ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 10, 2021

RE: A&B Summary – Key Provisions of the FY 2022 IPPS/LTCH PPS Final Rule (CMS-1752-F)

On August 2, 2021, the Centers for Medicare & Medicaid Services (CMS) released its final rule entitled, "*Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Policy Changes and Fiscal Year (FY) 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals (CAH); Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program (MSSP) (CMS-1752-F)*" (final rule).[1] The final rule implements many of the proposals described in the CY 2022 IPPS/LTCH PPS proposed rule (proposed rule), released on April 27, 2021 and published in the Federal Register on May 10, 2021.[2]

CMS finalized key changes, including:

1. Use of FY 2019 inpatient hospital utilization data instead of FY 2020 data due to the COVID-19 public health emergency (PHE);
2. Extension of new technology add-on payments (NTAPs) for technologies whose NTAPs would otherwise expire beginning FY 2022;
3. Extension of new COVID-19 treatments add-on payments (NCTAPs) through the end of the FY in which the PHE ends;
4. Repeal of the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage organization payers by MS-DRG;
5. Extension of the transitional cap on certain reductions to a hospital's wage index, and reinstatement of the imputed floor wage index policy as was in effect for FY 2018, as required by the American Rescue Plan Act;
6. Extension of the rural community hospital (RCH) demonstration, as required by the Consolidated Appropriations Act, 2021 (CAA);
7. Suppression of certain measures due to COVID-19 and other refinements to hospital quality programs including the Hospital Readmissions Reduction Program (HRRP), Hospital Value-Based Purchasing (VBP) Program, Hospital-Acquired Condition (HAC) Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, and PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program; and

Refinements to the Medicare and Medicaid Promoting Interoperability Programs. CMS received over 6,500 comments on the proposed rule. For certain proposals, CMS did not address comments in the final rule, but rather intends to address these proposals and comments in separate documents. Accordingly, proposals that will be addressed in the future in subsequent parts to this final rule are those relating to: (1) counting days associated with section 1115 demonstration projects in the Medicaid fraction for disproportionate share

[1] Public display version available here: https://public-inspection.federalregister.gov/2021-16519.pdf.
[2] 86 Fed. Reg. 25070 (May 10, 2021), available here: https://www.federalregister.gov/documents/2021/05/10/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the.

hospital (DSH) payments, (2) organ acquisition costs, and (3) the provisions of the CAA related to payments to hospitals for Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) costs.

Overall, CMS projects total Medicare spending on inpatient hospital services, including capital, will increase by approximately $2.3 billion in FY 2022. CMS projects total spending under the LTCH PPS will increase by approximately $42 million in FY 2022.

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I. Key Proposed IPPS Payment Updates

a. Proposed Changes in the Inpatient Hospital Update for FY 2022

CMS proposed a 2.5 percent market basket update, based on IHS Global Inc.'s fourth quarter 2020 forecast. CMS proposed a 0.2 percent multifactor productivity (MFP) adjustment. If more recent data subsequently becomes available, CMS will use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment for the final rule.

Final Rule: CMS updated the market basket update and MFP adjustment based on IHS Global Inc.'s second quarter 2021 forecast. The revised figures are shown in the table below.

FY 2022 Applicable Percentage Increases for the IPPS								
FY 2022	**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**	
	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
Market Basket Rate-of-Increase	2.5	**2.7**	2.5	**2.7**	2.5	**2.7**	2.5	**2.7**
Adjustment for Failure to Submit Quality Data	0	**0**	0	**0**	-0.625	**-0.675**	-0.625	**-0.675**
Adjustment for Failure to be a Meaningful EHR User	0	**0**	-1.875	**-2.025**	0	**0**	1.875	**-2.025**
Productivity Adjustment	-0.2	**-0.7**	-0.2	**-0.7**	-0.2	**-0.7**	-0.2	**-0.7**
Applicable Percentage Increase Applied to Standardized Amount	2.3	**2.0**	0.425	**-0.025**	1.675	**1.325**	-0.2	**-0.7**

b. Proposed Medical Severity-Diagnosis Related Group (MS-DRG) Documentation and Coding Adjustment

As required by section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[3] CMS proposed to make an adjustment of +0.5 percent to the standardized amount of Medicare payments to acute care hospitals for FY 2022. This adjustment is required for FY 2018[4] through FY 2023.

[3] Pub. L. 114-10.
[4] The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act (Pub. L. 114-255).

Final Rule: finalized as proposed.

c. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2022

CMS pays additional Medicare payments to hospitals that serve a significantly disproportionate number of low-income patients, known as the Disproportionate Share Hospital (DSH) adjustment. Most DSH adjustment recipients qualify through a formula that includes the hospital's ratios of Medicaid to total inpatient days and low-income Medicare to Medicare inpatient days. Under this method, the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: (1) the "Medicare fraction" (hospital inpatient days furnished to patients entitled to both Medicare Part A and Supplemental Security Income benefits divided by the total number of hospital patient days furnished to patients entitled to Part A benefits); and (2) the "Medicaid fraction" (hospital inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Part A divided by the total hospital inpatient days in the same period). A handful of hospitals qualify through the "Pickle method."[5]

Section 3133 of the Patient Protection and Affordable Care Act[6] (ACA) modified the methodology for computing the Medicare DSH payment adjustment. Under this change, hospitals that qualify for Medicare DSH payments receive 25 percent of the amount they would have received under the original formula; this 25 percent payment is referred to as the "empirically justified Medicare DSH payment." An additional payment amount is based on a hospital's amount of uncompensated care relative to the total amount of uncompensated care for all DSH-eligible hospitals. The methodology for this additional payment amount and proposed changes are described below.

i. Uncompensated Care Payment Factors

In addition to the empirically justified Medicare DSH payment (i.e., 25 percent), CMS pays an additional amount, called the "uncompensated care payment," equal to the product of three factors:

1. The difference between the aggregate amount of payments that would have been made under the pre-ACA calculation and the empirically justified Medicare DSH payment (i.e., 75 percent of the pre-ACA DSH payment adjustment) ("Factor 1");
2. 1 minus the percent change in the percent of individuals who are uninsured from 2013 to the most recent period for which data are available ("Factor 2"); and
3. The quotient of the amount of uncompensated care provided by a hospital and the aggregate amount of uncompensated care provided by all DSH payment adjustment recipients for a given time period selected by the Secretary of Health and Human Services (the "Secretary") ("Factor 3").

CMS proposed that Factor 1 for FY 2022 would be approximately $10,573,368,841.28, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2022[7] ($14,097,825,121.71

[5] Pickle hospitals (named for Congressman J.J. Pickle) are located in an urban area, have 100 or more beds, and more than 30 percent net inpatient care revenue derived from state and local government payments for care (other than Medicare or Medicaid). As of 2018, CMS recognized 10 Pickle hospitals.
[6] Pub. L. 111-148.
[7] The proposed rule states "FY 2021", but this is likely an error and should be FY 2022.

minus $3,542,456,280.43). More recent data may be used for purposes of projecting the final Factor 1 estimates for the FY 2022 IPPS/LTCH PPS final rule.

Final Rule: the final Factor 1 for FY 2022 is $ 10,488,564,546.74, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2022 ($13,984,752,728.99 minus $3,496,188,182.25).

CMS proposed that Factor 2 for FY 2022 would be 72.14 percent.[8] The proposed FY 2022 uncompensated care amount is $10,573,368,841.28 times 0.7214 = $7,627,628,282.10.

Final Rule: the final Factor 2 for FY 2022 is 68.57 percent.[9] The final FY 2022 uncompensated care amount is $ $10,488,564,546.74 times 0.6857 = $ 7,192,008,709.70.

Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount that each hospital receives relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amount of uncompensated care for a period based on appropriate data, and permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

For FY 2022, CMS proposed to apply the methodology adopted in the FY 2021 IPPS final rule, by applying: (1) the merger policies to incorporate the use of a multiplier to account for merger effective date; (2) the policy (for providers with multiple cost reports beginning in the same FY) of using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy (for the rare case when a hospital has a cost report that starts in one FY and spans the entirety of the following FY) of using the cost report that spans both FYs for the latter FY; (4) the new hospital policy (as modified in the FY 2020 IPPS final rule); (5) the newly merged hospital policy; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant cost-to-charge ratios and potentially aberrant uncompensated care costs reported on the Worksheet S-10. In addition, CMS proposed to continue to use a single year of data on uncompensated care costs from Worksheet S-10 of hospitals' FY 2018 cost report to distribute these funds. For IHS, tribal, and Puerto Rico hospitals, CMS proposed to continue to use data regarding low-income insured days (Medicaid days for FY 2013 and Supplemental Security Income benefits for FY 2018).[10]

Final Rule: Factor 3 methodology finalized as proposed (continuation of existing policy).

ii. Counting Days Associated with Section 1115 Demonstration Projects in the Medicaid Fraction

CMS notes that section 1115 demonstration projects have recently been used to authorize the funding of uncompensated care pools to offset the burden that treating the uninsured places on hospitals. CMS states that unlike demonstration projects that expand the population of people who are entitled to Medicaid benefits, uncompensated care pools do not provide inpatient health coverage directly to patients or make payments on behalf of specific, covered individuals. Instead, CMS states that these pools directly benefit hospitals and other providers by making Medicaid funds available to compensate them for the otherwise uncompensated costs they incur when providing medical care to the uninsured and under-insured. CMS

[8] 1-|((0.101 - 0.14)/0.14)| = 1 - 0.2786 = 0.7214.
[9] 1-|((0.096-0.14)/0.14)| = 1 - 0.3143 = 0.6857 (68.57 percent).
[10] A summary of the methodology for computing Factor 3 for FY 2022 is available on pages 1207-1208 of the display version of the final rule.

further states that these pools essentially serve the same function as Medicaid DSH payments by indirectly subsidizing the cost of treating the uninsured, while not extending Medicaid benefits to additional populations.

CMS's current policy is to exclude patient days of individuals provided limited benefits under a section 1115 expansion waiver from the numerator of the Medicaid fraction (described above) because the benefits provided are too limited to be considered similar to Medicaid coverage. As an example of the kind of waiver program that should not be counted in the Medicaid fraction, CMS described the regulatory and legal history of family planning benefits offered under a section 1115 waiver and how CMS's authority changed due to the subsequent Deficit Reduction Act of 2005 (DRA). Originally, CMS's position in the FY 2004 IPPS final rule was that family planning benefits offered under a section 1115 waiver should not be counted in the Medicaid fraction of the DSH calculation. Following two court decisions, which held that excluding populations from the numerator of the Medicaid fraction was inconsistent with the statutory requirements, Congress included a provision in the DRA, which provides HHS with the discretion to "regard" certain expansion populations as being "eligible for medical assistance under a State plan" for the purpose of the DSH calculation and to include them in the numerator of the Medicaid fraction.

CMS does not interpret the DRA to grant authority to include in the DSH calculation any patient who in any way benefits from a section 1115 demonstration project. Instead, CMS believes its authority is limited to including expansion populations (i.e., patients who can be "regarded" as eligible for medical assistance under a State Medicaid plan because they receive benefits through a section 1115 demonstration project that are comparable to traditional Medicaid benefits).

Consistent with its current policy of excluding patient days of individuals provided limited benefits (like family planning benefits), CMS also believes it is appropriate to exclude patient days for which hospitals receive payment from an uncompensated care pool or other similar funding source authorized under Social Security Act (SSA) section 1115(a)(2). Therefore, CMS concluded that patient days paid from such pools and other similar sources should *not* be included in the calculation of the Medicare DSH adjustment. CMS extends this principle to premium assistance, stating that the days of patients who receive premium assistance under a section 1115 expansion waiver (i.e., to help with the purchase of health insurance from a private entity) should also be excluded from the DSH calculation. CMS argued that premium assistance patients do not receive guaranteed health insurance coverage for inpatient hospital services. Rather, these patients receive money that can be used to purchase private health insurance that may not necessarily provide the same type of traditional Medicaid benefits. Further, CMS noted that premium assistance is usually offered on a sliding scale where individuals receiving premium assistance could be significantly wealthier than traditional Medicaid beneficiaries.

More recently, courts have decided that based on the language of current CMS regulations, CMS is required to count uncompensated care pool hospital payments and premium assistance in the numerator of the Medicaid fraction. The courts concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, the patient is eligible for the inpatient services within the meaning of the current regulation. Similarly, courts concluded that patients receiving premium assistance for insurance that covers inpatient hospital services also are eligible for inpatient services. CMS stated that this was not the intent of the regulations and continues to believe that it is inappropriate to include patient days associated with these types of expansion programs in the Medicare DSH calculation.

Therefore, CMS proposed to revise the regulation at 42 CFR 412.106(b)(4)(i) to explicitly state that a patient is deemed eligible for Medicaid for the purposes of the DSH calculation on a given day (and for that day to be included in the numerator of the Medicaid fraction) only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan that includes coverage for inpatient hospital care

on that day or directly receives inpatient hospital insurance coverage on that day under a waiver authorized under SSA section 1115(a)(2).

Final Rule: Due to the number and nature of the comments that CMS received on this proposal, CMS intends to address the public comments in a separate document.

d. New "COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)" Quality Measure

CMS proposed a new measure, COVID-19 Vaccination Coverage Among HCP, beginning with a shortened reporting period from October 2021 through December 2021. The measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19. The denominator would exclude persons with contraindications to COVID-19 vaccination. This measure is not endorsed by NQF, and the Measure Applications Partnership raised concerns, but provided conditional support for the measure. As described further below, CMS proposed to include this measure in the Hospital IQR Program and PPS-exempt Cancer Hospital Quality Reporting Program.

Final Rule: CMS finalized its proposal to adopt the COVID-19 Vaccination Coverage Among HCP measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 for the FY 2023 payment determination, and continuing with quarterly reporting deadlines for the CY 2022 reporting period/FY 2024 payment determination and subsequent years. CMS also finalized its proposal to publicly report the measure, which will begin with the October 2022 Care Compare refresh, or as soon as technically feasible, using data from Q4 2021. CMS finalized a proposal with modifications; specifically, instead of adding one additional quarter of data during each advancing refresh until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data, CMS will only report the most recent quarter of data.

e. Delay of Application of Non Complication or Comorbidity (NonCC) Subgroup Criteria to MS-DRGs

MS-DRGs are subdivided into one, two, or three severity level base DRGs. Specifically, CMS applies a five-factor test to determine whether creation of a Complication or Comorbidity (CC) subgroup, a Major Complication or Comorbidity (MCC) subgroup, or NonCC subgroup is warranted. In the FY 2021 IPPS final rule, CMS finalized the expansion of the five criteria to include the NonCC subgroup for a three-way severity level split. In evaluating requests to split an existing base MS-DRG into severity levels, CMS typically analyzes the most recent two years of data.

For FY 2022, CMS used the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file to analyze how applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure for FY 2022. CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) and the creation of 58 new MS-DRGs.[11] These updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases.

[11] For a list of the 96 MS-DRGs that would be subject to deletion and the 58 new MS-DRGs that would be proposed for creation in FY 2022 if this policy were applied, see Table 6P.1c, available at https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page.

CMS is concerned about the impact of implementing this volume of MS-DRG changes during the COVID-19 PHE, and believes it would be appropriate to delay application of the NonCC subgroup criteria to existing MS-DRGs in order to maintain more stability in the MS-DRG structure. As such, CMS proposed to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023.

Final Rule: finalized as proposed; application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split is delayed until FY 2023 or later.

II. Key Changes to the Hospital Wage Index

Overall, there were several proposed changes to the hospital wage index for FY 2022.[12] These primarily stem from the reinstatement of the imputed floor for all-urban States, as required by the American Rescue Plan Act of 2021 (ARPA). These proposed changes and their potential impacts are described in detail below.

a. Application of the Rural Floor, Application of the State Frontier Floor, Continuation of Low Wage Index Hospital Policy, and Budget Neutrality Adjustment

i. Rural Floor

Federal law requires that the area wage index applicable to any hospital located in an urban area may not be less than the area wage index applicable to hospitals located in rural areas in the same State. This is referred to as the rural floor. By law, the rural floor is subject to a national budget neutrality adjustment. CMS did not propose any changes to the rural floor policy for FY 2022.

ii. Imputed Floor for All-Urban States

For States without any rural areas—"all-urban States"[13]—CMS has historically adopted an imputed floor policy beginning in FY 2005 and ending in FY 2018. During this time period, CMS established two alternative methodologies to calculate the imputed floor for an all-urban state.

- The first, original imputed floor methodology, established in FY 2005, calculates the ratio of the lowest-to-highest Core Based Statistical Area (CBSA) wage index for each all-urban State, as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. The higher of these ratios is multiplied by the highest CBSA wage index value in the State to find the imputed floor for the State.
- The second, alternative imputed floor methodology was established in FY 2013 to address the concern that the first methodology does not benefit an all-urban State with only one CBSA. This methodology calculates the average percentage difference between the pre- and post-rural floor post-reclassified wage index for all CBSAs receiving the rural floor. The lowest post-reclassified wage index in an all-urban State is increased by this factor to establish the State's alternative imputed floor.

CMS implemented the second, alternative methodology in FY 2013, along with a policy that the minimum wage index value for a State is the higher of the value determined under the original or alternative

[12] Additional information, including hospital wage index data tables and Public Use Files, is available at the FY 2022 Wage Index Home Page (https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page).
[13] Delaware, New Jersey, Rhode Island, and, if finalized as proposed, Connecticut and Washington, D.C.

methodology. As stated above, the imputed floor policy was discontinued after FY 2018, and no imputed floor was applied for FYs 2019, 2020, and 2021.

Section 9831 of ARPA, enacted on March 11, 2021, reinstates the imputed floor wage index policy as was in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 to 2018, however, ARPA requires that the imputed floor wage index shall not be applied in a budget neutral manner. As such, CMS proposed to apply the imputed floor after the application of the rural floor and to apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. CMS was not able to incorporate the changes required by ARPA relating to the imputed floor into the calculation of the provider wage index for the proposed rule, but included it in the final rule. Estimated imputed floor values by state for FY 2022 are available on the CMS website.[14]

The amendments made by ARPA also added a definition of "all-urban State" for the purposes of the imputed floor wage index. Under the revised statute, "all-urban State" means a State in which there are no rural areas or a State in which there are no hospitals classified as rural. This definition would include a State that has a rural area but no hospitals that receive the State's rural area wage index. This definition applies to more States than the historical imputed floor policy, which was not applied to a State if it had a rural area, even if all hospitals in the rural area were reclassified to receive an urban area wage index. For the purposes of this definition, hospitals redesignated as rural through 42 CFR 412.103 rural reclassification would be considered classified as rural if they receive the rural wage index; however, hospitals that are deemed urban in Lugar[15] counties or are reclassified to an urban area through Medicare Geographic Classification Review Board (MGCRB) reclassifications would not be considered classified as rural because they do not receive the rural wage index. Under this expanded definition of "all-urban State," Connecticut would be eligible for the imputed floor because while there is one rural county in Connecticut, all hospitals in that county are either deemed urban or receive an MGCRB reclassification.

Further, because the term "State" is defined in the Social Security Act to include the District of Columbia and Puerto Rico, CMS interprets the new statutory definition of "all-urban State" to mean that the District of Columbia and Puerto Rico may also qualify if they meet the criteria.

Based on data available for the proposed rule, the following States would be all-urban States, whose hospitals would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, D.C.

Final Rule: finalized as proposed.

iii. State Frontier Floor

Federal law requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0. CMS proposed no changes to the frontier floor policy for FY 2022. As such, 44 hospitals located in Montana, North Dakota, South Dakota, and Wyoming would receive the frontier floor of 1.0 for their FY 2022 proposed wage index. Nevada, which also meets the criteria of a frontier State, does not have any hospitals that currently receive a wage index of less than 1.0.

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[14] See https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.

[15] "Lugar" counties are counties that would otherwise be rural, but due to their proximity and commuting patterns to one or more Metropolitan Statistical Areas, they are treated as urban counties. Subsequently, hospitals located in Lugar counties are deemed to be located in an urban area and their IPPS payments are determined based on the urban area to which they are reassigned.

Final Rule: finalized as proposed.

iv. Continuation of Low Wage Index Hospital Policy; Budget Neutrality Adjustment

CMS implemented the Low Wage Index Hospital Policy in the FY 2020 IPPS final rule,[16] which reduces the disparity between high and low wage index hospitals by (1) increasing the wage index for hospitals with a wage index value below the 25th percentile wage index value by half the value of the difference between the hospital's wage index and the 25th percentile wage index, and (2) applying the changes in a budget neutral manner. CMS noted that this policy is effective for at least four years, beginning in FY 2020. As such, CMS proposed to continue this policy in FY 2022, including the budget neutrality adjustment to the FY 2022 standardized amount similar to what was implemented for FY 2021. Based on the data available for the proposed rule, the FY 2022 proposed 25th percentile wage index value was 0.8418.

Final Rule: finalized as proposed. Based on updated data in the final rule, the FY 2022 25th percentile wage index value is 0.8437.

b. Proposed Core-Based Statistical Areas (CBSAs) for the FY 2022 Hospital Wage Index

In last year's FY 2021 IPPS final rule, CMS adopted revised geographic area delineations as set forth in an Office of Management and Budget (OMB) Bulletin (No. 18-04) issued in September 2018. These revised delineations resulted in significant changes, including hospital reclassifications in impacted areas. To mitigate the impact of these changes, CMS adopted a policy to place a 5 percent cap on any decrease in a hospital's wage index for FY 2021. This transition is set to expire at the end of FY 2021.

CMS sought comment on whether to continue to apply this transition to the FY 2022 wage index for hospitals negatively impacted by the adoption of updates from OMB Bulletin No. 18-04, in light of the impact of COVID-19. For example, such hospitals could be held harmless from any reduction relative to their FY 2021 wage index. CMS also sought comment on making this transition budget neutral, as is their usual practice, in the same manner as the transition implemented for FY 2021.

CMS proposed to adopt updates set forth in OMB Bulletin No. 20-01, issued March 6, 2020.[17] However, the revised geographic area delineations in OMB Bulletin No. 20-01 would not affect the Medicare wage index for FY 2022. Specifically, the updates consist of changes to New England City and Town Area (NECTA) delineations and the creation of a new Micropolitan Statistical Area, which was then added as a new component to an existing Micropolitan Statistical Area. Because CMS does not use NECTA definitions and includes Micropolitan Statistical Areas in each State's rural wage index, no specific wage index updates would be necessary as a result of adopting the changes in OMB Bulletin No. 20-01.

Final Rule: Based on comments received, CMS finalized an extended transition to the FY 2022 wage index for hospitals. Specifically, for hospitals that received the transition in FY 2021, CMS is continuing a wage index transition for FY 2022 under which it will apply a 5 percent cap on any decrease in the hospital's wage index compared to its wage index for FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. CMS is implementing the transition in a budget neutral manner.

c. Occupational Mix Adjustment to the FY 2022 Wage Index

[16] 84 Fed. Reg. 42044 (Apr. 16, 2019).
[17] Available here: https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.

CMS collects data every three years on the occupational mix of employees for each Medicare-participating short-term, acute care hospital in order to construct an occupational mix adjustment to the wage index. The occupational mix adjustment is meant to control for the effects of hospitals' employment choices on the wage index. Data collected in 2016 was used to compute the occupational mix adjustment for FYs 2019, 2020, and 2021. As such, FY 2022 is the beginning of a new three-year data cycle. CMS proposed to calculate the occupational mix adjustment for FY 2022 based on the 2019 Medicare Wage Index Occupational Mix Survey using its prior methodology. The proposed FY 2022 occupational mix adjusted national average hourly wage is $46.37. CMS proposed to apply the occupational mix adjustment to 100 percent of the FY 2022 wage index.

Final Rule: finalized as proposed. The final FY 2022 Occupational Mix Adjusted National Average Hourly Rate is $46.47. The effect of the finalized change to the occupational mix adjustment are demonstrated below.

Comparison of the FY 2022 Occupational Mix Adjusted Wage Indexes: 2016 Survey to 2019 Survey	
Number of Urban Areas Wage Index Increasing	198 (48.1%)
Number of Rural Areas Wage Index Increasing	18 (38.3%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	109 (26.5%)
Number of Urban Areas Wage Index Increasing by 5 percent or More	15 (3.6%)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	10 (21.3%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	3 (6.4%)
Number of Urban Areas Wage Index Decreasing	214 (51.9%)
Number of Rural Areas Wage Index Decreasing	29 (61.7%)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	117 (28.4%)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	15 (3.6%)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	19 (40.4 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	1 (2.1 %)
Largest Positive Impact for an Urban Area	14.58%
Largest Positive Impact for a Rural Area	6.1%
Largest Negative Impact for an Urban Area	10.76 %
Largest Negative Impact for a Rural Area	6.03 %

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

The MGCRB reclassification process allows hospitals to reclassify from one area to another for wage index purposes. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. MGCRB wage index reclassifications are effective for 3 years.

CMS proposed changes to the process by which a hospital can appeal an MGCRB decision to the Administrator. Specifically, CMS proposed to add flexibility to adapt to future technology platforms by permitting the Office of Attorney Advisor to specify the manner in which to submit a request for Administrator review. CMS also proposed to permit tolling for good cause of the 105 calendar days timeframe in which the Administrator can issue a decision in the case of review at the discretion of the Administrator, as is the current policy with hospital-requested reviews.

Final Rule: finalized as proposed.

The out-migration adjustment provides an increase in 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. CMS did not propose any changes to the methodology or data source for FY 2022's out-migration adjustment, and would continue to use commuting pattern data from 2008-2012.

Final Rule: finalized as proposed.

The 42 CFR 412.103 reclassification process allows urban hospitals to reclassify as rural. A hospital can have both an MGCRB and 42 CFR 412.103 reclassification simultaneously. If an application is approved by the CMS Regional Office after the FY ratesetting lock-in date, the final rule rural wage index value would most likely not include the data for this hospital in the ratesetting calculation. Hospitals could time their applications to avoid reducing the State's rural wage index, then cancel their rural reclassifications (effective for the next FY) and then reapply again after the lock-in date. CMS is concerned that some hospitals are gaming the system in this manner to manipulate a State's rural wage index to the detriment of the stability and accuracy of the Medicare wage index system. As such, CMS proposed that requests to cancel rural reclassifications must be submitted to the CMS Regional Office not earlier than one calendar year (CY) after the reclassification effective date. For example, a hospital that was approved to receive a rural reclassification effective October 1, 2021 would not be eligible to request cancelation until October 1, 2022. Further, CMS proposed to make cancellation requests effective for the FY that begins in the CY after the CY in which the cancelation request is submitted. For example, a cancelation request submitted on December 31, 2021 would be effective October 1, 2022; but a cancellation request submitted one day later on January 1, 2022 would not become effective until October 1, 2023.

Final Rule: CMS finalized its proposal that rural reclassification be in effect for at least one year before cancellation can be requested. However, CMS did not finalize its proposal to require cancellation requests be effective for the FY that begins in the CY after the CY in which the cancelation request is submitted. Rather, CMS is delaying and potentially revising this proposal, and will evaluate alternative methods to ensure that the policy effectively targets the form of wage index manipulation discussed above.

e. Other Wage Index Adjustments

CMS proposed to continue using its prior methodologies for verifying Worksheet S-3 Wage Data and computing the proposed FY 2022 Unadjusted Wage Index.

Final Rule: finalized as proposed. The final FY 2022 Unadjusted National Average Hourly Wage is $46.52.

III. Transparency Requirements

CMS did not propose any changes to the price transparency requirements finalized in the CY 2020 OPPS/ASC PPS, Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule. CMS proposed to repeal the market-based MS-DRG relative weight policies finalized in the FY 2021 IPPS final rule. Specifically, CMS proposed to repeal the prior policies, which:

- Required hospitals to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021 (42 CFR 413.20(d)(3));

- Established a new market-based methodology for calculating the IPPS MS-DRG relative weights to reflect relative market-based pricing (as submitted under the Medicare cost reporting requirement) beginning in FY 2024.

Final Rule: finalized as proposed. In addition, CMS did not finalize an alternative approach to maintain the market-based data collection requirement, but delay implementation. CMS states it will continue to evaluate and consider the usefulness and appropriateness of market-based data for ratesetting purposes.

IV. Chimeric Antigen Receptor (CAR) T-cell Therapies

a. Changes to MS-DRG 018 for CAR T-cell Immunotherapy

In the FY 2021 IPPS final rule, CMS finalized a new MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy" for cases reporting procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). Several commenters to the FY 2021 IPPS proposed rule expressed concern that MS-DRG 018 is specific to one mechanistic approach to cellular therapy and sought clarification on how future CAR T-cell and non-CAR T-cell therapy products would be assigned. CMS stated in the FY 2021 final rule that if additional cellular therapies became available, it would use its established process to determine the MS-DRG assignment. In the FY 2022 IPPS proposed rule, CMS noted that during the September 2020 ICD-10 Coordination and Maintenance Committee meeting, several topics involving requests for new procedure codes related to CAR T-cell therapies, non-CAR T-cell therapies and other immunotherapies were discussed.[18] CMS proposed to assign several new procedure codes listed below that were finalized through the ICD-10 Coordination and Maintenance Committee meeting process to MS-DRG 018. CMS also proposed to rename MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies that would be assigned to this MS-DRG.

ICD-10-PCS Code	Description	New?
XW033C3	Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3	No
XW043C3	Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3	No
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes

[18] Meeting materials available at https://www.cms.gov/files/document/september-2020-agenda-and-handouts.pdf.

XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	Yes
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	Yes

CMS also proposed to continue its relative weight methodology established in FY 2021 by excluding clinical trial claims when calculating the average costs for MS-DRG 018, so that the relative weight reflects the costs of the cellular therapy drug.

Final Rule: finalized as proposed.

b. Payment Adjustment for CAR T-cell Clinical Trial Cases

Cases involving clinical trials, like non-clinical trial cases, are generally paid using the relative weight for the MS-DRG to which the case is assigned. However, given that the drug cost is an extremely large portion of the total costs of the non-clinical trial CAR T-cell therapy cases, and that the relative weight for MS-DRG 018 assumes that the provider has incurred the costs of the CAR T-cell therapy drug, CMS finalized an adjustment to the payment amount for clinical trial cases that would group to MS-DRG 018 in the FY 2021 IPPS final rule. Consistent with the FY 2021 IPPS final rule, CMS proposed in the FY 2022 IPPS proposed rule to continue calculating this adjustment by (1) calculating the average cost for cases to be assigned to proposed new MS-DRG 018 that contain ICD-10-CM diagnosis code Z00.6 (a clinical trial-specific code) or contain standardized drug charges of less than $373,000; (2) calculating the average cost for cases to be assigned to MS-DRG 018 that do not contain ICD-10-CM diagnosis code Z00.6 or standardized drug charges of at least $373,000; (3) calculating an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2; and (4) applying this adjustor when calculating payments for clinical trial cases that group to MS-DRG 018 by multiplying the relative weight for MS-DRG 018 by the adjustor.

For FY 2022, based on the claims data from the March 2020 update of the FY 2019 MedPAR files, the ratio of the average cost for CAR T-cell therapy cases identified as clinical trial cases to the average cost for non-clinical trial CAR T-cell therapy cases is 0.17. As such, CMS proposed that the adjustor that would be applied to CAR T-cell therapy clinical trial cases would be 0.17.

CMS sought comment on an alternative approach of using the FY 2020 MedPAR file that it would ordinarily use for purposes of the FY 2022 rulemaking, rather than the FY 2019 MedPAR files as proposed.

CMS may consider finalizing this alternative approach for FY 2022 based on consideration of comments received. CMS notes that if it used the FY 2020 MedPAR file, the adjustor that would be applied to clinical trial cases assigned to MS-DRG 018 would be 0.25, rather than 0.17.

Final Rule: finalized as proposed, using FY 2019 MedPAR files and an adjustor of 0.17.

V. New Technology Add-on Payments (NTAPs)

CMS provides additional payment for new, high-cost technologies in the inpatient setting above the standard MS-DRG payment amount for technologies that meet three criteria: (1) the medical service or technology must be new (the "newness criterion"); (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 (the "cost criterion"); and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies (the "substantial clinical improvement criterion"). In addition, as finalized in FY 2021, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient NTAP pathway—specifically, devices that are part of FDA's Breakthrough Devices Program, drugs designated by the FDA as a Qualified Infectious Disease Product (QIDP), and, beginning in FY 2022, a drug approved by the FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). Under the alternative NTAP pathway, these products need only satisfy the cost criterion, as the newness and substantial clinical improvement criteria are presumed.

For new technologies other than a QIDP or LPAD for which the cost of discharge exceeds the full DRG payment, Medicare provides an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For QIDPs and LPADs, the add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

a. FY 2022 Status of Technologies Approved for FY 2021 NTAPs

Final FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments (NTAP)					
Technology	**Applicant**	**Newness Start Date**	**Continue or Discontinue NTAP for FY 2022**	**Max. NTAP Amt. for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
Azedra®	Progenics Pharmaceuticals, Inc.	5/21/2019[19]	Continue because 3-year anniversary date (5/21/2022) will occur in the second half of FY 2022	$98,150	XW033S5 and XW043S5
Balversa™	Johnson & Johnson o/b/o Janssen Oncology, Inc.	4/12/2019	Continue because 3-year anniversary date (4/12/2022) will occur in the second half of FY 2022	$3,563.23	XW0DXL5

[19] Newness start date updated in final rule in response to comments; was previously July 30, 2018. Because the later newness date extends Azedra's NTAP, it is no longer among the technologies subject to extended NTAPs (listed in the table under section V.b of this summary).

JAKAFI™	Incyte Corporation	5/24/2019	Continue because 3-year anniversary date (5/24/2022) will occur in the second half of FY 2022	$4,475.38[20]	XW0DXT5
BAROSTIM NEO® System	CVRx	8/16/2019	Continue because 3-year anniversary date (8/16/2022) will occur in the second half of FY 2022	$22,750	0JH60MZ in combination with 03HK0MZ or 03HL0MZ
FETROJA® (Cefiderocol)	Shionogi & Co., Ltd	2/24/2020	Continue because 3-year anniversary date (2/24/2023) will occur after FY 2022	$7,919.86	XW03366 or XW04366
Optimizer® System	Impulse Dynamics	10/23/2019	Continue because 3-year anniversary date (10/23/2022) will occur after FY 2022	$14,950	0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ
RECARBRIO™	Merck	1/6/2020	Continue because 3-year anniversary date (1/6/2023) will occur after FY 2022	$3,532.78	XW033U5 or XW043U5
Soliris®	Alexion	6/27/2019	Continue because 3-year anniversary date (6/27/2022) will occur in second half of FY 2022	$21,199.75	XW033C6 and XW043C6
XENLETA™	Nabriva Therapeutics	9/10/2019	Continue because 3-year anniversary date (9/10/2022) will occur in the second half of FY 2022	$1,275.75	XW03366, XW04366 or XW0DX66
ZERBAXA®	Merck	6/3/2019	Continue because 3-year anniversary date (6/3/2022) will occur in the second half of FY 2022	$1,836.98	XW03396 or XW04396

b. Proposal to Extend NTAPs

CMS typically uses FDA approval as the indicator of the time when a technology begins to become available on the market and the beginning of the two- to three-year timeframe during which new technologies are eligible for the NTAP. CMS does not typically consider case volume relevant to the determination as to whether a product is "new." CMS typically extends NTAPs for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming FY. However, in light of the unique circumstances for FY 2022 ratesetting stemming from the use of the FY 2019 MedPAR claims data rather than the FY 2020 MedPAR claims data due to the impacts of the COVID-19 PHE, CMS believed it appropriate to make a one-time exception to its NTAP discontinuation policy for all technologies approved for NTAPs for FY 2021, but for which the add-on payments would otherwise be discontinued beginning in FY 2022 because their 3-year anniversary date occurs prior to the second half of FY 2022. As such, CMS proposed to provide a one-year extension of NTAPs for such technologies. CMS noted that if it were to finalize its alternative approach of using the FY 2020 data for FY 2022 ratesetting, the agency would also finalize its proposal to discontinue the NTAPs for these technologies.

[20] Maximum NTAP amount updated in final rule based on updated wholesale acquisition cost (WAC) data; was previously $4,096.21.

Final Rule: CMS finalized its proposal to extend NTAPs for technologies that would normally be discontinued beginning in FY 2022. Specifically, technologies that would be normally be discontinued because their 3-year anniversary date occurs prior to the second half of FY 2022 are granted a one-year extension of NTAPs, as set forth in the table below.

Final One Year Extension for Technologies for which NTAPs Would Otherwise Be Discontinued in FY 2022					
Technology	**Applicant**	**Newness Start Date**	**NTAP Status for FY 2022**	**Max. NTAP Amt. for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
Cablivi®	Sanofi	2/6/2019	One-year extension; 3-year anniversary date (2/6/2022) will occur prior to the second half of FY 2022	$33,215	XW013W5, XW033W5 and XW043W5
Elzonris™	Stemline Therapeutics	12/21/2018	One-year extension; 3-year anniversary date (12/21/2021) will occur prior to the second half of FY 2022	$144,116.04[21]	XW033Q5 and XW043Q5
AndexXa™	Portola Pharmaceuticals, Inc.	5/3/2018	One-year extension; 3-year anniversary date (5/3/2021) will occur prior to the second half of FY 2022	$18,281.25	XW03372 or XW04372
Spravato®	Johnson & Johnson o/b/o Janssen Oncology, Inc.	3/5/2019	One-year extension; 3-year anniversary date (3/5/2022) will occur prior to the second half of FY 2022	$1,014.79	XW097M5
Zemdri®	Achaogen, Inc.	6/25/2018	One-year extension; 3-year anniversary date (6/25/2021) will occur prior to the second half of FY 2022	$4,083.75	XW033G4 and XW04G4
T2 Bacteria® Panel	T2 Biosystems, Inc.	5/24/2018	One-year extension; 3-year anniversary date (5/24/2021) will occur prior to the second half of FY 2022	$97.50	XXE5XM5
ContaCT	Viz.ai Inc.	10/1/2018	One-year extension; 3-year anniversary date (10/1/2021) will occur prior to the second half of FY 2022	$1,040	4A03X5D
Eluvia™ Drug-Eluting Vascular Stent System	Boston Scientific	10/4/2018	One-year extension; 3-year anniversary date (10/4/2021) will occur prior to the second half of FY 2022	$3,646.50	X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5
Hemospray®	Cook Medical	7/1/2018	One-year extension; 3-year anniversary date (07/01/2021) will occur prior to the second half of FY 2022	$1,625	XW0G886 and XW0H886

[21] Updated in final rule.

Final One Year Extension for Technologies for which NTAPs Would Otherwise Be Discontinued in FY 2022					
Technology	**Applicant**	**Newness Start Date**	**NTAP Status for FY 2022**	**Max. NTAP Amt. for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
IMFINZI®/ TECENTRIQ®	AstraZeneca PLC / Genentech, Inc.	3/18/2019	One-year extension; 3-year anniversary date (3/18/2022) will occur prior to the second half of FY 2022	$6,875.90	Imfinzi XW03336 or XW04336 Tecentriq XW033D6 or XW043D6
NUZYRA®	Paratek Pharmaceuticals	2/1/2019	One-year extension; 3-year anniversary date (2/1/2022) will occur prior to the second half of FY 2022	$1,552.50	XW033B6 or XW043B6
SpineJack® System	Stryker, Inc.	10/11/2018	One-year extension; 3-year anniversary date (10/11/2021) will occur prior to the second half of FY 2022	$3,654.72	XNU0356 and XNU4356
Xospata®	Astellas Pharma U.S., Inc.	11/28/2018	One-year extension; 3-year anniversary date (11/28/2021) will occur prior to the second half of FY 2022	$7,312.50	XW0DXV5

c. FY 2022 NTAP Applications

New Technology	*Applicant*	*FY 2022 Final Rule Outcome*
FY 2022 NTAP Applications (Traditional Pathway)		
Aidoc Briefcase for PE	Aidoc Medical Ltd.	**Not approved** – could not determine substantial clinical improvement
RYBREVANT™ (amivantamab)	Johnson & Johnson Health Care Systems, Inc.	**Approved** – maximum NTAP is $6,405.89 for FY 2022
Breyanzi® (lisocabtagene maraleucel)	Juno Therapeutics	**Not approved** – could not determine substantial clinical improvement; considered not new and substantially similar to YESCARTA® and KYMRIAH®
Ciltacabtagene autoleucel	Janssen Biotech, Inc.	*Application withdrawn*
COSELA (Trilaciclib)	G1 Therapeutics	**Approved** – maximum NTAP is $5,526.30 for FY 2022
Ellipsys® Vascular Access System	Avenu Medical, Inc.	**Not approved** –considered not new and substantially similar to original version
ENSPRYNG™	Genentech, Inc.	**Not approved** – could not determine substantial clinical improvement
ABECMA® (idecabtagene vicleucel)	Celgene Corporation	**Approved** – maximum NTAP is $272,675.00 for FY 2022
INDIGO® Aspiration System with Lightning Aspiration Tubing	Penumbra, Inc.	**Not approved** – could not determine substantial clinical improvement
Ischemia Care Respiratory and Stroke Test Kit	Ischemia Care, LLC	*Did not receive FDA approval by July 1, 2021*
Lifileucel	Iovance Biotherapeutics	*Application withdrawn*
Narsoplimab	The Omeros Corporation	*Application withdrawn*

NexoBrid™	Vericel Corporation	*Application withdrawn*
Olumiant® (baricitinib)	Eli Lilly and Company	*Did not receive FDA approval or clearance by July 1, 2021*
Pure-Vu® System	Motus GI Holdings, Inc.	**Not approved** – could not determine substantial clinical improvement
Rapid ASPECTS	iSchemaView (soon to be RapidAI)	**Not approved** – could not determine substantial clinical improvement
Steripath® Micro™ Blood Collection System	Magnolia Medical Technologies, Inc.	**Not approved** – could not determine substantial clinical improvement
StrataGraft™ Skin Tissue	Stratatech Corporation	**Approved** – maximum NTAP is $44,200.00 for FY 2022
Tecartus™ (brexucabtagene autoleucel)	Kite Pharma	**Approved –** maximum NTAP is $259,350.00 for FY 2022
TERLIVAZ® (terlipressin)	Mallinckrodt Pharmaceuticals	*Application withdrawn*
VEKLURY® (remdesivir)	Gilead Sciences, Inc.	**Approved –** maximum NTAP is $2,028.00 for FY 2022[22]
ZEPZELCA™ (lurbinectedin)	Jazz Pharmaceuticals	**Approved –** maximum NTAP is $8,622.90 for FY 2022
FY 2022 NTAP Applications (Alternative Pathways)		
Alternative Pathway for Breakthrough Devices		
Aprevo™ Intervertebral Body Fusion Device	Carlsmed, Inc.	**Approved –** maximum NTAP is $20,475.00 for FY 2022
aScope™ Duodeno	Ambu, Inc.	**Approved –** maximum NTAP is $1,715.59 for FY 2022
Caption Guidance™	Caption Health, Inc.	**Approved –** maximum NTAP is $1,868.10 for FY 2022
CERAMENT® G	BONESUPPORT Inc.	*Did not receive FDA approval or clearance by July 1, 2021*
EXALT™ Model D Single-Use Duodenoscope	Boston Scientific Corporation	**Approved –** maximum NTAP is $1,715.59 for FY 2022
FUJIFILM EP-7000X System	Fujifilm Corporation	**Not approved** – no operating costs
Harmony™ Transcatheter Pulmonary Valve (TPV) System	Medtronic	**Approved –** maximum NTAP is $26,975.00 for FY 2022
Neovasc Reducer™	Neovasc Inc.	*Application withdrawn*
Phagenyx® System	Phagenesis Ltd.	*Did not receive FDA approval or clearance by July 1, 2021*
PRCFC (pathogen reduced cryoprecipitated fibrinogen complex)	Cerus Corporation	**Approved –** maximum NTAP is $2,535.00 for FY 2022
RECELL® Autologous Cell Harvesting Device	Avita Medical	**Not approved** –considered not new
Shockwave C2 Intravascular Lithotripsy (IVL) System	Shockwave Medical Inc.	**Approved –** maximum NTAP is $3,666.00 for FY 2022
Thoraflex™ Hybrid Device	Terumo Aortic	*Application withdrawn*
Alternative Pathways for Qualified Infectious Disease Products (QIDPs)		
CONTEPO™ (Fosfomycin)	Nabrivia Therapeutics US, Inc.	**Approved –** maximum NTAP is $2,625.00 for FY 2022
FETROJA® (cefiderocol) (specific to HABP/VABP indications)	Shionogi & Co., Ltd	**Approved –** maximum NTAP is $8,579.84 for FY 2022

[22] Note that cases involving the use of VEKLURY® in FY 2022 are eligible for both NTAPs and New COVID-19 Treatments Add-on Payments (NCTAPs). The NCTAP for an eligible case will be reduced by the amount of any NTAP. As such, cases involving the use of VEKLURY® are eligible for both NTAPs and NCTAPs, with the NCTAP to be reduced by a maximum of $2,028 for the same treatment.

RECARBRIO™ (imipenem, cilastatin, and relebactam) (specific to HABP/VABP indications)	Merck & Co.	**Approved –** maximum NTAP is $9,577.00 for FY 2022

d. Treatment of NTAP Newness Period for Products Available through an Emergency Use Authorization (EUA) for COVID-19

CMS's general policy is to begin the newness period for technologies subject to NTAPs on the date of FDA approval or clearance, or, if later, the date of availability of the product on the U.S. market, when data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In the FY 2021 IPPS final rule, CMS specified the various types of FDA approvals, clearances, licensures, and classifications that CMS considers under its NTAP policy, clarifying that new technologies must receive FDA marketing authorization (e.g., pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the FY for which the application is being considered. Under longstanding CMS policy, an EUA allows a product to be used for emergency use, but would not be considered an FDA marketing authorization for the purpose of NTAPs, as a product available only through an EUA is not considered to have an FDA approval or clearance. As such, CMS believes a product available only through an EUA would not be eligible for NTAPs.

CMS sought comment on how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for NTAPs for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

Final rule: CMS responded to comments and concluded that as the safety and effectiveness of therapies under an EUA continue to be evaluated, CMS is therefore unable to consider EUA as FDA marketing authorization for the purposes of NTAPs. As such, CMS will not consider costs of a product with an EUA for the purposes of the 2-year to 3-year period of newness for NTAP eligibility, and will continue to determine the start of the newness period based on the date of FDA approval or clearance.

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

In an interim final rule with comment period issued November 6, 2020,[23] CMS established the NCTAP under the IPPS for COVID-19 cases that meet certain criteria. The purpose of NCTAPs is to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. As such, effective for discharges occurring on or after November 2, 2020 and until the end of the COVID-19 PHE, CMS established the NCTAP to pay hospitals the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID-19.

[23] See 85 Fed. Reg. 71142 (Nov. 6, 2020) at 71157-58.

CMS anticipates that there might be inpatient cases of COVID-19 beyond the end of the PHE for which payment based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, CMS proposed to continue the NCTAP for cases involving eligible treatments for the remainder of the FY in which the PHE ends (for example, if the PHE were to end in FY 2022, until September 30, 2022).

Further, CMS believes that any NTAPs approved for a COVID-19 treatment (such as remdesivir, which is the subject of an application for FY 2022 NTAP) would sufficiently mitigate potential financial disincentives for hospitals to provide such new COVID-19 treatment, such that the NCTAP would no longer be necessary. As such, CMS proposed to discontinue the NCTAP beginning on or after October 1, 2021 for a product that is approved for NTAPs beginning FY 2022.

Final Rule: CMS finalized its proposal to extend NCTAPs through the end of the fiscal year in which the PHE ends. CMS did not finalize its proposal to discontinue NCTAP for discharges on or after October 1, 2021 for a product that is approved for NTAPs beginning in FY 2022. Instead, CMS finalized extension of NCTAP through the end of the FY in which the PHE ends for all eligible products, including those approved for NTAPs for FY 2022. However, CMS will reduce the NCTAP for an eligible case by the amount of any NTAPs so that there is no financial disincentive between technologies with both NCTAP and NTAP compared to technologies with NCTAP only.

VI. Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME) Costs

a. IME Payment Adjustment Factor

SSA section 1886(d)(5)(B)(ii)(XII) provides that, for discharges occurring during FY 2008 and FYs thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2022, the formula multiplier is 1.35. CMS estimated that application of this formula multiplier for the FY 2022 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

Final Rule: finalized as described in the proposed rule.

b. Implementing the Consolidated Appropriations Act of 2021 (CAA)

Division CC of the CAA contained three provisions that affect Medicare IME and DGME payments to teaching hospitals (sections 126, 127, and 131). CMS proposed regulations to implement these provisions.[24]

Final Rule: due to the large number and nature of comments in response to the proposed policies, CMS intends to address these comments and final policies in a separate document.

i. Proposal for Intern and Resident Information System (IRIS) Data

Effective for cost reporting periods beginning on or after October 1, 2021, CMS proposed that hospitals must comply with these IRIS updates and inconsistency in the calculation will result in the cost report being rejected for lack of supporting documentation. Providers also would be required to use the new XML IRIS format for all cost reports beginning October 1, 2021.

[24] See 86 Fed. Reg. 25502-25523.

Final Rule: finalized with modifications. While the GME (weighted and unweighted) and IME FTE counts on the submitted IRIS must match the total GME and IME FTE counts reported on the cost report, for cost reporting periods beginning on or after October 1, 2021 and before October 1, 2022, the cost reports will not be rejected if the GME (weighted and unweighted) and IME FTEs on the submitted IRIS do not match the total related FTEs reported on the cost report. Further, CMS finalized the requirement that the IRIS data must be in the XML format for cost reporting periods beginning on or after October 1, 2021.

VII. RCH Demonstration

Division CC, section 128 of the CAA requires a 15-year extension period of the RCH demonstration (an additional five years beyond the current extension period) beginning immediately after the last day of the initial 5-year period, instead of the 10-year extension period mandated by the Cures Act. In addition, the CAA provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. CMS notes that four hospitals ended the 5-year period authorized by the Cures Act during FY 2020.

CMS proposed to adhere to the policy finalized for the previous extensions and apply the cost-based reimbursement methodology to the date following the last day of the previous period for each hospital that elects to continue participation. Further, CMS proposed that each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023, and the hospital that withdrew in February 2020, would be eligible for an additional 5-year period starting after the hospital's specified end date. Under this proposal, the participation period for the last hospital in the model would be extended until June 30, 2028.

For the newly enacted extension period, CMS proposed to continue to use the general budget neutrality methodology used in previous years. For FY 2022, CMS proposed to use a methodology similar to the one used in previous years to estimate demonstration costs. CMS conducted its estimate for FY 2022 based on the 27 hospitals that are eligible to continue participation in the demonstration for FY 2022. In the proposed rule, CMS estimated the amount of costs of the demonstration to be $63.8 million, which would be incorporated into the budget neutrality offset adjustment for FY 2022. CMS proposed to subtract this amount from the national IPPS rates for FY 2022.

Final Rule: finalized as proposed. For FY 2022, CMS estimates the amount of the costs of the demonstration to be $65.8 million, which will be incorporated into the budget neutrality offset adjustment for FY 2022.

VIII. Key Changes to the Hospital Quality Programs

a. Hospital Readmissions Reduction Program (HRRP) (42 CFR 412.150-412.154)

Under HRRP, Medicare payments for discharges may be reduced to account for certain excess readmissions. This rule makes changes to HRRP to respond to the impact of the COVID-19 pandemic as well as makes appropriate updates to attempt to link payment to quality hospital care.

i. Flexibility for Changes that Affect Quality Measures during a Performance Period in HRRP

CMS recognizes that the COVID-19 PHE is a significant external factor that is impacting the provision of care across the country and that the HRRP quality measurement scores may be distorted and impact payment for hospitals. To account for the PHE, CMS proposed to adopt a policy for the duration of the PHE that would suppress the use of quality measures via adjustment to the HRRP's scoring methodology

if necessary. Under the policy, if CMS determines that the suppression of a measure is warranted, it will calculate the measure's rates for that program year but then suppress the use of those rates to make changes to hospitals' Medicare payments. In effect, this would have the effect of temporarily weighting the affected measure at zero percent in the HRRP's scoring methodology until adjustments are made, the affected portion of the performance period for the measure is no longer applicable to program scoring, or the measure is removed entirely through rulemaking.

CMS also developed a number of Measure Suppression Factors that they believe should guide any determination to propose to suppress a measure for one or more program years that overlap with the PHE. These take into consideration the circumstances caused by the COVID-19 PHE that would affect a quality measure significantly enough to warrant suppression in a value-based purchasing program. CMS proposed to adopt the following factors:

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

Final Rule: finalized as proposed.

ii. Proposals to Address the Impact of COVID-19 on Current HRRP Measures

In response to the COVID-19 PHE, CMS conducted an analysis of the six current HRRP measures to determine whether and how COVID-19 may have impacted the condition/procedure-specific readmission measures. CMS determined that the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization measure (30-Day Pneumonia Readmission Measure) was severely impacted and cannot be fairly assessed. However, in the September 2020 IFC,[25] CMS noted it would except the use of any first or second quarter CY 2020 claims from its calculation for applicable FYs. Under the exception, the FY 2022 applicable period for this measure would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data from the COVID-19 PHE. Therefore, CMS has determined that it is not necessary to suppress this measure for the FY 2022 program year. However, CMS proposed to suppress this measure for the FY 2023 program year.

Final Rule: finalized as proposed.

CMS did not propose to suppress the five remaining condition/procedure-specific measures. However, CMS did propose technical changes to the measures discussed below.

Proposal to Suppress the CMS 30-Day Pneumonia Readmission Measure for FY 2023 Program Year

[25] 85 Fed. Reg. 54833 (Sept. 2, 2020).

CMS proposed to temporarily suppress the 30-Day Pneumonia Readmission Measure for the FY 2023 program year under the proposed suppression factor 2 (described above). This would mean the measure would be weighted at zero percent in the HRRP payment methodology. CMS would continue to monitor the measure and provide feedback reports to hospitals to ensure they are aware of the proposed changes in the performance rates.

Final Rule: finalized as proposed.

Technical Measure Specific Update to Exclude COVID-19 Diagnosed Patients from All Other Condition/Procedure-specific Readmission Measures Beginning with FY 2023

CMS will update the remaining five measures[26] to exclude COVID-19 diagnosed patients from the measure denominators. These are technical updates to measure specifications pursuant to the subregulatory process to incorporate technical measure specification updates finalized in the FY 2015 IPPS final rule.[27] CMS states that the update will modify the measures to exclude certain ICD-10 Codes that represent patients with a secondary diagnosis of COVID-19 from the measure denominators.

Final Rule: finalized as proposed.

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

As finalized in the FY 2019 and FY 2020 IPPS final rules, the "applicable period" to calculate the readmission payment adjustment factor for FY 2022 is the 3-year time period of July 1, 2017 through June 30, 2020 (first and second quarter data from CY 2020 is excluded from consideration due to nationwide extraordinary circumstance exception granted due to the COVID-19 PHE, as described below).

CMS did not propose any updates to its policy regarding the automatic adoption of "applicable periods" for FY 2023 and subsequent years. As finalized in the FY 2021 IPPS final rule, the applicable period for the HRRP beginning in FY 2023 will be the 3-year period beginning one year advanced from the previous program FY's start of the applicable period. In other words, the applicable period for FY 2023 would be the 3-year time period of July 1, 2018 through June 30, 2021. For all subsequent years, CMS would advance the 3-year period by one year unless other specified by CMS, which would be conveyed through rulemaking.

iv. Proposal to Identify Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2022

When calculating the numerator (aggregate payments for excess readmissions), CMS determines the base operating DRG payment amount for an individual hospital applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. For FY 2022, CMS proposed to continue to exclude admissions for patients enrolled in Medicare Advantage, as identified in the Medicare Enrollment Database. CMS proposed to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR

[26] Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505); Hospital 30-Day, All-Cause, Unplanned, RSRR Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515); Hospital 30-Day, All-Cause, RSRR Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891); Hospital 30-Day, All-Cause, RSRR Following Heart Failure Hospitalization (NQF #0330); and Hospital-Level 30-Day, All-Cause RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).
[27] 79 FR 50039.

claims with discharge dates that align with the FY 2022 applicable period. In addition, CMS proposed to use the update of the MedPAR file for each FY, which is updated six months after the end of each FY within the applicable period as its data source.

Final Rule: finalized as proposed.

v. Automatic Adoption of the Use of MedPAR Data Corresponding to the Applicable Period beginning in FY 2023

CMS proposed to automatically adopt the use of MedPAR data corresponding to the applicable period for the HRRP calculations for FY 2023 and all subsequent program years. Beginning in FY 2023, the MedPAR data used to calculate aggregate payments for each condition/procedure and for all discharges would be the 3-year period beginning one year advanced from the previous program fiscal year's MedPAR data corresponding to the applicable period for the HRRP calculations. For all subsequent years, CMS would advance this three-year period by one year unless changed through rulemaking. CMS also proposed to automatically adopt the use of the update of the MedPAR file for each FY as its data source and to similarly advance this by one year from the previous program fiscal year.

Final Rule: finalized as proposed.

vi. Extraordinary Circumstances Exception (ECE) policy for HRRP

CMS adopted the HRRP ECE policy in the FY 2016 IPPS final rule, recognizing that there may be periods of time that a hospital is not able to submit data in an accurate or timely fashion due to an extraordinary circumstance beyond the hospital's control. In the September 2020 IFC,[28] CMS updated the previously announced application of the COVID-19 ECE to exclude any data submitted regarding care provided during the first and second quarters of 2020 for FY 2022, FY 2023, and FY 2024. Comments solicited on this policy in the IFC are addressed in the FY 2022 IPPS/LTCH final rule. In response to the nationwide ECE, several hospitals requested individual ECEs due to extraordinary circumstances from the continuing impact of the PHE. In the proposed rule, CMS clarified that although an approved ECE for the HRRP would exclude excepted data from the HRRP payment reduction calculations, it did not propose to waive claims data submission requirements. CMS explained that the HRRP only uses claims data, and hospitals must continue to submit claims in order to receive reimbursement outside the scope of the HRRP for services provided. CMS also clarified that the HRRP ECE policy excludes excepted data from HRRP payment reduction calculations, but does not exempt hospitals from HRRP payment reductions altogether.

CMS also conducted an analysis on the impact of excluding the first two quarters of data from HRRP and found it would have minimal impact. CMS found that there would be a minimal impact on hospitals if six months of data were removed from HRRP calculations. CMS notes that they are performing additional analyses as CY 2020 data becomes available. Finally, CMS clarified that the impact of the nationwide ECE on payment adjustment factor components will be addressed through the subregulatory process.[29]

CMS also proposed to update regulatory text to refer to the "Hospital Compare" website as "Care Compare" or "successor website" throughout the applicable regulations for HRRP.

Final Rule: finalized as proposed.

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[28] 85 Fed. Reg. 54833 (Sept. 2, 2020).
[29] For more details on these subregulatory updates, see the Hospital Specific Report (HSR) User Guide at: https://qualitynet.cms.gov/inpatient/hrrp/reports.

b. Hospital Value-Based Purchasing (VBP) Program

Under the Hospital VBP program, value-based incentive payments are made to hospitals that meet performance standards established for a performance period.

i. Flexibilities for the Hospital VBP Program in Response to the COVID-19 PHE

1. Measure Suppression Policy During the COVID-19 PHE

CMS has recognized the need for flexibility in its quality programs to account for external factors that negatively impact performance that is outside the control of providers. CMS recognizes that the COVID-19 PHE is one such external factor that impacts quality. Further, CMS recognizes that the Hospital VBP quality scores that are calculated using data submitted during the PHE are distorted and will result in skewed payment incentives and inequitable payments, particularly for hospitals that have treated more COVID-19 patients than others.

Therefore, CMS proposed to adopt a policy for the duration of the COVID-19 PHE to enable it to suppress the use of data for a number of measures, if the agency determines that the PHE has affected measures and performance scores significantly. CMS also proposed to suppress all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains for the FY 2022 program year as the COVID-19 PHE has significantly affect those measures, and will adopt a special scoring and payment rule for that program year. Under the special rule for FY 2022, CMS would calculate measure rates for all measures, including the measures CMS proposed to suppress, but would only calculate achievement and improvement scores for the measures in the Clinical Outcomes Domain, which CMS did not propose to suppress. Because the Clinical Outcomes Domain is only weighted at 25 percent of the total performance score (TPS) and because CMS would have no other Domain scores, CMS proposed not to calculate TPSs for hospitals. Lastly, CMS would reduce each hospital's base-operating DRG payment amount by two percent, as required by law, but because no hospital would receive a TPS for FY 2022, CMS would assign to each hospital a value-based incentive payment percentage that results in a value-based incentive payment amount that matches the two percent reduction to the base-operating DRG payment amount. According to CMS, the net result of the adjustments would be neutral for hospitals.

For the FY 2023 program year, CMS proposed to suppress only one measure, Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) (MORT-30-PN), because CMS has determined it has been affected significantly by the COVID-19 PHE. However, CMS did not propose any changes to the FY 2023 scoring methodology, as it believes that suppression of this measure sufficiently minimizes the negative impact on the eligibility, scoring, and payment distributions under the Hospital VBP Program. Although the FY 2024 and FY 2025 program years rely on CY 2020 data, CMS did not propose to suppress the MORT-30-PN measure during those years at this time.

CMS considered circumstances caused by the COVID-19 PHE that would affect a quality measure significantly to warrant its suppression in the Hospital VBP program. CMS proposed the following measure suppression factors, which are identical to the factors for HRRP:

1. Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
2. Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID-19.

3. Rapid or unprecedented changes in: (1) clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or (2) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly of a novel disease or pathogen of unknown origin.
4. Significant national shortages or rapid or unprecedented changes in: (1) healthcare personnel; (2) medical supplies, equipment, or diagnostic tools or materials; or (3) patient case volumes or facility-level case mix.

Final Rule: finalized as proposed.

2. Proposals to Suppress Specific Measures for the FY 2022 or FY 2023 Program Year

CMS conducted an analysis of the Hospital VBP measures with the exception of CMS Patient Safety and Adverse Events Composite (CMS PSI-90) (NQF #0531) to determine whether COVID-19 has impacted the validity of these measures. CMS did not analyze CMS PSI-90 as it would not be included in TPS calculations until FY 2023 and CMS proposed to remove the measure beginning with FY 2023. CMS proposed to suppress the following measures for the FY 2022 program year:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166) (Person and Community Engagement Domain)
- Medicare Spending Per Beneficiary (MSPB) – Hospital (NQF #2158) (Efficiency and Cost Reduction Domain)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (Safety Domain)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (Safety Domain)
- American College of Surgeons – Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Safety Domain)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measures (NQF #1716) (Safety Domain)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) (Safety Domain)

As mentioned above, CMS also proposed to suppress MORT-30-PN for the FY 2023 program year.

Proposal to Suppress the HCAHPS Survey Measure (NQF #0166) for the FY 2022 Hospital VBP Program Year

CMS proposed to suppress this measure for FY 2022 under measure suppression factor 1 (described above). CMS would calculate hospitals' HCAHPS measure rates but would not use the measure to generate achievement or improvement points for the measure. Since this measure is the only measure in the Person and Family Engagement Domain, the domain would not be calculated in FY 2022. Hospitals would still report the measure's data to CMS and CMS would continue to provide confidential feedback reports as well as publicly report 2020 Q3 and Q4 measure rate data, with appropriate caveats.

Final Rule: finalized as proposed.

Proposal to Suppress the MSPB measure (NQF #2158) for the FY 2022 Hospital VBP Program Year

CMS proposed to suppress this measure for the FY 2022 program year under the measure suppression factor 4 (described above). CMS would calculate hospitals' measure rates but would not use the rates to generate achievement or improvement points for the measure. Since this measure is the only measure included in the Efficiency and Cost Reduction Domain, CMS would not calculate the domain for FY 2022. Hospitals would continue to report the measure's data to CMS and CMS would continue to provide feedback in confidential reports while also publicly reporting CY 2020 Q3 and Q4 data, with appropriate caveats.

Final Rule: finalized as proposed.

Proposal to Suppress the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2022 Hospital VBP Program Year

CMS proposed to suppress the five HAI safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) under the proposed suppression factor 1 (described above). CMS would calculate the measures but would not use them to measure achievement or improvement. Since these measures make up the entirety of the Safety Domain, CMS would not calculate hospitals' FY 2022 Safety Domain score for the domain. Hospitals would continue to report the measure's data and CMS would provide confidential feedback reports while also publicly reporting CY 2020 Q3 and Q4 data with appropriate caveats.

Final Rule: finalized as proposed.

Proposal to Suppress the MORT-30-PN Measure (NQF #0468) for the FY 2023 Program Year

CMS proposed to suppress the MORT-30-PN measure beginning with the FY 2023 program year under the proposed suppression factor 2 (described above). From the currently available data, CMS found a high percentage of Medicare beneficiaries that had pneumonia and COVID-19 and therefore believed this measure was skewed due to the COVID-19 PHE. CMS would still calculate the measure but would not use it to generate achievement and improvement points for the measure. CMS would also continue to provide confidential feedback reports to hospitals. CMS also explained that the FY 2022 performance period for this measure is September 1, 2017 through June 30, 2020. However, CMS is not using any first or second quarter data for CY 2020 (as described above). Therefore, CMS does not believe it is necessary to suppress the measure for FY 2022.

Final Rule: finalized as proposed.

ii. FY 2022 Program Year Payment Details

In the FY 2022 IPPS/LTCH PPS proposed rule, CMS explained that if the proposed policies related to the measure suppression for the FY 2022 program year are finalized, each hospital would receive the payment reduction for the Hospital VBP Program as required by statute (SSA section 1886(o)). CMS also described how, if the policies are not finalized, the FY 2022 program year payment details would be impacted. Additionally, CMS noted if the proposals to suppress measures are ***not*** finalized, CMS will rely on Table 16A of the proposed rule. However, if the proposals are finalized, CMS said it will rely on Table 16 of the proposed rule. Further, if CMS explained that if the policies are finalized as proposed, CMS will *not* post Table 16B, which CMS typically does to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the applicable program year, after hospitals have been given an opportunity to review and correct their actual TPSs.[30]

[30] The tables referenced in this section are available here: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page#1735.

Final Rule: CMS finalized the policies related to measure suppression for the FY 2022 program year as proposed. Therefore, hospitals will receive the payment reduction for the Hospital VBP Program as required by statute (SSA section 1886(o)). Additionally, CMS did not update Table 16 as Table 16A in the final rule and did not post Table 16B.

iii. Retention and Removal of Quality Measures

CMS did *not* propose: (1) changes to the retention of previously adopted Hospital VBP Program measures and to the relationship between the Hospital IQR and Hospital VBP Program measures sets; (2) changes to the measure removal factors for the Hospital VBP Program; and (3) to add new measures to those adopted in the FY 2021 IPPS final rule for the FY 2023, 2024, and 2025 program years. Therefore, the Hospital VBP Program measure set for the FY 2022, 2023, 2024, and 2025 program years contains the following measures:

Table V.H-4: Summary of Measures for the FY 2022 Program Year with Finalized Measure Proposals

Measure Short Name	Domain/Measure Name	NQF #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter- Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility- wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility- wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP- KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB*	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* As described above, CMS finalized its proposal to suppress these measures for the FY 2022 program year.

Table V.H-5: Summary of Measures for the FY 2023, FY 2024, and FY 2025 Program Years with Finalized Measure Proposals		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter- Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility- wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility- wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN* (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30- COPD*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30- CABG*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP- KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for FY 2023 and exclude patients with a principal or secondary diagnosis of COVID-19 from the measure denominators in the remaining condition-specific mortality measures.

CMS proposed:

- To remove the CMS Patient Safety and Adverse Events Composite (CMS PSI-90) measure (NQF #0531) under removal Factor 8 (the costs associated with the measure outweigh the benefit of its use in the program). This would be effective beginning with the FY 2023 program year.
- To update the following four condition-specific mortality measures and one procedure-specific complication measure to exclude patients with either principal or secondary diagnoses of COVID-19 from the measure denominators beginning with the FY 2023 program year:
    - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following AMI Hospitalization (NQF #0230);

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery (NQF #2558);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following COPD Hospitalization (NQF #1893);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229); and
- Hospital-Level Risk-Standardized Complication Rate Following Elective Primary THA and/or TKA (NQF #1550).

CMS notes that it does not need to update these measures for the FY 2022 program year because the only data that would have been affected by the COVID-19 PHE is from the first and second quarters of CY 2020, which are excluded under the ECE granted due to the COVID-19 PHE.

Final Rule: finalized as proposed.

iv. Previously Adopted Baseline and Performance Periods

CMS proposed to update the baseline periods for the FY 2024 program year due to the ECE granted in response to the COVID-19 PHE as reflected in the following tables.

Table V.H-6: Previously Adopted Baseline and Performance Periods for the FY 2023 Program Year

Domain	Baseline Period	Performance Period
Person and Community Engagement • HCAHPS	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30- COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** • COMP-HIP-KNEE	• July 1, 2013 – June 30, 2016 • April 1, 2013 – March 31, 2016	• July 1, 2018 – June 30, 2021* • April 1, 2018 – March 31, 2021*
Safety*** • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021
Efficiency and Cost Reduction • MSPB	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf),* and then updated in the August 25th COVID-19 IFC (*85 FR 54820*).

** As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for the FY 2023 program year.

*** As described above, CMS finalized its proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year, which is the first year it would have been included in TPS calculations.

Table V.H-7: Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement • HCAHPS	• January 1, 2019 – December 31, 2019*	• January 1, 2022 – December 31, 2022
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30- COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** • COMP-HIP-KNEE	• July 1, 2014 – June 30, 2017 • April 1, 2014 – March 31, 2017	• July 1, 2019 – June 30, 2022* • April 1, 2019 – March 31, 2022*
Safety*** • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2019 – December 31, 2019*	• January 1, 2022 – December 31, 2022
Efficiency and Cost Reduction • MSPB	• January 1, 2019 – December 31, 2019*	• January 1, 2022 – December 31, 2022

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf),* and then updated in the August 25th COVID-19 IFC (*85 FR 54820*). CMS finalized its proposal to update the baseline periods for the measures included in the Person and Family Engagement, Safety, and Efficiency and Cost Reduction domains.
** As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for the FY 2023 program year.
*** As described above, CMS finalized its proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year, which is the first year it would have been included in TPS calculations.

Table V.H-8: Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement • HCAHPS	• January 1, 2021 – December 31, 2021	• January 1, 2023 – December 31, 2023
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30- COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** • COMP-HIP-KNEE	• July 1, 2015 – June 30, 2018 • April 1, 2015 – March 31, 2018	• July 1, 2020 – June 30, 2023 • April 1, 2020 – March 31, 2023*
Safety*** • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2021 – December 31, 2021	• January 1, 2023 – December 31, 2023
Efficiency and Cost Reduction • MSPB	• January 1, 2021 – December 31, 2021*	• January 1, 2023 – December 31, 2023

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-*

participating-quality-reporting; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf),* and then amended in the August 25th COVID-19 IFC (*85 FR 54820*).
** As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for the FY 2023 program year.
*** As described above, CMS finalized its proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year, which is the first year it would have been included in TPS calculations.

Table V.H-9: Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2026 Program Year

Domain	Baseline Period	Performance Period
Person and Community Engagement • HCAHPS	• January 1, 2022 – December 31, 2022	• January 1, 2024 – December 31, 2024
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30- COPD, MORT-30-CABG, MORT-30-PN (updated cohort)* • COMP-HIP-KNEE	• July 1, 2016 – June 30, 2019 • April 1, 2016 – March 31, 2019	• July 1, 2021 – June 30, 2024 • April 1, 2021 – March 31, 2024
Safety** • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2022 – December 31, 2022	• January 1, 2024 – December 31, 2024
Efficiency and Cost Reduction • MSPB	• January 1, 2022 – December 31, 2022	• January 1, 2024 – December 31, 2024

* As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for the FY 2023 program year.
** As described above, CMS finalized its proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year, which is the first year it would have been included in TPS calculations.

Table V.H-10: Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2027 Program Year

Domain	Baseline Period	Performance Period
Person and Community Engagement • HCAHPS	• January 1, 2023 – December 31, 2023	• January 1, 2025 – December 31, 2025
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30- COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** • COMP-HIP-KNEE	• July 1, 2017 – June 30, 2020* • April 1, 2017 – March 31, 2020*	• July 1, 2022 – June 30, 2025 • April 1, 2022 – March 31, 2025
Safety*** • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2023 – December 31, 2023	• January 1, 2025 – December 31, 2025
Efficiency and Cost Reduction • MSPB	• January 1, 2023 – December 31, 2023	• January 1, 2025 – December 31, 2025

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at*

https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; *CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf),* and then amended in the August 25th COVID-19 IFC (*85 FR 54820*).
** As described above, CMS finalized its proposal to suppress the MORT-30-PN measure for the FY 2023 program year.
*** As described above, CMS finalized its proposal to remove the CMS PSI-90 measure beginning with the FY 2023 program year, which is the first year it would have been included in TPS calculations.

v. Performance Standards for the Hospital VBP Program

CMS states that the proposed measure suppression for the FY 2022 and FY 2023 program years will not affect the performance standards for those program years. However, CMS proposed to not generate achievement or improvement points for any suppressed measures for FY 2022. As previously described, CMS proposed to update the FY 2024 program year baseline periods for measures included in the Safety, Person and Community Engagement, and Efficiency and Cost Reduction domains. CMS will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for these measures. In accordance with the current methodology for calculating performance standards, CMS estimates additional performance standards for the FY 2024 program year.

Final Rule: finalized as proposed.

Previously established and newly updated performance standards for the measures in the FY 2024 program year are included in Table V.H-11. Table V.H-12 includes the newly updated performance standards for the FY 2024 program year Person and Community Engagement Domain.

For the FY 2025 program year, CMS proposed to remove the CMS PSI-90 measure (starting with the FY 2023 program year), and therefore is not including performance standards for this measure. CMS notes that the performance standards for the MSPB measure are based on performance period data and, therefore, CMS is unable to provide numerical equivalents for the standards at this time.

Final Rule: finalized as proposed.

Previously established performance standards for the FY 2025 program year are included in Table V.H-13.

Previously established performance standards for the FY 2026 program year are included in Table V.H-14.

For the FY 2027 program year, CMS is establishing new performance standards for the Clinical Outcomes and the Efficiency and Cost Reduction domains. The newly established performance standards for the FY 2027 program year are included in Table V.H-15.

vi. Scoring Methodology and Data Requirements

As previously described, CMS proposed to calculate measure rates for all measures in the FY 2022 program year, but for measures CMS proposed to suppress, CMS would not use the measure rates to generate achievement and improvement points within the current scoring methodology. CMS proposed that it would only calculate the achievement and improvement points and the domain score for the Clinical Outcomes Domain. Further, CMS proposed not to award TPSs to any hospital for FY 2022. CMS proposed to provide FY 2022 confidential feedback reports that contain measure rates calculated for the FY 2022 program year, in addition to the scores for measures in the Clinical Outcomes Domain and a related score.

CMS did *not* propose any changes to:

- The domain weights for the FY 2023 program year and subsequent years for hospitals that receive a score on all domains or for hospitals that receive scores on fewer than four domains.
- The minimum number of measures for Hospital VBP Program domains.
- The minimum number of cases for Hospital VBP Program measures.
- The previously adopted administrative policies for NHSN HAI measure data.

Final Rule: finalized as proposed.

vii. Changes to CFR Language and Technical Changes

CMS proposed the following CFR language updates and technical changes:

- Replace the term "QualityNet System Administrator" with "QualityNet security official" (42 CFR 412.167(b)(5)).
- Indicate that the *Hospital Compare* website is now available on the "Care Compare" site (https://www.medicare.gov/care-compare) (42 CFR 412.163(d) and 412.164(b)).
- Update the QualityNet website to "QualityNet.cms.gov" (42 CFR 412.165(c)(2) and (4)).

Final Rule: finalized as proposed.

c. HAC Reduction Program (42 CFR 412.170)

CMS did not propose to add or remove any measures to the Hospital-Acquired Condition (HAC) Reduction Program. CMS also did not propose any measure removal and retention factor policy changes. Additionally, CMS did not propose any changes to the HAC Reduction Program scoring methodology or Scoring Calculations Review and Corrections Period.

However, in response to the impact of the COVID-19 PHE, CMS proposed a cross-program measure suppression policy that would allow CMS to suppress the use of measure data if CMS determines that circumstances caused by the COVID-19 PHE have affected those measures and the resulting quality scores significantly. CMS proposed this policy to ensure that these programs do not reward or penalize hospitals based on circumstances caused by the COVID-19 PHE that the measures were not designed to accommodate. For consistency, CMS proposed to adopt this measure suppression policy for the HAC Reduction Program, as well as the following value-based purchasing programs: Hospital VBP Program; HRRP; Skilled Nursing Facility VBP Program; and End-Stage Renal Disease Quality Incentive Program.

Specifically, CMS proposed to adopt a policy for the duration of the COVID-19 PHE that would allow CMS to suppress a number of measures from the FY 2022 and FY 2023 Total HAC Score calculations for the HAC Reduction Program if CMS determines that circumstances caused by the COVID-19 PHE have affected these measures and the resulting Total HAC Scores significantly. Under this policy, CMS would calculate measure rates for that program year but then suppress the use of those rates to generate Total HAC Scores. CMS would instead assign each hospital a zero percent weight for any suppressed measures in the Total HAC Score calculation. CMS would also provide confidential feedback reports to hospitals on their FY 2022 and FY 2023 performance to ensure they are made aware of the observed changes in performance rates. Finally, CMS would publicly report the FY 2022 and FY 2023 data with appropriate caveats noting the limitations of the data due to the COVID-19 PHE.

Based on these considerations, CMS developed a number of Measure Suppression Factors to guide CMS's determination of whether to propose to suppress HAC Reduction Program measures for one or more program years that overlap with the COVID-19 PHE. The Measure Suppression Factors are:

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

CMS also proposed to suppress the third and fourth quarters of CY 2020 CDC NHSN HAI and CMS PSI-90 data from performance calculations for the FY 2022 and FY 2023 program years. Although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such data, which would be used for public reporting purposes.

The suppression of Q3 and Q4 2020 HAI and CMS PSI-90 measure data would result in the following applicable periods for calculating Total HAC Scores for FY 2022 and FY 2023 HAC Reduction Programs:

- For the FY 2022 HAC Reduction Program, the applicable period used for scoring for the CMS PSI-90 measure would remain the same as from the previously granted ECE (that is, the 18-month period from July 1, 2018 through December 31, 2019). For the CDC NHSN HAI measures, the applicable period would be the 12-month period from January 1, 2019 through December 31, 2019.
- For the FY 2023 HAC Reduction Program, the applicable period used for scoring the CMS PSI-90 measure would be shortened to the 12-month period from July 1, 2019 through December 31, 2019 and January 1, 2021 through June 30, 2021. For the CDC NHSN HAI measures, the applicable period would be the 12-month period from January 1, 2021 through December 31, 2021.

CMS also proposed to clarify that an approved ECE granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and/or the agency may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period, depending on the exact circumstances under which the request was made. However, CMS also clarified that an approved ECE does not exempt hospitals from payment reductions under the HAC Reduction Program. In short, an approved ECE does not "except" a facility from the quality program; instead, that the facility would be "excepted" from reporting data for the approved data-reporting period.

CMS also proposed to update the regulatory text to reflect the renaming of the Hospital Compare website to "Care Compare."

Final Rule: finalized as proposed.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

a. Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting quality program that reduces payment to hospitals that fail to meet program requirements. Hospitals that do not submit quality data or fail to meet all Hospital IQR Program requirements are subject to a one-fourth reduction in their Annual Payment Update under the IPPS. In the FY 2022 IPPS/LTCH PPS proposed rule, CMS proposed to adopt five new measures, remove five existing measures, and make changes to the existing EHR certification requirements along with other administrative updates. CMS also requested comment on the potential future adoption of a COVID-19 mortality measure and patient reported outcome measure following elective primary total hip and/or knee arthroplasty.

The new and removed measures are listed below. One new measure of particular interest is the COVID-19 Vaccination Coverage Among HCP measure, which will begin on October 1, 2021 (the start of FY 2022). CMS believes it is important to incentivize and track HCP vaccination in acute care facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of hospitals to continue serving their communities throughout the PHE and beyond. The new measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19. The denominator would be the number of HCP eligible to work in the healthcare facility for at least one day during the submission period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC. The numerator would be the cumulative number of HCP eligible to work in the health care facility for at least one day during the submission period and who received a completed vaccination course (one or two shots, depending on the vaccine) against COVID-19 since the date the vaccine was first available or on a repeated interval if revaccination is recommended.

Hospitals would be required to collect the numerator and denominator for the COVID-19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital IQR Program requirements. Each quarter, the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS would publicly report each quarterly COVID-19 HCP vaccination coverage rate as calculated by the CDC.

The Measure Applications Partnership (MAP) offered only conditional support for rulemaking on this measure contingent on CMS bringing the measure back to the MAP once the specifications are further refined, specifically stating that "the incomplete specifications require immediate mitigation and further development should continue."[31] CMS notes that while it values input from the MAP, the agency believes it is important to adopt the measure as quickly as possible to address the urgency of the COVID-19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns. CMS also notes that this measure is not NQF-endorsed and has not been submitted to NQF for endorsement consideration. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle. Although CMS is statutorily required to have quality reporting program measures endorsed by the entity under contract (currently NQF), there is an exception to this requirement that allows CMS to specify a non-endorsed measure (SSA section 1886(s)(4)(D)(ii)). CMS believes an exception applies as it found no other feasible and practical measures on COVID-19 vaccination among HCP.

[31] Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Available at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

CMS proposed to adopt the following five new measures:

1. Maternal Morbidity Structural Measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 affecting the CY 2021 reporting period/FY 2023 payment determination;
2. Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years;
3. COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination and for subsequent years;
4. Hospital Harm-Severe Hypoglycemia eCQM (NQF #3403e), beginning with the CY 2023 reporting period/FY 2025 payment determination; and
5. Hospital Harm-Severe Hyperglycemia eCQM (NQF #35333e), beginning with the CY 2023 reporting period/FY 2025 payment determination.

Final Rule: CMS is finalizing its proposal to adopt the above five new measures. However, CMS is modifying its proposal regarding the COVID-19 Vaccination Coverage Among HCP measure. Specifically, based on public comment, CMS is not finalizing its plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, CMS will only report the most recent quarter of data.

CMS also proposed to remove the following five measures:

1. Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI-04) beginning with the CY 2021 reporting period/FY 2023 payment determination;
2. Exclusive Breast Milk Feeding (PC-05) (NQF #0480) beginning with the CY 2024 reporting period/FY 2026 payment determination;
3. Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) (NQF #0497) beginning with the CY 2024 reporting period/FY 2026 payment determination;
4. Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436) beginning with the CY 2024 reporting period/FY 2026 payment determination; and
5. Discharged on Statin Medication eCQM (STK-06) (NQF #0439) beginning with the CY 2024 reporting period/FY 2026 payment determination.

Final Rule: After consideration of public comments, CMS is finalizing its proposal to remove the Exclusive Breast Milk Feeding (PC-05) measure; its proposal to remove the Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) measure; and its proposal to remove the Discharged on Statin Medication eCQM (STK-06) measure beginning with the CY 2024 reporting period/FY 2026 payment determination. However, CMS is not finalizing its proposal to remove the Death Rate Among Surgical Inpatients with Serious Treatable Complications (PSI-04) measure and is not finalizing its proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03).

Additionally, beginning with the CY 2023 reporting period/FY 2025 payment determination, CMS proposed to require hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data. CMS also proposed to require hospitals to use only certified technology that has been updated consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years.

Final Rule: finalized as proposed.

CMS also proposed an update to revise 42 CFR 412.140(a)(2) and 42 CFR 412.140(e)(2)(iii) to replace the terms "Security Administrator" and "System Administrator" with the term "security official" in alignment with other CMS quality programs. Due to an updated URL for the QualityNet website from QualityNet.org to QualityNet.cms.gov, CMS also proposed to revise Hospital IQR Program regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to reflect this change. CMS also proposed to extend the effects of the educational review process for chart-abstracted measures beginning with validations affecting the FY 2024 payment determination.

Final Rule: finalized as proposed.

Also, in the FY 2021 IPPS/LTCH PPS final rule, CMS proposed to progressively increase (over a three-year period) the number of quarters for which hospitals are required to report electronic clinical quality measures (eCQM) data. Specifically, CMS proposed increasing the submission requirement from one self-selected quarter of data to all four quarters of data. For the CY 2021 reporting period (FY 2023 payment determination), hospitals are required to report two self-selected quarters of data for each of the four self-selected eCQMs. For the CY 2022 reporting period, hospitals are required to report three self-selected quarters of data for each required eCQM (three self-selected eCQMs and the Safe Use of Opioids eCQM). For the CY 2023 reporting period and subsequent years, hospitals are required to report all four calendar quarters of data for each required eCQM. While CMS did not propose any changes to these policies, they clarified that beginning with the CY 2021 reporting period/FY 2023 payment determination, the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year.

CMS also proposed changes to the Hospital IQR data validation process. Specifically, CMS proposed changes to its Educational Review Process to extend the effects of the educational review policy beginning with validations affecting the FY 2024 payment determination and for subsequent years. Previously, CMS could only correct scores for the first 3 quarters of validation due to the inability to calculate the confidence interval in a timely manner for the 4th quarter of validation. CMS now believes it is feasible to calculate the confidence interval and use the corrected scores identified through an educational review for all 4 quarters of validation for chart-abstracted measures. Note that this policy does not apply to the educational review process for eCQMs, which CMS is not changing at this time.

Final Rule: finalized as proposed.

b. PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program

Beginning with the FY 2024 program year, CMS proposed to remove the following measure: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383) (PCH-15). CMS proposed to remove this measure because it is not feasible to implement the measure specifications. Beginning with the FY 2023 program year, CMS also proposed to adopt the COVID-19 Vaccination Coverage Among Healthcare Personnel measure (discussed in detail above).

Final Rule: CMS is finalizing its proposal to remove the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF # 0383) measure and its proposal to adopt the COVID-19 Vaccination Coverage Among HCP measure. However, CMS is modifying its proposal regarding the COVID-19 Vaccination Coverage Among HCP measure. Specifically, based on public comment, CMS is not finalizing its plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. Instead, CMS will only report the most recent quarter of data

CMS also proposed making a technical update to terminology for this program by replacing the term "QualityNet Administrator" with "QualityNet security official."

Final Rule: finalized as proposed.

CMS also proposed codifying existing PCHQR Program policies in CMS regulations. Specifically, CMS proposed to amend 42 CFR 412.23(f) by adding a new paragraph (3) that requires cancer hospitals, as classified under that paragraph, participating in the PCHQR Program to follow all requirements listed in the new section 42 CFR 412.24. CMS also proposed to add a new section at 42 CFR 412.24 that contains the following regulations that govern the PCHQR Program:

- Participation requirements, including the PCHQR Program registration process;
- Data submission requirements for quality measures that are selected by CMS under SSA section 1866(k) and must be submitted in a form and manner, and at a time, specified by CMS;
- Quality measure removal and retention factors;
- Public reporting requirements for quality measure data reported by PCHs, with measure information displayed on the CMS website; and
- CMS's extraordinary circumstances exception policy detailing the process for CMS to grant an extension or exception to quality measure reporting requirements under the PCHQR Program.

Final Rule: finalized as proposed.

X. Medicare and Medicaid Promoting Interoperability Programs

CMS proposed several changes to the Medicare Promoting Interoperability Program to reduce burden on eligible hospitals and CAHs. Specifically, CMS proposed to: (1) continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and CAHs for CY 2023 and to increase the EHR reporting period to a minimum of any continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024; (2) maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from 5 points to 10 points; (3) modify technical specifications of the Provide Patients Electronic Access to Their Health Information measure to include establishing a data availability requirement; (4) add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation beginning in CY 2022 to the HIE objective as an optional alternative to the two existing measures; (5) require reporting "yes" on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) or requesting applicable exclusion(s); (6) add a new SAFER Guides measure requiring hospitals to attest to having completed an annual assessment of all nine SAFER Guides under the Protect Patient Health Information objective; (7) remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking attestation requirement; and (8) increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) to be considered a meaningful EHR user.

Final Rule: CMS is not finalizing its proposal to modify the Provide Patients Electronic Access to Their Health Information measure by requiring eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. CMS is finalizing the remaining seven changes described above as proposed.

Table IX.F.-04: Performance-Based Scoring Methodology
EHR Reporting Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.
*Signifies a final policy adopted in this FY 2022 IPPS/LTCH final rule.

In alignment with proposals for the Hospital IQR Program, CMS also proposed to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, in addition to removing four eCQMs from the measure set beginning with the reporting period in CY 2024. Specifically, CMS proposed to adopt the following two new eCQMs: (1) Hospital Harm – Severe Hypoglycemia (NQF #3503e); and (2) Hospital Harm – Severe Hyperglycemia (NQF #3533e). CMS proposed to remove the following four eCQMs: (1) STK-03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter); (2) STK-06 (Discharged on Statin Medication); (3) PC-05 (Exclusive Breast Milk Feeding); and ED-2 (Admit Decision Time to ED Departure Time for Admitted Patients).

Final Rule: CMS is not finalizing its proposal to remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03). CMS is finalizing the remaining measure adoption/removal proposals described above without modification.

Additionally, beginning with the reporting period in CY 2023, CMS proposed to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for eCQMs. This is in alignment with the proposal for the Hospital IQR Program discussed above.

Final Rule: finalized as proposed.

* * *

We hope this summary was helpful to you. Please do not hesitate to contact us if you have any questions.