hfma
healthcare financial management association

PROPOSED RULE
Fiscal Year 2021 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule
SUMMARY

On May 11, 2020, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule describing federal fiscal year (FY) 2021 policies and rates for Medicare's prospective payment systems for acute care inpatient hospitals (IPPS) and the long-term care hospital prospective payment system (LTCH PPS). The final rule will be published in the *Federal Register* on May 29, 2020. The public comment period ends at 5:00 PM on July 10, 2020.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1735-P) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in long-term care hospitals paid under their respective prospective payment systems. The 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.

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

Table of Contents

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 3,199 acute care hospitals paid under the IPPS by about $2.07 billion in FY 2021 compared to FY 2020. The rule indicates that the increase results from an additional $1.98 billion in IPPS operating and uncompensated care payments and $89 million in IPPS capital and new technology add-on payments. While combined IPPS operating and uncompensated care payments are increasing $1.98 billion, uncompensated care payments are declining 6.4 percent or approximately $534 million.

A. Inpatient Hospital Operating Update

The proposed rule would increase IPPS operating payment *rates* by 3.1 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 3.1 percent rate increase is the net result of a market basket update of 3.0 percent less an annual multi-factor productivity (MFP) adjustment of 0.4 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 2.6 percent increase rather than a 3.1 percent increase.

Factor	Percent Change
FY 2021 Market Basket	3.0
Multifactor productivity adjustment	-0.4
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	3.1

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 2021, 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 3.0 percent or -0.75 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 2.25 percentage points.

CMS estimates that 54 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; 67 hospitals because they are not meaningful EHR users; and 14 hospitals are estimated to be subject to both reductions.

The update for hospitals that have not successfully submitted quality data will be 1.85 percent for FY 2021. The reduction to the update is applied before application of the MACRA

documentation and coding adjustment and equals the 2.6 percent market basket net of MFP less 0.75 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of 0.35 percent for FY 2021. This update is also applied before application of the MACRA documentation and coding adjustment and equals the 2.6 percent market basket net of MFP less 2.25 percentage points.

Hospitals that have neither successfully submitted quality data nor qualified as meaningful EHR users will receive an update of -0.4 percent or the 2.6 percent market basket net of MFP less 3.0 percentage points (the entire market basket).

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2021 payments increasing 2.5 percent. Not all policy changes are reflected in this total. For example, the total does not include increases in uncompensated care payments. The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2021 increase in payment rates	+3.1[1]
Outliers	-0.4[2]
Residual	-0.2[3]
Total	+2.5[4]

[1]Weighted average of hospital-specific rate update of 2.6 and 3.1 percent for all other hospitals.
[2] CMS has no actual FY 2019 claims data upon which to make an estimate of its FY 2020 outlier payments.
[3]CMS explains the residual and the total may be explained by "interactive effects among various factors" that CMS cannot isolate.

Table I Impact Analysis

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

Hospital Type	All Proposed Rule Changes
All Hospitals	2.5%
Urban	2.5%
Rural	2.3%
Major Teaching	2.7%

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

Other provisions having an impact include:

Rural Floor: The rural floor raises the wage index of urban hospitals such that an urban wage index may not be below the wage index for the rural area of its state. CMS calculates a national rural floor budget neutrality adjustment factor of 0.993991 (-0.6 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.1 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no change in payments; and urban hospitals in the New England region can expect a 2.1 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 payment by about $70 million to 45 hospitals and the out-migration adjustment that increases payments about $46 million to 203 providers.

New Technology Add-On Payments (NTAP).

CMS is changing its practice and approving 9 applications for NTAP payments in the proposed rule. In prior years, CMS did not evaluate whether a product met the substantial clinical improvement criterion until the IPPS final rule after considering public comments. However, technologies approved by the Food and Drug Administration (FDA) as a breakthrough technology or a qualified infection disease product (QIDP) are automatically deemed to have met the substantial clinical improvement criterion. If the technologies with these designations also meet the newness and cost criterion, CMS will indicate approval for NTAP in the proposed rule.

CMS estimates that costs for these technologies will be $240 million in FY 2021. NTAP payments are not subject to budget neutrality. The proposed rule provides a description of another 15 NTAP applications where CMS will make a decision in the final rule after considering public comments.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 6.4 percent or about $534 million. More detail on these calculations is in section IV. F.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2021 payments to an estimated 2,583 hospitals or 85 percent of all hospitals. The readmissions penalty is estimated to affect 0.69 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 2020.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute about $1.9 billion (2 percent of base operating MS-DRG payments) based on hospitals' performance scores. CMS includes an unnumbered table that illustrates the average

net percentage payment adjustment by category of hospital (e.g. Large Urban, Other Urban, Rural, etc.) in FY 2020.

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 780 of 3,125 non-Maryland hospitals with a HAC score.

Rural Community Hospital Demonstration Program. CMS is applying a budget neutrality adjustment for the Rural Community Hospital Demonstration Program based on $40.7 million in costs for FY 2021. For the final rule, the adjustment will be based on net costs of the demonstration in FY 2021 or total costs in FY 2021 less adjustments for updated 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 standardized amounts for this cost.

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

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] = 2.6 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.85 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.35 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.4 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 final rule were calculated applying the additional MACRA mandated documentation and coding adjustment of +0.5 percentage points for FY 2021. Additional budget neutrality adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 0.998761 (a decrease of 0.12 percent);
- Wage index, 0.9999362 (a decrease of 0.06 percent);
- Geographic reclassification, 0.988003 (a reduction of 1.20 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.998241 or -0.18 percent;

- Budget neutrality for a 5 percent cap on reductions to wage indexes of 0.99858 or -0.14 percent;
- The outlier offset factor is 0.949 or -5.1 percent;
- The rural community hospital demonstration program adjustment is 0.999642 or -0.04 percent;
- The adjustment for paying allogeneic hematopoietic stem cell acquisition cost on the basis of reasonable costs rather than under the IPPS is 0.999861 or -0.01 percent.

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

Factor	**Net Change**
Update	2.6%
DRG Recalibration	-0.124%
Wage index	-0.060%
Geographic Reclassification	+0.260%
25th Percentile	+0.035%
5% Cap	+0.026%
Outlier	0.000%
Rural Community Hospital	-0.013%
Allogeneic Hematopoietic Stem Cell	-0.014%
Doc and Coding	+0.500%
Net Change	3.16%

The capital rate increases by 1.3 percent from $462.33 to $468.36. The combined increase in the operating standardized amount and the capital rate will be 3.0 percent for FY 2021.

Note that the standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 2028 absent new legislation. The sequester reduction is applied as the last step in determining the payment amount for submitted claims and it does not affect the underlying methodology used to calculate MS-DRG weights or standardized amounts.

FY 2021 RULE TABLES 1A-1D

TABLE 1A. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2021							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.6 Percent)		**Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)**		**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)**		**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$4,084.16	$1,895.58	$3,994.60	$1,854.01	$4,054.31	$1,881.72	$3,964.74	$1,840.15

TABLE 1B. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX LESS THAN OR EQUAL TO 1)—FY 2021							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.6 Percent)		**Hospital Submitted Quality Data and is a NOT a Meaningful EHR User (Update = 0.35 Percent)**		**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update =1.85 Percent)**		**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,707.44	$2,272.3	$3,626.14	$2,222.47	$3,680.34	$2,255.69	$3,599.03	$2,505.86

TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE	
	Rate
National	$468.36

D. Outlier Payments and Threshold

To qualify for outlier payments for high cost cases, a case must have costs greater than the sum of the prospective payment rate for the MS-DRG, plus IME, DSH, uncompensated care and new technology add-on payments, plus the "outlier threshold" or "fixed-loss" amount, which is $26,552 in FY 2020. The sum of these components is the outlier "fixed-loss cost threshold" applicable to a case. To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's total covered charges billed for the case are converted to estimated costs using the hospital's cost-to-charge ratio (CCR). An outlier payment for an eligible case is then made based on a marginal cost factor, which is 80 percent of the estimated costs above the fixed-loss cost threshold (90 percent for patients in the burn DRGs).

FY 2021 outlier threshold. CMS is proposing to adopt an outlier threshold for FY 2021 of $30,006. CMS projects that the proposed outlier threshold for FY 2021 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 0.946097 to the capital federal rate to fund operating and capital outlier payments respectively.

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

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

FY 2018: $61,533.34 ($582,022,123,240 / 9,458,647 cases)
FY 2019: $65,442.49 ($601,183,502,371 / 9,186,440 cases)
Annual Rate of Increase: 6.4 percent (1.06353)
Two Year Rate of Increase: 13.1 percent (1.131096).

CCRs. CMS is using hospital CCRs from the December 2019 update to the Provider-Specific File (PSF) – the most recent data available for the proposed rule – and to apply an adjustment

factor to the CCRs to account for cost and charge inflation. The adjustment methodology compares the national average case-weighted operating and capital CCRs from the most recent (December 2019) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (December 2018 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:
December 2018: 0.255979
December 2019: 0.249649.
% Change: -2.47 percent or 0.975271.

Capital:
December 2018: 0.021043
December 2019: 0.020255.
% Change: -3.74 percent or 0.962553.

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

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

For the FY 2021 outlier threshold, CMS is proposing to use the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a beginning date on or after October 1, 2014, and on or before September 30, 2015). CMS indicated these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC for the proposed rule. For the FY 2021 proposed rule, CMS is using the December 2019 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 2015 for FY 2021). 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 estimated that reconciliation in FY 2015 resulted in hospitals being owed $2.5 million or less than 0.01 percent of total operating IPPS payments. As this figure rounds to 0.0 percent, CMS is not making any adjustment for reconciled operating outlier payments in setting the proposed FY 2021 outlier threshold.

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 payments to total payments is -0.01 percent based $965,065 in reconciled capital outlier payments owed to 16 hospitals.

FY 2019 Outlier Payments. CMS' current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.38 percent of actual total MS-DRG payments. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2019 are equal to the projected 5.1 percent of total MS-DRG payments.

FY 2020 Outlier Payments. While CMS says in this section that FY 2020 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2020, the impact section says that 2020 outliers are approximately 5.5 percent of total payments based on FY 2019 data.

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 enactments require CMS to make a series of annual positive adjustments to offset prior negative ones through FY 2023. For FY 2021, consistent with section 414 of the Medicare Access and CHIP Reauthorization Act, CMS is implementing a positive 0.5 percentage point adjustment to the standardized amount.

B. Proposed Changes to Specific MS-DRG Classifications

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

In the FY 2018 IPPS final rule, CMS changed the deadline to request updates to the MS-DRGs to November 1 of each year. CMS has found that with the ICD-10 coding system, some requests for changes to the MS-DRG classification require more time to identify and analyze all the data to evaluate the potential change. As a result, some of the topics discussed below require more analysis and CMS will continue to consider these topics in future rulemaking. In addition, to provide more time to evaluate requests, CMS is changing the deadline to request changes to the MS-DRGs to October 20th of each year. **To be considered for any updates or changes in FY 2022, comments should be submitted by October 20,**

2020 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 38 on its website. This test software reflects the proposed GROUPER logic for FY 2021; it includes the new diagnosis and procedure codes effective for FY 2021 and does not include the diagnosis codes that are invalid beginning in FY 2021. CMS is also making available a supplemental file in Table 6P.1a that includes the mapped Version 38 FY 2021 ICD-10-CM codes and the deleted Version 37 FY 2020 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' MS-DRG analysis is based on ICD-10 claims data from the September 2019 update of the FY 2019 MedPAR file, which contains hospital bills received through September 30, 2010 for discharges occurring through September 30, 2019.

In deciding on modifications to the MS-DRGs for particular circumstances, CMS considers whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG (discussed in greater detail in previous rulemaking, 76 FR 51487). CMS evaluates patient care costs using average costs and lengths of stay. CMS 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 criterion:

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

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

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

Criteria Number	Three-Way Split 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 criterial fail, CMS will determine if criteria are satisfied for a two-way split. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for the base MS-DRG. CMS notes that in a response to a request to specifically split an existing base MS-DRG into a two-way split, it will evaluate the criteria for both of the two-way splits, but it will not also evaluate the criteria for a three-way split.

CMS invites comment on the MS-DRG classification proposed changes as well as proposals to maintain certain existing MS-DRGs. Highlights of the discussions are summarized below; the reader is referred to the proposed rule for more specific details.

2. Pre-MDC

a. Bone Marrow Transplants

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

utilize the resources of an operating room, and are not surgical procedures. CMS proposes to re-designate MS-DRGs 014, 016 and 017 as medical MS-DRGs.

During the review of the logic for MS-DRGs 016 and 017, CMS identified 8 procedures that are currently designated as O.R. procedures and it proposes to re-designate these procedure codes from O.R. to non O.R. procedures.

CMS also received a request to split MS-DRG 014 into two severity levels based on the presence of an MCC.[1] CMS conducted analysis of MS-DRG 014 to determine if the criteria to create subgroups were met and found that the claims data did not support a two-way severity level split. CMS proposes to maintain the current structure of MS-DRG 014.

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

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

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

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

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

Section II.E.2.b of the preamble of this rule discusses the proposed relative weight calculation for the proposed new MS-DRG 018 for CAR T-cell Therapy and section IV.I for discusses the proposed payment adjustment for CAR T-cell clinical trial cases.

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

a. Carotid Artery Stent Procedures

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

During the review of claims data for these six codes, CMS reviewed the logic list for MS-DRGs 252, 253, and 254 (Other Vascular Procedures) and identified 36 ICD-10-PCS codes for procedures that describe dilation of the carotid artery with an intraluminal device with an open approach that are not currently assigned to MDC 01. CMS' clinical advisors supported adding these codes to MS-DRGs 034, 035, and 036 in MDC 01. For FY 2021, CMS proposes to reassign the identified 36 ICD-10-PCS codes (listed in the proposed rule) that describe procedures involving dilation of the carotid artery with an intraluminal device through an open approach to the GROUPER logic for MS-DRGs 034, 035, and 036.

b. Epilepsy with Neurostimulator

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

Based on its analysis of MS-DRG 023, CMS determined that the number of cases involving the RNS© neurostimulator (81 cases) is too small to warrant creating a new MS-DRG for these cases. CMS also examined the reassignment of these cases to MS-DRGs 020, 021, and 022 (Intracranial Vascular Procedures with PDX Hemorrhage). CMS' clinical advisors reviewed the claims data and the clinical issues and did not support reassigning these cases. CMS explored alternative options, including examining if these cases had at least one other procedure designated as an O.R. procedure and found that of the 81 cases, 19 reported at least one other procedure which had higher costs compared to the average costs of the other cases. CMS also reviewed the secondary diagnosis conditions reported for these 81 cases and found

that these patients typically have multiple MCC and CC conditions which contribute to the increased cost for these patients. CMS concludes there is insufficient data to reassign these cases to another MS-DRG and anticipates that in the future, additional data based on an increased number of cases could be used to evaluate these cases. CMS proposes to maintain the assignment of RNS© neurostimulator cases.

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

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

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

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

a. Left Atrial Appendage Closure (LAAC)

CMS received two separate but related requests involving the procedure codes describing the technology utilized in the performance of LAAC procedures. The first request was to reassign ICD-10-PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) from MS-DRG 274 (Percutaneous Intracardiac Procedures without MCC) to MS-DRG 273 (Percutaneous Intracardiac Procedures with

[2] All these tables are available on the CMS website at https://www.cms.gov/MEdicar/Medicare-Fee-for-Service-PAyment/AcuteInpatientPPS/index

MCC); ICD-10-PCS 02L73DK identifies the WATCHMAN LAAC device. The second request was to create a new MS-DRG specific to all LAAC procedures or to map all LAAC procedures to a different cardiovascular MS-DRG that have payment rates appropriate for the procedural costs. Cases involving LAAC procedures with a percutaneous or percutaneous endoscopic approach are assigned to MS-DRGs 273 and 274 (Percutaneous Intracardiac Procedures).

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

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

CMS' clinical advisors did not support creating a new MS-DRG for all LAAC procedures. The clinical advisors believe that procedure codes that describe a LAAC procedure with an open approach are more suitably grouped to MS-DRGs 273 and 274. CMS proposes to reassign the open approach ICD-10-PCS codes 02L70CK, 02L70DK, and 02L70ZK from MS-DRGs 250 and 251 to MS-DRGs 273 and 274.

b. Endovascular Cardiac Valve Replacement and Supplement Procedures

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

c. Insertion of Cardiac Contractility Modulation Device

CMS received a request to review the MS-DRG assignment for cases that identify patient who receive a cardiac contractility modulation (CCM) device system for congestive heart failure. CCM utilizes electrical signals which are intended to enhance the strength of the heart and overall cardiac performance. The requestor stated that MS-DRGs 222 through 227 (Cardiac Defibrillator Implant DRGs) include code combinations describing the insertion of the CCM device but the MS-DRG GROUPER logic needs to be revised to group cases reporting the use of the CCM device appropriately. The requestor noted that to date the procedure has been performed on an outpatient basis, but it is expected that some Medicare patients will receive CCM devices as hospital inpatients.

CMS agrees that the MS-DRG GROUPER logic needs to be revised and proposes to delete 12 clinically invalid code combinations for CCM devices to add 24 ICD-10-PSC combinations for CCM devices (listed in the proposed rule) to MS-DRGs 222 through 227.

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

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

Based on analysis of the claims data and input from its clinical advisors, CMS proposes to (1) maintain the current assignment of K35.20 to MS-DRGs 341, 342, and 342; (2) reassign diagnosis code K35.32 from MS-DRGs 338, 339, and 340 to MS-DRGs 341, 342, and 342; and (3) remove K35.32 from the complicated principal diagnosis list in MS- DRGs 338, 339, and 340.

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

a. Cervical Radiculopathy

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

Based on claims data for cases reporting a principal diagnosis of cervical radiculopathy with a spinal cord fusion, CMS found the average costs of the cases are consistent with the average costs of all the cases in MS-DRGs 028, 029, and 030 and also consistent with the average costs of all the cases in MS-DRGs 471, 472, and 473. CMS' clinical advisors did not support reassigning the diagnosis codes that describe radiculopathy in the cervical/cervicothoracic

area of the spine until it performs additional analysis of the appropriate assignment of these codes and other diagnosis codes describing radiculopathy. CMS proposes to maintain the diagnosis codes in MDC 01 at this time. CMS will do further analysis of this issue and **solicits comments on the appropriate assignment for all of the diagnosis codes describing radiculopathy, including input from neurology and orthopedic societies**.

b. Hip and Knee Joint Replacements

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

Based on claims data analysis and input from its clinical advisors, CMS does not agree with the first and second option suggested by the requestor. For option three, the clinical advisors recommended CMS conduct further review of cases reporting a hip replacement procedure with a principal diagnosis of hip fracture, with or without an oxidized zirconium bearing surface implant. CMS performed additional analysis of cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture for both MS-DRGs 469 and 470. Based on this analysis, the clinical advisors supported differentiating the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture from those cases without a hip fracture by assigning them to a new MS-DRG. CMS applied the criteria to create subgroups in a base MS-DRG and found the criteria for a two-way split for the "with MCC" and "without MCC' met all five criteria.

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

CMS notes that the Comprehensive Care for Joint Replacement (CJR) model includes episodes for hip fracture triggered by MS-DRGs 469 and MS-DRG 470. **CMS invites comments on the effect of the proposal to create new MS-DRGs 521 and 522 would have on the CJR model and whether to incorporate these new MS-DRGs, if finalized, into the CJR model's proposed extension to December 31, 2023**.[3]

[3]CMS notes the comment period for the CJR proposed rule closes on June 23, 2020 (85 FR 22978).

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

a. Kidney Transplants

CMS received two requests to review the MS-DRG assignment for procedures describing kidney transplantations. The first request was to designate kidney transplants as a Pre-MDC MS-DRG in the same manner as other organ transplants. The requestor stated it did not appear appropriate that a kidney transplant would group to MS-DRG 981 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) when diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease) was a legitimate principle diagnosis for this procedure. The requestor also suggested a severity level split for the MS-DRG for kidney transplants. The second request was to create a new MS-DRG for kidney transplant cases where the patient received dialysis during the inpatient stay and after the date of the transplant.

CMS notes that in the FY 2020 IPPS rules,[4] it proposed to add procedure codes for transplantation of allogeneic kidneys (ICD-10-PCS 0TY00Z0 and 0TY10Z0) to MS-DRG 264 in MDC 05. (Disease and Disorders of the Circulatory System). Cases reporting a principal diagnosis in MDC 05 with a procedure describing a kidney transplantation would group to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05. Commenters opposed CMS' proposal and raised concerns that the proposal would reduce the reimbursement for kidney transplantation of recipients with serious cardiac conditions by 33 percent. Commenters stated that cases involving both chronic kidney disease and heart failure should not be paid less that cases involving patients without serious comorbid conditions. After consideration of comments, CMS did not finalize its proposal and stated it would continue to examine this issue. Cases reporting a principal diagnosis in MDC 05 with a procedure describing kidney transplantation continue to group to MS-DRGs 981 through 983.

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

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

CMS acknowledges that MS-DRG 652 is one of the only transplant MS-DRGs not currently defined as a Pre-MDC. For Pre-MDC DRGs, the initial step in DRG assignment is based on the high costs of certain surgical procedures instead of the principal diagnosis. Pre-MDC

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

DRGs were added to Version 8 of the DRGs for services that were considered as very resource intensive. CMS states the current proposed refinements to MS-DRG 652 represent how it may further consider the concept of allowing certain procedures to affect MS-DRG assignment regardless of the MDC from which the diagnosis is reported. This might allow removing the Pre-MDC category and allow resource intensive procedures currently assigned to Pre-MDC MS-DRGs to be assigned to MS-DRGs within the clinically appropriate MDC.

(2). Create a new MS-DRG for kidney transplant cases where the patient receives dialysis. CMS' examined the impact of dialysis in cases in MS-DRG and found that the average length of stay and average cost of cases in MS-DRG 652 where the patient received hemodialysis and a kidney transplant were higher than for all cases in the MS-DRG. CMS did a similar analysis with patients that require a simultaneous pancreas/kidney transplant procedure and found similar findings for cases in Pre-MDC MS-DRG 008 (Simultaneous Pancreas/Kidney Transplant). CMS' clinical advisors believe that hemodialysis procedures performed either before or after kidney transplant or a simultaneous pancreas/kidney transplant contribute to increased resource consumption for these patients. Although the data only had a few cases describing a simultaneous pancreas/kidney transplant with hemodialysis procedures, CMS believes creating a separate MS-DRG for these cases would be consistent with the President's Executive Order on Advancing American Kidney Health.[5] CMS also examined if the criteria were met for severity level subgroups.

CMS proposes the following:

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

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

b. Proposed Addition of Diagnosis to Other Kidney and Urinary Tract Procedures Logic

CMS received a request to add 29 ICD-10-CM diagnosis codes to the list of principal diagnoses assigned to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract

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

Procedures) in MDC 11 when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices.

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

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

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

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

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

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

a. Adding Procedure and Diagnosis Codes

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

CMS proposes to move the cases reporting the procedures and/or principal diagnosis codes described below from MS-DRGs 981 through 983 and 987 through 989 into one of the

surgical MS-DRGs for the MDC which the principal diagnosis or procedure is assigned. The reader is referred to the proposed rule for a discussion of the following diagnoses:

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

b. Reassignment of Procedures.

CMS proposes the following reassignments

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

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

CMS has a list of procedures that are considered O.R. procedures. CMS 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.[6] 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.[7] CMS notes these proposed

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

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

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

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

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or 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 following requests:

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

- Endoscopic Revision of Feeding Tubes

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

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

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

Under the IPPS MS-DRG classification, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule[8], 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.[9] CMS hosted a listening session on October 8, 2019[10] to provide CMS an opportunity to receive public input on its analysis and to address any questions to assist the public in formulating written comments for consideration in the FY 2021 rulemaking.

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

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

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

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 invites 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.

a. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2021[11]

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
- Table 6J.2 – Proposed Deletions to the CC List

b. 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 a request to consider removing diagnosis codes describing any type of stroke that is designated as an MCC in the code range I60.00 through I63.9 from the CC Exclusion List when a principal diagnosis of diabetes in the code range E08.00 through E13 is reported. CMS reviewed this request and proposes to accept this request as reflected in Tables GH.1 and GH.2 for the CC Exclusion List.

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.

[11] 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; and
- Table 6D - Invalid Procedure Codes.

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

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 Version 37 manual file, along with the link to the mainframe and compute software for the MCE Version 37 (and ICD-10 MS-DRGs) are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS discusses requests it received by November 1, 2019 to examine specific code edit lists. The interested reader is referred to the proposed rule for discussion of the following edits:

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

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 encourages **comments on whether there are additional concerns with the current edits**, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to MSDRGClassificationChange@cms.hhs.gov by November 1, 2019 for FY 2021.

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.

Based on the MS-DRG proposals for FY 2021, the following tables, reproduced form the proposed rule, summarize the proposals for changes for Appendix D MS-DRG Surgical Hierarchy by MDC and MS-DRG of the ICD-10 MS-DRG Definitions Manual Version 38.

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

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

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

Proposed Surgical Hierarchy: MDC 08	
Proposed New MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity

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

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

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

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

- For diagnosis codes contact Donna Pickett, Co-Chairperson, ICD-10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments can also be sent to: nchsicd10cm@cdc.gov.
- For procedure codes send questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

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

CMS notes there were not any requests for an expedited April 1, 2020 implementation of a new code at the September 10-11, 2019 Committee meeting. However, as announced by the CDC on December 9, 2019, a new ICD-10 emergency code was established by the WHO for vaping related disorders, U07.0. In addition, a new emergency code was established on January 31, 2020 in response to the 2019 COVID-19 outbreak, U07.1. Effective with discharges on and after April 1, 2020, diagnosis code U07.0 is assigned to MDC 04 in MS-DRGs 205 and 206 (Other Respiratory System Diagnoses) and diagnosis code U07.1 is assigned to MDC 04 in MS-DRGs 177, 178, and 179 (Respiratory Infections and Inflammations).

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[12], 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

[12] 72 FR 47246 through 47251

those MS-DRGs. In the FY 2012 IPPS/LTCH final rule,[13] 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.

CMS generally maps new MS-DRGs onto the list when they are formed from procedures previously assigned to MS-DRGs that are already on the list. Therefore, if the applicable proposed MS-DRG changes are finalized, CMS would add proposed MS-DRGs 140, 141, 142, 552, and 552 to the list. CMS also proposes to continue to include the existing MS-DRGs current subject the policy as displayed in the table reproduce below from the proposed rule. These proposals are reflected in the table below (reproduced from the proposed rule).

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	129	Delete
MDC 03	130	Delete
MDC 03	141	Major Head and Neck Procedures with MCC
MDC 03	142	Major Head and Neck Procedures with CC
MDC 03	143	Major Head and Neck Procedures without CC/ MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 5	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC

[13] 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	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 5	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 5	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC
MDC 5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
MDC 5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without
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
MDC 5	320	Other Endovascular Cardiac Valve Procedures without MCC
MDC 8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with

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 8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without
MDC 8	466	Revision of Hip or Knee Replacement with MCC
MDC 8	467	Revision of Hip or Knee Replacement with CC
MDC 8	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC
MDC 8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC

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. In developing relative weights for the FY 2021, CMS uses two data sources:

- FY 2019 MedPAR data: Bills received through December 31, 2019 from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage claims and claims from facilities currently classified as critical access hospitals (CAH) are excluded. CMS used data from approximately 9,184,114 million Medicare discharges regrouped using the FY 2021 MS-DRG classifications.
- FY 2018 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2018 cost reporting periods, using the December 31, 2019 update of the FY 2018 HCRIS.

CMS calculates the IPPS relative weights by reducing hospital charges to cost using CCRs for 19 distinct cost centers. For FY 2021, CMS is not proposing to make 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 2021 on the CMS website at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-home-page#DataFiles Select file #4 under FY 20201 Proposed Rule Data files (HCRIS Data File FY 2021 Proposed Rule).

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

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

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

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

Group	FY 2020 CCR	FY 2021 CCR
Routine Days	0.432	0.422
Intensive Days	0.358	0.347
Drugs	0.189	0.190
Supplies & Equipment	0.299	0.304
Implantable Devices	0.299	0.300
Therapy Services	0.297	0.291
Laboratory	0.109	0.108
Operating Room	0.173	0.169
Cardiology	0.098	0.095
Cardiac Catheterization	0.106	0.102
Radiology	0.140	0.138
MRIs	0.072	0.070
CT Scans	0.034	0.034
Emergency Room	0.152	0.149
Blood and Blood Products	0.283	0.272
Other Services	0.346	0.350
Labor & Delivery	0.373	0.369
Inhalation Therapy	0.150	0.148
Anesthesia	0.077	0.074

The proposed rule cost-based relative weights were normalized by an adjustment factor of 1.818392 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

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

D. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(K) and (L) of the Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the IPPS. The regulations at 42 CFR 412.87 specify three criteria for a new medical service or technology to receive add-on payments under the IPPS: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

CMS notes that even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 or 3 years. CMS uses three criteria for evaluating whether a new technology is substantially similar to an existing technology[14]:

1. Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome;
2. Whether a product is assigned to the same or a different MS-DRG; and
3. Whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.

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

For purposes of the cost criterion, for FY 2021, CMS included the applicable MS-DRG thresholds in the data files associated with the FY 2020 annual IPPS rules. The proposed MS-DRG thresholds applicable to FY 2022 are included in the data files associated with the FY 2021 proposed rule on the CMS website.[15] As discussed below (section D.5.), CMS proposes using threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for new applicants and previously approved technologies, if those technologies would be assigned to a proposed new MS-DRG for that same fiscal year.

[14] 74 FR 43813 and 43814

[15] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

Under the third criterion, a medical service or technology must represent an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS final rule[16], CMS codified (§412.87(b)) the following aspects of how it evaluates substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of circumstances is considered when making a determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries.
- A determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries means the new service or technology offers:
- A treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The ability to diagnose a medical condition in a patient population where that condition is currently undetectable; the ability to diagnose a medical condition earlier than methods currently available and the evidence supports that making a diagnosis affects the management of the patient; or
- Significant improvement in clinical outcomes relative to services or technologies previously available as demonstrated by one of the following:
  - Reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
  - Decreased rate of at least one subsequent diagnostic or therapeutic intervention;
  - Decreased number of future hospitalizations or physician visits;
  - More rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
  - Improvement in one or more activities of daily living;
  - Improved quality of life; or
  - Demonstrated greater medication adherence or compliance; or
  - The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following 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).

Alternative Inpatient New Technology Add-on Payment Pathway. In the FY 2020 IPPS final rule[17], CMS finalized that 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. As discussed below (section D.8.), CMS proposes expanding the alternative pathway for QIDPs to include products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway and to refer more broadly to "certain antimicrobial products" instead of referring to a particular FDA program for antimicrobial products.

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

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

In the FY 2020 IPPS final rule[18], CMS finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology, other than a medical product designated as a QIDP, beginning with discharges on or after October 1, 2019, Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 65 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. For medical products designated as a QIDP, Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 75 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medical payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for a QDIP) of the

[17] 84 FR 42292 through 42297

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.[19]

Applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. CMS also notes that for FY 2022, complete application information, along with final deadlines for submitting an application, will be posted as it becomes available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. This web site will also post the tracking forms completed by each applicant and will be available before the publication of the proposed rule for FY 2022.

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

In their evaluation of individual applications, CMS considers the presentations made at the town hall meeting and written comments received by January 3,2020. 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

[19] 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.

[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.

consistent with the current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure.

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

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

For FY 2020, CMS proposes to discontinue eight new technology add-on payments for KYMRIAH™, VYXEOS™, VABOMERE™, the remedē® System, Giapreza™, the Sentinel® Cerebral Protection System, the AQUABEAM System, and ERLEADA™. CMS proposes to continue ten new technology add-on payments for ZEMDRI™, AndexXa™, AZEDRA®, CABLIVI®, ELZONRIS™, Balversa™, SPRAVATO™, XOSPATA®, JAKAFI™, T2Bacteria® Panel.

CMS summarizes these proposals in a table which is reproduced on the next page of this summary. The table includes information about the newness start date, CMS' decision, relevant final rule citations, the proposed maximum new technology add-on payment for FY 2021, and HCPCS coding used to identify cases eligible for the add-on payment. The reader is referred to the proposed rule for details about each decision.

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

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

Cost Criterion for new MS-DRGs[21]. In the FY 2016 IPPS final rule[22], CMS discussed whether the cost threshold value associated with a proposed new MS-DRG should be considered in determining whether the applicant meets the cost criterion. CMS invited public comments on this issue and after consideration of the comments, CMS agreed with the commenters and decided to use the cost threshold in effect at the time the new technology add-on application was submitted to determine if an applicant exceeded the cost threshold. CMS also agreed with commenters that this policy was most predictable for applicants. At the time of the FY 2106 final rule, however, CMS did not anticipate the onset of new, extremely high cost technologies, such as CAR T-cell therapy and the significant variance between the thresholds at the time of application and the thresholds based on the finalized MS-DRG assignment for the upcoming year. Based on the data file released with the FY 2021 final rule for FY 2022 applications, the threshold amount for the MS-DRG 016 (the current DRG assignment for CAR T-cell therapies) is $170,573 as compared to the threshold amount of $1,237,393 for the proposed new MS-DRG 018 for CAR T-cell therapies.

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

For example, CMS considers a technology assigned to MS-DRG ABC at the time of its application for FY 2022, and the procedure coding associated with the new technology is proposed to be assigned to a proposed new MS-DRG XYZ in the FY 2022 proposed rule. Instead of using the threshold for MS-DRG ABC based on the data file released with the FY 2021 final rule for FY 2022 new technology add-on payment applications, CMS proposes to use the proposed threshold for the newly proposed MS-DRG XYZ based on the data file released with the FY 2022 proposed rule (which would be considered the proposed thresholds for FY 2023 applications).

CMS believes this policy is consistent with section 1886(d)(5)(K)(ix) of the Act which requires that before establishing any add-on payment for a new medical service or technology, the Secretary seeks to identify one or more DRGs associated with the new technology (based on similar clinical or anatomical characteristics and the cost of the technology) and assign the new technology into a DRG where the average costs of care most closely approximate the costs of

[21] This issue is discussed in Section II.G.5.i of the preamble, in the discussion about the new technology add-on payment application for KTE-X19.
[22] 80 FR 49481 and 49482

care using the new technology. CMS notes this provision also states that no add-on payment will be made with respect to such new technology.

CMS invites public comment on its proposal to use the proposed threshold for the upcoming fiscal year for any proposed new MS-DRG to evaluate the cost criterion for technologies that would be assigned to the proposed new MS-DRG, beginning with FY 2022 new technology add-on payments for all other non-CAR T-cell therapies.

As discussed below, CMS proposes to apply this proposed policy to the new FY 2021 CAR T-cell applications, KTE-X19 and Liso-cel. CMS would also apply this policy to KYMRIAH and YESCARTA if they were still considered new and within the 3-year anniversary date of entry onto the U.S. market.

New Technology Applications. CMS received 15 applications for new technology add-on payments for FY 2021. The summary below provides a high-level discussion of each 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. Accelerate Pheno Test™ BC kit for use with Accelerate Pheno system

Accelerate Diagnostics, Inc. submitted an application for the Accelerate Pheno Test™ BC kit used with the Accelerate Pheno™ system used for fast diagnosis of bacteria and yeast blood stream infection and antimicrobial susceptibility testing (AST). The applicant states this is a novel technology that provides results in approximately 7 hours, as opposed to standard of care methods that typically take 2 to 3 days. The applicant stated that the T2 DX Biosystems with T2 Bacterial Panel provides a rapid organism identification (ID) but does not provide antibiotic susceptibility results.

Newness. The Accelerate Pheno Test™ BC kit received FDA de novo clearance on February 23, 2017 and the technology was immediately available on the market. On September 22, 2019, Accelerate Diagnostics submitted a 510(k) submission to FDA for product enhancements, including an additional organism-antimicrobial combination to the panel. 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 that the Accelerate Pheno Test™ BC kit is the only fast, automated, phenotypic, direct-from-blood culture ID/AST technology. The applicant explained that other FDA-cleared ID technologies require overnight culturing to produce an isolated colony of the pathogen and therefore take 1 to 2 days longer. The applicant also explained that rapid ID/genotypic resistance marker tests can provide fast results in hours directly from blood cultures but stated that these methods only provide partial results with less diagnostic certainty. The applicant also provided information describing the differences between the 510(k)-submission product (K192665) and the predicate product (DEN160032) approved by FDA in 2017. The applicant believes the product should be considered new because there is no other comparable technology and the technology has not yet experienced widespread use in hospitals. The applicant also believes the software updates and assay changes in the FDA 510(k) submission are substantive and meet the newness criteria.

For the second criterion (same or different MS-DRG), CMS believes that cases involving this technology would be assigned to the same MS-DRGs as cases using the 2017 FDA approved version and competing technologies. Similarly, for the third criterion (same or similar disease or patient population), CMS believes that the technology and the 2017 FDA approved technology, as well as competing technologies, would treat the same or similar type of disease and patient population.

CMS is concerned that the updated technology (510(k) submission) would not meet the newness criterion because it may be substantially similarly to the first version that was approved and available on the market in February 2017. CMS believes that both tests may use the same mechanism of action which consists of phenotypic, direct-from-positive blood culture identification and AST technology that provides minimum inhibitory concentration (MIC) values and susceptible, intermediate or resistant (SIR) antibiotic results. CMS also notes that similar to other diagnostic tests, the Accelerate Pheno Test™ BC kit uses positive blood cultures to identify microorganisms.

CMS is also concerned with lack of information from the applicant about the second and third substantial similarity criteria. CMS believes the costs associated with the Accelerate Pheno Test™ BC kit should be reflected in the relative payment weights for the MS-DRGs to which cases involving treatment with the 2017 version would be assigned. CMS notes that whether or not a technology has widespread adoption in U.S. hospitals is not relevant to the determination of whether the technology is "new". If a product is more than 2 to 3 years old, CMS considers its costs to be included in the MS-DRG relative weights, regardless of its use in the Medicare population.

Cost. The applicant identified 43 ICD-10-CM diagnosis codes that apply to conditions that may use its technology; 80 percent of the cases mapped to 8 MS-DRGs. Using the FY 2018 MEDPAR Limited Data Set (LDS), the applicant performed two analyses; the first based on 100 percent of the claims that included the specified ICD-10 codes and the second based on 80 percent of claims that mapped to the top 8 MS-DRGs. For both analyses, the applicant removed charges (approximately $339) for prior technology or technology being replaced, and other charges including cost savings related to reduced length of stay. The applicant reported that both analyses met the cost criterion. For the analysis based on 100 percent, the applicant computed a final inflated average case weighted standardized charge per case of $107,422 as compared to an average case-weighted threshold amount of $75,1010. For the analysis based on the 80 percent of cases, the applicant computed a final inflated average case weighted standardized charge per case of $86,956, as compared to the average case-weighted threshold amount of $71,401.

Substantial Clinical Improvement. The applicant states that data shows that the Accelerate Pheno Test™ BC kit offers the ability to diagnose a medical condition earlier than currently available methods and studies suggest that the kit improves clinical outcomes, including lower mortality, a decrease in inappropriate therapy, and the termination of antibiotic therapy. The applicant submitted fifteen published peer-reviewed articles supporting these statements, four outcomes peer reviewed articles, and six posters presented at conferences; CMS summarizes this information in the proposed rule. CMS is concerned that the studies appear to rely on the use of the first version of the device (2017 FDA approval) and information doesn't distinguish the clinical outcomes achieved by the updated version as compared to the original version. CMS would be interested in additional information about which studies involved the updated version

of the device which is the basis for the new technology add-on payment application. CMS also notes that several of the studies showed empirical results with the Accelerate Pheno Test™ BC kit that were less favorably than the current standard of care.

New Technology Town Hall. In response to a question raised during the meeting, the applicant provided further explanations of study details and data for the clinical outcome studies. Responding to another question, the applicant also provided further explanation of the Accelerate Pheno Test™ BC kit and how the technology differs from T2 Biosystems' instrument. CMS will take this information into consideration when evaluating the substantial clinical improvement criterion.

b. BioFire® FilmArray® Pneumonia Panel

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

Newness. The BioFire® FilmArray® Pneumonia Panel received FDA clearance via 510(k) on November 9, 2018, based on a determination of substantial equivalence to a legally marketed predicate device (Curetis Unyvero™). The product was available in the U.S. market on December 11, 2018. A Proprietary Laboratory Analyses (PLA) code, PLA Code 0151U was assigned to the device and became effective January 1, 2020. 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 that the BioFire® FilmArray® Pneumonia Panel is the only sample-to-answer, rapid (about 1 hour), and comprehensive molecular panel for the diagnosis of the major causes of infectious pneumonia. In addition, the device is also the only semi-quantitative molecular solution available for diagnosis of infectious pneumonia. The applicant described the other methods for determining the bacterial organism and noted that the current best practice is the standard culture technique. The applicant stated that other comprehensive molecular technologies, including Curetis Unyvero™ are more complex, only have bacterial targets, and only provide qualitative results.

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

CMS is concerned that it lacks sufficient information to determine whether the mechanism of action of The BioFire® FilmArray® Pneumonia Panel is different from existing polymerase chain reaction (PCR) tests. CMS notes that the FDA decision summary describes the test as a multiplex nucleic acid test, or PCR, accompanied by the applicant's software. In addition, the

product does not appear to treat a different disease or population compared to other products. CMS also does not believe the evidence provided by the applicant supports differentiation of the test from other products.

Cost. The applicant used 2018 data from Definitive Health Care and identified 297,956 cases for the 3 MS-DRGs for simple pneumonia and pleurisy (MS-DRGs 193, 194, and 195). The applicant indicated the data was obtained from one hospital in Indianapolis; CMS notes that it is unlikely a single hospital in Indiana would have that many cases of simple pneumonia in 1 year. CMS also notes that the applicant does not indicate how these cases correspond to the cost analysis. The applicant did not remove any charges for any prior technologies, standardized the charges and then inflated the charges using an inflation factor of 5.50 (CMS notes the published 1-year inflation factor in the FY 2020 IPPS final rule was 5.4 percent.) To estimate the cost of the technology, the applicant used the per-test list cost of the BioFire® FilmArray® Pneumonia Panel. The applicant did not include technician time or an estimate of instrumentation cost because it thought technician time was minimum, and most labs had sufficient instruments to run the test. The applicant computed a final inflated average case-weighted standardized charge per case of $78,156 as compared to an average case-weighted threshold amount of $42,812.

CMS raises several concerns about the applicant's analysis, including using proprietary data from one hospital. It is also unclear if the analysis included all the cases in the 3 MS-DRGs and why the analysis only looked at these MS-DRGs and did not include other MS-DRGs such as MS-DRGs 177, 178 and 179 (Respiratory Infections and Inflammations).

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

c. ContaCT

Viz.ai submitted an application for ContaCT, a radiological computer-assisted triage and notification system used by hospitals and clinicians to identify patients with a suspected large vessel occlusion on computed tomography angiogram (CTA) images of the brain.[23] The system analyzes CTA images of the brain, sends notifications to a neurovascular specialist(s) that a suspected large vein occlusion (LVO) has been identified, and recommends review of those images.

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

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

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

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

CMS is concerned that streamlining hospital workflow might not represents a unique mechanism of action; as per the FDA, ContaCT is not used for diagnostic purposes and still requires a clinician to review the scan and make the diagnosis. CMS notes that the mechanism of action for ContaCT might be the use of AI to analyze images and notify physicians instead of streamlining hospital workflow. CMS is concerned, however, that the use of AI, an algorithm, or software are not unique mechanisms of action and wonders how updates to AI, an algorithm or software would affect an already approved technology or a competing technology. Specifically, CMS questions if software changes for an already approved technology could be considered a new mechanism of action and if an improved algorithm by a competitor would represent a unique mechanism of action if the outcome is the same as the initial technology. **CMS solicits comments regarding the general parameters for identifying a unique mechanism of action based on the use of AI, an algorithm and/or software**.

Cost. The applicant provided several analyses based on data from the FY 2018 MedPAR dataset. In the first analysis, the applicant used the admitting diagnoses codes to identify cases of stroke due to LVO, stroke not due to LVO, no stroke, and using a multi-step approach identified 375,925 cases across 143 MS-DRGs, approximately 66 percent of cases mapped to seven MS-DRGs. The applicant did not remove any changes for a prior technology but based on published studies, the applicant reduced some charges related to a reduced LOS associated with a mechanical thrombectomy. The applicant standardized the charges and applied an inflation factor of 11.1% (the same inflation factor CMS used to update the outlier threshold in the FY 2020 IPPS PPS final rule). Because the technology is provided by a subscription, the applicant added the charges for the new technology by determining the cost per case across a hospital and then averaging the cost per case across all hospitals to determine the average cost per patient. The applicant calculated a case-weighted threshold amount of $51,358 and a final inflated average case-weighted standardized charge per case of $62,006. The applicant submitted three additional cost analyses using the same methodology but with limited MS-DRGs. CMS believes

that a case weight provides more accuracy in determining the average cost per case as compared to the applicant's average of costs per case across all hospitals. CMS repeated the applicant's analyses and in all the scenarios, the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold amount by an average of $2,961.

CMS is concerned that the applicant used a single list price of ContaCT per hospital with a cost per patient that can vary based on the utilization of the technology by the hospital. The cost per patient could be skewed by a small number of hospitals utilizing the technology with low case volumes. CMS describes an alternative methodology for determining the cost per patient.

CMS acknowledges there are unique circumstances to determine a cost per case for technologies that utilize a subscription for its cost. **CMS solicits comments about the appropriate method to determine a cost per case for such technologies**. If the cost per case should be estimated based on the subscriber hospital data, and the technology is approved for a new technology add-on payments, CMS solicits comments on whether the cost analyses should be updated based on the most recent year for which the technology may be eligible for the new technology add-on payment.

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

The applicant provided a total of 19 articles: four retrospective studies, nine randomized clinical trials (RCTs), three meta-analyses, one registry, one guideline, and one systematic review. CMS discusses specific concerns with the submitted information, including the FDA decision memorandum stating that ContaCT is limited to analysis of imaging data and should not be used in-lieu of patient evaluation or relied upon to make or confirm a diagnosis. In addition, CMS notes that the RCTs evaluated outcomes from specific treatment for patients who suffered strokes and not the time of imaging to treatment. Based on the RCTs and meta-analyses, CMS is concerned the evidence does not indicate a substantial clinical improvement for shorter notification times of a LVO. CMS notes that the guidelines and systematic literature review supports the urgency of stroke care but do not demonstrate how ContaCT supports the urgency of stroke care.

At the Town Hall meeting, several commenters asserted that studies demonstrate the important relationship between time to treatment and improved clinical outcomes in patients with ischemic stroke, and that the incorporation of ContaCT should result in better outcomes. The applicant also responded to questions received at the Town Hall meeting, including acknowledging that there is no data directly evaluating patient outcomes from ContaCT.

d. Supersaturated Oxygen (SSO_2) Therapy (DownStream® System)

TherOX, Inc. submitted an application for the DownStream® System, an adjunctive therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in patients receiving treatment for an acute myocardial infarction (AMI). According to the

applicant, SSO_2 Therapy is used for patients receiving treatment for an ST-segment elevation myocardial infarction (STEMI). The applicant asserted that the net effect of SSO_2 Therapy is to reduce the infarct size and therefore preserve heart muscle.

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

The applicant previously submitted an application for new technology add-on payments for FY 2019, which was subsequently withdrawn before the FY 2019 final rule. The applicant submitted an application for FY 2020; a new technology add-on payment was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over available therapies to treat STEMI patients.

Newness. SSO_2 Therapy received premarket approval from the FDA on April 4, 2019. The applicant states that the use of SSO_2 Therapy can be identified by the ICD-10-PCS procedure codes 5A0512C and 5A0522C.

In the FY 2020 IPPS final rule (84 FR 42275), CMS determined that SSO_2 Therapy has a unique mechanism of action and meets the newness criterion. CMS considered the beginning of the newness period as the date of FDA approval on April 2, 2019.

Cost. The applicant searched the FY 2018 MedPAR file for claims reporting four ICD-10-CM diagnosis codes for anterior ST-Elevation Myocardial Infarction (STEMI) and identified 9,111 potential cases across four MS-DRGs. The applicant standardized the charges but did not remove charges for the current treatment because SSO_2 Therapy will be used as an adjunctive treatment option following successful PCI with stent placement. The applicant added charges for the technology and additional supplies used in the administration of SSO_2 Therapy, including procedure room time, technician labor, and additional blood tests. The inflated average case-weighted standardized charge per case was $150,115 and the average case-weighted threshold amount was $98,332. Because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained the technology meets the cost criterion.

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

In addition to the studies submitted with both its FY 2020 and FY 2021 applications, the applicant provided additional information to support that the technology provides a treatment option for a patient population unresponsive to current treatments. CMS summarizes these studies and the additional information provided to address CMS' prior concerns. CMS reiterates it previous concern that standard of care for STEMI has evolved since two studies (AMIHOT I and AMIHOT II) were conducted and it is not clear whether the use of SSO_2 Therapy would demonstrate the same clinical improvement when compared to current standard of care. It also notes that the studies may be based on patients with all types of STEMI and not specific to the FDA-approved indication for the treatment of anterior STEMI. After reviewing all the information, CMS continues to believe that the data presented does not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy.

At the Town Hall meeting, several commenters were supportive of SSO_2 Therapy and that it provided an important treatment option for patients.

d. Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System which is comprised of an implantable endoprosthesis and a stent delivery system (SDS). The drug-eluting stent system is indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. The Eluvia™ stent system was granted approval of 16 ICD-10-PCS procedure codes, effective October 1, 2019.

The applicant previously submitted an application for new technology add-on payments for FY 2020. The application was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over existing technologies (84 FR 42220 through 42231).

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

Cost. The applicant searched the FY 2018 MedPAR file for cases reporting the ICD-10-PCS procedure codes the applicant believed would represent potential cases and conducted two analyses based on 100 percent and 76 percent of identified claims. The analysis using 100 percent of cases included 11,051 cases spanning 150 MS-DRGs. The applicant removed all device-related charges and standardized the charges, applied an inflation factor of 11.1% (the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS final rule), and added charges for the Eluvia™ stent. The applicant calculated an average case-weighted threshold amount of $100,851 and a final inflated average standardized charge per case of $157,343. The analysis based on 76 percent of identified claims included 8,335 cases across 8 MS-DRGs. The applicant used the same methodology and determined an average case-weighted

threshold amount of $98,196 and a final inflated average standardized charge per case of $147,343.

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

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

The applicant resubmitted its application and included updated two-year primary patency results to demonstrate the device represents a substantial clinical improvement over existing technologies. The applicant also addressed the FDA concerns about paclitaxel and stated that the Eluvia™ stent is not associated with increased all-cause mortality and that two-year all-cause mortality are consistent with FDA-published rates for uncoated angioplasty devices. In addition, the applicant reiterated that the Eluvia™ stent was not included in the FDA meta-analysis and highlighted flaws in the analysis. The applicant cited the FDA June 2019 advisory panel conclusion that the benefits of paclitaxel-coated devices should be considered in individual patients along with potential risks.

CMS summarizes these studies and the additional information provided to address CMS' prior concerns. CMS reiterates it previous concerns with the studies and the FDA meta-analysis results. It remains concerned that there is an increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limb. CMS cites the FDA's statement in the August 2019 letter[24] that because of the uncertainty regarding the long-term benefit-risk profile of paclitaxel-coated devices, clinical studies should collect long-term safety and effectiveness data.

At the Town Hall meeting, the applicant provided two-year results from the IMPERIAL global randomized controlled clinical trial. CMS will take this information into consideration for the new-technology add-on payment determination.

f. GammaTile™

GT Medical Technologies, Inc. submitted an application for GammaTile™, a brachytherapy technology for use in the treatment of patients diagnosed with brain tumors using cesium-131

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

radioactive sources embedded in a collagen matrix.[25] GammaTile™ is biocompatible and bioabsorbable and is in the body permanently without the need for future surgical removal.

An application for GammaTile™ was submitted for a new technology add-on payment for FYs 2018 and 2019; both were withdrawn because the technology did not receive FDA approval or clearance in the time required. An application was submitted for FY 2020 and was not approved because CMS could not determine that the therapy represented a substantial clinical improvement over existing technologies (84 FR 42260 through 42265).

Newness. The applicant received FDA clearance under section 510(k) as a medical device on July 6, 2018 and was not commercially available until January 2019. The FDA cleared GammaTile™ as a Class II medical device under the corporate name of GT Medical Technologies on March 13, 2019. The indication for the device is to provide radiation therapy for patients diagnosed with recurrent intercranial neoplasms. ICD-10-PCS procedure code 00H004Z identifies procedures involving the use of GammaTile™. In the FY 2020 IPPS final rule (84 FR 42261), CMS determined that GammaTile™ has a unique mechanism of action and meets the newness criterion.

Cost. The applicant worked with the Barrow Neurological Institute at St Joseph's Hospital and Medical Center to obtain claims from mid-2015 through mid-2016 for craniotomies that did not involve placement of the GammaTile™ technology. The applicant found 460 claims that were assigned to 3 MS-DRGs. The applicant calculated an estimate for ancillary charges associated with placement of the GammaTile™ device. The applicant concluded that the technology meets the cost criterion because the final inflated average case-weighted standardized charge per case (including the charges for GammaTile™) of $270,445 exceeds the average case-weighted threshold amount for MS-DRG 23.

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

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

g. Hemospray® Endoscopic Hemostat

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

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

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

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

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

Cost. The applicant stated patients who would use Hemospray® are identified by using of combination of one ICD-10-PCS procedure code and one ICD-10-CM diagnosis code and provided a list of combinations. The applicant extracted claims from the FY 2018 MedPAR database based on these combinations; 64 percent of cases grouped to the MS-DRGs for GI Hemorrhage. A total of 40,012 cases grouped to these MS-DRGs. The applicant standardized the charges and used the 2-year inflation factor of 11.1% from the FY 2020 IPPS final rule. No charges for any current treatment were removed because the applicant indicated the device may not replace other therapies. The applicant added $8,361.20 in charges for the cost of the technology. The final inflated average case-weighted standardized charge per case of $60,193 exceeds the average case-weighted threshold amount of $46,568.

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

h. IMFINZI® (durvlaumab)

AstraZeneca PLC submitted an application for IMFINZI®, a selective, high-affinity human IgG1 monoclonal antibody (mAb) for first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) used in combination with etoposide and either carboplatin or cisplatin. IMFINZI® blocks programmed death-ligand 1 (PD-L1) binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity. SCLC is considered a rare disease, with approximately 30,000 new cases diagnosed each year as compared to 200,000 cases of non-small cell lung cancer (NSCLC).

Newness. The FDA granted IMFINZI® orphan drug designation for ES-SCLC on July 12, 2019. IMFINZI® received FDA approval on March 27, 2020 for use in combination with etoposide and either carboplatin or cisplatin as first-line treatment of patients with ES-SCLC.[26] There are no approved ICD-10-PCS procedure codes to uniquely identify administration of IMFINZI®; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant states the drug has a unique mechanism of action that blocks PD-L1 binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity; a mechanism of action distinct from standard chemotherapy. For the second criterion (same or different MS-DRG), the applicant stated that cases representing patients with ES-SCLC are identified under category C34 (Malignant neoplasm of bronchus and lung) within ICD-10-CM, which does not distinguish between lung cancer subtypes. Using category C34, the applicant concluded that patients with ES-SCLC map to MS-DRGs 180, 181, and 182 (Respiratory Neoplasms) but notes that the coding system does not allow distinction between ES-SCLC patients and NSCLC patients (NSCLC patients receive IMFINZI® and other immune-oncology therapies). Based on analysis of data from the Premier Hospital Database, the applicant stated that over 60 percent of ES-SCLC patients map to MS-DRGs 180, 181, and 164. CMS agrees with the applicant that patients receiving IMFINZI® would map to the same DRGs as patients receiving standard therapy for ES-SCLC. For the third criterion (same or similar disease or patient population), the applicant stated

[26] IMFINZI® is also approved for treatment of adult patients with locally advanced or metastatic urothelial carcinoma and patient with unresectable, Sage III NSCLC.

that the use of IMFINZI® would involve treatment of a similar patient population as compared to standard chemotherapy options.

CMS notes it also received an application for TECENTRIQ® (discussed below), which received FDA approval on March 18, 2019 for use in combination with carboplatin and ectoposide for the first-line treatment of patients with ES-SCLC. CMS notes that both drugs seem to be intended for similar patients and treat the same conditions and therefore should be considered as a single application for purposes of new technology add-on payments. **CMS is interested in how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.**

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

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

Substantial Clinical Improvement. The applicant stated that IMFINZI® represents a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to current treatments and reduces mortality, decreases disease progression, and improves quality of life. The applicant provided supporting information from the CASPIAN clinical trial, a randomized, multicenter, active-control, open-label, phase 3 trial. The major efficacy outcome measure was overall survival (OS); the applicant stated the results showed a sustained OS benefit following treatment with IMFINZI® plus chemotherapy. The applicant also stated that other key endpoints demonstrated consistent and durable improvement for IMFINZI®, including progression free survival.

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

i. KTE-X19

Kite Pharma submitted an application for KTE-X19, a CAR T-cell immunotherapy for the treatment of adult patients with relapse and refractory (r/r) mantle cell lymphoma (MCL). KTE-X19 is a single infusion product consisting of autologous T-cells that have been 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 states that MCL is a rare and aggressive subtype of non-Hodgkin lymphoma (NHL), accounts for 3-6% of all cases of NHL, has distinct characteristics which differentiate it from diffuse large B-cell NHL. The first line therapy for newly diagnosed MCL includes chemotherapy in combination with rituximab and rituximab is the only approved therapy for maintenance in patients with remission. The median progression free survival ranges from 18 to 51 months with most MCL patients eventually relapsing. 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 states 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. The applicant submitted a BLA for KTE-X19 on December 11, 2019 with a request for priority review and anticipates receiving FDA approval by July 1, 2020. KTE-19 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 use of KTE-X19 would be coded with ICD-10-PCS codes for engineered autologous CAR-T cells, differentiated by the route of administration (XW033C3 and XW043C3) and assigned to MS-DRG 016 (Autologous Bone Marrow Transplant or T-Cell Immunotherapy). The applicant submitted a request for a unique ICD-10-PCS code to describe the use of KTE-X19.

For the first criterion (same or similar mechanism of action), the applicant states KTE-X19 will be the first CAR T-cell immunotherapy for the treatment of r/r MCL. The applicant states that KTE-X19 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; KTE-X19 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 CMS previously stated that all CAR T-cell therapies would likely map to the same MS-DRG as other FDA-approved CAR T-cell therapies. The applicant asserted that KTE-X19 could not be reported with the same ICD-10-PCS codes as YESCARTA and KYMRIAH. The applicant also noted that patients treated with KTE-X19 would be assigned to ICD-10-CM diagnosis code C83.10 (MCL) which is not assigned to patients treated with 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 believes this distinction is evidence that KTE-X19 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 is 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 KTE-X19

provides a unique mechanism of action. CMS also believes that cases reporting the use of KTE-X19 would be assigned to the same MS-DRG as existing CAR T-cell technologies. In addition, although the applicant describes differences between MCL and DLBCL, patients present with similar clinical presentations and it is concerned that this therapy may involve treatment of a similar type of disease when compared to existing CAR T-cell therapies.

Cost. The applicant used the FY 2018 MedPAR claims file to identify cases reporting an ICD-10-CM diagnosis code C88.10 (MCL) and the two ICD-10-PCS codes for CAR T-cell infusion to identify potential patients. The applicant identified two sets of cohorts: a Primary Cohort included cases that the applicant believed most closely aligned with r/r MCL patients who would receive KTE-X19 (293 claims mapped to 13 MS-DRGs) and a Sensitivity Analysis Cohort that included patients with a principal or secondary diagnosis of MCL (953 claims mapped to 72 MS-DRGs). For the Primary Cohort, without consideration of KTE-X19 charges, the applicant calculated a final inflated average case-weighted standardized charge per case of $201,459 and an average case-weighted threshold amount of $170,573. The applicant stated that the Sensitivity Analysis Cohort did not meet the cost criterion when compared to MS-DRG 016 average case-weighted threshold amount but that it would have met the cost criterion if the charges for KTE-19 were included.

CMS proposes to evaluate whether KTE-X19 meets the cost criterion using the proposed new MS-DRG 018 threshold amount of $1,237,393. CMS notes the applicant's final inflated average case-weighted standardized charge per case for the Primary Cohort without the charges for KTE-19 were $201,459. Using data from the FY 2019 MedPAR data, CMS calculates a standardized charge per case for MS-DRG 018 of $913,224. Because this estimated average case-weighted standardized charge per case does not exceed the average case-weighted threshold amount for proposed MS-DRG 018, CMS does not believe the technology would meet the cost criterion.

CMS solicits public comments on its proposal to evaluate these cost criterion using the proposed threshold for the newly proposed MS-DRG 018 to which procedure codes describing CAR T-cell therapies would be assigned in FY 2021, and whether KTE-19 meets the cost criterion based on this proposal.

Substantial Clinical Improvement. The applicant stated that KTE-X19 represents a new treatment option for an adult patient population unresponsive to, or ineligible for, currently available treatments and that the use of KTE-X19 significantly improves clinical outcomes for a patient with r/r MCL as compared to currently available therapies, including BTK inhibitors. The applicant provided results from a Phase 2 study (ZUMA-2 study) and meta-analyses. The applicant initially submitted information from its interim analysis of ZUMA-2 which included 28 subjects treated with KTE-X19 followed for 12 months. The applicant provided supplemental information which included all 60 subjects followed for 6 months after the Week 4 disease assessment and the 28 subjects from the interim analysis followed for 24 months.

CMS discusses several concerns with the ZUMA-2 study, including the generalizability of the findings from ZUMA-2 to the general Medicare population. CMS wonders whether the ZUMA-2 patients have the same characteristics of the Medicare population, including the severity of disease. In addition, CMS is interested in the longer-term analysis of this population to evaluate the overall survival and mortality data and is concerned about the adverse events reported with the treatment. CMS is also concerned with the relatively small combined sample size from the

ZUMA-2 study and the additional literature provided by the applicant. In addition, CMS raises issues about the lack of a direct study comparing outcomes of patients with r/r MCL treatment with KTE-X19 and BTK inhibitors.

j. Liso-cel (Lisocabtagene Maraleucel)

Juno Therapeutics submitted an application for Liso-cel, 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.

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. Patients with relapses of aggressive B-cell lymphomas have several second-line treatment options that include chemotherapy and autologous stem cell transplantation. Available treatment for after two or more lines of systemic therapy include CAR T-cell immunotherapy with YESCARTA and KYMRIAH, and treatment with KETRUDA (a programmed death receptor-1-blocking antibody. The applicant notes that the safety profiles of these therapies exclude many r/r DLBCL patients from undergoing treatment.

Newness. The applicant submitted a BLA for Liso-cel in October 2019. Liso-cel was granted Breakthrough Therapy Designation on December 15, 2016. Cases reporting the use of Liso-cel would be coded with ICD-10-PCS codes for engineered autologous CAR-T cells, differentiated by the route of administration (XW033C3 and XW043C3) and assigned to MS-DRG 016 (Autologous Bone Marrow Transplant or T-Cell Immunotherapy). The applicant submitted a request for a unique ICD-10-PCS code to describe the use of Liso-cel.

For the first criterion (same or similar mechanism of action), the applicant states the mechanism of action for Liso-cel 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 Liso-cel infusion is configured to contain the same dosage of both cell types. The applicant asserts that controlling the dosage of CD8 CAR-T cells could provide 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 Liso-cel 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 Liso-cel 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 represents 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 Liso-cel would treat a patient population different from these CAR T-cell therapies.

Cost. The applicant searched the FY 2018 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment with Liso-cel with ICD-10-CM codes that do not differentiate r/r patients from the broader DLBCL population. Based on a clinical literature search that identified that the r/r population makes up one-third of the DLBVL population, and the observation that r/r patients typically have higher inpatient costs, the applicant selected one-third of the total identified cases with the highest total charges. The applicant found 1,798 cases reporting one of the identified diagnosis codes or the two ICD-10-PCS codes for CAR-T infusion across 22 MS-DRGs. The applicant analyzed the top third of the costliest discharges and randomly selected 20 percent of the remaining cases to account for the variety of treatment options for patients with DLBCL. The applicant removed all charges in the drug cost center. Without consideration of Liso-cel charges, the applicant calculated a final inflated average case-weighted standardized charge per case of $117,726 and an average case-weighted threshold amount of $170,573. The applicant expects the cost of Liso-cel to be higher than the new technology add-on payment threshold amount for MS-DRG 016 and concludes it would have met the cost criterion if the charges for Liso-cel were included.

CMS proposes to evaluate whether Liso-cel meets the cost criterion using the proposed new MS-DRG 018 threshold amount of $1,237,393. CMS notes the applicant's final inflated average case-weighted standardized charge per case without the charges for Liso-cel were $117,726. Using data from the FY 2019 MedPAR data, CMS calculates a standardized charge per case for MS-DRG 018 of $913,224. Because this estimated average case-weighted standardized charge per case does not exceed the average case-weighted threshold amount for proposed MS-DRG 018, CMS does not believe the technology would meet the cost criterion.

CMS solicits public comments on its proposal to evaluate these cost criterion using the proposed threshold for the newly proposed MS-DRG 018 to which procedure codes describing CAR T-cell therapies would be assigned in FY 2021, and whether Liso-cel meets the cost criterion based on this proposal.

Substantial Clinical Improvement. The applicant stated that Liso-cel 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 form 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 Liso-cel were over the age of 65 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 Liso-cel, YESCARTA and KYMRIAH.

CMS is concerned that no published studies directly compare Liso-cel 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 Liso-cel 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 Liso-cel treatment.

k. Soliris

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

Newness. The FDA approved Soliris for treatment of NMOSD patients who are AQP4 antibody positive on June 27, 2019. Soliris was first approved by the FDA on March 19, 2007 for the treatment of patients with paroxysmal nocturnal hemoglobinuria and has received subsequent approval for additional complement mediated diseases. There are no approved ICD-10-PCS procedure codes to uniquely identify NMOSD cases where Soliris is used; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant states Soliris is the only FDA approved treatment for NMOSD, although several off-label products are used to treat relapse prevention in NMOSD. For the second criterion (same or different MS-DRG), the applicant stated that cases representing patients involving the administration of Soliris will likely to be assigned to the same MS-DRGs as other currently used treatments for NMOSD. For the third criterion (same or similar disease or patient population), the applicant maintains that although Soliris will be treating the same disease and patient population as currently available treatments, it is the only approved treatment for this specific patient population.

Cost. The applicant searched claims in the FY 2018 MedPAR final rule reporting an ICD-10-CM diagnosis code of G36.0 and identified 1,151 cases spanning 14 MS-DRGs. According to the applicant most cases eligible for treatment would map to the MS-DRGs for Multiple Sclerosis and Cerebellar Ataxia (MS-DRGs 058,059 and 060) and these three MS-DRGs accounted for about 32 % or 376 cases of the original cases identified. The applicant limited its analysis to these 376 cases. The applicant removed charges for other technologies which included drug therapies and plasma exchange procedures. The applicant included charges for Soliris. The applicant computed a final inflated average case-weighted standardized charge per case of $72,940 as compared to a calculated threshold value of $44,420.

Substantial Clinical Improvement. The applicant stated that Soliris represents a substantial clinical improvement over existing technologies because it significantly improves clinical outcomes relative to technologies previously available, including the prevention of relapses in patients with NMOSD. The applicant provided a randomized, controlled trial (PREVENT) and a poster presentation of post hoc efficacy analyses in pre-specified subgroups from the PREVENT

study. CMS is concerned that the supporting information is only one study and all additional supporting documents are all based on the same trial. CMS notes that the study compared Soliris to placebo but there was no comparison of Soliris to currently available treatments. CMS also is concerned about the dosage amounts used in the study and would be interested in more information about the dosage amounts in the PREVENT trial.

l. SpineJack® System

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

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

Newness. The applicant states the device received FDA 510(k) clearance on August 30, 2018 and was available on the U.S. market October 11, 2018. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using the system; a request for approval for a unique code was submitted.

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

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

Cost. The applicant searched the FY 2018 MedPAR file for claims reporting ICD-10-PCS procedure codes combinations involving the reposition of a vertebra and use of synthetic substitute and identified 15,352 cases spanning 130 MS-DRGs, including BKP procedures. Approximately 77 percent of the cases mapped to 6 MS-DRGs. The applicant performed two separate analysis, one based on the 100 percent sample and the other based on the 77 percent sample. For the analyses the applicant first removed 50 percent of the charges for the technology being replaced by the SpineJack® system because the SpineJack® system would replace some but not all of the device charges. The applicant stated that removing 50 percent of the charges was a conservative assumption. The applicant added the charges for the SpineJack® system. In the analysis based on 100 percent of claims the final inflated average case-weighted standardized charge per case was $108,760 as compared to an average case-weighted threshold amount of $77, 395. For the analysis based on 77 percent of the claims the final inflated average case-weighted standardized charge per case was $92,904 as compared to an average case-weighted threshold amount of $72,273.

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

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

CMS acknowledges the results of the SAKOS trial and notes the results do not appear to have been corroborated in any other randomized controlled study. In addition, since the PEEK coiled system was considered the predicate device for the SpineJack 510, CMS is interested in information comparing the SpineJack® system to the PEEK coiled implant. CMS is also interested in information comparing the SpineJack® system to conservative medical therapy and notes an active study on clinicaltrials.gov comparing the system to conservative therapy. CMS notes that two recent systematic reviews of vertebral compression fractures[27] for the American Society for Bone and Mineral Research (ASBMR) do not support vertebral augmentation procedures due to lack of evidence comparing the treatment to conservative medical

[27]Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., "Percutaneous vertebroplasty for osteoporotic vertebral compression fracture," Cochrane Database Syst Rev. 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A.,Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A.,Bouxsein M.L., "The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report." J Bone Miner Res., 2019, vol. 34(1), pp. 3-21

management. The ASBMR recommends more rigorous studies of treatment options that include placebo controls and more data on serious adverse events.

m. TECENTRIQ® (atezolizumab)

Genentech, Inc. submitted an application for TECENTRIQ®, a programmed death-ligand (PD-L1) blocking antibody with four different oncology treatment indications, including one in combination with carboplatin and etoposide, for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC). PD-L1 is a protein expressed on the surface of cancer and immune cells, which allows them to inactivate the T-cells of the immune system; TECENTRIQ® blocks the PD-L1 protein, allowing the Y-cells to attack the cancer cells. The applicant states that TECENTRIQ® is usually given in the outpatient setting but that sometimes ES-SCLC patients are diagnosed in the inpatient setting and need immediate treatment with TECENTRIQ®.

Newness. The FDA approved TECENTRIQ® in combination with carboplatin and etoposide for the first-line treatment of adult patients with ES-SCLC on March 18, 2019. TECENTRIQ® was initially approved by the FDA on March 18, 2016 for treatment of locally advanced or metastatic urothelial carcinoma. There are no approved ICD-10-PCS procedure codes to uniquely identify administration of; a request for approval for a unique code for TECENTRIQ® was submitted.

For the first criterion (same or similar mechanism of action), the applicant states the drug has a unique mechanism of action that blocks PD-L1 binding to programmed cell; a mechanism of action distinct from standard chemotherapy. The applicant states the current standard of care drugs etoposide, carboplatin, and cisplatin are cytotoxic by interfering with DNA replication.

For the second criterion (same or different MS-DRG), the applicant noted that current standard of care involve non-FDA approved therapies that would use similar MS-DRGs as TECENTRIQ®. The applicant also stated that the MS-DRG payment system cannot differentiate between patients with NSCLC and ES-SCLC and that MS-DRGs 180 and 181 (Respiratory Neoplasms) apply to both diseases. In addition, category C 34 (Malignant neoplasm of bronchus and lung) of the ICD-10-CM diagnosis coding system does not differentiate between the diseases. As a result, TECENTRIQ® and an existing technology, even one used to treat NSCLC, may be assigned to the same MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant stated that the use of TECENTRIQ® would not involve treatment of a similar patient population as compared standard chemotherapy options. The applicant reiterated that although SCLC and NSCLC share a MS-DRG they are different diseases with different patient populations. The applicant added that it believes there is no evidence of utilization of TECENTRIQ® in inpatient ES-SCLC cases in either the 2017 or 2018 Medicare Standard Analytical Files (SAF).

CMS notes it also received an application for IMFINZI® (discussed above), which received FDA approval on March 18, 2019 for use in combination with carboplatin and ectoposide for the first-line treatment of patients with ES-SCLC. CMS notes that both drugs seem to be intended for similar patients and treat the same conditions and therefore should be considered as a single application for purposes of new technology add-on payments. **CMS is interested in how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.**

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

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

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

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

o. WavelinQ™ (4F) ENDO AVF System

Becton Dickinson submitted an application for the WavelinQ™ (4F) ENDO AVF System, a FDA approved device for the creation of an arteriovenous (AV) fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site in patients with chronic kidney disease needing hemodialysis. According to the applicant, the Endovascular AV fistula created by the WavelinQ™ EndoAVF System is achieved by using flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), venography (to fluoroscopically guide placement and alignment of the venous magnetic RF catheter, ultrasound and final fistulogram to document AV fistula creation.

Newness. According to the applicant, the predicate device WavelinQ™ (6F) ENDO AVF System received FDA marketing on June 22, 2018 for creation of an arteriovenous (AV) fistula using concomitant ulnar artery and ulnar vein in patients with minimum artery and vein diameters of

2.0 mm at the fistula creation site in patients with chronic kidney disease needing hemodialysis. On February 6, 2019 the WavelinQ™ (4F) ENDO AVF System cleared the FDA via its 510(k) pathway for expanded access indication with a smaller 4F catheter. The applicant states the only difference between the two technologies and their respective FDA approvals is the size of the catheters (6F vs 4F) and the expanded indication to treat the radial arteries and veins for the WavelinQ™ (4F) ENDO AVF System. The applicant includes diagnosis and procedure codes applicable to the WavelinQ™ (4F) ENDO AVF System.

For the first criterion (same or similar mechanism of action), the applicant states that the WavelinQ™ (4F) ENDO AVF System uses a different mechanism of action that any commercially available technology on the market for hemodialysis for fistula creation. The technology does require an open surgical approach and utilizes magnetic-guided catheters that utilize radiofrequency energy to create a communicating channel between the arterial and venous system. The applicant indicates that the Ellypsis® Vascular Access System received marketing authorization by the FDA on January 25, 210 and although the Ellipsys® supports an endovascular method for creating an AV fistula, the applicant details differences between the two technologies, including different mechanism of action, procedural processes, and anatomical locations. For the second criterion (same or different MS-DRG), the applicant acknowledged that cases using the WavelinQ™ (4F) ENDO AVF System will be assigned to the same MS-DRGs as procedures creating an AV fistula. For the third criterion (same or similar disease or patient population), the applicant states that the diagnoses associated with this treatment and the patient population are similar to those existing procedures and technologies.

Based on the FDA approvals for the WavelinQ™ (6F) ENDO AVF System and the WavelinQ™ (4F) ENDO AVF System, CMS believes that for purposes of the ulna arteries and veins, the WavelinQ™ (4F) ENDO AVF System would be considered substantially similar to the WavelinQ™ (6F) ENDO AVF System as the only difference is the size of the catheters. Based on these distinctions, CMS states the newness period for the use in the ulnar arteries and veins would be June 22, 2018 and the newness period for use in the radial arteries and veins would begin on February 6, 2019.

Cost. The applicant searched the FY 2018 MedPAR for claims identifying cases that may be eligible for the WavelinQ™ (4F) ENDO AVF System, limited the analysis to the five most common MS-DRGs and obtained 2,472 cases. The applicant removed supply charges with revenue code 027X and for the operating room. The applicant did not inflate the charges because it wanted to provide a conservative cost estimate. The applicate added charges for the new technology and procedure related charges. The final inflated average case-weighted standardized charge per case was $121,749 and the average case-weighted threshold amount was $83,372.

Substantial Clinical Improvement. The applicant asserts that the WavelinQ™ (4F) ENDO AVF System represents a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to or ineligible for current treatments. The applicant states the WavelinQ™ (4F) ENDO AVF System improves clinical outcomes for patients requiring hemodialysis in comparison to AV surgical fistulas and the Ellipsys Vascular Access System. The applicant provided four studies and additional information supporting these statements. CMS is concerned that there is no study directly comparing the WavelinQ™ (4F) ENDO AVF System to surgical AVF or Ellipsys Vascular Access System as the submitted studies use

historical data for surgical AVF. CMS is concerned about the limited number of participants in the clinical trials and whether the results are generalizable to the entire Medicare population.

CMS summarizes the applicants written public comment from questions raised at the Town Hall meeting. The applicant provided additional information comparing the methodology used by WavelinQ™ system and the Ellipsys system. The applicant also acknowledged that there are no controlled randomized studies comparing the WavelinQ™ (4F) ENDO AVF System to surgical AVFs and provided additional published retrospective studies comparing the techniques. The applicant has no plans to publish the EU post market study but has made the data available to the public via WavelinQ's Instructions for Use (IFU) and provided CMS the most recent IFU information which contained a summary of the study safety and effectiveness measures.

p. Zulresso™

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

Newness. Zulresso™ received Priority Review and Breakthrough Therapy designations and was granted FDA approval on March 19, 2019 for treatment of PPD. On June 17, 2019, the Drug Enforcement Administration placed Zulresso™ into Schedule IV of the Controlled Substances Act and it became commercially available. There are no ICD-10-PCS procedure codes to identify procedures involving Zulresso™; the applicant has submitted a request for two unique ICD-10-PCS codes.

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

Cost. The applicant used the FY 2018 MedPAR LDS to identify potential patients eligible for treatment with Zulresso™ and identified 75 cases reporting ICD-10-CM diagnosis code F53[28] (Puerperal psychosis) spanning 26 different MS-DRGs; 58 percent mapping to 3 MS-DRGs and 49 percent mapped to 2 MS-DRGs. The applicant did not remove charges for other PPD

[28] The applicant noted that ICD-10-CM code F53.0 (Postpartum depression) became effective October 1, 2018 and was not found in any FY 2018 inpatient claims.

treatments because these treatments (including oral anti-depressants) may be continued. The applicant added charges for Zulresso™. The final average case-weighted standardized charge per case was $225,056 and the average case-weighted threshold amount was $33,012.

CMS notes that a sub-analysis of the top 2 MS-DRGS and a sub-analysis assigning 90 percent of the cases to the highest paying DRG would still exceed the threshold. CMS is concerned with the limited number of cases but acknowledges the difficulty in obtaining cost data for a condition that has a low prevalence in the Medicare population.

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

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

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

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

CMS received ten applications for new technology add-on payments under the alternative pathway. One applicant withdrew its applications, three of the technologies received a Breakthrough Device designation from the FDA and six have been designated as a QIDP. 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, the new the new technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case.

a. Alternative Pathway for Breakthrough Devices

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

CMS proposes to approve the BAROSTIM NEO® System for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the device is $35,000. CMS proposes a maximum new technology add-on payment for a case involving the BAROSTIM NEO® System would be $22,750 for FY 2021.

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

Subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020, CMS proposes to approve the NanoKnife® System for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the NanoKnife® System is $11,086. CMS proposes the maximum new technology add-on payment for a case involving the NanoKnife® System would be $7,205.90 for FY 2021.

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

CMS proposes to approve The Optimizer® System for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the device is $23,000. CMS proposes a maximum new technology add-on payment for a case involving The Optimizer® System would be $14,950 for FY 2021.

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

(1) Cefiderocol (Fetroja). Shionogi & Co. submitted an application for Cefiderocol, a ß-lactam antibiotic indication for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, caused by multi-resistant gram-negative pathogens. Cefiderocol is designated as

a QIDP and received FDA approval on November 19, 2019. The drug was not commercially available until February 24, 2020. There are no current ICD-10-PCS procedure codes for the administration of Cefiderocol; the applicant has submitted a request for a new ICD-10-PCS code. CMS agrees with the applicant that the drug meets the cost criterion.

CMS proposes to approve Cefiderocol for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug is $10,559.81. CMS proposes a maximum new technology add-on payment for a case involving the Cefiderocol would be $7,919.86 for FY 2021.

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

Pending FDA approval, CMS proposes to approve CONTEPO™ for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug administered over 12.5 days is $3,125. CMS proposes a maximum new technology add-on payment for a case involving CONTEPO™ would be $2,343.75 for FY 2021.

(3) NUZYRA® for Injection. Paratek Pharmaceuticals submitted an application for NUZYRA® for Injection, a tetracycline class antibacterial indicated for the treatment of community-acquired bacterial pneumonia and acute bacterial skin infections caused by susceptible microorganisms. NUZYRA® for Injection was designated as a QIDP and received FDA approval on October 2, 2018. The drug became commercially available in February 2019. The applicant has submitted a request for approval of a new ICD-10-PCS procedure code. CMS agrees with the applicant that the drug meets the cost criterion.

CMS proposes to approve NUZYRA® for Injection for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug is $2,070. CMS proposes a maximum new technology add-on payment for a case involving NUZYRA® for Injection would be $1,552.50 for FY 2021.

(4) 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 cUTIs and complicated intra-abdominal infections. RECARBIO™ received FDA approval on July 16, 2019 and is designated as a QIDP. The drug became commercially available on the market on January 6, 2020. CMS agrees with the applicant that the drug meets the cost criterion.

CMS proposes to approve RECARBIO™ for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug is $4,710.37. CMS proposes a maximum new technology add-on payment for a case involving RECARBIO™ would be $3,532.78 for FY 2021.

(5) XENLETA. Nabriva Therapeutics submitted an application for XENLETA, a pleuomutilin antibacterial agent for community-acquired bacterial pneumonia. The drug is administered as a tablet or as an IV infusion. XENLETA was approved by the FDA under the QIDP designation

and received FDA approval on August 19, 2019 for the treatment of community-acquired bacterial pneumonia. The drug was commercially available on September 10, 2019. The applicant has submitted a request for approval of a unique ICD-10-PCS procedure code. CMS agrees with the applicant that the drug meets the cost criterion.

CMS proposes to approve XENLETA for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug is $1,701. CMS proposes a maximum new technology add-on payment for a case involving RECARBIO™ would be $1,275.75 for FY 2021.

(6) ZERBAXA®. Merck submitted an application for ZERBAXA® a combination of cerolozane and tazobactam used for patients with complicated intra-abdominal infections (cIAI), cUTIs, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). ZERBAXA® was initially approved by the FDA on December 19, 2014 for treatment of cIAI and for cUTIs. ZERBAXA® was approved by the FDA on June 3, 2019 for HABP/VABP. ZERBAXA® was designated as a QIDP. CMS believes that only the indication approved in 2019 for treatment of HABP/VABP is eligible for new technology add-on payments. The applicant has submitted a request for a new ICD-10-PCS procedure code for ZERBAXA®. CMS agrees with the applicant that the drug meets the cost criterion.

CMS proposes to approve ZERBAXA® for new technology add-on payments for FY 2021. Based on preliminary information provided from the applicant the cost of the drug is $2,449.31. CMS proposes a maximum new technology add-on payment for a case involving ZERBAXA® would be $1,836.98 for FY 2021.

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

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

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

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

CMS discusses recent information from the CDC[29] that continues to highlight the significant concerns and impacts related to antimicrobial resistance and the importance of this issue to the

[29] https://www.cdc.gov/drugresistance/biggest-threats.html

overall public health of the U.S., especially Medicare beneficiaries. To address these concerns, CMS proposes changes to the alternative pathway for certain antimicrobial products.

a. Proposed Changes to the Alternative Pathway for Certain Antimicrobial Products

The FDA has a Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) which encourages the development of safe and effective drugs for serious bacterial and fungal infections.[30] An antibacterial or antifungal drug approved under the LPAD is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs. CMS proposes to expand the alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD.[31] Specifically, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial drug is approved by the FDA under the LPAD program it will be considered new and not substantially similar to an existing technology and does not need to meet the requirement that it represents an substantial clinical improvement relative to existing technologies (§412.87(d)(ii)). An antimicrobial product that is approved by FDA under the LPAD pathway will need to meet the cost criterion (§412.87(b)(3)). CMS also proposes to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway from 65 to 75 percent.

The FDA may approve a drug under the LPAD pathway if it meets certain statutory standards for approval. Although the FDA may provide advice on potential LPAD eligibility, it makes the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. Thus, an applicant that has not received FDA approval and has requested approval under the LPAD pathway may not know when submitting an application to under the proposed expanded alternative pathway whether it will qualify for approval under the LPAD pathway. If an applicant's drug does receive FDA approval but does not receive approval under the LPAD pathway and is not designated as a QIDP, the technology would not be eligible for the alternative pathway for certain microbial products. To seek approval for a new technology add-on payment, the applicant would need to re-apply under the traditional pathway for the following fiscal year.

Similar to the clarification regarding marketing authorization for transformative new devices alternative pathway, CMS clarifies that a new medical product seeking approval for a new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation (§41.87(d)(1)).

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

CMS requires that all applications for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered ((§41.87(e)). CMS believes July 1 of each year provides the agency sufficient time to review each application and provide notice and comment before

[30] Section 506(h) of the FD&C Act, 21 U.S.C. 356(h)

[31] CMS proposes to revise the title of existing §412.87(d) to refer more broadly to "Certain antimicrobial products" rather that specifying in the title the particular FDA program for antimicrobial products subject to this alternative pathway.

publication of the IPPS final rule by August 1 of each year. CMS continues to believe this policy is appropriate for new technology add-on payments but because of the significant ongoing concerns about antimicrobial resistance, it believes that the new technology add-on payment for certain antimicrobial products may warrant additional flexibility. In addition, CMS notes that the review of products under the alternative pathway do not need to demonstrate significant clinical improvement which reduces the time required for CMS to review the application.

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

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

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

Regulatory Impact. CMS estimates that FY 2021 new technology add-on payments for technologies that were approved in FY 2020 would be approximately $208 million. Based on preliminary information from the applicants at the time of this proposed rule, CMS estimates that total payments for the nine technologies that applied under the alternative pathway, if approved, would be approximately $240 million for FY 2021. Total estimated FY 2021 payments for new technologies that are designated as a QIDP would be approximately $200 million, and total estimated FY 2021 payments for new technologies that are part of the Breakthrough Device program would be approximately $40 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.

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

A. Labor Market Areas

Hospitals are assigned to labor market areas and the wage index reflects the weighted (by hours) average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) Core-Based Statistical Areas (CBSAs) delineations as labor market areas. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01 and 17-01.

Typically, OMB bulletins issued between decennial censuses have only minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18-03 and the September 14, 2018 OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical between decennial censuses. The new delineations have implications for the wage index and geographic reclassification.

Urban Counties Becoming Rural. A total of 34 counties (and county equivalents) including 10 hospitals will go from urban to rural classification. Under current policy, the wage data for all hospitals located in these counties will now go into calculating the state's rural wage index. For purposes of DSH, CMS will follow a pre-established policy that will transition the hospital's payments based on two-thirds of the urban formula and one-third of rural formula in FY 2021; one-third of the urban formula and two-thirds of the rural formula in FY 2022 and 100 percent of the rural formula in FY 2023.

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

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

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

B. Worksheet S-3 Wage Data

The proposed rule wage index values are based on data from FY 2017 submitted cost reports. Categories of included and excluded costs from prior years are unchanged for FY 2020.

CMS indicates that it has received appeals on how physician compensation is accounted for in the calculation of the wage index. Compensation of physician time spent in Part A activities is allowable for the wage index while compensation for Part B billable activities is not. Physician activities, such as funded research, that are not paid under either Part A or Part B of Medicare are reported in a non-reimbursable cost center. The proposed rule describes the documentation requirements (such as physician allocation agreements and time studies) for costs to be included in the wage index. The rule indicates that the MAC makes the final determination on the adequacy of the records maintained for the allocation of physicians' compensation.

CMS calculates the FY 2021 wage index based on wage data of 3,196 hospitals. CMS states that the data file used to construct the final wage index includes FY 2017 data submitted to CMS as of February 7, 2019.[32] General wage index policies are unchanged from prior years. However, CMS notes that it proposed to exclude 84 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 2021 wage index.

C. Method for Computing the Unadjusted Wage Index

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

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

[32] This date is likely erroneous and probably intends to refer to a date in 2020.

2016 is used for the occupational mix adjustment applied to the FY 2019 through FY 2021 IPPS wage indexes.

Hospitals were required to submit completed 2019 occupational mix surveys to their MACs (not directly to CMS), on the Excel hospital reporting form, by July 1, 2020 via email attachment or overnight delivery. CMS is granting an extension until August 3, 2020 for hospitals that may be unable to meet the July 1, 2020 deadline due to the COVID-19 public health emergency. (See https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/2019-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2022).

CMS reports having occupational mix data for 97 percent of hospitals (3,113 of 3,196) used to determine the FY 2021 wage index. The FY 2021 national average hourly wage, unadjusted for occupational mix, is $45.11. The occupational mix adjusted national average hourly wage is $45.07.

E. Occupational Mix Adjusted Wage Index

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

F. Rural and Frontier Floors and Low Wage Index Hospital Policy

Rural Floor. The rural floor is a provision of statute that prevents an urban wage index from being lower than the wage index for the rural area of the same state. CMS estimates that the rural floor will increase the FY 2021 wage index for 255 hospitals requiring a budget neutrality adjustment factor of 0.993991 (-0.6 percent) applied to hospital wage indexes.

Frontier Floor Wage Index. The Affordable Care Act requires a wage index floor for hospitals in the low population density states of Montana, Nevada, North Dakota, South Dakota and Wyoming. CMS indicates that 45 hospitals will receive the frontier floor value of 1.0000 for FY 2021. This provision is not budget neutral, and CMS estimates an increase of approximately $70 million in IPPS operating payments due to the frontier floor.

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

Increase the wage index by one-half the difference between the hospital's otherwise applicable wage index and the 25th percentile wage index value. CMS proposes to continue this policy for FY 2021 through FY 2023. For FY 2021, the 25th percentile wage index value across all hospitals is 0.8420. CMS proposes to apply a budget neutrality adjustment of -0.18 percent for this policy.
Remove the wage data from urban hospitals reclassifying as rural from the calculation of the rural floor wage index.

Not apply a floor on a county's wage index based on the rural area wage index that results from a hospital in that county reclassifying from urban to rural.
Limit reductions in a hospital's wage index for any reason to 5 percent in a single year. For FY 2021, the budget neutrality adjustment for this policy will be -0.026 percent.

G. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at:
https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-home-page.

Select #2 under FY 2021 Proposed Rule Tables.

H. Revisions to the Wage Index Based on Hospital Reclassifications

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

Geographic Reclassifications. There are 435 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021. There are 244 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2019 that will continue for FY 2021, and 279 hospitals approved for wage index reclassification in FY 2020 that will continue for FY 2021. Nine hundred and fifty-seven hospitals are in an MGCRB reclassification status for FY 2021 (with 101 of these hospitals reclassified back to their home area).

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

Hospitals with One or Two Years of Wage Data Seeking MGCRB Reclassification. CMS proposes to modify 42 CFR §412.230(d)(2)(ii)(A) to clarify that a hospital may qualify for an individual wage index reclassification if the hospital only has 1 or 2 years of wage data. The regulations state that a 3-year average hourly wage is used to support the reclassification application. The proposed revision will clarify that the hospital may use 1 or 2 years of data in such circumstances as when a hospital is new and does not have 3 years of data. This policy also applies to a change of hospital ownership where the new owner does not accept the provider agreement of the prior owner.

Revised OMB Labor Market Area Delineations on Reclassified Hospitals. Hospitals applied for reclassification based on the prior OMB delineations, not the revised delineations proposed for

FY 2021. CMS encourages hospitals with current reclassifications to verify they remain reclassified to an area with a higher wage index. If not, hospitals may withdraw or terminate their FY 2021 reclassifications by July 13, 2020 using the procedure outlined in 42 CFR §412.273(c). Hospitals with an FY 2019 or FY 2020 reclassification that may continue into FY 2021 as well as new reclassification beginning with FY 2021 may withdraw the more recent reclassification in favor of a prior one.

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

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

Individual hospitals may request and be granted an alternative reclassification assignment if the requested area contains at least one county from the CBSA to which they are reclassified for FY 2020 and for which they meet the applicable proximity criteria. For county groups, a hospital or group of hospitals may request and be granted reassignment to another CBSA that would contain a county that is part of the current FY 2020 CBSA to which it is reclassified if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules. All requests must be submitted by July 13, 2020 and can be emailed to: wageindex@cms.hhs.gov.

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

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

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

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

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

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

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

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

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

The rule indicates that all 34 counties including 10 hospitals that are becoming rural will qualify for Lugar status. An additional two counties in New York State would qualify for Lugar status but hospitals in these counties have existing geographic reclassifications that would supersede these "Lugar" reclassifications.

I. Out-Migration Adjustment

CMS proposes to use the same policies for the FY 2021 out-migration adjustment that it has been using since FY 2012. Estimates of increased payments are $46 million in FY 2021 to 203 hospitals. This provision is not budget neutral.

J. Reclassification from Urban to Rural

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.

Allowing Electronic Appeals of MGCRB Decisions. Regulations require that appeals of MGCRB applications must be mailed to the Administrator in care of the Office of the Attorney Advisor with a hardcopy to CMS' Hospital and Ambulatory Policy Group. Appeals may be not submitted by facsimile or other electronic means. CMS proposes to revise the regulation to remove the prohibition on electronic or facsimile submissions. Copies to the Hospital and Ambulatory Policy Group would be required by electronic means.

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

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

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:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page. Select file #1. This website also includes all of the public use files that CMS has made available during the wage index development process.

In response to an inquiry, CMS clarifies that 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.

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. CMS is proposing to continue using a national labor-related share of 68.3 percent for FY 2021. If a hospital has a wage index of less than 1.0, its IPPS payments will be higher with a labor-related share of 62 percent. If a hospital has a wage index that is higher than 1.0, its IPPS payments will be higher using the national labor-related share.

IV. Other Decisions and Changes to the IPPS

A. Post-Acute Care Transfer Policy and Special Payment MS-DRGs

1. Background

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

"special payment methodology" and is cases that exhibit exceptionally higher costs very early in the hospital stay.

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

2. Changes for FY 2021

CMS proposed to make changes to a number of MS-DRGs effective for FY 2021. As a result of its review, CMS is proposing to add MS-DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) to the list of MS-DRGs subject to the post-acute care transfer policy and the special payment methodology.

B. Inpatient Hospital Updates

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

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

The IHS Global Insight, Inc. (IGI) second quarter 2020 forecast (with historical data through the first quarter of 2020) for the hospital market basket is 3.0 percent. Using IGI's second quarter 2020 forecast (with historical data through the first quarter of 2020), CMS is adopting an MFP adjustment of -0.4 percentage points.

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

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.75	-0.75
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.25	0.0	-2.25
MFP Adjustment	-0.4	-0.4	-0.4	-0.-4
Applicable Percentage Increase	**2.6**	**0.35**	**1.85**	**-0.4**

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

C. Short Cost Reporting Periods and Sole Community Hospitals

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

D. Rural Referral Centers: Annual Updates to Case-Mix Index and Discharge Criteria

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. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, a rural hospital with fewer than 275 beds available for use must meet the specific geographic criteria and:

- Have a CMI value for FY 2019 that is at least—
    - 1.70435 (national—all urban), or
    - The median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) for the census region in which the hospital is located (see table on page 788 of the display copy of the rule for the regional CMIs).
- Have at least 5,000 discharges (3,000 for an osteopathic hospital) for its cost reporting period that began during FY 2018.

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

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

To meet the minimum number of discharges criterion, the regulations require the hospital to use the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. CMS recently encountered a situation where the applicable cost reporting period was shorter than 12 months. The hospital would have met the discharge criterion based on 12 months of data but did not based on a short-period cost report. For this reason, CMS is modifying the regulations to clarify that if the applicable cost reporting period is shorter or longer than 12 months to

determine whether the discharge criterion is met, the number of discharges will be annualized to reflect a 12-month cost reporting period.

E. 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, 2020**. 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 2020 may continue to receive a low-volume hospital payment adjustment in FY 2020 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).

F. 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.

G. Disproportionate Share and Uncompensated Care

1. Background

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

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

- Factor 1: 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) without application of the ACA;
- Factor 2: The ratio of the percentage of the population insured in the most recent year to the percentage of the population insured in a base year prior to ACA implementation; and
- Factor 3: A hospital's uncompensated care costs for a given 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 2021 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) December 2019 Medicare DSH estimates, which were based on the September 2019 update of the HCRIS and the FY 2020 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's December 2019 Medicare estimates of DSH is $15.359 billion. **The proposed Factor 1 amount is seventy-five percent of this amount or $11.519 billion.** The proposed Factor 1 for 2021 is about $919 million less than the final Factor 1 for FY 2020.

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

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

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2018	1.018088	0.983	1.018	1.03145	1.0508	14.716
2019	1.0185	0.9549	1.01	1.02025	1.0022	14.748
2020	1.031	0.9756	1.005	0.9961	1.0069	14.850
2021	1.031	0.9959	1.005	1.00225	1.0342	15.359

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

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

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

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2020	3.0	0	-0.4	0.5	3.1
2021	3.0	0	-0.4	0.5	3.1

3. Proposed FY 2021 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. For FYs 2014-2017, the statute required CMS to use CBO's 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.[33]

For FY 2021, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2020 and 2021 is 9.5 percent. As required, the Chief Actuary of CMS certified these estimates.

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

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2020: 9.5 percent.
- Percent of individuals without insurance for CY 2021: 9.5 percent.
- Percent of individuals without insurance for FY 2021 (0.25 times 0.095) +(0.75 times 0.095): 9.5 percent

Proposed Factor 2 = 1-|((0.095-0.14)/0.14)| = 1- 0.3214 = 0.6786 (67.86 percent)

CMS calculated Factor 2 for the FY 2021 proposed rule to be 0.6786 or 67.86 percent, and the uncompensated care amount for FY 2021 to be $11.519 billion x 0.6786 = $7,816,726,243 which is about $534 million less than the FY 2020 UCP total of about $8.351 billion;[34] the percentage decrease is 6.4 percent. The below tables show the Factor 1 and Factor 2 estimates for FY 2020 and the proposed factors for FY 2021:

[33]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

[34] CMS includes the wrong value for Factor 1 in the uncompensated care calculation on page 833 of the display copy; instead of $15.357 billion multiplied by 0.6786 it should state $11.519 billion multiplied by 0.6786.

FY 2021 Change in UCP

	FY 2020	FY 2021	$ Change ($ in billions)	% Change
Factor 1	$12.438	$11.519	-$0.919	-7.4%
Factor 2	0.6714	0.6786	+.0072	+1.1%
UCP	$8.351	$7.817	-$0.534	-6.4%

4. Proposed Factor 3 for FY 2021

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

Factor 3 equals the proportion of hospitals' aggregate uncompensated care attributable to each IPPS hospital (including Puerto Rico hospitals). The product of Factors 1 and 2 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[35] 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[36] and one year of Worksheet S-10 data (FY 2014). In FY 2019, CMS continued that transition by using one year of low-income patient days[37] and two years of Worksheet S-10 data (FY 2014 and FY 2015).

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

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

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

CMS notes that uncompensated care payments to hospitals whose FY 2017 Worksheet S-10 data have been audited represent about 65 percent of the proposed total uncompensated care payments for FY 2021. CMS uses data from the HCRIS extract updated through February 19, 2020. It intends to use the March 2020 update for the FY 2021 final rule and the respective March updates for all future final years.

---

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

[36] 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).

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

CMS invites comment on its intention to use the March update of HCRIS or whether it should consider using more recent data prior to the development of the final rule for purposes of calculating the final Factor 3.

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

CMS proposes that for FY 2022 and all subsequent years, it would use the most recent single year of cost report data that have been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to calculate Factor 3 for all eligible hospitals, with the exception of IHS and Tribal hospitals. It believes that such a policy would help providers have greater predictability for planning purposes. CMS states that it could revisit this policy through future rulemaking based on comments received.

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

d. Proposed Definition of "Uncompensated Care"

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

e. Proposed Methodological Considerations for Calculating Factor 3

Merger Multiplier for Acquired Hospital Data
CMS proposes to modify the annualization policy that was finalized in the FY 2019 IPPS/LTCH final rule with respect to merged hospitals that annualized the uncompensated care data if a hospital's cost report does not equal 12 months of data.[38] CMS notes that in situations when the merger effective date does not coincide with the start date of the surviving hospital's cost reporting period, the policy of annualizing the acquired hospital's data before combining data across hospital cost reports could substantially overestimate the acquired hospital's UCC. Annualizing acquired

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

hospital's data may double-count UCC for the portion of the year that overlaps with the remainder of the surviving hospital's cost reporting period.

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

Newly Merged Hospitals
CMS 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 2021, this data would be the FY 2017 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 2021 cost report.

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

New Hospitals for Purposes of Factor 3

CMS proposes to continue its "new hospital" policy methodology where a new hospital with a CCN established after October 1, 2015 eligible for DSH based on its FY 2021 cost report would receive uncompensated care payments based on its FY 2021 uncompensated care costs as a percent of FY 2017 national uncompensated care costs. The new hospital would not receive interim uncompensated care payments before cost report settlement because CMS would have no FY 2017 uncompensated care data on which to determine those interim payments.

Indian Health Service and Tribal Hospitals and Subsection(d) Puerto Rico hospitals that have a FY 2013 cost report.
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 continues to consider feedback provided during IHS and Tribal consultation for purposes of determining what policies should apply with respect to DSH and uncompensated care payment for these hospitals in future years. **CMS seeks further comment on this issue to inform future rulemaking.**

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

Proposed CCR Trim Methodology
Similar to the FYs 2018, 2019, and 2020 process, CMS proposes the following steps for trimming CCRs in FY 2021.

Methodology for Trimming CCRs	
Step 1	Remove Maryland hospitals and all-inclusive rate providers
Step 2	For FY 2017 cost reports, CMS would calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. Based on the information currently available to CMS, this trim would remove 12 hospitals that have a CCR above the calculated ceiling of 0.937 for FY 2017 cost reports.
Step 3	Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2017 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S-3, Part I, Line 14, Column 15.
Step 4	Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling"). Under the proposed rule, the statewide average CCR would apply to 12 hospitals, of which 4 have FY 2017 Worksheet S-10 data.
Step 5	For providers that did not report a CCR on Worksheet S-10, Line 1, CMS would assign them the statewide average CCR as determined in step 3.

After completing the steps above, CMS 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 and FY 2020 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2017 are an extremely high ratio (greater than 50 percent) of its total operating costs, CMS proposes that data from the FY 2018 cost report would be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2017 would be trimmed by multiplying its FY 2017 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2018 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2017 for purposes of determining Factor 3 for FY 2021. For hospitals whose FY 2017 cost report has been audited, CMS will not apply the trim methodology.

CMS proposes to amend the regulation at §412.106 by adding a new paragraph (g)(1)(iii)(C)(7) to reflect the proposed methodology for computing Factor 3 for FY 2021. CMS also proposes to add a new paragraph (g)(1)(iii)(C)(8) to reflect the proposal for all subsequent fiscal years to use the most recent available single year of audited Worksheet S-10 data to calculate Factor 3 for all eligible hospitals, except IHS and Tribal hospitals.

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

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, CMS calculates a per discharge amount of interim uncompensated care by dividing the hospital's total uncompensated care payment amount by the hospital's 3-year average of discharges. This per

discharge payment amount is used to make interim uncompensated care payments to each projected DSH eligible hospital. These interim payments are reconciled following the end of the year.

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

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

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of each year's proposed rule to review the tables and notify CMS in writing of any inaccuracies.[39]

For FY 2021, CMS proposes that after the publication of the FY 2021 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 acknowledges that this is less time compared to previous years, but states that there is only a limited amount of time to review submitted information by hospitals and to implement the finalized policies before the beginning of the fiscal year. CMS believes that if there are any remaining merger updates and/or upload discrepancies after the final rule, 15 days from the date of public display should be sufficient time to make any corrections to Factor 3 calculations. In addition, CMS states that it intends to revisit whether this additional comment period after the final rule is even necessary.

Impact Analysis

The regulatory impact analysis presented in Appendix A of the proposed rule includes the estimated effects of the changes to uncompensated care payments (UCP) for FY 2021 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,410 hospitals that are projected to be eligible for DSH in FY 2021. CMS presents estimates based on its proposal to use to use FY 2017 Worksheet S-10 data to determine Factor 3.

The total amount of UCP is estimated at $7.817 billion, a 6.39 percent decrease from FY 2020 UCP (about $534 million). Changes in FY 2021 UCP compared to FY 2020 are accounted for primarily by a proposed decrease in Factor 1, a proposed increase in Factor 2, as well as slightly

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

fewer hospitals being eligible to receive DSH. Factor 1 is estimated to decrease from $12.643 billion to $11.519 billion while Factor 2 is estimated to increase from 67.14 percent to 67.86 percent. The payment decrease for any individual hospital will vary as payment impacts solely from Factor 3 are redistributive. A percent change in UCP payments lower than negative 6.39 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 6.39 percent indicates the category of hospitals is receiving a smaller decrease in UCP than the average for all hospitals. The table below shows impacts for selected categories of hospitals.

Hospital Type	Dollar Difference FY 2020-FY 2021 ($ in millions)	Percent Change
All Hospitals	-$534	-6.39%
Urban	-474	-6.05
Large Urban	-244	-5.09
Other Urban	-229	-7.57
Rural	-60	-11.48
Beds: 0-99 (Urban)	-10	-3.55
Beds: 250+ (Urban)	-345	-6.12
New England (Urban)	-38	-15.01
Middle Atlantic (Urban)	-123	-11.68
West North Central (Urban)	-2	-0.62
West South Central (Urban)	-159	-9.37
Pacific (Urban)	+22	3.31
Major Teaching	-197	-6.57
Non-Teaching	-157	-6.28
Voluntary	-252	-5.52
Proprietary	-92	-7.41
Government	-190	-7.46

Under its proposal, rural hospitals are projected to receive a larger percentage decrease in UCP (11.48%) than urban hospitals (6.05%) in FY 2021 compared to FY 2020. Urban hospitals in the New England, the Middle Atlantic, West South Central, and Mountain regions are the most negatively affected. Rural hospitals in all regions are expected to receive larger than average decreases, except for rural hospitals in the East North Central and West North Central regions. The variation by teaching status is minimal and the percent change in payments is similar to the overall average payment decrease of 6.39 percent. Proprietary and government hospitals are projected to receive larger than average decreases of 7.41 and 7.46 percent respectively, whereas voluntary hospitals are projected to receive a payment decrease of 5.52 percent.

H. Allogeneic Hematopoietic Stem Cell Acquisition Costs

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

hematopoietic stem cell acquisition costs to be made on a reasonable cost basis instead for through the IPPS.

CMS is proposing to revise the regulations to:

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

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

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

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

The statute requires the new reasonable cost payment for allogeneic hematopoietic stem cell acquisition costs to be adopted without increasing or decreasing Medicare spending. CMS

proposes to make a -0.01 percent adjustment ($15.9 million) to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral. This estimate reflects charges reported on the hospital's inpatient claim in revenue center code 0815 (which is reflected in the MedPAR field for the Revenue Center Allogeneic Stem Cell Acquisition/Donor Services) reduced to costs using the hospital's overall operating CCR that is used for outlier payments. CMS will update this estimate for the final rule.

I. Payment Adjustment for CAR-T Clinical Trial Cases

CMS is proposing to create new MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Immunotherapy for CAR-T cell therapy cases. To calculate the relative weight, CMS has proposed not using clinical trial cases where the hospital does not have a cost for the CAR-T cell therapy product. Similarly, CMS is proposing to adjust for clinical trial cases to not pay for the cost of the CAR-T cell therapy product that the hospital did not incur.

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

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

J. Hospitals with a High Percentage of ESRD Discharges

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

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

CMS is also proposing to remove MS-DRG 652 (because this MS-DRG no longer includes cases receiving hemodialysis) and MS-DRG 685 (because it is deleted) from the list of excluded MS-DRGs that count towards the 10 percent threshold.

K. Hospital Readmissions Reduction Program

In this rule, CMS proposes to automatically adopt applicable periods beginning with FY 2023, as discussed further below. No changes are proposed to HRRP measures, the factors used by CMS in removing measures, use of subregulatory processes to make nonsubstantive changes to measures and other program features, or the methodology for calculating the payment adjustment.

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 2020 is: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective total hip arthroplasty (THA)/total knee arthroplasty (TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass surgery (CABG).

A hospital subject to the HRRP receives an adjustment factor that is between 1.0 (no reduction) and 0.9700 (or a greatest possible reduction of 3 percent) of base operating DRG payments. Beginning with FY 2019, hospitals are assigned to one of five peer groups based on the proportion of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligibles[40] and the HRRP formula compares a hospital's performance to the median for its peer group.

Using the March update to the MedPAR file for a 3-year "applicable period," hospitals are grouped by quintiles (five peer groups) based on the proportion of dual-eligible patients. The payment adjustment for a hospital is calculated using the following formula comparing a hospital's excess readmissions ratio to the median excess readmission ratio (ERR)[41] for the hospital's peer group, where "payment" refers to base operating DRG payments, dx refers to an HRRP condition (i.e., AMI, HF, pneumonia, COPD, THA/TKA, or CABG), and NM_M is a budget neutrality factor (neutrality modifier)[42] that is the same across all hospitals and all conditions.

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

[40] These are individuals who are entitled to Medicare Part A benefits and who meet the definition of full benefit dual eligible individual under section 1935(c)(6) of the Social Security Act, which for a state for a month is an individual who– (i) has coverage for the month for covered part D drugs under a Part D prescription drug plan or an MA-PD plan; and (ii) is determined eligible by the state for full Medicaid benefits for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for full Medicaid benefits, as determined by the Secretary.

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

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

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

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

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

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

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

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

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

3. Confidential Reporting of Stratified Readmissions Data

As promised in the FY 2020 IPPS/LTCH final rule, CMS indicates that in the spring of 2020 it will provide confidential hospital-specific reports including data on the six readmissions measures stratified by patient dual eligible status. Results will be provided using two disparity

methodologies: the within-hospital disparity method compares readmissions rates for dual eligibles and other beneficiaries, and the dual eligible outcome measure compares performance in care for dual eligibles across hospitals. These methods differ from the HRRP stratification and will not be used for any payment calculations. CMS is providing the data because it believes that it allows for a more meaningful comparison and will provide additional perspectives on health care equity.

4. Impact Analysis

Using the FY 2020 HRRP payment adjustments, in the regulatory impact analysis section of the proposed rule CMS estimates that 2,583 hospitals, or 85 percent of those eligible, will be penalized under the HRRP in FY 2021, with aggregate penalties representing 0.69 percent of payments to hospitals. (An estimated dollar total of penalties is not provided.) A table shows the variation in these impacts by hospital characteristics. In general, larger hospitals and teaching hospitals are more likely than average to be penalized under the HRRP but the penalties for these groups represent a smaller than average share of payments.

L. Hospital Value-Based Purchasing Program

No changes are proposed to the Hospital VBP Program for FY 2021. The previously adopted measures; domain weights (25 percent each across the four domains); case minimums; and payment adjustment methodologies would be continued. The proposed rule includes tables displaying previously adopted baseline and performance periods, and previously adopted and newly estimated performance standards for FYs 2023 through 2026. A summary table with the previously adopted measures is shown at the end of this summary section and includes the National Quality Forum (NQF) number for measures which have been endorsed by that body.

1. Background

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

For each payment year, CMS specifies through rulemaking a VBP Program measure set. For each measure, a baseline period and a performance period are finalized. A hospital's performance on each measure during the performance period is assessed (resulting in achievement points) and compared to its performance during the baseline period (resulting in improvement points). Measures available for inclusion in the Hospital VBP Program are those that are included in the IQR Program and have been included on the *Hospital Compare* website for at least one year prior to the start of the relevant performance period. CMS calculates a TPS for each hospital by summing the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score, and

adding together the weighted domain scores. CMS then converts each hospital's TPS into a value-based incentive payment percentage using a linear exchange function, under which the sum of all hospitals' payments will equal the amount of dollars contributed to the VBP funding pool.

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

2. Baseline and Performance Periods; Performance Standards

The proposed rule includes tables with the previously adopted baseline and performance periods for FYs 2023 through 2026. Additional tables show previously adopted and newly estimated performance standards for those fiscal years. All the performance standards will be updated in the final rule.

3. Impact Analysis

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

CMS has posted on the FY 2021 IPPS proposed rule web page a Table 16 which includes proxy hospital-specific value-based incentive payment adjustment factors for FY 2021. These proxies are based on hospitals' TPSs from the FY 2020 Hospital VBP Program. Table 16 will be replaced at the time of publication of the final rule with an updated Table 16A still based on FY 2020 TPSs. Final FY 2021 adjustment factors will be posted as Table 16B in the fall of 2020, after hospitals have been able to review and correct their actual TPSs for FY 2021. At that time the final exchange function slope, and estimated amount available for the FY 2021 program year will also be provided.

Summary Table VBP-1: Measures and Domains by Payment Year

Measure	NQF #	2020	2021	2022	2023/ 2024
Clinical Outcomes Domain					
Acute Myocardial Infarction (AMI) 30-day mortality rate	0230	X	X	X	X
Heart Failure (HF) 30-day mortality rate	0229	X	X	X	X
Pneumonia (PN) 30-day mortality rate	0468	X	X	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty	1550	X	X	X	X

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**NQF #**	**2020**	**2021**	**2022**	**2023/ 2024**
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate	1893		X	X	X
CABG 30-day mortality rate	2558			X	X
Safety Domain					
CMS Patient Safety and Adverse Events Composite*	0531				X
Central Line Associated Blood Stream Infection (CLABSI)	0139	X	X	X	X
Catheter Associated Urinary Tract Infection (CAUTI)	0138	X	X	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections	0753	X	X	X	X
Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	1716	X	X	X	X
Clostridium Difficile Infection (CDI)	1717	X	X	X	X
Perinatal Care: elective delivery < 39 weeks gestation	0469	X	Removed		
Person and Community Engagement Domain					
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	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.					

M. Hospital-Acquired Condition Reduction Program

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

1. Background

Under the HAC Reduction Program, which was implemented beginning in FY 2015, a 1-percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile with respect to a set of HAC measures. Currently, performance is assessed on six measures: five healthcare-associated infection (HAI) measures from the Centers for

Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and the CMS PSI 90 patient safety measure.[43]

Beginning in FY 2017 CMS began to use the "Winsorized Z-Score Method" for determining a hospital's score for each program measure. The Total HAC Score for a hospital is calculated by giving each measure an equal weight and then summing its weighted measure Winsorized z-scores. These Total HAC Scores are then used to define the top quartile of hospitals (i.e., worst performers) subject to the penalty. An extraordinary circumstances exception policy was adopted for the HAC Reduction Program beginning in FY 2016.

More information on the program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program. Certain requirements of the HAC Reduction Program are codified at §§412.170 through 412.172.

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

CMS has previously finalized a 24-month "applicable period", or performance period, for the HAC Reduction Program. The applicable period has been adopted annually in the IPPS/LTCH final rule. For example, the applicable period previously adopted for FY 2022 is the 24-month period from July 1, 2018 through June 30, 2020 for the PSI-90 measure, and January 1, 2019 through December 31, 2020 for the NHSN measures.

In this rule, CMS proposes the automatic adoption of applicable periods for FY 2023 and all subsequent program years. Specifically, beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures would be the 24-month period beginning 1 year after the start of the applicable period for the previous program year. For example, for FY 2023, the applicable period for the CMS PSI 90 measure would be the 24-month period from July 1, 2019 through June 30, 2021, and the applicable period for CDC NHSN HAI measures would be the 24-month period from January 1, 2020 through December 31, 2021.[44] All subsequent years would advance the 24-month periods by 1 year unless the Secretary specified otherwise, which CMS says would be done through notice and comment rulemaking. CMS believes that this proposed change would streamline the process and provide additional clarity and consistency to the program. The proposed change would be codified in regulatory text at §412.170 by modifying the definition of "applicable period."

3. HAC Reduction Program Data Validation

In the FY 2019 IPPS/LTCH final rule, CMS adopted a HAC Reduction Program data validation process to replace the one used for the IQR Program. (This was necessitated by removal of HAC Reduction Program measures from the IQR Program.) Under the policy, the five chart-abstracted NHSN measures will be subject to validation under the HAC Reduction Program beginning with Q3 2020 discharges for FY 2023 payment. This reflects the timing of adoption of the data collection requirements for the NHSN measures for the HAC Reduction Program. All subsection

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

[44] The proposed rule states this period to be January 1, 2020- December 31, 2022, which is a 36-month period and inconsistent with past performance periods and the proposal for automatic adoption of periods.

(d) hospitals are eligible for random selection for the data validation sample because they are all subject to the HAC Reduction Program. Sample sizes were continued from the IQR Program: 400 randomly selected hospitals and 200 hospitals selected using targeting criteria. Hospitals eligible for targeted selection are those that failed validation in the previous year; submit data to NHSN after the data submission deadline has passed; have not been randomly selected in the past 3 years; passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or failed to report to NHSN at least half of actual infection events detected as determined through the previous year's validation.

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

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

Aligning data submission quarters. To align data submission quarters across the two programs, CMS proposes that for FY 2023 HAC Reduction Program data validation, it would use only data for the third and fourth quarters of 2020 for both the random and targeted validation pools. The current schedule for data validation under the HAC Reduction Program (detailed in a table in the proposed rule) FY 2023 would include data for these two quarters and for the first two quarters of 2021. For FY 2024[45], CMS would use data from all of calendar year 2021 for both the HAC Reduction Program and the IQR Program. The data submission deadline for chart-abstracted measures would be the middle of the fifth month following the end of the reporting quarter.

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

[45] CMS describes this policy as continuing for subsequent years, suggesting that calendar year 2022 data would be used for FY 2025 data validation, etc. Yet here and in section VIII with respect to the IQR Program, it says that data for 2021 would be used for data validation in FY 2024 and subsequent years.

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

In discussing the proposal to require digital files, CMS appreciates that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records, and further notes that almost two-thirds of medical records submission to the CMS Clinical Data Abstraction Center (CDAC) contractor, use the option to submit PDF copies of medical records as electronic files. CMS believes that the electronic submission can be a more effective and efficient process for the hospitals selected for validation and requiring electronic file submissions reduces the burden of coordinating, copying and shipping to the CDAC numerous paper-based pages of medical records. Comments on this proposal are invited as part of the IQR Program proposals as summarized in section VIII.A below.

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the decrease in burden resulting from the proposed changes to the HAC Reduction Program data validation process would save a total of $558,720 across all hospitals each year.

4. Impact Analysis

The impact analysis section of the proposed rule includes a table that shows the estimated FY 2021 distribution of hospitals in the worst performing quartile of Total HAC scores by hospital characteristic. The estimates are based on data for the FY 2021 performance period for the CMS PSI 90 measure and for the FY 2020 performance period for the CDC NHSN HAI measures. While by definition, 25 percent of hospitals overall will be in the worst quartile and subject to the penalty (estimated 780 hospitals total), the estimated proportion varies from about 16 percent for rural hospitals with 100-149 beds to 49 percent of teaching hospitals with 100 or more medical residents. High-DSH and safety net hospitals are also more likely than others to be in the worst performing quartile. No estimate of the dollar amount of HAC Reduction Program penalties is provided.

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

N. Payments for Indirect and Direct Graduate Medical Education Costs

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

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

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

To apply for the temporary increase in the Medicare resident cap, the receiving hospital is required to submit a letter to its Medicare Administrative Contractor within 60 days of beginning the training of the displaced residents. CMS is modifying the requirement for information

included in this letter to no longer require the full social security number for each resident. Instead, only the last four digits of the resident social security number would be required.

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

O. Rural Community Hospital Demonstration Program

1. Background

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

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

2. FY 2021 Budget Neutrality Adjustment

CMS identifies 23 hospitals that will participate in the program in FY 2021. Eight of these hospitals are scheduled to end participation before September 30, 2021; CMS prorates the reasonable cost amounts for these hospitals for the portion of their cost reporting periods in the demonstration that are within FY 2021.

CMS estimates that the demonstration program will cost $40,804,704 in FY 2021. As of the date of publication of the proposed rule, CMS did not have completed cost reports for all 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 data become available. The total budget neutrality adjustment would be based on $40,804,704 or a proposed adjustment to the IPPS standardized amounts of 0.999642. CMS will update these figures for the final rule.

P. Market-Based MS-DRG Relative Weights

1. Overview

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

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

The rule then reviews the history of cost-based payment for hospital services, the IPPS and the use of charges reduced to cost to set the relative weights and make outlier payments. This history raises concerns for CMS that "chargemaster (gross) rates rarely reflect the true market costs" and CMS sets a goal of Medicare reducing its reliance on the hospital chargemaster and adjusting Medicare payment rates so that they reflect the relative market value for inpatient items and services.

EO 13890 *Protecting and Improving Medicare for Our Nation's Seniors* was issued on October 3, 2019. This EO describes the "market benefits provided under the Medicare Advantage [MA] program as providing, 'efficient and value-based care through choice and private competition.'" In this proposed rule, CMS looks to MA and the commercial market for "approaches to modify Medicare FFS payments to…encourage more robust price competition, and otherwise to inject market pricing into Medicare FFS reimbursement."

In order to reduce the Medicare program's reliance on the hospital chargemaster, CMS proposes that hospitals would be required to report:

1. the median payer-specific negotiated charge that the hospital has negotiated with all of its MA plans, by MS-DRG; and
2. the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA plans, by MS-DRG.

Hospitals would be required to report this information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021, to be used in potentially setting the IPPS MS-DRG relative weights beginning in FY 2024.

For third-party payers that do not negotiate rates by MS-DRG, the hospital would determine and

report the median payer-specific negotiated charges by MS-DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS-DRG. CMS believes that use of these data in the MS-DRG relative weight setting methodology would represent a significant and important step in reducing the Medicare program's reliance on hospital charge masters, and would better reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

2. Market-Based MS-DRG Relative Weight Estimation

a. Overview

Section 1886(d)(4)(A) of the Act requires the Secretary establish a classification of inpatient hospital discharges by DRG. Section 1886(d)(4)(B) requires that the Secretary establish a weighting factor which reflects the relative hospital resources within a DRG relative to the average across all DRGs. Consistent with the desire to reduce the Medicare program's reliance on the hospital chargemaster, as well as to inject market pricing into Medicare FFS reimbursement, CMS is contemplating using market data from MA plans and 3rd party payers to set the relative weights consistent with this statutory mandate. This system would replace the relative weight methodology that uses charges on Medicare claims in combination with cost-to-charge ratios from Medicare cost reports as described in section II. B and E.

b. Research Comparing Medicare, Medicare Advantage Organization, and Commercial Payment Rates

CMS' literature review indicates that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less.[46] Another study found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare.[47] A third study found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. In addition, "there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS."[48]

Taken as a whole, CMS believes research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are generally not as well-correlated with Medicare IPPS payment rates. Considering the public availability of payer-specific negotiated charges starting in 2021 and its desire to reduce the Medicare program's reliance on the hospital chargemaster consistent with EOs 13813 and 13890, CMS believes, it could adjust the methodology for calculating the MS-DRG relative

[46] Berenson RA, Sunsine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. Health Aff (Millwood). 2015;34(8):1289-1295.
[47] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. Health Aff (Millwood). 2016;35(8):1444-1451.
[48] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? The Journal of Health Care Organization, Provision, and Financing. 2018;55(1-8)

weights to reflect a more market-based approach under sections 1886(d)(4)(A) and 1886(d)(4)(B) of the Act.

c. Proposed Market-Based Data Collection

While CMS does not explicitly state it is proposing this new data collection under the authority of sections 1815(a) and 1833(e) of the Act, it does cite these authorities as providing for no Medicare payments unless a provider has furnished information requested by the Secretary to determine its Medicare payments. CMS is proposing that the data collected be furnished through the Medicare hospital cost reports. If CMS were to finalize its proposal, all of the data would become publicly accessible on the Hospital Cost Report Information System (HCRIS) dataset in a de-identified manner and would be usable for analysis by third parties. The data would be de-identified since the hospital transparency rule directs the hospital to calculate and report a median rate and thus a specific rate negotiated between a hospital and a specific third-party would not be reported on its hospital cost report.

The hospital price transparency final rule requires that hospitals make standard charges for all items and services publicly available via a single machine-readable file and (2) a consumer-friendly list of standard charges for at least 300 shoppable services. CMS is proposing that hospitals would calculate the median payer-specific negotiated charge by MS-DRG using the payer-specific negotiated charge data by MS-DRG from the single machine-readable file for all items and services.

To determine the median payer-specific negotiated charge for MA organizations for a given MS-DRG, a hospital would list, by MS-DRG, each discharge in its cost reporting period that was paid for by an MA organization and the corresponding payer specific negotiated charge. Once each discharge and its corresponding MA negotiated rate is arrayed, the hospital would calculate and report the median MA negotiated rate on its cost report. CMS would separately require the same process to be followed for all for other (non-MA) 3rd party payer median negotiated charges.

CMS is proposing to use the same definitions of "payer specific negotiated charge" and "items and services," that it used in the hospital price transparency rule. The rule explains that an MS-DRG is a type of service package consisting of items and services based on patient diagnosis and other characteristics. CMS is proposing this definition of items and services, because it captures the types of items and services, including service packages, that a hospital uses to calculate and report the median payer-specific negotiated charges.

An MA organization is a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements. CMS proposes to use this established definition of an MA organization. CMS proposes to define "third-party payer" as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service.

CMS recognizes that hospitals may negotiate rates with third party payers as a percent discount

off chargemaster rates, on a per diem basis, or by MS-DRG or other similar DRG system. There may be hospitals that do not negotiate charges for service packages by MS-DRG or for service packages that could be crosswalked to an MS-DRG. Given the variety of negotiated payment arrangements, **CMS is seeking comments on whether and how to use data to determine the relative weights where data is not collected by MS-DRGs as well as alternative ways to capture market-based information for the potential use in Medicare FFS payments**.

As an alternative, CMS considered requiring hospitals to submit a median of the actual payments received rather than just the median of the negotiated rates. CMS provides an example where the payer-specific negotiated charge is $30,000 with a 3rd party payer for major joint replacement paid under the All Patient Refined (APR)-DRG system (equivalent to MS-DRG 470). The hospital and payer have agreed to additional payment above a stop loss threshold ($150,000) based on 50 percent of charges as well as 60 percent of the cost of implanted hardware.

In this example, the hospital's payer-specific negotiated charge for a major joint replacement (MS-DRG 470 equivalent) is $30,000. However, the resulting payment per discharge will vary, depending on whether the patient's cost exceeded the stop loss threshold or the patient received implanted hardware. Under CMS' proposal, the hospital would only consider the $30,000 negotiated rate in determining the median. Under the alternative proposal, the hospital would consider the additional payments above the stop-loss threshold and for implantable equipment when considering the median payment to report. CMS requests comment on this alternative approach as well as the potential burden of calculating and submitting a median negotiated reimbursement relative to a median negotiated charge.

CMS proposes that this policy would apply to IPPS hospitals in the 50 states, DC and Puerto Rico. The policy would exclude CAHs that are not paid on the basis of negotiated rates and hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model. Federally owned and operated hospitals as well as hospitals operated under the Indian Health Care Improvement Act that do not receive payment based on negotiated rates would also be excluded.

d. Potential Market Based MS-DRG Relative Weight Methodology Beginning in FY 2024

CMS is requesting comments on whether to use the data it is proposing that hospital report (or any of the alternatives that are being considered or arise as a result of the public comment process) beginning with cost reporting ending in FY 2021 for determining the MS-DRG relative weights, beginning in FY 2024. If CMS adopted this idea, it would propose further details in the FY 2021 IPPS/LTCH PPS final rule. The proposed rule outlines the following steps for incorporating these data into the relative weight calculation:

- Step One: Standardize the Median MA Organizations Payer-Specific Negotiated Charges. Remove the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the current MS-DRG relative weight calculation for those effects.
- Step Two: Create a Single Weighted Average Standardized Median MA Organization Payer-Specific Negotiated Charge by MS-DRG Across Hospitals. For each MS-DRG,

CMS would use each hospital's transfer-adjusted case count to weight the standardized payer-specific negotiated charge as it does under the current MS-DRG relative weight methodology (84 FR 42621). CMS would further consider whether to use unadjusted Medicare case counts, or other alternative approaches based on the review of public comments.

- Step Three: Create a Single National Weighted Average Standardized Payer Specific Negotiated Charge Across all MS-DRGs. CMS would create a single national weighted average across MS-DRGs of the results of Step Two, where the weights are the national Medicare transfer adjusted case counts by MS-DRG (or the unadjusted case counts if that is what is used for Step 2).
- Step Four: Calculate the Market-based Relative Weights. For each MS-DRG, the result from Step 2 for each MS-DRG would be divided by the result from Step 3 across all MS-DRGs to create each MS-DRG's relative weight.
- Step Five: Normalize the Market-based Relative Weights As under the current cost-based MS-DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration such that aggregate payments neither increase or decrease as required by section 1886(d)(4)(C)(iii) of the Act.

CMS is requesting comments on the above methodology including alternatives and suggested refinements as well as:

- Whether CMS should continue to estimate and publicly provide the MS-DRG relative weights using the current cost-based estimation methodology as well as the revised methodology;
- Whether to provide a transition to any new market-based MS-DRG methodology, and, if so, on the appropriate design of any such transition.
- Other ways to further reduce the role of hospital chargemasters in Medicare IPPS payments and further reflect market-based approaches in Medicare FFS payments.

V. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2021. For FY 2020, CMS established a national capital Federal rate of $462.33. CMS is proposing a national capital Federal rate of $468.36 for FY 2021.

Update Factor:

For FY 2021, CMS will increase the national capital Federal rate by 1.5 percent based on the capital input price index (CIPI) of 1.5 percent and other factors shown in Table 1 below. For FY 2021, CMS projects a 0.5 percent total increase in the case-mix index. CMS estimates that real case-mix increase will equal 0.5 percent for FY 2021. The net adjustment for change in case-mix is the difference between the projected total increase in case-mix and real increase in case-mix. Therefore, CMS is applying an adjustment for case-mix change in FY 2021 of 0.0 percentage

points. There is no adjustment for FY 2019 reclassification and recalibration or forecast error correction.

Table 1

CMS FY 2020 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE	
FY 2014-based CIPI	1.5
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	1.5
Effect of FY 2018 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.5

Other Adjustments:

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS is reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes below the 25th percentile and capping reductions in wage indexes at 5 percent) in the budget neutrality adjustment. CMS determines a net GAF budget neutrality adjustment of -0.13 percent (0.9987) in two steps as follows:

- Isolate the impact of just the change to the wage data (e.g. without the increase to the lowest quartile wage indexes and 5 percent cap on wage index decreases) on FY 2021 payments. Adjustment = 1.0025.
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases on the FY 2021 payments. Adjustment = 0.9963.

The budget neutrality adjustment for changes in the GAFs will be 0.9987 (1.0025 x 0.9963). CMS incorporates an adjustment for MS-DRG changes and recalibration of the relative weights of 0.9995. This combined adjustment for GAFs and MS-DRG changes and recalibration is 0.9983 (0.9987 x 0.9995 or -0.17 percent).

For FY 2021, CMS is taking outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.40 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.01 percentage points for amounts refunded to hospitals. This makes capital outlier payments 5.39 percent of total capital payments. Therefore, the FY 2021 outlier adjustment factor is 0.9461 (-5.39 percent), compared to 0.9463 in FY 2019. The net change is -0.02 percent (0.9461/0.9463). Thus, the outlier adjustment decreases the FY 2021 capital federal rate by 0.02 percent.

Proposed Rule Calculation:

The final rule includes the following chart to show how each of the factors and adjustments affect the computation of the FY 2021 national capital Federal rate compared to the FY 2020 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2020 and FY 2021 Capital Federal Rate

	FY 2020	FY 2021	Change	Percentage Change
Update Factor*	N/A	1.015	1.015	1.50
GAF/DRG Adjustment Factor*	N/A	0.9983	0.9983	-0.17
Outlier Adjustment Factor**	0.9463	0.9461	0.9998	-0.02
Capital Federal Rate	$462.33	$468.36	1.0130	1.30

* The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2020 to FY 2021 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2021 is a net change of 0.9983 (or -0.17 percent).
** The outlier adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2021 outlier adjustment factor is 0.9461/0.9463, or 0.9998 (or -0.02 percent).

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2021 of $468.36, a 1.3 percent increase over the FY 2020 rate of $462.33

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.

VI. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals

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

The annual update to the TEFRA limit is based on IGI's 2019 4th quarter forecast of the hospital market basket for FY 2021 and is estimated at 3.0 percent.

B. Critical Access Hospitals

The Frontier Community Health Integration Project (FCHIP) Demonstration[49] is designed to develop and test new models of care by permitting enhanced reimbursement for telemedicine, nursing facility, ambulance, and home health services. Ten CAHs in Montana, Nevada, and North Dakota participated in the 3-year demonstration beginning August 1, 2016.

The demonstration was intended to be budget neutral through reduced transfers and admissions to other health care providers that offset any increase in payments under the waivers. However, if that is not the case, CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to all CAHs nationwide beginning with FY 2020. The final budget neutrality estimates for the FCHIP demonstration will be based on costs incurred during the entire demonstration period, which is August 1, 2016 through July 31, 2019.

Based on the currently available data, the estimate of costs under the demonstration remain uncertain. CMS proposes to delay the implementation of any budget neutrality adjustment and will revisit this policy in rulemaking for FY 2022.

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

A. Background

Since FY 2016, LTCHs have been paid under a dual-rate payment structure. An LTCH case is either paid at the "LTCH PPS standard federal payment" when the criteria for site neutral payment rate exclusion are met or a "site neutral payment rate" when the criteria are not met. Site neutral cases will be paid an IPPS comparable amount. The criteria for exclusion from the site neutral payment remain the same for FY 2021:

- Case cannot have a principal diagnosis relating to a psychiatric diagnosis or rehabilitation (the DRG criterion).
- Case must be immediately preceded by discharge from an acute care hospital that included at least 3 days in an intensive care unit (the ICU criterion).
- Case must be immediately preceded by discharge from an acute care hospital and the LTCH discharge must be assigned to an MS-LTC-DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH (the ventilator criterion).

To be paid the LTCH PPS standard federal payment, the case must meet the DRG criterion and either the ICU or ventilator criterion.

CMS 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

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

standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS final rule made conforming changes to the regulations to implement the extended transitional blended payment.

Summary of Proposed Changes to LTCH PPS Rates for FY 2021*	
Standard Federal Rate, FY 2020	$42,677.64
Proposed Rule Update factors	
Update as required by Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.5%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.5% (1.025)
Net update LTCHs not reporting quality data	0.5% (1.005)
Proposed Rule Adjustments	
Proposed average wage index budget neutrality adjustment	1.0018755
Proposed permanent budget neutrality adjustment factor of 0.991249 for the cost of the elimination of the 25-percent threshold policy for FY 2021 (and subsequent years); removal of FY 2020 adjustment factor of 0.990737	1.000517
Proposed Standard Federal Rate, FY 2021	
LTCHs reporting quality data ($42,677.64*1.025*1.0018755*1.000517)	$43,849.28
LTCHs not reporting quality data ($42,677.64*1.005*1.0018755*1.000517)	$42,993.68
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$30,515
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$30,006
Impact of Proposed Policy Changes on LTCH Payments in 2021	
Total estimated impact	-0.9% (-$36 million)
LTCH standard federal payment rate cases (75% of LTCH cases)	+2.1% (+$69 million)
Site neutral payment rate cases (25% of LTCH cases)**	-21% (-$105 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 2021". 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.	

B. LTCH PPS MS-DRGs and Relative Weights

1. Background

Similar to FY 2020, the annual recalibration of the MS-LTC-DRG relative weights for FY 2021 is determined using data only from claims qualifying for LTCH PPS standard federal rate payment and claims that would have qualified if that rate had been in effect. Thereby, 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 2021 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.

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

In developing the FY 2021 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 2021 proposed relative weights are derived from the December 2019 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 December 2019 update.) The applicable LTCH data are used with Version 38 of the GROUPER to calculate the FY 2021 MS-LTC-DRG proposed relative weights.

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

CMS proposes to continue to use its HSRV methodology in FY 2021, unchanged from FY 2020, to mitigate relative weight distortions due to nonrandom case distribution across MS-LTC-DRGs and charge variation across providers. The HSRV methodology scales each LTCH's average relative charge value by its case mix.

6. Volume-related adjustments

CMS 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 252 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 2021 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 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 2021 MS-LTC-DRG and relative weights update (Step 7). First, a normalization adjustment is applied to the recalculated relative weights to ensure that the recalibration does not change the average case mix index (1.25878 proposed for FY 2021). Second, a budget neutrality factor is applied to each normalized relative weight (0.9993445 proposed for FY 2021).

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 1,017 to 1,034 of the display copy).

C. LTCH PPS Payment Rates and Other Changes

1. Overview LTCH PPS Payment Rate Adjustments

Only LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. The LTCH PPS uses a single payment rate to cover both operating and capital-related costs, so that the LTCH market basket includes both operating and capital cost categories.

2. Proposed Annual Update for LTCHs

The proposed annual update to the LTCH PPS standard federal payment rate is equal to 2.9 percent. As discussed in section VII.D of the proposed rule (summarized below), CMS proposes to rebase and revise 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 2.9 percent less 0.4 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 2021. The proposed LTCH update for FY 2021 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	2.9%	2.9%
Multifactor Productivity	-0.4 PP	-0.4 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.5%	0.5%

3. Area Wage Levels and Wage-Index

CMS proposes to adopt the revised labor market area delineations announced in OMB Bulletin No. 18-04 effective for FY 2021 under the LTCH PPS. This proposal is consistent with the changes proposed under the IPPS for FY 2021 as described in section III.A. of this summary. Under the proposal:

- 34 counties (and county equivalents) currently considered part of an urban CBSA would be considered to be located in a rural area;
- 47 counties (and county equivalents) located in rural areas would be considered to be located in urban areas; and
- Some urban counties would shift from one urban CBSA to another urban CBSA or would shift between existing and new CBSAs.

Because some LTCHs would experience decreases in their wage index values under the proposal, CMS proposes to implement a budget neutral transition policy to help mitigate significant negative impacts that LTCHs may experience due to its proposal to adopt the revised OMB delineations. It proposes 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; thus, an LTCH's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. However, CMS does not propose a cap on the overall increase in an LTCH's wage index.

As noted above, CMS proposes to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year. CMS proposes an FY 2021 labor-related share of 68.0 percent based on IGI's fourth quarter 2019 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (63.6%) and capital costs (4.4%). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related; administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services. CMS notes that the difference from the FY 2020 labor-related share is attributable to the revision to the base year cost weights, the revision to the starting point of the

calculation of base year from 2013 to 2017, and the use of an updated IHS Global Inc. forecast and reflecting an additional year of inflation.

CMS 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. 18-04. It proposes an area wage level budget neutrality adjustment of 1.0018755.

4. Elimination of the 25 percent Rule

In the FY 2019 IPPS rule, CMS adopted a policy to eliminate the 25 percent rule. This rule would have paid LTCHs at an IPPS comparable amount for all discharges not meeting the criteria to be paid the LTCH standard rate above 25 percent of the LTCH's total discharges. CMS adopted a policy to make elimination of this policy budget neutral through two temporary one-time adjustments to the LTCH standardized amount (0.990878 for FY 2019 and 0.990737 for FY 2020) and one permanent one-time adjustment to the LTCH standardized amount of 0.991249 for FY 2021 and subsequent years. A one-time temporary adjustment means the adjustment is removed for the following year while a one-time permanent adjustment stays on the rate and is not removed.

For FY 2021, CMS removes the 0.990737 adjustment (calculated by applying a factor of 1/0.990737) and applies the permanent one-time adjustment of 0.991249. The language in the preamble on this issue appears to be incomplete. In section V.A.2. of the Addendum to the proposed rule, CMS calculates an adjustment factor of 1.000517 for FY 2021.

5. Proposed LTCH Standard Federal Payment Rate Calculation

CMS proposes the following LTCH PPS standard federal payment rates for FY 2021:

- $43,849.28 for LTCHs reporting quality data, calculated as follows: $42,677.64 (FY 2020 payment rate) * 1.025 (statutory update factor) * 1.0018755 (area wage budget neutrality factor) * 1.000517 (25% threshold budget neutrality factor) = $43,849.28

- $42,993.68 for LTCHs not reporting data to the LTCH QRP, calculated as follows: $42,677.64 (FY 2020 payment rate) * 1.005 (statutory update factor less quality adjustment) * 1.0018755 (area wage budget neutrality factor) * 1.000517 (25% threshold budget neutrality factor) = $42,993.68

6. 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. The COLA is determined by comparing Consumer Price Index growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city. The COLA is capped at 25 percent and updated every 4 years. Shown below are the FY 2021 COLAs.

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2021	
Alaska	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
All other areas of Alaska	1.25
Hawaii	
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

7. High-Cost Outlier (HCO) Case Payments

Section 1886(m)(7)(A) of the Act requires CMS to reduce the LTCH standard federal payment rate by 8 percent for HCOs. Section 1886(m)(7)(B) requires CMS to set the outlier threshold such that estimated outlier payments equal 99.6875 percent of the 8 percent estimated aggregate payments for standard federal payment rate cases (that is, 7.975 percent). Consistent with the statute, CMS proposes an HCO threshold of $30,515 for FY 2021 which CMS estimates will result in 7.975 of LTCH standard federal payment rate cases being paid as HCOs. The HCO payment continues to equal 80 percent of the estimated care cost and the outlier threshold (adjusted standard rate payment plus fixed-loss amount). If an HCO case is also an SSO case, the HCO payment will equal 80 percent of the estimated case cost and the outlier threshold (SSO payment plus fixed-loss amount). Consistent with historical practice, CMS will use the most recent available LTCH claims data and CCR data for the final rule.

CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2021, CMS proposes a fixed-loss amount for site neutral payment rate cases of $30,006. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2021. Consistent with the policy adopted in FY 2019, CMS 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.

8. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS proposes to continue its policy that the calculations of the "IPPS comparable amount" (42 CFR §412.529) and the "IPPS equivalent amount" (§412.534 and §412.536) include an applicable operating Medicare DSH and uncompensated care payment amount. For FY 2021, the DSH/uncompensated care amount equals 75.90 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

D. Rebasing the LTCH Market Basket

1. Background

CMS is proposing to rebase and revise the LTCH market basket. The current LTCH market basket is from a 2013 base year. CMS proposes to base the LTCH market basket on data from cost reports beginning in FY 2017. Rebasing and revising the market basket may result in changes in the cost weights and price proxies used to develop the price index value that is used to update the rates for LTCH services.

2. Proposed 2017-Based LTCH Market Basket Cost Categories and Weights

To determine the index, CMS proposes to use only those LTCHs that have a Medicare average length of stay that is within 25 percent of the LTCH's average length of stay for all patients. CMS believes this selection criterion will result in a more accurate reflection of the structure of costs for Medicare covered days. This selection criterion is the same as was used for the FY 2013-based LTCH market basket.

The proposed selection criterion results in exclusion of 9 percent of LTCH providers. Included LTCH providers had an average Medicare length of stay of 25 days; an all patient average length of stay of 27 days, and aggregate Medicare utilization (based on days) of 58 percent. Excluded LTCH providers had an average Medicare length of stay of 27 days, average facility length of stay of 70 days, and aggregate Medicare utilization of 15 percent.

The LTCH market basket includes seven categories of costs plus a residual "all other" category. CMS proposes to derive the cost weights the same way for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket with the exception of home office/related organization contract labor:

(1) Wages and Salaries. Costs reported on Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91, and 93 and the proportion of overhead salaries that are attributed to Medicare allowable costs centers.

(2) Employee Benefits. Costs reported on Worksheet S-3, part II, column 4, lines 17, 18, 20, and 22. Worksheet S-3 is voluntary for LTCHs. Only 20 percent of LTCHs reported these data. However, CMS believes it has a large enough sample to produce a reasonable employee benefits cost weight because it did not change materially after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region).

(3) Contract Labor. Costs reported on Worksheet S–3, part II. Only 44 percent of LTCHs voluntarily reported costs on Worksheet S-3 part II. CMS's analysis indicates there is a large enough sample to produce a reasonable contract labor cost weight.

(4) Pharmaceuticals. Costs reported on Worksheet B, part I, column 0, lines 15 and 73 and then removing a portion of these costs attributable to salaries (adjusted by the ratio of Worksheet A,

column 1, lines 15 and 73 divided by the sum of Worksheet A, columns 1 and 2, lines 15 and 73).

(5) Professional Liability Insurance. Premiums, paid losses and self-insurance costs reported on Worksheet S-2, part I, columns 1 through 3, line 118.

(6) Home Office/Related Organization Contract Labor. Costs reported on Worksheet S–3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551 for those LTCH providers reporting total salaries on Worksheet S-3, part II, line 1. For the 2013-based LTCH market basket, CMS used the 2007 Benchmark Input-Output expense data published by the Bureau of Economic Analysis. CMS believes the proposed methodology for the 2017-based LTCH market basket is a technical improvement over the prior methodology because it represents more recent data that is representative compositionally and geographically of LTCHs.

(7) Capital. Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93.

(8) All Other. Reflects all remaining costs that are not captured in the seven cost categories listed.

CMS proposes to exclude those LTCHs with cost weights that are less than or equal to zero for a category as well as those cost weights that are in the top and bottom 5 percent for all cost categories except home office/related organization contract labor. For this cost category, CMS proposes to remove the top 1 percent only as not all LTCHs have a home office and the cost weight for this category may appropriately be zero.

Major Cost Categories	2013 Weight	Proposed 2017 Weight
Wages and Salaries	46.6	46.4
Employee Benefits	7.3	6.8
Professional Liability	0.9	0.5
Pharmaceuticals	7.6	6.2
Home Office/Related Organization Contract Labor	N/A	1.9
Capital	9.7	9.9
All Other	27.8	28.3

The above table does not separately show contract labor. As it did for the 2013-based LTCH market basket, CMS is allocating contract labor to wages and salaries and employee benefits based on its share of costs attributable to each of these categories (87 percent wages and salaries and 13 percent to employee benefits).

CMS provides further detail on the data sources used to derive weights within the capital and all other category. The final detailed cost weights including the subcomponents of capital and all other are found in table E4 (beginning on page 1,062 of the display copy).

3. Selection of Proposed Price Proxies

CMS is proposing to use the same price proxies for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket with one highly technical change to how CMS proposes to determine the weight for chemicals—a subcomponent of the all other category.

4. Proposed FY 2021 Market Basket Update for LTCHs

CMS is proposing an FY 2017-based LTCH market basket update of 2.9 percent for FY 2021. This figure will be revised in the final rule based on more recent data. If continued, the FY 2013-based LTCH market basket update would have been 3.0 percent. The FY 2013-based LTCH market basket and the FY 2017-based LTCH market basket differed by 0.2 percentage points or less for each year between FYs 2016-2019 and forecast for FY 2020 through FY 2023. The FY 2017-based LTCH market basket averaged 0.1 percentage point lower in this time period than the FY 2013 LTCH market basket.

5. Proposed FY 2021 Labor-Related Share

The labor-related share of the LTCH standard federal rate is adjusted for area differences in costs. The remaining portion of the LTCH standard federal rate is a uniform national amount. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market.

CMS proposes to use the same labor-related categories of costs for the FY 2017-based LTCH market basket as it did for the FY 2013-based LTCH market basket: wages and salaries; employee benefits; professional fees: labor-related services; administrative and facilities support services; installation, maintenance, and repair services; all other: labor-related services; and a portion of the capital-related costs from the 2017-based LTCH market basket. Professional fees: labor-related services include a proportion of the home office/related organization contract labor costs.

The proposed labor-related share is 68.0 percent compared to 66.3 percent based on the 2013-based LTCH market basket. The different contribution of each cost weight category to the overall difference is shown in the table below:

Major Cost Categories	2013-Based LTCH MB	2017-Based LTCH MB
Wages and Salaries	46.6	46.9
Employee Benefits	7.2	6.8
Professional Fee: Labor-Related	3.4	4.5
Administrative and Facilities Support Services	0.9	1.0
Installation, Maintenance, and Repair Services	2.1	2.1
All Other: Labor-Related Services	2.0	2.3
Subtotal	62.2	63.6
Labor-Related Portion of Capital (46%)	4.1	4.4
Total Labor-Related Share	66.3	68.0

E. Impact of Payment Rate and Policy Changes to LTCH PPS Payments

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2020 to FY 2021, will result in a decrease of 0.9 percent or $36 million in aggregate payments from $3.797 billion to $3.761 billion for the 360 LTCHs included in this impact analysis. This impact results from a decrease in payment to site neutral cases of $105 million and an increase in payment to LTCH standard federal payment rate cases of $69 million.

CMS indicates that there will no longer be any transitional payment for site-neutral cases in FY 2021 like there was in FY 2020 based on the start date of the LTCH's cost reporting period. The lack of a transitional payment will result in a reduction in payment estimated at 21 percent or approximately $105 million for the 25 percent of cases that are estimated to be paid at a site neutral rate.

For the approximately 75 percent of cases estimated to be paid at the standard federal rate, payment is estimated to increase 2.1 percent or approximately $69 million. This increase is primarily due to the proposed 2.5 percent annual update to LTCH standard federal rate for FY 2021 and a 0.5 percent decrease in the proportion of FY 2021 LTCH payments attributed to high cost outliers.

CMS estimates that high cost outliers in FY 2020 will be about 8.5 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 payment are made as high cost outliers. The difference between the 8.5 percent figure for FY 2020 and the estimate of 8.0 percent for FY 2021 accounts for the 0.5 percent reduction in payment for high cost outliers.

CMS was unable to model the impact of LTCH PPS payment changes for site neutral payment rate cases as it did for standard federal payment rate cases. Thus, Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2021" in the 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.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2021		
	Number of LTCHs	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	360	2.1%
By Location:		
Rural	17	1.8%
Urban	343	2.1%
By Ownership Type:		
Voluntary	60	2.1%
Proprietary	290	2.1%
Government	10	2.9%

By Region		
New England	10	1.8%
Middle Atlantic	23	1.9%
South Atlantic	62	2.0%
East North Central	55	2.0%
East South Central	31	1.8%
West North Central	22	1.7%
West South Central	105	2.2%
Mountain	29	2.0%
Pacific	23	2.7%
*More detail is available in Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2021" on pages 1568-1569 of the display copy.		

Tables. The complete set of tables providing detail on the LTCH PPS for FY 2021 is accessible at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Regulations-and-Notices-Items/LTCH-PPS-CMS-1716-F.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, changes are proposed for the quality reporting programs that apply to acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. In addition, changes to the Medicare and Medicaid Promoting Interoperability Programs are proposed.

A. Hospital Inpatient Quality Reporting (IQR) Program

As further described below, CMS proposes changes to the IQR Program that would (1) modify the data validation program (2) gradually increase the number of cases for which electronic clinical quality measure (eCQMs) must be submitted, and (3) begin public reporting of hospital performance on eCQMs on *Hospital Compare*. No changes are proposed to IQR Program measures or policies regarding the retention, removal, addition, or updating of measures or other program policies. The data submission requirements for chart-abstracted measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, and the CDC NHSN measure remaining in the IQR Program would be maintained without change. These include procedural requirements and deadlines, sampling and case thresholds, data accuracy and completeness acknowledgement, reconsideration and appeals, and the Extraordinary Circumstances Exception policy.

More information on the IQR Program is available at https://www.qualitynet.org/inpatient/iqr. A summary table at the end of this section shows previously adopted IQR Program measures for FYs 2020 through 2024.

1. Reporting and Submission Requirements for eCQMs

Under the IQR Program for FY 2023 (reporting period of CY 2021) hospitals must submit data for four self-selected electronic clinical quality measures (eCQMs) chosen from a list of nine possible eCQMs. Beginning with FY 2024 payment (CY 2022 reporting) hospitals are to report

four measures: three are to be chosen by the hospital from among a list of eight possible eCQMs and the fourth must be reported by all hospitals: the Safe Use of Opioids – Concurrent Prescribing eCQM. (The summary table at the end of this section lists the eCQMs available for reporting.)

In this rule, CMS proposes to increase the number of quarters for which hospitals must report eCQMs and to modify the file identification elements for eCQM reporting. No changes are proposed to the measures that must be reported or the data submission deadlines. The requirements that hospitals must use EHR technology certified to the 2015 Edition and that EHRs be certified to all available eCQMs would continue.

Under the proposal the number of quarters for which a hospital must report eCQM data under the IQR Program would be increased over 3 years. Currently, for the four eCQMs that it reports, a hospital must submit one self-selected quarter of data. Under the proposal, this requirement would be increased to four quarters of data as follows:

- For FY 2023 payment (CY 2021 reporting) hospitals would report data for 2 self-selected calendar quarters
- For FY 2024 payment (CY 2022 reporting) hospitals would report data for 3 self-selected calendar quarters
- For FY 2025 payment (CY 2023 reporting) and subsequent years, hospitals would report data for all 4 calendar quarters.

CMS believes that this proposal would produce more comprehensive and reliable quality measure data for patients and providers because a single quarter of data is not enough to capture trends in performance over time. In addition, hospitals would have a more continuous information stream to monitor their performance. CMS reminds readers that the current policy of reporting data for only one calendar quarter was established in response to stakeholder feedback about challenges in reporting eCQM data and was intended to provide hospitals with time to upgrade systems and undergo training to support eCQM reporting. CCMS believes the proposal to gradually increase the amount of data to be reported for eCQMs would provide hospitals and vendors time to plan and build on investments already made in EHR infrastructure.

No changes are proposed to the eCQM submission deadlines. CMS notes that In the FY 2017 IPPS/LTCH PPS final rule the Hospital IQR Program eCQM submission deadline was aligned with that of the Medicare Promoting Interoperability Program to be the end of 2 months following the close of the calendar year. The submission deadline may be moved to the next business day if it falls on a weekend or federal holiday.

With respect to file identification, CMS proposes to add EHR Submitter ID as a fifth key element for file identification beginning with reporting for FY 2023 payment. Hospitals are currently required to submit eCQM data using the Quality Reporting Document Architecture (QRDA) I file format, which CMS expects to contain four elements for file identification: (1) CMS Certification Number (CCN); (2) CMS Program Name; (3) EHR Patient ID; and (4)

Reporting period specified in the Reporting Parameters Section of the CMS Implementation Guide for the applicable reporting year. (See https://ecqi.healthit.gov/qrda)

The rationale for this proposal is that in situations where a hospital uses multiple vendors to submit QRDA I files, the EHR Submitter ID would prevent a file previously submitted by another vendor from being overwritten. The EHR Submitter ID for hospitals is the CCN, and for vendors is the Vendor ID assigned by QualityNet another vendor from being overwritten.

2. Data Submission and Reporting of Hybrid Measures

Currently, the IQR Program includes one measure that is calculated using a hybrid of claims data and data reported by the hospital through EHR Technology. The Hybrid Hospital-Wide Readmission (HWR) measure is open for reporting in two voluntary reporting periods (dates) and will be a mandatory measure beginning with the FY 2025 payment determination. For purposes of reporting this measure, hospitals are required to use EHR technology certified to the 2015 Edition, and to submit the required data elements using the QRDA I file format.

In this rule, CMS proposes that the requirements for using the 2015 Edition and QRDA I file format would also apply to any future hybrid measure adopted for the IQR Program. **CMS invites comments on these proposals.**

3. Validation of IQR Program Data

CMS proposes to combine the validation processes for chart-abstracted data and eCQM data over time. It notes that only one clinical process of care measure subject to chart abstracted data validation (the sepsis measure) remains in the IQR Program for the 2021 reporting period (FY 2023 payment). The proposal includes the seven elements, listed as follows. **Comments are invited on all the proposed changes to data validation procedures.**

(1) Modify data submission quarters. The quarters of data used for both chart-abstracted and eCQM data validation would be aligned over time. For the FY 2023 payment determination, instead of requiring that hospitals selected for data validation provide samples for four quarters (Q3 2020 – Q2 2021), the proposal would require data for chart abstracted measure be provided only for Q3 and Q4 of 2020. No change would be made to the quarters for data validation of the eCQMs; for these measures, hospitals provide data for a sample of charts for the self-selected calendar quarter of 2020 for which the hospital has elected to report the eCQMs. For the FY 2024 payment determination, the proposal would require that the quarters of data validation for chart-abstracted measures be Q1-Q4 of 2021.

(2) Expand targeting criteria to include hospital selection for eCQMs. The previously adopted separate data validation process for eCQMs would be eliminated beginning with the FY 2024 payment determination, and eCQMs would be incorporated into the data validation process established for chart-abstracted measures. A single pool of hospitals would be selected for validation, and a selected hospital would submit data for both

chart-abstracted measures and eCQMs. The current criteria for targeted validation[50] would continue to apply. CMS clarifies that a hospital that has been granted an Extraordinary Circumstances Exception under the IQR Program could still be selected for validation under the targeting criteria.

(3) *Reduce validation pool from 800 to 400 hospitals.* Beginning with data validation for FY 2024 payment, the number of hospitals randomly selected for validation would be reduced from the current 400 hospitals to up to 200 hospitals, and the number of hospitals selected for targeted validation would remain at 200, for a total of up to 400 hospitals. Currently because the eCQM validation program is separate, CMS may validate data from as many as 800 hospitals each year for chart-abstracted and eCQMs combined. CMS notes that a very high percentage of hospitals pass validation, about 96 percent for both the FY 2018 and 2019 payment determinations. Because of this, it believes that with a random sample of up to 200 hospitals it could be highly confident that at least 95 percent of all hospitals it he IQR Program are achieving the required validity score. The 200-hospital random sample would also be used for validation of the NHSN HAI measures used for the HAC Reduction Program. (See section IV.M of this summary above.) The change from a fixed 400 hospital random sample to "up to 200" hospitals for IQR Program validation is made in recognition that although all hospitals are subject to the HAC Reduction Program, a small percentage do not participate in the IQR Program.

(4) *Remove exclusions for eCQM validation selection.* Current exclusion criteria that apply before random selection of up to 200 hospitals for eCQM validation[51] would be removed beginning with validation affecting the FY 2024 payment determination. The combined validation pool of up to 200 hospitals for validation of chart-abstracted measures and eCQMs would be chosen without regard to these exclusion criteria. Final adoption of this proposal is contingent on CMS finalizing the combination of the two validation pools.

(5) *Require electronic file submissions for chart-abstracted measure validation data.* CMS proposes that beginning with data validation for the FY 2024 payment determination (Q1 2021 data submissions), hospitals submitting medical records for validation of IQR Program measures would be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. Hospitals could no longer submit the required records via paper copies, DVDs, CDs, or flash drives. CMS would reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts. In discussing this proposal, CMS notes that almost two-thirds of medical records submission to the CDAC contractor use the option to submit PDF copies of medical records as electronic files. It believes that

[50] The criteria target any hospital (1) with abnormal or conflicting data patterns (examples are offered in the proposed rule); (2) with rapidly changing data patterns defined as a hospital that improves its quality for one or more measure sets by more than 2 standard deviations from 1 year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$); (3) that submits data to NHSN after the Hospital IQR Program data submission deadline has passed; (4) that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated; (5) that has not been randomly selected for validation in any of the previous 3 years; (6) that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; (7) that failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

[51] For eCQM data validation, CMS currently excludes any hospital that (1) has been selected for chart-abstracted measure validation; (2) has been granted an Extraordinary Circumstances Exception; or does not have at least 5 discharges for at least one eCQM included in its QDRA I submissions.

electronic submission can be a more effective and efficient process for the hospitals selected for validation and requiring electronic file submissions reduces the burden of coordinating, copying, and shipping to the CDAC numerous paper-based pages of medical records.

(6) *Align the eCQM and chart-abstracted data validation scoring processes.* The separate validation scoring for chart-abstracted measures and eCQMs would be combined into a single score. However, because eCQM validation does not currently assess the accuracy of the eCQMs reported by the hospital, the combined score would weight the chart abstracted measure agreement rate at 100 percent. Hospitals would still be required provide at least 75 percent of the requested medical records for eCQM validation. Because under the proposed rule the number of eCQM validation cases will increase over time as more quarters of eCQM reporting are required, CMS anticipates that in the future it will propose increasing the weight of the eCQM validation score as more data permit calculation of a statistically robust validation score for eCQMs.

(7) *Update the educational review process to address eCQM validation results.* The process established for chart-abstracted data validation under which a hospital may request an educational review if they believe they have been scored incorrectly or have questions about the validation results would be adapted to include eCQM validation. A hospital would have 30 days after receiving eCQM validation results, which occurs annually, to contact the Validation Support Contractor and request a written review. CMS proposes that this would be provided to the requesting hospital through a CMS-approved secure file transmission process.

No changes are proposed to the number of cases that hospitals selected for data validation are required to submit. However, CMS notes that elsewhere in this proposed rule it would expand the number of quarters for which hospitals must report eCQMs under the IQR Program. As a result, hospitals selected for data validation would have to submit validation data for each quarter for which eCQM data were submitted. For example, for validation affecting the FY 2024 payment determination, hospitals would report a total of 16 requested cases from 2 calendar quarters of data (8 cases x 2 quarters). This would increase to 32 requested cases (8 cases x 4 quarters) for validation affecting the FY 2026 payment determination and for subsequent years.

4 Public Display of eCQM Data

Hospital performance on eCQMs is not publicly reported on *Hospital Compare.* Initially the measures were voluntary, and CMS stated that it needed time to assess the data and develop a strategy for public reporting. This has included development of the data validation process for eCQMs. Analysis of data validation for the 2017 and 2018 reporting periods included more than 1,200 patient records across 190 hospitals per reporting period. CMS found that hospitals successfully submitted the requested medical records within the required time period, and that agreement rates between the eCQM submissions and the CDAC review of medical records exceeded 80 percent. CMS now concludes that eCQM data are accurate enough to be publicly reported in the aggregate.

CMS proposes that public reporting of eCQM data begin with data reported in 2021 for the FY 2023 payment determination. These data would be publicly posted as early as the fall of 2022.

Along with other IQR Program measures, eCQM data would be available for hospitals to review during the 30-day preview period. Any updates to posting locations would be conveyed through routine communication channels to hospitals, vendors, and Quality Improvement Organizations. These include memos, emails, and notices on the QualityNet and eCQI Resource Center websites.

5 Impact Analysis

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the additional burden on hospitals resulting from the proposal to expand reporting quarters for eCQMs and the associated increase in quarters of eCQM validation would total $253,480 across hospitals for the four-year period beginning with the FY 2023 payment determination.

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that for FY 2021, 54 hospitals will not receive the full market basket rate of increase for failure to meet the IQR Program requirements or choosing not to participate in the program, but are meaningful users under the Medicare Promoting Interoperability Program. Under the proposed rule, these hospitals would receive an update factor of 1.85 percent. Another 14 hospitals are estimated to receive a combined payment reduction of 3.0 percentage points, for an update of -0.4 percent, because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2020	**2021**	**2022**	**2023**	**2024**
Chart-Abstracted Process of Care Measures					
Severe sepsis and septic shock: management bundle (NQF #500)	X	X	X	X	X
PC-01 Elective delivery < 39 weeks gestation (NQF#0469)	X	X	X	X	X
ED-1 Time from ED arrival to departure for admitted patients (NQF#0495)	X	Removed			
ED-2 Time from admit decision to ED departure for admitted patients (NQF #0497)	X	X	Removed		
IMM-2 Immunization for influenza (NQF #1659)	X	Removed			
VTE-6 Incidence of potentially preventable VTE	X	Removed			
Electronic Clinical Quality Measures					
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) (NQF #0163) 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)	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		Report 4 of the following 8 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05	Report 4 of the following 9 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05	Report Safe use of Opioids and 3 of the following 8 eCQMs: ED-2 PC-05

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2020	**2021**	**2022**	**2023**	**2024**
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) PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469) PC-05 Exclusive breast milk feeding (NQF #0480) EDHI-1a Hearing screening prior to discharge (NQF 1354) CAC- 3 Children's asthma care – 3 Safe Use of Opioids – Concurrent Prescribing	STK-08 STK-10 VTE-1 VTE-2		STK-06 VTE-1 VTE-2	STK-06 VTE-1 VTE-2 Safe use of Opioids	STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2
Healthcare-Associated Infection Measures					
Central Line Associated Bloodstream Infection (CLABSI)	X	X	Removed		
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	X	Removed		
Catheter-Associated Urinary Tract Infection (CAUTI)	X	X	Removed		
MRSA Bacteremia	X	X	Removed		
Clostridium Difficile Infection (CDI)	X	X	Removed		
Healthcare Personnel Influenza Vaccination (NQF #0431)	X	X	X	X	X
Claims-Based Measures					
Mortality					
Pneumonia 30-day mortality rate	X	Removed			
Stroke 30-day mortality rate	X	X	X	X	X
COPD 30-day mortality rate	X	Removed		***O***	
CABG 30-day mortality rate	X	X	Removed		
Readmission/Coordination of Care					
Hospital-wide all-cause unplanned readmission (NQF #1789)	X	X	X	X	X*
Hybrid (claims+EHR) hospital-wide readmission**	Voluntary				
Excess days in acute care after hospitalization for AMI (NQF #2881)	X	X	X	X	X
Excess days in acute care after hospitalization for HF (NQF #2880)	X	X	X	X	X
Excess days in acute care after hospitalization for PN (NQF #2882)	X	X	X	X	X
Patient Safety					
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)	X	X	X	X	X
THA/TKA complications	X	X	X	Removed	
Efficiency/Payment					
AMI payment per 30-day episode of care (NQF #2431)	X	X	X	X	X
Heart Failure payment per 30-day episode of care (NQF # 2436)	X	X	X	X	X
Pneumonia payment per 30-day episode of care (NQF #2579)	X	X	X	X	X
THA/TKA payment per 30-day episode of care	X	X	X	X	X
Patient Experience of Care					

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2020	**2021**	**2022**	**2023**	**2024**
HCAHPS survey + 3-item Care Transition Measure (NQF #0166 and #0228)	X	X	X	X	X
*Beginning with the FY 2026 payment determination, this measure will be replaced by the Hybrid HWR measure. **This measure will be mandatory beginning in FY 2026. Two more voluntary reporting periods will be held before that (July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023).					

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

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in FY 2014 and follows many of the policies established for the Hospital IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program. Currently, there are 11 PPS-exempt cancer hospitals.[52] No policy has been adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS has previously indicated its intention to address the issue in future rulemaking. Five initial measures were previously adopted for FY 2022, as shown in a table below. Technical specifications for measures and other program information are available on the QualityNet.org website at https://qualitynet.org/pch/pchqr.

In this rule, CMS proposes to modify the CLABSI and CAUTI measures to adopt updated measure specifications from the CDC. The revised measures were endorsed by the NQF in October 2019. The revisions employ a new risk adjustment methodology that calculates measure rates that are stratified by patient locations within hospitals, including oncology units. CMS believes that the stratified measures make them more representative of the quality of care within PCHs, and improve comparisons of performance, especially when PCHs compared with other acute care hospitals which already use the updated methodology. **Public comments are invited on this proposal.**

If the proposal to adopt the revised CLABSI and CAUTI measures is finalized, public display of these measures would begin in the fall of 2022 using data from 2021. Current versions of the measures would not be displayed. **Comments are welcome on the proposed addition of these measures for public display**. Measures previously finalized for public display are shown in the table below.

Other PCHQR Program measures and policies would continue unchanged.

PCHQR Program Measures for 2022 and 2023	
Measure	**Public Display Began**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	2019
NHSN CDI (NQF #1717)	2019
NHSN MRSA bacteremia (NQF #1716)	2019

[52] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html.

PCHQR Program Measures for 2022 and 2023	
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	2019
NHSN CLABSI (NQF #0139)**	Deferred until 2022
NHSN CAUTI (NQF #0138)**	Deferred until 2022
Clinical Process/Oncology Care	
Oncology: Plan of Care for Pain (NQF #0383)	2016
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOLChemo) (NQF #0210)	
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	
Patient Experience of Care	
HCAHPS (NQF #0166)**	2016
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	As soon as feasible
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	
Surgical Treatment Complications for Localized Prostate Cancer	

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

The LTCH QRP was first implemented in FY 2014, as required under section 1886(m) of the Act. Further developed in subsequent rulemaking, the LTCH QRP follows many of the policies established for the IQR Program, including the principles for selecting measures and the procedures for hospital participation in the program. An LTCH must meet LTCH QRP patient assessment and quality data reporting requirements or be subject to a 2.0 percentage point update factor reduction. LTCHs submit data on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument to CMS using the Quality Improvement Evaluation System Assessment Submission and Processing (QIES ASAP) system.

No changes are proposed to the LTCH QRP in this rule. The table below displays the measures previously adopted for the LTCH QRP for FYs 2020 through 2022.

LTCH QRP Measures, by Year				
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	X	X	X
Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678)	X	Replaced		
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury		X	X	X

LTCH QRP Measures, by Year				
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
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.				

D. 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 is subject to an update factor reduction equal to three quarters of the market basket. In the impact analysis section of this proposed rule, 67 hospitals are estimated to fail to meet the meaningful use requirements for FY 2021 payment and would receive an update factor of 0.35 percent. An additional 14 hospitals fail to meet both the meaningful use and IQR Program requirements and under the proposed rule would receive an update factor of -0.4 percent.

1. Reporting Periods in 2022

A continuous 90-day reporting period was previously adopted for the Medicare and Medicaid Promoting Interoperability Program reporting in 2021 for new and returning participants. CMS proposes to extend continuous 90-day reporting for the Medicare Promoting Interoperability Program EHR reporting periods in 2022. It reminds readers that under the statute, the Medicaid Promoting Interoperability Program will end in 2021. Reporting periods for these programs are codified in the definition of *EHR reporting period* at §495.4.

2. Query of Prescription Drug Monitoring Program (PDMP) Measure

CMS discusses the history of the PDMP measure, which in past rulemaking was added as an optional measure for EHR reporting periods in 2019 and 2020 and finalized to be a mandatory measure for FY 2021. Hospitals electing to report this measure report "yes" if for least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

Stakeholders continue to express concern to CMS that making this measure mandatory for reporting in 2021 is premature. PDMPs themselves are still maturing, and they are not yet consistently integrated into EHR workflow. CMS notes that a recent assessment of PDMPs by the Office of the National Coordinator for Health Information Technology (ONC) found that less than half of hospitals reported integration of PDMP queries into the EHR workflow.[53]

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 2021. In light of the variation in how providers interact with PDMPs, it now believes that it would be burdensome to require this measure in 2021 reporting and that more time is needed before the measure is made mandatory for performance-based scoring. **Comments are sought on this proposal.**

3. Change in Measure Name

CMS proposes to change the name of the Health Information Exchange Objective measure "Support Electronic Referral Loops by Receiving and Incorporating Health Information" to

[53] The proposed rule does not provide a link to the recent ONC assessment but refers readers to an ONC analysis of 2017 AHA survey data at: https://www.healthit.gov/buzz-blog/health-it/new-data-show-nearly-one-third-of-hospitals-can-access-pdmp-data-within-their-ehr

"Support Electronic Referral Loops by Receiving and Reconciling Health Information." It believes that the word "reconciling" better reflects the actions required by the measure.

4. Scoring the Medicare Promoting Interoperability Program for EHR Reporting Periods in 2021

In order to be considered a meaningful user an eligible hospital or CAH must meet all of the following requirements:

- Report on all the required measures across all four objectives, unless an exclusion applies*
- Report "yes" on all required yes/no measures, unless an exclusion applies*
- Attest to completing the actions included in the Security Risk Analysis measure*
- Achieve a total score of at least 50 points.

*Failure on this requirement results in a total score of zero.

Taking into account the proposals above, the scoring methodology for 2021 is shown in the following table.

Proposed Performance-Based Scoring Methodology for EHR Reporting Periods in 2021

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose any two of the following: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	10 points

5. eCQM Reporting Periods and Criteria for 2021, 2022 and 2023

As part of being a meaningful user under the Medicare and Medicaid Promoting Interoperability Programs, eligible hospitals and CAHs must report on eCQMs selected by CMS. For the 2021 reporting period eligible hospitals and CAHs must report on four of the available eCQMs for one self-selected quarter of data during the calendar year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program. The 8 eCQMs available for 2021 reporting are:

- STK-2 Discharged on antithrombotic therapy for ischemic stroke (NQF #0435)
- STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)
- STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)

- STK-6 Discharged on statin (NQF #0439)
- VTE-1 Venous thromboembolism (VTE) prophylaxis (NQF #0371)
- VTE-2 ICU VTE prophylaxis (NQF #0372)
- ED-2 Median time from admit decision to ED departure for admitted patients (NQF #0497)
- PC-05 Exclusive breast milk feeding (NQF #0480)
- Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e).

The Safe Use of Opioids measure was also finalized as a mandatory measure beginning with the 2022 reporting period. At that time, eligible hospitals and CAHs must report that measure and three others selected from among the eight.

In this rule, CMS proposes to progressively increase the number of quarters for which a hospital must report eCQM data under the Promoting Interoperability Programs over a 3-year period. A parallel change is proposed for eCQM reporting for the IQR Program, as discussed in section VIII.A above. Currently, for the four eCQMs that it reports, an eligible hospital or CAH must submit one self-selected quarter of data. Under the proposal, this requirement would be increased to four quarters of data as follows:

- For 2021 reporting an eligible hospital or CAH would report data for 2 self-selected calendar quarters
- For 2022 reporting an eligible hospital or CAH would report data for 3 self-selected calendar quarters
- For 2023 reporting and subsequent years, an eligible hospital or CAH would report data for all 4 calendar quarters.

Additionally, CMS proposes that the data submission period would continue to be the 2 months following the end of the respective calendar year. **Comments are solicited on these proposals.**

6. Public Reporting of eCQMs

Consistent with the IQR Program proposal discussed in section VIII.A above, CMS proposes that eCQM data would be publicly reported. CMS proposes that public reporting of eCQM data would begin with data reported in 2021 for the FY 2023 payment determination. These data would be publicly posted as early as the fall of 2022. Along with other IQR Program measures, eCQM data would be available for hospitals to review during the 30-day preview period. **CMS requests public comment on this proposal, especially with respect to possible effects on existing incentives and burdens under the Promoting Interoperability Program.**

7. Technical Corrections to Regulatory Text

CMS proposes to make several technical corrections to regulatory text. Of note, it would correct the transition factors for Puerto Rico hospitals whose first payment year under the program is 2018, at §495.104(c)(5)(viii) so that all four years of the transition are referenced.

8. Future Direction of the Medicare Promoting Interoperability Program

CMS indicates that it will continue to consider changes to the Medicare Promoting Interoperability Program for future years to support goals including reducing administrative burden, supporting alignment with the Quality Payment Program and the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT.

In particular, CMS will consider potential areas of overlap with the 21st Century Cures Act final rule (85 FR 25642), including information blocking, transitioning from the Common Clinical Data Set (CCDS) to the United States Core Data for Interoperability (USCDI), finalization of a new certification criterion for a standards-based Application Programming Interface, and other updates to 2015 Edition certification criteria and the ONC Health Information Technology Certification Program. **Comments are solicited on how Medicare can best support these areas of overlap.**

IX. Changes for Hospitals and Other Providers

A. Submission of Electronic Patient Records to Quality Improvement Organizations (QIO)

1. Background

A QIO is an organization comprised of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare. Current law authorizes QIOs to have access to the records of providers, suppliers, and practitioners under Medicare in order to perform their functions. Providers and practitioners are required to provide patient care data and other pertinent data to the QIO when the QIO is collecting review information. The proposed regulation would make electronic submission the default method of submission, mandating all providers and practitioners who provide patient records to the QIO to submit them in electronic format unless they have an approved waiver.

2. Proposed Changes

CMS is proposing:

- To define "patient record" as all patient care data and other pertinent data or information (whether or not part of the medical record) relating to care or services provided to an individual patient, in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.
- Patient records must be delivered in electronic format, unless a QIO approves a waiver. Initial waiver requests by those providers that are required to execute a written agreement with the QIO would be expected to be made at the time of the written agreement although the waiver could be requested later if necessary. Other providers and practitioners who are not required to execute a written agreement with a QIO would request a waiver by giving the QIO notice of their lack of capability to submit patient records in electronic format.

- Establish reimbursement rates of $3.00 per patient record that is submitted to the QIO in electronic format and $0.15 per page for requested patient records submitted by facsimile or by photocopying and mailing (plus the cost of first-class postage for mailed photocopies), after a waiver is approved by the QIO. Only one reimbursement would be provided by the QIO for each patient record submitted, per request, even if a particular patient record is submitted to the QIO using multiple different formats, in fragments, or more than once in response to a particular request.

These proposed changes would be applicable to all providers and practitioners providing patient records to QIOs for purpose of QIO reviews. CMS proposes a number of regulatory changes to ensure that reimbursement is permitted for all healthcare providers and practitioners, on the same basis and at the same rates. It is further streamlining all of the regulations related to submission and payment for providing medical records to be in the same section of the regulations.

CMS proposes to remove a step-by-step analysis of how the cost of photocopying was calculated from the regulations. That same step-by-step analysis for the updated rate is included in the preamble to the regulations and is also furnished for the $3.00 electronic record fee and $0.15 facsimile fee.

These fees were determined by using the annual salary and fringe benefits cost of a GS-5, step 5 medical records clerk ($53,918 per year or $26 per hour) in combination with assumptions about productivity and workload for electronic patient records plus the additional costs of a photocopier and supplies for photocopied records and a telephone for facsimile records.

CMS estimates these policies will save $71.8 million over 5 years; $37.6 million from reimbursement for sending patient records via facsimile, photocopying and mailing and $34.2 million from payment to QIOs to cover the cost of scanning and uploading paper-based patient records.

B. Electronic Filing of Provider Review Reimbursement Board (PRRB) Appeals

1. Background

The PRRB is an independent forum for resolving payment disputes typically arising from certain Medicare Part A final determinations (usually cost report audit appeals). Staff support is provided to the PRRB by the Office of Hearings (OH). On August 16, 2018, the OH and the Board released the OH Case and Document Management System (OH CDMS)—a web-based portal where providers can file appeals and the PRRB can release outgoing electronic correspondence and Board decisions with immediate system notification of an action. This system is already in use by all MACs and many others that have appeals before the PRRB.

2. Technical Changes to Support Electronic Filing

The OH is proposing technical changes to the regulations consistent with use of the OH CDMS electronic system:

- Update the definitions of "date of receipt" and "reviewing entity" to indicate that submissions to an electronic filing system are considered received on the date of electronic delivery.
- "In writing or written" means hard copy or electronic submission. (Date of receipt by a party or affected nonparty continues to be presumed to be 5 days after the date of issuance).
- Technical changes are made throughout to apply terms to both hard copy and electronic submissions.
- Updates provisions related to subpoenas, so that it generally conforms to other technical changes being proposed except for adding "If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena must be sent by certified mail" in accordance with section 205(d) of the Act.

3. Intention to Revise Board Instructions to Require Mandatory Electronic Submissions

No earlier than FY 2021, the PRRB may require that all new submissions be filed electronically using OH CDMS. Stakeholders can access the Electronic Filing webpage located at: https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Electronic-Filing. The OH recommends that parties to PRRB appeals, who have not already done so, sign up for and begin using OH CDMS as soon as possible to allow time to become familiar with the system and avoid any issues that may arise if signing up for the system is delayed until after use of the system becomes mandatory.

C. Medicare Bad Debt Policy

1. Background

Under the Medicare program, beneficiaries may be responsible for payments of premiums, copayments, deductibles, and coinsurance amounts that are related to covered services. In accordance with section 1861(v)(1) of the Act and regulations at §413.89, Medicare pays some of the uncollectible deductible and coinsurance amounts to certain providers, suppliers and other entities eligible to receive reimbursement for bad debt of Medicare beneficiaries. To be an allowable Medicare bad debt, the debt must meet all of the following criteria (see §413.89(e) and Provider Reimbursement Manual (PRM), Chapter 3, Section 308):

- The debt must be related to covered services and derived from deductible and coinsurance amounts.
- The provider must be able to establish that reasonable collection efforts were made.
- The debt was actually uncollectible when claimed as worthless.
- Sound business judgment established that there was no likelihood of recovery at any time in the future.

Statute prohibited the Secretary from making changes to Medicare bad debt policies for hospitals in effect on August 1, 1987. This moratorium ended for cost reporting periods beginning on or after October 1, 2012. CMS is using this proposed rule to clarify certain Medicare bad debt policies that have been the subject of litigation, and generated interest and questions from

stakeholders over the past several years. Additionally, CMS will recognize the new Accounting Standards Update – Topic 606 for revenue recognition and classification of Medicare bad debts and make technical corrections to the regulations.

CMS is proposing to make many of these changes effective retroactively and prospectively under the authority of section 1871(e)(1)(A)(ii) of the Act that allows retroactive rulemaking when the alternative is contrary to the public interest. The proposed rule explains why it would be in the public interest for these policies to apply retroactively. In other circumstances, CMS is proposing prospective changes to the regulations effective for cost reporting periods beginning on or after October 1, 2020.

2. Proposed Revisions to Regulations

a. Reasonable Collection Efforts. CMS is proposing significant revisions to §413.89(e)(2). Currently, this section of the regulation only states that "the provider must be able to establish that reasonable collection efforts were made." More detailed requirements were in the PRM. Below is a list of items added to this section of the regulation:

Non-Indigent Beneficiaries. Reasonable collection efforts are only required from non-indigent beneficiaries. CMS proposes to add §413.89(e)(2)(i) that states: "A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes. The preamble indicates this policy is not new and has existed since the promulgation of Medicare bad debt policy.

Later in the preamble, CMS provides further detail on determining indigency by the provider when the beneficiary is not eligible for Medicaid.

Issuance of a Bill. CMS proposes to codify requirements currently in the PRM into §413.89(e)(2) including the following:

- The collection effort must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.
- For cost reporting periods beginning before October 1, 2020, the effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.
- For cost reporting periods beginning on or after October 1, 2020, the effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:
    - The date of the Medicare remittance advice.
    - The date of the remittance advice from the beneficiary's secondary payer, if any.
- The collection effort must also include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort.

CMS proposes to make all of the above requirements effective retroactively except for the provisions that has an effective date of cost reporting periods beginning on or after October 1, 2020. For the regulations that have retroactive effect, the rule indicates the policies are long-standing from the PRM that are being codified in regulation.

The provisions effective on or after October 1, 2020 are intended to give more precise meaning to the term "shortly after." For cost reporting periods beginning prior to October 1, 2020, providers are only required to issue a bill "shortly after discharge or the death of the beneficiary." For cost reporting periods beginning on or after October 1, 2020, the requirement is to issue a bill on or before 120 days after the latter of the date of the Medicare remittance advice or the date of remittance advance from the beneficiary's secondary payer, if any.

120-day Collection Effort and Reporting Period for Writing Off Bad Debts. CMS is making two changes in this section of the rule. First, CMS is adding a requirement to §413.89(e)(2) that a bill cannot be considered uncollectible until at least 120 days have passed since the provider first attempted to receive payment. If the provider receives partial payment, the 120-day period restarts. This policy will be effective retroactively as CMS states that it merely codifies in regulation what was an established policy in the PRM. CMS indicates that the requirement to restart the 120 days upon receiving a partial payment is a clarification of a policy CMS established in response to inquiries.

Second, CMS is revising an existing provision of the regulations (§413.89(f)) to clarify that any payment on the account made by the beneficiary, or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report. If the collection is made in a cost reporting period after the debt has been written off as uncollectible, the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered. However, the amount of such reduction in the period of recovery must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period. CMS proposes to make this policy effective retroactively.

Similar Collection Effort and Collection Agency Fees. As indicated above, CMS is proposing to modify §413.89(e)(2) to add the following provision:

- The collection effort must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.

This proposed provision of the regulation codifies an existing provision of the PRM. CMS clarifies confusion over how this policy has been understood. Similar collection efforts mean that the provider must take the same actions to collect Medicare and non-Medicare debts alike. For example, if a provider elects to refer its non-Medicare accounts to a collection agency, the provider must similarly refer Medicare accounts of "like amount." without regard to class of patient.

The collection agency's effort to collect the debt must also be similar between Medicare and non-Medicare patients. This means that for comparable amounts, the collection agency must use similar collection practices for both accounts. The effort must constitute a genuine, rather than a

token, collection effort. Collection accounts that remain at a collection agency cannot be claimed by the provider as a Medicare bad debt. Further, a fee charged by a collection agency can be considered an allowable administrative expense but cannot be written off to bad debt. CMS proposes to make this policy effective retroactively.

Documentation of Reasonable Collection Efforts. CMS proposes to add §413.89(e)(2)(A)(i)(6) to codify long-standing provisions of the PRM related to documentation of reasonable collection efforts.

The provider must maintain and, upon request, furnish to the Medicare contractor documentation of the provider's collection effort, whether the provider performs the collection effort in house or whether the provider uses a collection agency to perform the required collection effort on the provider's behalf. The documentation of the collection effort must include: the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the patient account history documents which show the dates of various collection actions such as the issuance of bills, follow-up collection letters, reports of telephone calls and personal contact, etc. CMS proposes to make this policy effective retroactively.

b. Determining Indigency. For beneficiaries that are not Medicaid eligible, CMS indicates that the PRM requires that the beneficiary's total resources be considered when a provider evaluates a beneficiary's indigence. CMS proposes that new paragraph (e)(2)(ii)(A) that provides detailed specifications for how a provider is to determine indigence for beneficiaries that are not Medicaid eligible. CMS proposes to make this policy effective retroactively.

c. Dual Eligible Beneficiaries. Dual eligible beneficiaries are Medicare beneficiaries who are enrolled in Medicare (either Part A, Part B, or both), and are also enrolled in "full Medicaid" coverage and/or the Medicare Savings Program. Some of these dual eligible beneficiaries have full Medicaid coverage while others have partial Medicaid coverage where Medicaid may pay some or all of the beneficiary's Medicare cost sharing. The proposed rule provides a detailed discussion of these partial Medicaid programs as well as complex issues where Medicaid may not provide information on whether it has an obligation to pay for a Medicare beneficiary's liability because a provider is not enrolled in Medicaid or for other reasons.

To satisfy the reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether Medicaid (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. A provider satisfies this requirement: by (1) billing the state Medicaid program to determine that no source other than the patient would be legally responsible for the patient's medical bill; for example, Title XIX, local welfare agency and guardian (the "must bill requirement"); and (2) obtain and submit to the MAC, a Medicaid remittance advice (RA) from the state Medicaid program (the "RA requirement"). If a provider does not bill the state and submit the Medicaid RA to Medicare with its claim for bad debt reimbursement for dual eligible beneficiaries, the result is that unpaid deductible and coinsurance amounts cannot be included as an allowable Medicare bad debt.

CMS is codifying this policy in §413.89(e)(2). Any amount that the state is obligated to pay, either by statute or under the terms of its approved Medicaid state plan, will not be included as an allowable Medicare bad debt, regardless of whether the state actually pays its obligated amount to the provider or provides the Medicaid RA indicating that it has no obligation to pay. However, the Medicare deductible and/or coinsurance amount, or any portion thereof that the state is not obligated to pay, can be included as an allowable Medicare bad debt. Unpaid deductible and coinsurance without collection effort documentation will not be considered as allowable bad debts. CMS proposes to make this policy effective retroactively.

CMS acknowledges that challenges exist for providers when states do not comply with the federal statutory requirements and suggests potential alternatives to the "must bill" policy and Medicaid RA that it could adopt in the final rule. CMS welcomes suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA that a provider could obtain and submit to Medicare to evidence a beneficiary's Medicaid eligibility for the date of service and the state's Medicare cost sharing liability (or absence thereof) and regarding whether it should or could adopt such a policy effective for past cost reporting periods. Doing so would serve an important public interest by allowing providers with cases currently pending before the PRRB an avenue for timely and cost-effective resolution.

d. Accounting Standard Update Topic 606 and Accounting for Medicare Bad Debt

(1) Accounting Standard Update (ASU) Topic 606.

The Financial Accounting Standards Board's (FASB) ASU 2014-09, Revenue from Contracts with Customers (Topic 606), was published in May 2014 with the first implementation period in 2018. Under the ASU Topic 606, an amount representing a bad debt would generally no longer be reported separately as an operating expense in the provider's financial statements, but will be treated as an "implicit price concession," and included as a reduction in patient revenue. Topic 606 makes other related changes.

To implement Topic 606, CMS is modifying the regulations to add that, effective for cost reporting periods beginning on or after October 1, 2020 that "bad debts, also known as 'implicit price concessions' are amounts considered to be uncollectible from accounts that were created or acquired in providing services" and "bad debts, also known as 'implicit price concessions,' charity, and courtesy allowances represent reductions in revenue."

(2) Medicare Bad Debt and Contractual Allowances

CMS indicates that many providers are incorrectly writing off Medicare-Medicaid crossover bad debts to a contractual allowance account because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. Other providers are writing these amounts off to a contractual allowance account because the Medicaid remittance advice referenced the unpaid amount as a "Medicaid contractual allowance."

These Medicare-Medicaid crossover claims amounts do not meet the classification requirements for a Medicare bad debt because the amounts were written off to a contractual adjustment or allowance account instead of a bad debt expense account. CMS is proposing to add paragraph

(c)(3) to §413.89(c) to clarify that, effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession).

X. MedPAC Recommendations

In its March 2020 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the "Hospital Value Incentive Program (HVIP)." CMS responded that consistent with the statute, it is establishing an applicable percentage increase for FY 2020 of 2.6 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. CMS does have the authority to establish HVIP.

XI. Other Required Information

This section includes a listing and a description of the data files that are available with the final rule. All of those files are available at the link provided at the front of this summary or in links provided in the part of the summary that describe the relevant provision.

In addition, this section describes the information collection requirements associated with specific provisions of the final rule. Any relevant issues associated with the information collection requirements described in this section are included elsewhere in this summary where the issue is otherwise described.

TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2021

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
All Hospitals	3,199	3.1	0	0	0	0	0.1	2.5
By Geographic Location:								
Urban hospitals	2,459	3.1	0	0	-0.1	0	0.1	2.5
Rural hospitals	740	2.8	-0.3	0	1.1	-0.1	0.1	2.3
Bed Size (Urban):								
0-99 beds	634	3	-0.3	-0.1	-0.7	0.1	0.3	2.2
100-199 beds	752	3.1	-0.1	0	-0.1	0.2	0.2	2.5
200-299 beds	438	3.1	-0.1	0	0.2	0	0.2	2.4
300-499 beds	414	3.1	0	-0.1	0	0	0.1	2.5
500 or more beds	221	3	0.2	0.1	-0.2	-0.1	0	2.7
Bed Size (Rural):								
0-49 beds	300	2.8	-0.5	0	0.2	-0.2	0.2	2
50-99 beds	259	2.6	-0.3	0.1	0.8	-0.1	0.2	2.3
100-149 beds	98	2.8	-0.3	0.1	1.2	-0.1	0	2.3
150-199 beds	44	2.9	-0.2	-0.1	1	0	0.2	2.4
200 or more beds	39	2.9	-0.1	-0.1	1.9	-0.2	0	2.4
Urban by Region:								
New England	112	3.1	0.1	-0.9	1.5	2.1	0.1	2.4
Middle Atlantic	305	3.1	0	0.4	0.2	-0.3	0.1	2.7
South Atlantic	402	3.1	0	0.1	-0.5	-0.3	0	2.6
East North Central	380	3.1	0	0	-0.3	-0.3	0	2.5
East South Central	144	3.1	0	0	-0.3	-0.3	0	2.5
West North Central	159	3	0	-0.4	-0.6	-0.3	0.6	2.2
West South Central	364	3.1	0	0.1	-0.4	-0.3	0	2.6
Mountain	172	3	0	-0.4	-0.2	0	0.3	2
Pacific	371	3	0.1	0	0.3	0.6	0.1	2.7
Puerto Rico	50	3.1	0.1	-0.9	-0.9	0.2	0.1	1.9
Rural by Region:								
New England	19	2.9	0	-0.4	0	0.3	0	2.4
Middle Atlantic	50	2.8	-0.3	0.3	1.3	-0.1	0	2.5
South Atlantic	115	2.9	-0.3	0	1.4	-0.2	0	2.1
East North Central	114	2.7	-0.3	0.1	0.9	-0.1	0	2.4
East South Central	144	3	-0.3	-0.1	2	-0.2	0	2.4
West North Central	89	2.6	-0.4	0	-0.1	-0.1	0.3	2.1
West South Central	136	2.9	-0.3	0.1	2	-0.2	0.1	2.3
Mountain	49	2.6	-0.3	-0.2	-0.2	-0.1	1.1	2.1
Pacific	24	2.7	-0.2	0.2	1.1	-0.1	0	2.3

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
By Payment Classification:								
Urban hospitals	2,028	3.1	0	0	-0.5	0	0.1	2.6
Rural areas	1,171	3	0	0	0.8	-0.1	0.1	2.4
Teaching Status:		0	0	0	0	0	0	0
Nonteaching	2,043	3	-0.2	0	0.1	0	0.1	2.3
Fewer than 100 residents	901	3.1	-0.1	0	0	0	0.2	2.5
100 or more residents	255	3	0.3	0	-0.1	-0.1	0.1	2.7
Urban DSH:		0	0	0	0	0	0	0
Non-DSH	505	3.1	-0.1	0.1	-0.4	-0.1	0.2	2.3
100 or more beds	1,273	3.1	0	0	-0.4	0.1	0.1	2.6
Less than 100 beds	352	3.1	-0.3	-0.1	-0.5	0.2	0.2	2.2
Rural DSH:								
SCH	257	2.6	-0.3	0	0.1	-0.1	0.1	2.3
RRC	538	3	0	0	1.1	-0.1	0.1	2.5
100 or more beds	59	3.1	0.1	0	-0.9	-0.3	0.1	1.9
Less than 100 beds	215	3	-0.4	0.1	0.3	-0.3	0.2	2.2
Urban teaching and DSH:								
Both teaching and DSH	738	3.1	0.1	0	-0.5	0	0.1	2.6
Teaching and no DSH	70	3.1	0	0.1	-0.8	-0.2	0.1	2.2
No teaching and DSH	887	3.1	-0.1	-0.1	-0.2	0.3	0.1	2.4
No teaching and no DSH	333	3.1	-0.2	0.1	-0.6	-0.2	0.2	2.5
Special Hospital Types:								
RRC	471	3.1	0.1	0.1	1.1	-0.1	0.1	2.5
SCH	304	2.6	-0.2	0	0	-0.1	0.1	2.4
MDH	146	2.8	-0.4	0.2	0.3	-0.1	0.1	2.2
SCH and RRC	148	2.7	-0.2	-0.1	0.5	-0.1	0	2.4
MDH and RRC	24	2.8	-0.3	0.1	0.5	-0.1	0	2.3
Type of Ownership:								
Voluntary	1,884	3.1	0	0	0	0	0.1	2.5
Proprietary	826	3.1	-0.1	-0.1	0	0	0.1	2.6
Government	488	3	0.1	0.1	-0.2	0	0	2.5
Medicare Utilization as a Percent of Inpatient Days:								
0-25	601	3.1	0.1	0.1	-0.3	-0.1	0	2.7
25-50	2,108	3.1	0	0	0	0	0.1	2.5
50-65	391	3	-0.2	0	0.4	0.1	0.2	2.1
Over 65	64	2.8	-1.2	-0.4	-0.5	0.4	0	1.5
FY 2021 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	949	3	0	0.1	1.3	-0.1	0.1	2.6
Non-Reclassified Hospitals	2,250	3.1	0	-0.1	-0.9	0	0.1	2.5
Urban Hospitals Reclassified	778	3.1	0	0.1	1	-0.1	0.1	2.5

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
Urban Non-Reclassified Hospitals	1,693	3.1	0	-0.1	-0.9	0.1	0.1	2.6
Rural Hospitals Reclassified Full Year	310	2.8	-0.2	0	1.9	-0.1	0.1	2.3
Rural Non-Reclassified Hospitals Full Year	418	2.8	-0.3	0	-0.3	-0.2	0.2	2.2
All Section 401 Reclassified Hospitals	485	3	0.1	0	0.8	-0.1	0.1	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	3	-0.3	0.1	1.7	0.4	0	2.2

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2017 and FY 2016.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.6 percent update to the national standardized amount and the proposed hospital-specific rate (the estimated 3.0 percent market basket update reduced by 0.4 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 38 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998761 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2017 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 0.999362.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2021 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2021. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.988003.

[6] This column displays the effects of the proposed rural floor The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993991.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2020 to FY 2021 including an estimated decrease in outlier payments of 0.4 percent (from our current estimate of FY 2020 outlier payments of approximately 5.5 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this proposed rule calculated for purposes of this impact analysis). This column also includes the effects of the proposed adoption of the revised labor market area delineations in OMB Bulletin 18-04 and the effects of the proposed transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.