impact of social risk factors (minimal for dual-eligibility and Socioeconomic Index score); 3) successful testing of consistent EHR clinical data entry and extraction across hospitals; and 4) a voluntary reporting period prior to the start of required reporting. The MAP expressed conditional support for rulemaking contingent on measure endorsement by the NQF, which subsequently occurred (NQF # 3502).

Data Reporting and Submission. In keeping with the MAP's recommendation and the stepwise approach taken by CMS for a similar hybrid hospital readmission measure (Hospital HWR, NQF # 2879), the agency proposes an initial voluntary reporting period for the Hybrid HWM measure to run from July 1, 2022 through June 30, 2023. Mandatory reporting would begin July 1, 2023 through June 30, 2024 to be used for FY 2026 payment determinations, with a similar timeline for subsequent payment years. In keeping with established policies, hospitals would 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.[59] Hospitals would be required to submit data to CMS using Quality Reporting Data Architecture Category I (QRDA I) files.

CMS notes that the six linking variables should be submitted for 100 percent of discharges in the measurement period, but hospitals would meet IQR program requirements if they submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period. During the voluntary data collection period hospitals who fail to meet the proposed data submission requirements would not be penalized but once the Hybrid HWM measure becomes mandatory, failing to meet the requirements would result in the hospital receiving the IQR Program update penalty. CMS concludes by providing details of proposed timeline for public display of Hybrid HWM measure results on Care Compare that includes a 30-day review period for hospitals before results are posted. The first posting is expected to occur as part of the July 2025 Care Compare website refresh.

c. COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

Measure Details. CMS proposes to add a new process measure to the Hospital IQR Program beginning with IQR program payment year FY 2023 to track the percentage of healthcare personnel (HCP) who receive a complete COVID-19 vaccination course, calculated as:

> Numerator. The cumulative number of HCP eligible to work in the healthcare facility for at least one day in the submission period and who received a complete vaccination course against SARS-CoV-2.
> Denominator. The cumulative number of HCP eligible to work in the healthcare facility for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC.[60]

[59] Linking variables such as hospital CMS Certification Number and date of birth are used by CMS to match a patient's EHR clinical data to the associated claims data.
[60] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, Appendix B. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B

Risk adjustment is not required for this process measure. Full specifications are available on the CDC website: https://www.cdc.gov/nhsn/nqf/index.html.

Measure Rationale. In discussing the proposed measure, CMS reviews the declaration of COVID-19 as a PHE, methods of viral transmission, vulnerable patient groups, and guidelines for prioritizing vaccine recipients. 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.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process for stakeholder input. The proposed measure was included on the December 21, 2020 MUC list. The MAP conditionally supported the measure contingent upon clarification of measure specifications, and CMS returned to the MAP with results from further measure testing and updated specifications. CMS states its intention to seek NQF endorsement of the measure, but proposes to adopt the measure for FY 2023 given ongoing COVID-19 PHE impacts and having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Data Reporting and Submission. CMS proposes 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 proposes 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). Data submission would be required quarterly, and data would be submitted through the CDC National Health Safety Network (NHSN) web-based surveillance system for at least one week each month; the CDC would report data quarterly to CMS. Hospitals are familiar with NHSN reporting, which they already use for the existing HCP Influenza Vaccination measure. CMS plans to publicly report the CDC-calculated vaccination coverage rates.

d. Hospital Harm – Severe Hypoglycemia Electronic Clinical Quality Measure (eCQM) (NQF # 3503e)

Measure Details. CMS proposes to add a new eCQM to the Hospital IQR Program beginning with payment year FY 2025 to track the rate at which severe hypoglycemia events occur after hospital administration of antihyperglycemic medications.[61] The measure is calculated as:

> Numerator. The number of hospitalized patients with a blood glucose test result of less than 40 mg/dL (indicating severe hypoglycemia) with no repeat glucose test result greater than 80 mg/dL within 5 minutes of the initial low glucose test, and where an antihyperglycemic medication was administered within 24 hours prior to the low glucose result.
> Denominator. All inpatients aged 18 years or older discharged and to whom at least one dose of an antihyperglycemic medication was administered during the index admission.

There are no additional inclusion or exclusion criteria. Risk adjustment is not required for this outcome measure that addresses harm that is largely avoidable. Measure specifications are available at https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/1/cms816v1.

[61] For this measure, severe hypoglycemia is defined as a glucose test result of less than 40 mg/dL.

Measure Rationale. In discussing the proposed measure, CMS notes that hypoglycemic events are common after administration of antihyperglycemic medications to diabetic patients in the hospital setting but that rates vary considerably across facilities. 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.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process. The proposed measure was included on the December 2018 MUC list. 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).

Data Reporting and Submission. Data for this eCQM are collected through the facility's EHR and reported to CMS using the facility's Certified Electronic Health Record Technology (CEHRT) system. The submission deadline for this and all other Hospital IQR Program eCQMs is the end date of the second month following the close of the applicable calendar year reporting period (moved to the next business day if the deadline falls on a weekend or federal holiday). The first data submission deadline for this measure would be February 29, 2024.

e. Hospital Harm – Severe Hyperglycemia Electronic Clinical Quality measure (eCQM) (NQF # 3533e)

Measure Details. CMS proposes to add a new eCQM to the Hospital IQR Program beginning with payment year FY 2025 that would track the frequency of severe hyperglycemic events among hospitalized diabetic patients.[62] The measure is calculated as:

> Numerator. The total number of severe hyperglycemic events across inpatient hospitalizations.
> Denominator. The total number of eligible hospital days across inpatient hospitalizations of patients aged 18 years or older who have one or more of the following: a diagnosis of diabetes that starts before or during the index admission; administration of at least one dose of insulin or any antidiabetic medication during the index admission; or presence of at least one blood glucose value greater than 200 mg/dL at any time during the index admission.[63]

There are no additional inclusion or exclusion criteria. Risk adjustment is not required for this outcome measure that addresses harm that is largely avoidable. Measure specifications are available at https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/cms871v1.

Measure Rationale. In discussing the proposed measure, CMS notes that hyperglycemic events are common among inpatients and that event rates vary considerably among hospitals. These

[62] For this measure, a severe hyperglycemic event is defined as a day in which the patient's blood glucose result was > 300 mg/dL, or a day on which a glucose value was not documented but was preceded by two consecutive days during which at least one glucose value was ≥ 200 mg/dL.
[63] Hospital days are measured in 24-hour periods. Events occurring in the first 24-hour period after hospital arrival are not counted, nor those in the last pre-discharge period (if less than 24 hours) or after the tenth hospital day.

events are associated with increased infection rates and longer lengths of stay as well as higher costs. Evidence suggests that severe hyperglycemic events are largely avoidable with proper glycemic management.

Pre-rulemaking. CMS describes following the usual pre-rulemaking process. The proposed measure was included on the December 2019 MUC list and awarded conditional support for rulemaking by the MAP, contingent on NQF endorsement. The measure received NQF endorsement in July 2020 (NQF # 3533e).

Data Reporting and Submission. Data for this eCQM are collected through the facility's EHR and reported to CMS using the facility's Certified Electronic Health Record Technology (CEHRT) system. The submission deadline for this and all other Hospital IQR Program eCQMs is the end date of the second month following the close of the applicable calendar year reporting period (moved to the next business day if the deadline falls on a weekend or federal holiday). The first data submission deadline for this measure would be February 29, 2024.

2. Proposals to Remove Measures from the Hospital IQR Measure Set

CMS proposes to remove 5 measures from the Hospital IQR Program for the FYs 2023 through 2026 payment determinations. None would continue to be used in either the HRRP, the Hospital VBP Program or the HAC Reduction Program. The following table summarizes the measures proposed for removal, the removal factor cited, and whether the measure would remain in a hospital inpatient pay-for-performance program (HRRP, HVBP or HAC RP).

> Previously adopted factors considered by CMS in IQR program measure removal decisions: 1) the measure is "topped out;" 2) it does not align with current clinical guidelines or practice; 3) another more broadly applicable measure is available; 4) performance or improvement on the measure does not result in better patient outcomes; 5) another available measure is more strongly associated with the desired patient outcomes; 6) collection or public reporting of the measure leads to negative unintended consequences other than patient harm; 7) it is not feasible to implement the measure specifications; and 8) the costs associated with a measure outweigh the benefit of its continued use.

Measure Proposed for Removal	Removal Effective (payment year)	Removal factor	Retained another program?
Deaths Surgical Inpatients w/Serious Treatable Complications	FY 23	3–better/ broader	(1)
Exclusive Breast Milk Feeding eCQM	FY 26	5-tied to outcome	(2)
Admit decision time to ED departure (ED-2) eCQM	FY 26	8-costs	No
Anticoagulation Rx for Atrial Fibrillation/Flutter eCQM	FY 26	8-costs	No
Discharged on Statin Medication eCQM	FY 26	8-costs	No
(1) Removal contingent on adoption proposed HWM measure (2) Removal contingent on adoption of proposed Maternal Morbidity measure; reporting overlap will occur with new measure for two years			

CMS further discusses the proposed removal of each measure and provides information for each beyond that shown in the table:

- *Deaths Among Surgical Inpatients with Serious Treatable Complications.* The proposed new Hybrid HWM measure applies to a much broader set of patients and conditions and aligns with the IQR program goal to increase use of EHR data.
- *Exclusive Breast Milk Feeding (eCQM).* The proposed new Maternal Mortality measure is a more holistic assessment of the quality of maternal care.
- *Admit decision time to Emergency Department departure (ED-2) eCQM.* Recent studies show that this measure of ED boarding time is inconsistently reported and not strongly associated with adverse outcomes.
- *Anticoagulation Rx for Atrial Fibrillation/Flutter eCQM.* Hospitals seldom choose to report this measure and the patients are captured in stroke measure STK-02 eCQM.
- *Discharged on Statin Medication eCQM.* Current guidelines emphasize antiplatelet therapy over use of statins.

3. Considerations for Future Measures

a. 30-Day All-Cause Mortality Measure for Patients Admitted With COVID-19 Infection (COVID-19 mortality measure)

CMS is considering the development and inclusion of a hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID-10 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 on in 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.

CMS specifically seeks comment on:

- **The timeline and approach for implementing a COVID-19 mortality measure (e.g., confidential initial voluntary then public mandatory reporting);**
- **Patients to be included in the measure's cohort (e.g., specific diagnosis codes);**
- **Inclusion of both Medicare FFS beneficiaries and Medicare Advantage patients;**
- **Potential risk-adjustment factors available in administrative claims data; and**
- **Stratification of measure results, for example by social risk factors or COVID-19 disease prevalence.**

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. This measure has been available for voluntary reporting by hospitals participating in the Comprehensive Care for Joint Replacement (CJR) payment model since the model began in April 2016. CMS provides a detailed, lengthy history of the measure's evolution and also

reviews data concerning the prevalence of pain and disability attributed to hip and knee osteoarthritis, the frequency of THA and TKA performance, and reporting of outcomes as reported by patients.

Highlights include 1) variation in clinical practices and in PROs that suggest room for improvement; 2) use of pre-defined functional improvement scores derived from joint-specific PRO instruments (e.g., the Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement, HOOS, JR); and 3) comparison of preoperative functional scores to those at one year postoperatively. Also described are the measure's data sources, outcome, cohort, inclusion and exclusion criteria, risk adjustment, calculation as well as potential approaches for implementing the measure in the IQR program. Full measure specifications are addressed in the THA/TKA PRO-PM methodology report, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.

CMS specifically seeks public comment on the following:

- **A phased approach to implementation;**
- **Data collection and submission mechanisms;**
- **Required data thresholds (i.e., number of completed PRO instruments); and**
- **Applicability of the measure to procedures performed in outpatient settings (e.g., hospital outpatient departments, ambulatory surgical centers, and hospital observation stays).**

4. Potential Future Efforts to Address Equity in the Hospital IQR Program

CMS refers readers to a discussion and RFI concerning closing the equity gap in hospital quality programs in general (see sections IX.B of the rule and of this summary) before discussing future considerations specific to the IQR program.

a. Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

CMS seeks comment on:

- **The possibility of confidentially reporting in HSRs stratified results using indirectly estimated race and ethnicity, dual eligibility status and potentially by disability status, for the HWR claims-only measure, using both of CMS' disparity methods (within and across hospitals), and**
- **The possibility of publicly reporting stratified results using indirectly estimated race and ethnicity, dual eligibility and potentially by disability status, publicly on Care Compare, after at least one year of confidential reporting for the HWR claims-only measure.**

b. Potential Future Reporting of a Structural Measure to Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

CMS seeks comment on collecting one or more attestation-based structural measure(s) to assess priority domains related to organizational commitment to health equity, such as:

- **The degree to which the hospital organization regularly examines existing algorithms for the presence of bias, and regularly shares these findings with the hospital organization's leadership and board of directors;**
- **The presence of the hospital organizational disparities impact statement, along the lines of actionable steps as discussed in the CMS publication "Building an Organizational Response to Health Disparities: Disparities Impact Statement";[64]**
- **The presence of an updated language access plan as defined by the CMS Office of Minority Health, to competently care for individuals with limited English proficiency;[65]**
- **The presence of an updated communication access plan as described by the CMS Office of Minority Health, to competently care for individuals who have visual or sensory disabilities;[66]**
- **The degree to which the hospital's EHR system is capable of collecting demographic data elements (e.g., race, ethnicity, primary language) in alignment with national data collection and interoperable exchange standards[67]; and**
- **The degree to which the hospital conducts staff training on best practices in collection of demographic information.**

CMS further requests feedback about conceptual and measurement priorities for better illuminating organizational commitment to health equity, as well as an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities.

5. Form, Manner, and Timing of Data Submission

CMS reviews procedural and data submission requirements for the Hospital IQR Program; no changes are proposed to most of these policies except as described below.

a. Procedural Requirement Updates § 412.140

First, CMS proposes to update two references in this section to the QualityNet website to the current URL (QualityNet.cms.gov replaced QualityNet.org in November 2020). Second, CMS proposes to replace the terms QualityNet Administrator and QualityNet System Administrator

[64] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities. 2018. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
[65] A language access plan is defined as a document that spells out how to provide services to individuals who are non-English speaking or have limited English proficiency.
[66] Centers for Medicare and Medicaid Services. Improving Communication Access for Individuals Who Are Blind or Have Low Vision. https://www.cms.gov/files/document/omh-visual-sensory-disabilities-brochure-508c. pdf.
[67] 2015 Edition Cures Update certification criteria: Demographic Data, 45 C.F.R §170.315(a)(5); Standardized API for Patient and Population Services, 45 C.F.R. §170.315(g)(10); and United States Core Data for Interoperability, 45 C.F.R §213.

with QualityNet security official in two places in this section to align with other CMS quality programs. The identified individual's responsibilities would not change.

b. Proposed Updates to Requirements for eCQM Reporting

For eCQM reporting, hospitals are currently permitted to utilize health IT certified to the 2015 Edition or the 2015 Edition Cures Update. CMS is proposing to require hospitals to use only certified technology consistent with the 2015 Edition Cures Update beginning with CY 2023 reporting/FY 2025 payment determinations. If this change is finalized, all available eCQMs used in the Hospital IQR Program for CY 2023 reporting/FY 2025 payment and subsequent years would need to be reported using technology certified to the 2015 Edition Cures Update.

No changes are proposed to the previously adopted file formats and related policies (e.g., zero denominator declarations). Further, no changes are proposed to previously established deadlines for eCQM reporting: the date at the end of the second month following the close of the calendar year or the next business day when falling on a weekend or Federal holiday.

c. Proposed Updates to Requirements for Hybrid Measure Reporting

As for eCQM reporting, hospitals are currently permitted to utilize health IT certified to the 2015 Edition or the 2015 Edition Cures Update for hybrid measure reporting. CMS is proposing to require hospitals to use only certified technology consistent with the 2015 Edition Cures Update beginning with CY 2023 reporting/FY 2025 payment determinations.

No changes are proposed to the previously adopted file formats and related policies (e.g., zero denominator declarations) for hybrid measure reporting. Further, no changes are proposed to previously established reporting deadlines.

d. Reporting and Submission Period Updates for New Structural and NHSN Measures

Maternal Mortality Structural Measure. As described in summary section C.1.a above, CMS proposes to 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 would be 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 would follow the current 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. Hospitals would submit data using a CMS-approved web-based data collection tool available on the CMS Quality Net website (https://qualitynet.cms.gov/).

COVID-19 Vaccine Coverage Among HCP Measure. As described in summary section C.1.c above, CMS proposes 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 proposes 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) for each facility's CMS Certification Number. Data submission would be required quarterly, and data would be

submitted through the CDC National Health Safety Network (NHSN) web-based surveillance system for at least one self-selected week each month of each reporting quarter; the CDC would report data quarterly to CMS. CMS plans to publicly report the CDC-calculated vaccination coverage rates if the measure is finalized.

e. IQR Program Data Validation Educational Review Process

Heretofore, CMS 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, as the agency has been unable to calculate the necessary confidence interval in a timely manner for the fourth quarter of validation. CMS can now calculate the confidence interval for all four validation quarters and proposes to update the educational review process for chart-abstracted measures accordingly.

CMS provides several tables that show the quarters previously established for data validation of chart-abstracted measures for the FY 2023 and FY 2024 payment years. CMS proposes to use the corrected scores that result from educational reviews for all four quarters of data validation beginning with payment year 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. The remaining previously established timelines and processes would continue to apply without change for chart-abstracted measures.

CMS notes that no changes are being proposed to the educational review process for eCQMs, which can be requested once annually by a hospital following receipt of its annual validation results report from CMS.

f. Other Policies

No changes are proposed to multiple other IQR program data submission policies including those for data accuracy and completeness acknowledgment, public data display after a preceding period for hospital review, and previously finalized incremental increases in the number of quarters of required eCQM reporting. No changes are proposed to the ECE policy for the IQR program, not to policies for reconsideration and appeal of payment determinations.

Finally, no changes are made to the policies for calculating Overall Hospital Quality Star Ratings as updated and finalized in the CY2021 OPPS/ASC final rule (85 FR 86193 through 86236). Hospital IQR Program measure data will continue to be included in star rating calculations.

6. 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: IQR Program Measures by Payment Determination Year fy21 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 ED departure for admitted patients (NQF #0497)**	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 9 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2 Safe Use of Opioids	Report 4 of the following 11 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2 HH-01 HH-02 Safe Use of Opioids	Report Safe Use of Opioids AND 3 of the following 7 eCQMs: STK-02 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-05 VTE-1 VTE-2 HH-01 HH-02	Report Safe Use of Opioids AND 3 of the following 7 eCQMs: STK-02 STK-05 VTE-1 VTE-2 HH-01 HH-02
Healthcare-Associated Infection Measures						
Central Line Associated Bloodstream Infection (CLABSI)	X	Removed				
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

Summary Table: IQR Program Measures by Payment Determination Year fy21 X= Mandatory Measure, V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
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	Removed			
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 Mortality*			X	X	X	X
*Measure proposed for adoption in FY 22 rule ** Measure replaced by Hybrid HWR measure for FY26 *** Proposed for removal in this rule *** Proposed for removal effective FY26						

D. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

CMS provides a list of references to rules in which PCHQR program policies have been established. The program requires quality reporting by PCHs and measure data are publicly available but the results have no associated payment consequences. In this rule, CMS proposes one measure removal, one measure addition, two minor administrative updates, and to codify PCHQR Program requirements. No changes are proposed to policies for updating technical specifications, data submission procedural requirements, exceptional circumstances exceptions

or public data reporting via the CMS Provider Data Catalog (https://data.cms.gov/provider-data/),.

CMS refers readers to the RFI about closing health equity gaps in CMS quality programs (see section IX.B of the rule and this summary), noting that comments are invited regarding the potential stratification of quality measures and creation of a health equity score, including applicability to the PCHQR Program. Similarly, CMS refers readers to the RFI about expanding the use of the FHIR standard to move CMS quality programs, including the PCHQR, towards a fully digital measure portfolio (see section IX.A of the rule and this summary).

1. Measure Updates

PCHQR Program measures

a. Removal of the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology Measure (PCH-15) (NQF # 0383)

The PCHQR Program considers the same eight measure removal factors as those used in the Hospital IQR Program (listed above in summary section IX.C.2). CMS proposes to remove PCH-15 from the PCHQR program's measure set beginning with the FY 2024 program year based on Factor 7: it is not feasible to implement the measure specifications. CMS states that the measure steward is reverting to a prior measure version and will no longer maintain the specifications for the measure version used for PCHQR program reporting. The steward also has emphasized that the prior version, to which the steward is reverting, is designed to be paired with a measure that has been removed from the PCHQR program's measure set. CMS further notes that removal of this chart-abstracted measure would also reduce provider reporting burden and that the measure is approaching "topped out" status.

b. Adoption of the COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

CMS proposes to adopt into the PCHQR Program for reporting beginning with the FY 2023 program year the COVID-19 Vaccination Coverage HCP measure. The rationale for the measure and the pre-rulemaking process followed by CMS are identical to those described for the adoption of this measure into the Hospital IQR Program (see summary section IX.C.3). The measure specifications are also identical other than being adjusted to reflect numbers of PCH rather than those of IPPS hospital HCP. The proposed data reporting, submission, and public display requirements are also taken from the Hospital IQR Program measure (e.g., initial reporting period of October 1, 2021 through December 31, 2021 for PCHQR program year FY 2023).

2. Procedural Requirement Update

CMS proposes to replace the terms QualityNet Administrator with QualityNet security official to align with other CMS quality programs. The identified individual's responsibilities would not change. Relatedly, CMS clarifies that failure to maintain an active security official after a PCH

successful registers to participate in the PCHRQ Program will not result in a finding that the PCH did not successfully participate in the program.

3. PCHQR Program Regulations

CMS proposes to codify PCHQR Program requirements in new § 412.24 entitled "Requirements under the PPS-Exempt Caner Hospital Quality Reporting (PCHQR) Program". Also 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 2013IPPS/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/LTCHPPS 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 extraordinary circumstances exception policy (adopted in the FY 2014IPPS/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.

4. PCHQR Program Measures for the FY 2023 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in two tables at the end of section IX.D of the rule, combined and reproduced below with modifications.

PCHQR Program Measures for FY 2023 and Subsequent Years	
Measure	**Public Display Began**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	2019
NHSN CDI (NQF #1717)	2019
NHSN MRSA bacteremia (NQF #1716)	2019
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	2019
NHSN COVID-19 vaccination coverage among health care personnel	Proposed for program addition FY 2023
NHSN CLABSI (NQF #0139)	Deferred until 2022
NHSN CAUTI (NQF #0138)	Deferred until 2022
Clinical Process/Oncology Care	
Oncology: Plan of Care for Pain (NQF #0383)	2016; Proposed for program removal FY 2024

PCHQR Program Measures for FY 2023 and Subsequent Years	
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210)	Not Displayed
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	Not Displayed
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	Not Displayed
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	Not Displayed
Patient Experience of Care	
HCAHPS (NQF #0166)	2016
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	2020 Finalized for program removal FY 2022
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	Not Displayed
Surgical Treatment Complications for Localized Prostate Cancer	Not Displayed

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP is a pay-for-reporting quality program implemented in FY 2014. LTCHs submit data to CMS on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument using the Internet Quality Improvement Evaluation System Assessment Submission and Processing (iQIES ASAP) system. An LTCH that fails to meet the program's quality data reporting requirements is subject to a 2.0 percentage point reduction in the 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 proposes to adopt one new measure and to update the denominator of another; increase by two the number of publicly reported measures; and update the policy for public reporting of LTCH QRP data in response to impacts on the program by the COVID-19 PHE. CMS also issues RFIs about future LTCH QRP measures; strategies to move CMS quality programs onto digital platforms, including use of the FHIR standard; and closing the equity gap in the LTCH QRP and other CMS quality programs.

1. LTCH QRP Measures

a. Measures Adopted for FY 2022

CMS provides a table of the 17 measures previously adopted into the LTCH QRP for the FY2022 program year, reproduced below (with modifications).

LTCH QRP Measure Set, by Year				
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	X	X	X
Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678)	X	Replaced		
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury		X	X	X
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)	X	X	Removed	
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)	X	X	Removed	
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	X	X	X
All-Cause Unplanned Readmissions for 30 Days Post Discharge from LTCHs (NQF #2512)	Removed			
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)	X	X	X	X
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)	X	X	X	X
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)	X	X	X	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X	X
NHSN Ventilator Associated Event Outcome Measure	X	X	Removed	
Medicare spending per beneficiary MSPB-PAC LTCH	X	X	X	X
Discharge to Community PAC LTCH*	X	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X	X
Drug Regimen Review Conducted with Follow-up		X	X	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay		X	X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate		X	X	X
Transfer of Health Information to the Provider – PAC Measure				X
Transfer of Health Information to the Patient – PAC Measure				X
* Measure updated to remove baseline nursing facility patients beginning in FY 2020.				

b. New Measure: COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

CMS proposes to add a new process measure to the LTCH QRP beginning with FY 2023 to track the percentage of HCP who receive a complete COVID-19 vaccination course. The proposed measure could generate actionable quality improvement data on vaccination rates and aid patients with decision-making about post-acute care facilities. The measure would be calculated

as follows:

Numerator. The cumulative number of HCP eligible to work in the LTCH for at least one day in the reporting period who received a complete vaccination course against SARS-CoV-2.

Denominator. The cumulative number of HCP eligible to work in the LTCH for at least one day in the reporting period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC.[68]

Risk adjustment. Adjustment is not required for this process measure.

CMS developed this measure in collaboration with the CDC, and full specifications are available on the CDC website: https://www.cdc.gov/nhsn/nqf/index.html. In discussing the proposed measure, CMS reviews the declaration of COVID-19 as a PHE, methods of viral transmission, vulnerable patient groups such as LTCH residents, and guidelines for prioritizing vaccine recipients. Following the usual pre-rulemaking process for stakeholder input, the proposed measure was included on the December 21, 2020 Measures Under Consideration List. The Measure Applications Partnership (MAP) conditionally supported the measure contingent upon clarification of measure specifications, and CMS returned to the MAP with results from further measure testing and updated specifications.

CMS states its intention to seek NQF endorsement of the measure, but proposes to adopt the measure for FY 2023 given ongoing COVID-19 PHE impacts and having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical. CMS notes that the measure most similar to the proposed COVID-19 HCP measure is the NQF-endorsed measure of influenza vaccination among HCP (NQF #0431), a measure already included in the LTCH QRP.

CMS estimates the regulatory burden of data submission for this new measure would be 12 hours per year for each LTCH at an annual cost ranging from approximately $330 to $550 per LTCH. Aggregate burden for all SNFs is estimated to total approximately 4,608 hours and $160 million.

c. Updated Measure: Transfer of Health Information to the Patient-Post-Acute Care (TOH-Patient-PAC)

CMS proposes to update the specifications for this process measure's denominator beginning with FY 2023 to exclude patients discharged home under the care of an organized home health service or hospice. Currently the denominators for the TOH-Patient-PAC measure and the companion TOH-Provider-PAC measure both include patients discharged home under the care of an organized home health service or hospice. The revised TOH-Patient-PAC denominator would be limited to discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living.

[68] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, Appendix B. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B.

2. RFI: Future Year Quality Measures

CMS seeks comment on the importance, relevance, appropriateness and applicability on each of the following assessment-based quality measures and concepts under consideration for future addition to the LTCH QRP:

- Frailty,
- Opioid use and frequency,
- Patient reported outcomes,
- Shared decision-making process,
- Appropriate pain assessment and pain management processes,
- Malnutrition, and
- Health equity.

For this RFI and the others below, CMS states that it will not respond to these comments through the IPPS/LTCH PPS FY 2022 final rule, but they will be considered in future policy making.

3. RFI: Fast Healthcare Interoperability Resources (FHIR)

CMS requests input into the agency's planning for transformation to a fully digital quality enterprise, and specifically asks about the following:

- EHR/IT systems currently used by commenters and if they participate in a health information exchange;
- How commenters share information currently with other providers;
- Approaches by which CMS could incent or reward commenters who use health information technology (HIT) in innovative ways to reduce burden for LTCHs (and other post-acute care providers);
- Resources and tools for use by LTCHs (and other post-acute care providers) and HIT vendors to facilitate interoperable, fully electronic health information sharing that incorporates FHIR standards and secure application programming interfaces (APIs); and
- Willingness of HIT vendors who work with LTCHs (and other post-acute care providers) to participate in pilots or models that align measure collection standards across care settings (e.g., sharing patient data via secure FHIR-based APIs for calculating and reporting digital measures).

In providing background for this RFI, CMS offers a definition for digital quality measures (dQMs): quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. CMS notes that a dQM's score includes a calculation that processes digital data; the agency also lists multiple examples of dQM data sources (e.g., electronic health records - EHRs, wearable medical devices).

CMS discusses the potential role of FHIR-based standards for efficient exchange of clinical information across clinical settings by clinicians through APIs. Exploration is underway at the agency regarding the use of FHIR-based APIs to access quality data already being collected through its Quality Improvement and Evaluation System (QIES) and the Internet QIES (iQIES),

with consideration also being given to using FHIR interfaces to access standardized assessment data from LTCH EHRs.

CMS concludes the discussion of this RFI by committing to using policy levers and collaborating with stakeholders to transition to fully digital quality measurement across the agency, with staged implementation of a cohesive portfolio of dQMs and incorporation of principles from the HHS National Health Quality Roadmap.

4. RFI: Closing the Health Equity Gap in Post-Acute Care QRPs

CMS requests information on potential revisions to the LTCH QRP to facilitate comprehensive and actionable reporting of health disparities, specifically:

- Recommendations for measures or measurement domains addressing health equity;
- Guidance on social determinants of health to be added to those already included in the LTCH QRP as standardized patient assessment data elements (SPADES);
- Recommendations that promote equity in outcomes, such as providing facility-level performance data to each LTCH, stratified by social risk factors (similar to reports being given to hospitals about their readmissions for dual-eligible versus other beneficiaries);
- Data sources and methods already in use by commenters for reducing disparities and improving outcomes; and
- Changes to address current challenges in capturing and exchanging patient information on social determinants of health for use in care delivery and decision making.

As background for this RFI, CMS reviews multiple examples of poor health outcomes that could stem from disparate care across patient populations (e.g., higher COVID-19 complication rates for black, Latino, and Indigenous and Native Americans relative to whites). CMS adopts for purposes of this RFI a definition of equity taken from Executive Order 13985 issued on January 21, 2021: "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality". Finally, examples are provided of ongoing efforts by CMS to enhance the transparency of information about healthcare disparities, such as the addition of SPADES for required reporting of selected social determinants of health in the LTCH QRP beginning with FY 2020.

5. Form, Manner, and Timing of Data Submission: COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

Because the COVID-19 PHE is ongoing, CMS proposes for this measure an initial data submission period of October 1, 2021 through December 31, 2021 for use in the FY 2023 LTCH QRP. For FY 2024 and subsequent years, a full calendar year submission period is proposed (e.g., all 12 months of CY 2022 data would be reported for the FY 2024 program year). Data

submission through the CDC's NHSN web-based surveillance system by each LTCH would be required for at least one week each month, and the CDC would report data quarterly to CMS for use in the LTCH QRP. CMS proposes to require LTCHs to utilize the NHSN's specifications and data collection tools as specified for this measure by the CDC when LTCHs submit their data (NHSN materials are available at http://www.cdc.gov/nhsn/).

6. Policies Regarding Public Display of Measure Data for the LTCH QRP

LTCH QRP measure data can be accessed through CMS' Care Compare and Provider Data Catalog web pages in the *Long-term care hospitals* section.[69]

a. Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Measure

CMS proposes to begin public reporting of the LTCH SBT Day 2 measure beginning with the March 2022 Care Compare refresh, or as soon as technically feasible. Data reporting for this measure by LTCH providers began July 1, 2018. The inaugural data publicly displayed on Care Compare would be from July 1, 2020 through June 30, 2021 while the Provider Data Catalog would contain data from July 1, 2018 through December 31, 2019.

Acceptable reliability of the LTCH SBT Day 2 measure requires 20 or more eligible cases during each performance period. The criteria for "eligible cases" are contained within the measure's denominator specifications. CMS proposes to flag on Care Compare those LTCHs with fewer than 20 eligible cases during a performance period as having too few cases to report, and no results would be displayed for those facilities.

b. Ventilator Liberation Rate for the PAC LTCH QRP Measure

CMS proposes to begin 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 would be from July 1, 2020 through June 30, 2021 while the Provider Data Catalog would contain data from July 1, 2018 through December 31, 2019.

Acceptable reliability of the LTCH Ventilator Liberation Rate measure requires 20 or more eligible cases during each performance period. CMS proposes to flag on Care Compare those LTCHs with fewer than 20 eligible cases during a performance period as having too few cases to report, and no results would be displayed for those facilities.

c. COVID-19 Vaccination Coverage among HCP

CMS proposes to begin public reporting of the COVID-19 Vaccination HCP Coverage measure beginning with the September 2022 Care Compare refresh, or as soon as technically feasible. Data collection for this measure, using Q4 2021 data. An additional quarter of data would be

[69] See https://www.medicare.gov/care-compare/ and https://data.cms.gov/provider-data/, respectively.

added with each subsequent refresh until a rolling four quarters of data could be shown continuously.

7. Public Reporting of Measures with Fewer than Standard Numbers of Quarters Due to COVID-19 Effects

Overview. CMS proposes temporary changes to the data collection quarters specified in prior rulemaking for LTCH QRP measure results that are publicly displayed on Care Compare. The proposed collection period changes are designed to account for incomplete data reporting during the COVID-19 pandemic and to return to pre-pandemic public reporting timelines as rapidly as feasible, while preserving the usefulness and accuracy of the displayed results.

Normally four successive quarters of data are used in calculating measures derived from the LTCH's LCDS patient assessment instrument and eight quarters for claims-based measures.[70] CMS notes that its guidance memo of March 27, 2020 included an exception to extant data reporting policy that allowed all LTCHs to voluntarily forgo QRP data reporting for Q4 2019, Q1 2020, and Q2 2020.

Analytic Approach and Results: *Initial Steps*. CMS discusses at length the data analyses used in developing the proposed changes. Analytic steps included 1) identifying all of the quarterly Care Compare refreshes of LTCH QRP results that could be impacted by the suspension of data reporting; and 2) separately analyzing the data actually submitted by LTCHs during Q4 2019, as those data were generated before the PHE was declared, though may have been submitted after the declaration. CMS lists the Care Compare refreshes identified as being potentially impacted by the PHE in Table IX.E.-03 of the rule. The agency also found that when compared to data from FY 2018 and FY 2019, the Q4 2019 data were similar for level of reporting and for outcomes trends; therefore, the Q4 2019 data were included in the October 2020 refresh as had been established in prior rulemaking.

Analytic Approach and Results: Data Freeze and the COVID-19 Affected Reporting (CAR) Scenario. After reviewing the available Q1 2020 and Q2 2020 data, CMS decided not to utilize them for public display. Instead, the agency determined that the most straightforward, efficient, and equitable approach was to freeze (hold constant) the Care Compare-displayed data with the October 2020 refresh values, until reliability of the results for subsequent quarters approached pre-pandemic levels. To shorten the duration of the data freeze, CMS explored reducing the number of data quarters used at each refresh. In this analysis, termed the CAR scenario, data quarters were decreased from 4 to 3 for measures derived from the MDS and from 8 to 6 for claims-based measures. Reportability and reliability were found to be acceptable under the CAR scenario.

Revised and Proposed Schedules for Data Display. The combined revised (data freeze) and proposed (CAR scenario) reporting schedule for SNF QRP measures based on the MDS is shown in Table IX.E-04 of the rule. December 2020 refresh data would be frozen through the

[70] One LCDS-based measure uses 8 quarters of data collection for publicly displayed results: Change in Mobility Among LCH Patients Requiring Ventilator Support, and it is treated as if it were a claims-based measure in CMS' proposal.

September 2021 refresh, the CAR scenario would be applied for the December 2021 refresh, and normal (4-quarter) reporting would resume with the March 2023 refresh.

The combined revised (data freeze) and proposed (CAR scenario) reporting schedule for claims-based measures is shown in IX.E-05 of the rule. Data would be frozen through the September 2021 refresh, the CAR scenario would be applied through the June 2023 refresh, and normal (8-quarter) reporting would resume with the September 2023 refresh.

CMS worked with CDC on assessing and analyzing the data collection quarters for the LTCH QRP's publicly displayed CDC-NHSN measures (CAUTI, CLABSI, CDI, Vaccination Coverage for Influenza among HCP). A data freeze and CAR scenario combination approach was developed and is included as a proposal in this rule. Readers are directed to Tables IX.E-06 through IX.E-09 and the accompanying narrative for the operational details for each measure.

F. Medicare and Medicaid 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 (PIP) is subject to an update factor reduction equal to three quarters of the market basket. In the impact analysis section of this proposed rule, 105 hospitals are estimated to fail to meet the meaningful use requirements for FY 2022 payment and would receive an update factor of 0.425 percent. An additional 24 hospitals are estimated to fail to meet both the meaningful use and IQR Program requirements and under the proposed rule would receive an update factor of -0.2 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 proposes to extend continuous 90-day reporting for the Medicare Promoting Interoperability Program EHR reporting periods in 2023. For 2024, it proposes an EHR reporting period of a minimum of any continuous 180-day period for new and returning participants. **CMS seeks comments on these proposals.**

CMS reminds readers that under the statute, the Medicaid Promoting Interoperability Program will end in 2021 and that December 31, 2021 is the last date states may make Medicaid PIP payments to Medicaid eligible hospitals.

Reporting periods for these programs are codified in the definition of *EHR reporting period* at §495.4.

2. Query of Prescription Drug Monitoring Program (PDMP) Measure

CMS discusses the history of the PDMP measure, which in past rulemaking was added as an optional measure for EHR reporting periods in 2019, 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 where 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.

In this rule, CMS proposes 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 also proposes to 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 would align with the MIPS Promoting Interoperability performance category. **Comments are sought on this proposal.**

Noting the importance of this measure and its desire to make the Query of PDMP measure mandatory in the near future, **CMS seeks comments on the future direction for the measure with respect to the following:**

- To what degree would all eligible hospitals and CAHs be prepared to report on the current attestation-based Query of PDMP measure in the near future? What additional considerations would need to be addressed before transitioning to a performance-based version of the measure?
- Would changes to the Query of PDMP measure be necessary to accommodate other technical approaches that may be implemented in the future, such as exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®?
- What, if any, exclusions should be made available as part of the measure's specifications with regard to eligible hospitals and CAHs?
- When will state PDMPs be ready to effectively exchange data with provider systems using HL7® FHIR® to support this measure? What are the most common standards and approaches used to access PDMP data through provider systems currently?
- What technical considerations exist for intrastate vs. interstate PDMP queries? How could health information exchange networks play a role in expanding access to PDMP data? In what ways could FHIR® applications be supported to safely share PDMP data within a clinician's workflow?

3. Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

Beginning with the EHR reporting period in 2022, CMS proposes 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. This would include all patient health information from encounters on or after January 1, 2016.

CMS notes the January 1, 2016 encounter start date aligns with the date of service finalized under the Patient Access and Interoperability final rule for MA organizations, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs to make available to beneficiaries and enrollees certain claims and clinical data that they maintain through a Patient Access API. CMS also considered alternative encounter start dates for its proposal, including January 1, 2012 and January 1, 2019. **It seeks comment on its proposal as well as the alternatives it considered.**

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 proposes the following new optional measure for the Health Information Exchange objective: Health Information Exchange (HIE) Bi-Directional Exchange measure (at §495.24(e)(6)(ii)(C)). It would serve as 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 proposed new measure would incentivize the eligible hospital or CAH 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. The new measure would be worth 40 points; would be reported by attestation; and would require a yes/no response. Eligible hospitals or CAHs would 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 proposed 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 would have to 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 would not be 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.

CMS seeks comment on the proposal.

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 6 finalized measures.[71] 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.

[71] 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.

b. Proposed Modifications to the Public Health and Clinical Data Exchange Objective

Beginning with the EHR reporting period in 2022, CMS proposes to require reporting on the following four measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. 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 proposes to change the setting for which data is required to be submitted from urgent care to the emergency department (POS 23). It would make a technical change to the first exclusion to the measure by eliminating a reference to urgent care.

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 does not propose any changes to the description of the measure or to any of the exclusions. It believes 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 does not propose any changes to the description of the measure and notes 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 would 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 does not propose any changes to the description of the measure or to any of the exclusions. It notes that electronic laboratory reporting by hospitals lags in comparison to larger commercial and clinical laboratories. The agency believes that requiring this measure would 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. Proposed Scoring of the Public Health and Clinical Data Exchange Objective

Beginning with the EHR reporting period in 2022, eligible hospitals and CAHs would receive 10 points for this 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 would 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, would 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 proposes to 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) would be 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 would make these measures optional, it proposes to eliminate the exclusions previously available for 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 proposes 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 would have to 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 would consist of one "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.

The measure would be required, but it would not be scored. Reporting a "yes" or "no" will not affect the total PIP score. CMS expects that the eligible hospital or CAH would 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 would not be 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 proposes to no longer require the second and third attestation statements. 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 discusses further specific examples of stakeholder confusion in the preamble to the proposed rule. It also proposes to make 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".

Table IX.F.-02 in the proposed rule lists the objectives and measures for the Medicare PIP for the EHR reporting period in 2022 as revised to reflect CMS' proposals. Table IX.F.-03 lists the 2015 Edition certification criteria required to meet the objectives and measures.

9. Proposed 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 has to 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 proposes to raise the minimum threshold score to 60 points. **It seeks comments on this proposal.**

Taking into account the proposals above, the scoring methodology for 2022 is shown in the following table.

Proposed 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 proposal made in the FY 2022 IPPS/LTCH proposed rule.

10. 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 one self-selected quarter of data during the calendar

year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program. The 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 proposes to adopt 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 proposes to remove the following four eCQMs for the PIP program beginning with the 2024 reporting period/FY 2026 payment determination:

- STK-03 Anticoagulation Therapy for Atrial Fibrillation/Flutter (NQF #0436)
- 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)

d. Proposed Updates to Certification Requirements for eCQM Reporting – 2015 Edition Cures Update

CMS proposes 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.

Comments are solicited on all these proposals.

11. Requests for Information

a. Additional Objectives or Measures Adopting FHIR-based API Standards

CMS intends to further align Medicare PIP measures with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), with the Health Information Exchange as well as the Public Health and Clinical Data Exchange

objectives. It notes that this is an ongoing development process in collaboration with ONC. **CMS seeks comments on the following questions**:

- To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective? What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update?

- How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures? What are promising FHIR-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability program and the ONC Health IT Certification Program?

- To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?

- What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?

b. Patient Access Outcomes Measures

Noting an overall increase in the number of patients accessing medical records online, including doing so to perform meaningful actions such as viewing test results, CMS believes that it is critical to have a strong partnership among EHR vendors, health care providers, and beneficiary users' outcomes to improve the future of health care and furthering interoperability. It seeks comment on potential changes to the Medicare PIP to better target patient access outcomes related to use of patient portals or third-party applications. **It seeks feedback on the following questions**:

- What do stakeholders believe would be useful ways to measure patients' access to their electronic health information using health IT methods such as patient portals and/or third-party applications? What actionable figures related to users' medical record behavior, including but not limited to, the frequency of logins, number of messages sent, or lab results viewed could be captured?

- How effectively is the Medicare PIP currently measuring the use of health IT-enabled processes to improve patient outcomes? What measures in the current program are most relevant to patient outcomes?

- Should CMS consider requiring providers to maintain a record of third-party applications which patients have used to access their patient health information through APIs incorporated within certified technology so that this information could be used to assess patient usage of these applications?

- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Medicare PIP) that can increase patient utilization of tools to access their health information? How do these technologies and features support improved access or usability within

EHR systems and other applications (for instance, alternate authentication technologies that can simplify consumer logon)? How could CMS reward health care providers for higher adoption rates and use of these available technologies?

- What are key administrative processes that could benefit from more efficient electronic workflows? How could CMS measure and reward participating eligible hospitals or CAHs for either greater uptake of patient portal access or subsequent health outcomes?

c. Clinical Notes

The ONC 21st Century Cures Act final rule finalized eight types of clinical notes required under the USCDI version 1: (1) Discharge Summary Note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedure Note. In the 2021 PFS final rule, CMS aligned the CEHRT definition under the Medicare PIP with the updates to certification criteria finalized under the ONC 21st Century Cures Act final rule, including updates to several certification criteria to refer to the USDCI and the expanded support for clinical notes specified in USCDI version 1.

CMS seeks feedback on changes that will better support the availability of clinical notes to patients. Specifically, with respect to the Provide Patients Access to their Health Information measure, are there additional changes to this measure, or other program guidance, that could further facilitate the availability of clinical notes to patients? It also seeks feedback on the development of a mandatory and independently scored measure for the Medicare PIP to allocate points for the use of "clinical notes" types supported by certified health IT. It also seeks comment on the types of clinical notes that are commonly sought by patients but not easily accessible to them.

d. Designating High Performing Hospitals

Noting that some industry-sponsored models have been developed to recognize and distinguish hospitals and CAHs for their adoption and utilization of EHR functionality, **CMS seeks comment on the development of, or support and adoption of, designating high performing hospitals in the context of EHR excellence**. Specifically, it solicits feedback on the following questions:

- Are there specific industry-based models that are wholly representative of HER excellence in the hospital or CAH setting? Which model is most representative and why?

- What are the limitations in applying for, or receiving one of the industry-based designations? What would help facilitate hospitals and CAHs to obtain and maintain such a designation?
- Does earning a designation accurately reflect EHR excellence within the patient community or amongst hospitals and CAHs?

- Is there interest in a CMS-driven designation program? If so, which components are most meaningful and valuable to hospitals and CAHs?

Additionally, CMS would like feedback on the potential of developing a Star Rating for Promoting Interoperability, or, adding Promoting Interoperability as a category for existing Star Ratings, and whether the effort would accurately represent EHR excellence.

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 proposes to address this problem by clarifying states' obligations to providers of services for dual eligible beneficiaries. Specifically, CMS proposes 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 proposed rule, a state Medicaid agency would be required to allow enrollment of 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 notes that the proposed 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.

CMS is considering for future rulemaking additional regulatory changes to address a related concern that 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 an item or service that exceeds Medicaid day limits or other conditions for payment but does not exceed Medicare day limits or conditions. **CMS is requesting feedback from stakeholders on this practice and seeks specific examples.**

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 estimates that updating Medicaid systems including other provider types under this proposal would require 26 states to make systems changes. Using LTCHs as an example, CMS estimates an aggregate burden of just over $1 million or about $42,700 per state.
- New providers and suppliers enrolling in state Medicaid systems are likely to each need between three and six hours to complete the state's enrollment process. At the average hourly rate for an office manager, it would cost between $15,600 and $31,200 in the aggregate or between $87 and $173 for each LTCH to enroll. States' costs for reviewing the applications are expected to be similar.
- Reducing Medicare bad debt appeals. The proposal 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, it describes the case of "Select Specialty Hospital – Denver, et al v. Azar" in which 77 LTCHs in 26 states under which CMS ultimately paid a total of $23.6 million for bad debt claims that were denied for a period from 2005 to 2010. There are currently 20 open cases on the same issue.

B. Organ Acquisition Payment

1. Background

a. History of Medicare Organ Acquisition Policies

Medicare supports organ transplantation by providing a payment for the variety of organ acquisition services. Organ acquisition costs are excluded from the IPPS and paid separately on the basis of reasonable costs. Current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92-603) that extended Medicare coverage to individuals with end stage renal disease who required dialysis or transplantation.

In 1978, Congress added section 1881 to the Act that set forth Medicare payment for kidney transplantation and the coverage of organ procurement costs and living donor expenses, including Part A and Part B benefits for the living donor. The proposed rule recounts the history of Medicare payment for organ acquisition costs including that much development of policy was

done through sub-regulatory guidance.

CMS is proposing to codify into the Medicare regulations longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and proposing to codify some new organ acquisition payment policies. It is also proposing to move existing organ acquisition payment regulations or portions of existing kidney acquisition regulations within title 42 of the CFR Part 412, subpart G and Part 413, subpart H to a new proposed Part 413, subpart L, so that all organ acquisition payment policies are together.

b. Overview of Medicare Payment for Organ Transplantation

CMS provides the following definitions to improve clarity regarding how to refer to entities that are involved in acquiring and transplanting organs and how those organizations are paid.

- *Transplant Hospitals (TH)*. Paid for the costs of the transplant surgery and follow-up care through the IPPS. Organ acquisition costs are paid for on a reasonable cost basis. Hospitals must meet specific conditions of participation to be considered a TH.

- *Organ Procurement Organizations (OPO)*. Coordinate the procurement, preservation and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. OPOs must meet specific requirements of statute (the Act and the Public Health Service Act) and Conditions for Coverage (CfCs) in order to receive payment under Medicare or Medicaid for organ procurement costs. THs can be OPOs (known as HOPOs). Payments are made on a reasonable cost basis.

- *Histocompatibility Laboratories.* Provide laboratory services to ensure compatibility between donor organs and potential recipients in preparation for transplants. May be independent or hospital-based. Paid on a reasonable cost basis unless payment under the IPPS is applicable.

2. Organ Acquisition Payment Policy Proposals

The below describes clarifications or changes CMS is proposing as part of adopting sub-regulatory guidance in regulations or moving existing provisions of regulations to new subpart L. There is no explanation of policy provisions in the proposed rule that are unchanged.

a. Definitions

The preamble clarifies the distinction between a TH and a transplant program and the meaning of "freestanding":

- *Transplant Hospital*. Means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.
- *Transplant Program.* Means an organ-specific transplant program within a transplant hospital.
- *Freestanding*. Means independent OPO (IOPO). For an OPO to be an IOPO, it must file a Medicare cost report separate from the hospital.

This terminology is intended to establish consistent use of the above terms in place of "transplantation center" which meant a "transplant program" and "certified transplant center" that meant a TH.

The definition of "organ" differs for payment purposes than it does for CfCs. For the CfCs, a pancreas used for research or islet cell transplantation may be considered an organ. For payment purposes, the definition of "organ" does not include a pancreas that is only used for research purposes.

CMS explains in detail that organ acquisition costs include costs incurred in obtaining an organ intended to be transplanted even though the organ may ultimately be unusable. Costs for organs acquired for research purposes are not included in organ acquisition costs except for those organs intended to be transplanted that were unusable and donated for use in research.

b. Medical Complications

The proposed rule notes that CMS has received questions as to whether medical complications of a living organ donor are considered "organ acquisition costs." Living kidney donor complications related to the surgery to remove a kidney, which occur after the date of discharge, are not considered kidney acquisition costs. Living kidney donor complications are statutorily authorized to be paid under Part A or Part B in section 1881(d) of the Act, with no liability for deductibles or coinsurance. Medicare covers costs incurred for living kidney donor complications only if they are directly attributable to the kidney donation.

c. "Medicare Organs."

Medicare organ acquisition payment policy includes the presumption that some organs are transplanted into Medicare beneficiaries, despite the category name "Medicare usable organs" or "Medicare kidneys." As a result, through unintended consequences, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

In a 1978 final rule (43 FR 58370), Medicare established its intention to pay for kidney acquisition costs incurred for kidneys transplanted into Medicare beneficiaries only. In a 1988

proposed rule, CMS expressed its belief that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act (53 FR 6672).

Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries was also applied to non-renal organs because of the lack of organ tracking capabilities over the years and has led Medicare to reimburse THs and OPOs for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. CMS now believes that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payor information so that organ acquisition costs can be more appropriately assigned to the Medicare program for organs transplanted into Medicare beneficiaries.

CMS presents data from the Scientific Registry of Transplant Recipients (SRTR) and how it compares to the shares reported on Medicare cost reports regarding the percentage of organs transplanted into Medicare patients. The below table shows that Medicare has been paying a higher share of organ acquisition costs than demonstrated by the SRTR data.

Organ	2017 Medicare Share	2017 SRTR Medicare Share	2018 Medicare Share	2018 SRTR Share
Kidney	68.2%	58.9%	67.8%	58.6%
Heart	42.0%	31.6%	42.8%	33.0%
Liver	39.1%	28.4%	38.6%	29.2%
Lung	44.2%	43.9%	46.6%	45.7%
Pancreas	61.6%	49.1%	58.0%	45.8%
Intestine	18.1%	14.7%	14.9%	15.4%

CMS notes that each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN). OPTN policy provides that OPOs use organ tracking capability, and some THs also optionally use organ tracking capability. Per OPTN policies, THs, histocompatibility laboratories, and organ procurement organizations enter data into the OPTN database that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, match patients with available donor organs and submit required OPTN data.

For these reasons, CMS is proposing that THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare. For cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, CMS is proposing that Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability for the organ transplant, and pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. Other provisions of the regulations for determining Medicare's share are unchanged.

d. Donor Community Hospitals

Medicare-certified hospitals that are not THs but collaborate with OPOs to procure organs from cadaveric donors for transplantation are referred to as "donor community hospitals." Currently, when a donor community hospital incurs costs for services provided to the cadaveric donor, as authorized by the OPO following the declaration of death and consent to donate, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate.

Stakeholders have made CMS aware that some donor community hospitals are charging OPOs amounts that are in excess of reasonable costs for harvesting organs from cadavers, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. When donor community hospitals charge OPOs amounts not reduced to costs, and the OPOs pay the charges shown on the bill, those charges become incorporated as organ acquisition costs to the TH and are subsequently shared by Medicare. CMS indicates that not reducing the charges to costs is inconsistent reasonable cost payment principles under section 1861(v) of the Act.

CMS proposes to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

Stakeholders have also made CMS aware that some donor community hospitals are improperly billing OPOs for services provided to cadaveric donors prior to the declaration of death and consent to donate. This would be inappropriate because hospital services provided prior to the declaration of death and consent to donate are billable to the donor's insurance in the same manner hospital services are billable to an individual receiving services, regardless of whether the payor is Medicare. CMS is proposing to add § 413.418(a) in new subpart L, to specify that a donor community hospital (a Medicare-certified non-transplant hospital) incurs organ acquisition costs for donor organ procurement services authorized by the OPO following declaration of death and consent to donate.

e. Comment Solicitation on Surgeon Fees for Cadaveric Donor Kidney Excisions

CMS indicates that cost report data from 48 OPOs showed average surgeon fee costs per local kidney of $745. Medicare's payment is limited to $1,250 for excising a cadaveric donor kidney. While this limit is above the costs that OPOs are incurring, CMS has received comments suggesting the $1,250 limit needs to be raised. CMS is not making a proposal but requests comment on this issue.

C. Medicare Shared Savings Program

In a 2018 final rule for the MSSP (83 FR 67816), CMS finalized a redesign of participation options for ACOs that includes a BASIC track on which an ACO moves along a five-level "glide path" (Levels A through E) that transitions from one to two-sided risk bearing. With rare

exceptions, ACOs on the BASIC track are automatically advanced at the end of each performance year (PY) to the next glide path level and its associated higher level of risk bearing. The increased risk is accompanied by enhanced opportunities to achieve shared savings.

The COVID-19 PHE has created uncertainties for ACOs who are held accountable for the total costs and quality of an attributed patient population. In response, CMS created an option for a BASIC track ACO to forgo its first automatic advancement along the glide path ("freeze") for PY 2021 before returning to the glide path for the following performance year. At that time, the ACO would return to the glide path as if automatic advancement had occurred each year (e.g., an ACO who opted for a freeze at Level B instead of advancing to Level C would return a year later to the glide path at Level D). Nearly three quarters of BASIC track ACOs chose the freeze option for PY 2021.

The duration of the COVID-19 PHE remains unpredictable and MSSP ACO participants have asked that they be able to have a second opportunity to forgo automatic advancement for PY 2022 (i.e., remain at the same glide path level for PY 2022 as for PY 2021). CMS proposes to require that the choice to "freeze" be executed by an ACO executive who has the authority to legally bind the ACO. ACOs would continue to have the choice to advance more rapidly along the glide path than is required (e.g., advance from Level A directly to Level D the following year).

CMS also proposes several changes to regulation text to allow suspension of automatic advancement for a second year and to correct a cross-reference error.

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 2.3 percent, 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.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2022

	Number of Hospitals[1]	Proposed Hospital Rate Update Under MACRA[2] (1)	Proposed FY 2022 Weights and DRG Changes with Budget Neutrality[3] (2)	Proposed FY 2022 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2022 MGCRB Reclassifications[5] (4)	Proposed Rural Floor with Application of Rural Floor Budget Neutrality[6] (5)	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment[7] (6)	All Proposed FY 2022 Changes[8] (7)
All Hospitals	3,198	2.8	0.0	0.0	0.0	0.0	0.1	2.7
By Geographic Location:								
Urban hospitals	2,459	2.8	0.0	0.0	-0.1	0.0	0.1	2.7
Rural hospitals	739	2.5	0.1	0.2	1.1	-0.2	0.1	2.9
Bed Size (Urban):								
0-99 beds	633	2.7	0.0	0.0	-0.6	0.1	0.3	2.8
100-199 beds	755	2.8	0.0	0.0	-0.2	0.2	0.1	2.7
200-299 beds	427	2.8	0.0	0.1	0.2	0.1	0.1	2.6
300-499 beds	421	2.8	0.0	0.0	0.0	0.0	0.2	2.7
500 or more beds	223	2.7	0.0	-0.1	-0.2	-0.1	0.0	2.7
Bed Size (Rural):								
0-49 beds	313	2.4	0.1	0.3	0.3	-0.1	0.2	4.0
50-99 beds	254	2.5	0.1	0.2	0.8	-0.1	0.2	2.6
100-149 beds	94	2.5	0.1	0.3	1.0	-0.2	0.0	2.6
150-199 beds	39	2.6	0.0	0.1	1.3	-0.2	0.1	2.7
200 or more beds	39	2.6	0.1	0.1	2.0	-0.2	0.0	3.0
Urban by Region:								
New England	112	2.8	0.0	-1.0	1.8	2.7	0.0	2.2
Middle Atlantic	304	2.8	0.0	-0.3	0.1	-0.3	0.1	2.0
East North Central	381	2.8	0.0	-0.1	-0.2	-0.3	0.0	2.8
West North Central	160	2.7	-0.1	0.3	-0.7	-0.3	0.7	3.1
South Atlantic	402	2.8	0.0	0.3	-0.5	-0.3	0.0	3.1
East South Central	144	2.8	0.0	-0.1	-0.3	-0.3	0.0	2.7
West South Central	364	2.8	0.0	-0.4	-0.5	-0.3	0.0	2.6
Mountain	172	2.7	0.0	0.0	0.0	0.0	0.2	2.6
Pacific	370	2.7	-0.1	0.5	0.2	0.4	0.1	2.9
Puerto Rico	50	2.8	-0.4	-0.2	-1.0	0.2	0.1	2.0
Rural by Region:								
New England	19	2.6	0.0	-0.4	1.4	-0.2	0.0	3.5
Middle Atlantic	50	2.5	0.2	0.3	0.7	-0.2	0.0	2.6
East North Central	114	2.5	0.1	0.2	0.8	-0.1	0.0	2.5
West North Central	89	2.3	0.0	0.0	0.3	-0.1	0.2	2.8
South Atlantic	114	2.5	0.1	1.0	1.3	-0.2	0.0	3.2

	Number of Hospitals[1]	Proposed Hospital Rate Update Under MACRA[2] (1)	Proposed FY 2022 Weights and DRG Changes with Budget Neutrality[3] (2)	Proposed FY 2022 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2022 MGCRB Reclassifications[5] (4)	Proposed Rural Floor with Application of Rural Floor Budget Neutrality[6] (5)	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment[7] (6)	All Proposed FY 2022 Changes[8] (7)
East South Central	144	2.7	0.1	-0.1	2.1	-0.2	0.1	2.9
West South Central	136	2.5	0.1	0.0	1.5	-0.3	0.0	2.6
Mountain	49	2.2	0.0	0.6	0.0	0.0	0.8	1.6
Pacific	24	2.4	0.0	0.0	1.1	-0.1	0.0	5.5
By Payment Classification:								
Urban hospitals	1,965	2.8	0.0	0.0	-0.5	0.0	0.1	2.6
Rural areas	1,233	2.7	0.0	-0.1	0.8	0.0	0.1	2.8
Teaching Status:								
Nonteaching	2,034	2.7	0.0	0.2	0.1	0.1	0.1	2.8
Fewer than 100 residents	907	2.8	0.0	0.0	0.0	0.0	0.2	2.6
100 or more residents	257	2.7	0.0	-0.1	-0.1	0.0	0.0	2.7
Urban DSH:								
Non-DSH	505	2.8	0.0	0.0	-0.5	0.0	0.2	2.6
100 or more beds	1,210	2.8	0.0	0.0	-0.5	0.0	0.1	2.7
Less than 100 beds	350	2.8	0.0	0.0	-0.5	0.3	0.2	2.9
Rural DSH:								
SCH	260	2.3	0.1	0.1	-0.2	0.0	0.1	2.7
RRC	622	2.7	0.0	-0.1	0.9	-0.1	0.1	2.7
100 or more beds	34	2.7	0.0	0.0	-0.5	1.5	0.0	2.5
Less than 100 beds	217	2.6	0.1	0.3	0.9	-0.3	0.2	3.3
Urban teaching and DSH:								
Both teaching and DSH	674	2.8	0.0	0.0	-0.6	-0.1	0.1	2.6
Teaching and no DSH	74	2.8	0.0	-0.1	-0.9	-0.2	0.1	2.0
No teaching and DSH	886	2.8	0.0	0.2	-0.4	0.2	0.1	2.8
No teaching and no DSH	331	2.8	0.0	0.1	-0.6	-0.2	0.2	2.7
Special Hospital Types:								
RRC	555	2.8	0.0	-0.1	0.9	-0.1	0.1	2.8
SCH	304	2.3	0.0	0.1	-0.1	0.0	0.0	2.7
MDH	148	2.5	0.1	0.0	0.4	-0.1	0.1	2.8
SCH and RRC	151	2.4	0.0	0.1	0.4	0.1	0.0	2.5
MDH and RRC	24	2.4	0.0	0.0	0.4	-0.1	0.0	2.3
Type of Ownership:								
Voluntary	1,883	2.8	0.0	-0.1	0.1	0.0	0.1	2.6
Proprietary	828	2.8	0.0	0.1	0.0	0.0	0.1	2.8
Government	487	2.7	0.0	0.2	-0.3	0.0	0.0	2.9
Medicare Utilization as a Percent of Inpatient Days:								
0-25	643	2.8	0.0	0.0	-0.5	-0.1	0.0	2.8
25-50	2,113	2.8	0.0	0.0	0.1	0.0	0.1	2.7
50-65	366	2.7	0.0	-0.1	0.1	0.4	0.2	2.0
Over 65	51	2.6	0.1	0.1	-0.9	-0.2	0.1	3.3
FY 2022 Reclassifications:								
All Reclassified Hospitals	1,048	2.7	0.0	-0.1	1.0	0.0	0.1	2.7
Non-Reclassified Hospitals	2,150	2.8	0.0	0.1	-0.9	0.0	0.1	2.7

	Number of Hospitals[1]	Proposed Hospital Rate Update Under MACRA[2] (1)	Proposed FY 2022 Weights and DRG Changes with Budget Neutrality[3] (2)	Proposed FY 2022 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2022 MGCRB Reclassifications[5] (4)	Proposed Rural Floor with Application of Rural Floor Budget Neutrality[6] (5)	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment[7] (6)	All Proposed FY 2022 Changes[8] (7)
Urban Hospitals Reclassified	860	2.8	0.0	-0.1	0.9	0.0	0.1	2.6
Urban Non-Reclassified Hospitals	1,612	2.8	0.0	0.1	-1.0	0.0	0.1	2.7
Rural Hospitals Reclassified Full Year	304	2.5	0.1	0.2	1.9	-0.2	0.0	2.7
Rural Non-Reclassified Hospitals Full Year	422	2.5	0.1	0.2	-0.3	-0.1	0.2	3.3
All Section 401 Reclassified Hospitals	550	2.7	0.0	-0.1	0.7	0.0	0.1	2.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.6	0.1	0.0	2.6	-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 FY2019, 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 proposed hospital rate update and other adjustments, including the proposed 2.3 percent update to the national standardized amount and the proposed hospital-specific rate (the estimated 2.5 percent market basket update reduced by 0.2 percentage point for the proposed multifactor productivity adjustment), and the proposed 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 39 GROUPER, the proposed 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 proposed recalibration budgetneutrality factor of 1.000098 in accordance with section 1886(d)(4)(C)(iii) of the Act.