T (202) 354-2600 vizientinc.com



Vizient Office of Public Policy and Government Relations

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

May 10, 2021

Background & Summary

On April 27, the Centers for Medicare & Medicaid Services (CMS) issued the <u>annual proposed</u> rule to update the Fiscal Year (FY) 2022 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS) ("Proposed Rule"). The Proposed Rule includes several policy recommendations, including repeal of the market-based MS-DRG relative weight methodology that was finalized in the FY 2021 IPPS/LTCH PPS final rule, implementation of various provisions from COVID-19 relief laws, and use of FY 2018 cost report data and 2019 claims data for various purposes (e.g., MS-DRG rate-setting), as opposed to more recent data, due to the impact of the COVID-19 Public Health Emergency (PHE). CMS also proposes new measure suppression policies for various hospital quality payment programs and is soliciting feedback on two requests for information related to digital quality measures and promoting health equity.

In a <u>summary</u> released by CMS, the agency indicated the proposed policies seek to "sustain hospital readiness to respond to future public health threats, enhance the health care workforce in rural and underserved communities, and revise scoring, payment and public quality data reporting methods to lessen the adverse impacts of the pandemic and future unplanned events."

Comments are due **no later than 5PM on June 28, 2021**. Vizient looks forward to working with members to help inform our letter to the agency.

Proposed IPPS Payment Rate Updates for FY 2022

After accounting for inflation and other adjustments required by law, the Proposed Rule increases IPPS operating payment rates by 2.8 percent for hospitals that successfully report quality measures and are meaningful users of electronic health records (EHR). The Proposed Rule includes an initial market-based update of 2.5 percentage points, minus 0.2 percentage points for productivity mandated by the Affordable Care Act (ACA). Regarding the MS-DRG Documentation and Coding Adjustment, which partially restores cuts as a result of the American Taxpayer Relief Act (ATRA), CMS proposes a 0.5 percentage point positive adjustment. These changes are reflected in the following tables and would be applied to all hospitals.

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update	2.5%
Multi-Factor Productivity Adjustment	-0.2%
MS-DRG Documentation and Coding Adjustment	0.5%
Estimated payment rate update for FY 2022 (before applying budget neutrality factors)	2.8%

Proposed IPPS Payment Rate Updates for FY 2022

In addition, CMS proposes four applicable percentage increases applied to the standardized amount, as demonstrated in the below table. To determine the proposed applicable percentage increase, CMS applies adjustments to the proposed market-basket rate-of-increase. Two of these adjustments are dependent on two factors: (1) whether a hospital submits quality data; and (2) whether a hospital is a meaningful EHR user. In addition, there is a 0.2 percentage point reduction for the multifactor productivity adjustment.

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 market basket rate-of-increase	2.5	2.5	2.5	2.5
Proposed adjustment for not submitting quality data	0	0	-0.625	-0.625
Proposed adjustment for not being a Meaningful EHR User	0	-1.875	0	-1.875
Proposed Multi-Factor Productivity adjustment	-0.2	-0.2	-0.2	-0.2
Proposed applicable percentage increase applied to standardized amount	2.3	0.425	1.675	-0.2

Proposed FY 2022 Applicable Percentage Increases for the IPPS

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

The ACA required changes, which began in 2014, regarding the way disproportionate share hospital (DSH) payments are made to hospitals. Under this payment formula, hospitals receive 25 percent of the Medicare DSH funds that they would have received under the prior formula ("empirically justified"). The other 75 percent flows into a separate pool that is reduced relative to the number of uninsured and then distributed based on the proportion of total uncompensated care each Medicare DSH provides. This pool is distributed based on three factors:

- Factor 1: 75 percent of the Office of the Actuary estimate of the total amount of estimated Medicare DSH payments
- Factor 2: Change in the national uninsured rates
- Factor 3: Proportion of total uncompensated care each Medicare DSH provides

For FY 2022, CMS estimates DSH payments will be \$10.573 billion, a decrease of approximately \$805 million compared to FY 2021. Of the \$10.573 billion, \$7.628 billion is for uncompensated care payments, a decrease of \$660 million compared to FY 2021. The payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments. The calculated payment amount is not directly tied to a hospital's number of discharges.

Hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive the additional Medicare uncompensated care payment for the year. In the Proposed Rule, CMS clarifies eligibility requirements for certain hospitals (e.g., subsection (d) Puerto Rico hospitals; Medicare-dependent, small rural hospitals, hospitals participating in certain innovation models or demonstration programs), and does not propose changes to the empirically justified Medicare DSH payment processes.

Regarding uncompensated care payments, to determine Factor 1 for FY 2022, CMS does not propose methodology changes and aims to continue its policy established in the FY 2014 IPPS/LTCH Final Rule. To calculate Factor 1 and model the impact of this Proposed Rule, CMS describes the various data sources it utilized, including the Office of the Actuary's January 2021 Medicare DSH estimates which were based on data from the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2011 IPPS/LTCH final rule IPPS Impact File. CMS notes which factors applied for FY 2019 – FY 2022 to estimate Medicare DSH expenditures were adjusted for the impact of COVID-19 (e.g., discharges, case-mix, Medicaid enrollment).

For Factor 2, for FY 2022, CMS proposes to use a methodology similar to the one used from FYs 2018-2021. Again, in the Proposed Rule, CMS describes the data sources and COVID-19 related impacts and assumptions (e.g., rate of uninsurance) and notes that, due to the timing for the development of the Proposed Rule, impacts from the American Rescue Plan Act are not reflected in certain uninsured estimates. Using a weighted average approach to estimate the rate of uninsurance, CMS finds Factor 2 would be 72.14 percent.

For Factor 3, for FY 2022, CMS proposes to use a single year of Worksheet S–10 data from FY 2018 cost reports (99.6 percent audited) and apply that data in their methodology for all eligible hospitals (except Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals). This is consistent with CMS's approach for FY 2021. For purposes of the Proposed Rule, CMS used an HCRIS extract updated through February 19, 2021, but intends to use the March 2021 update to calculate the final Factor 3 in the FY 2022 IPPS/LTCH final rule. Generally, a hospital's uncompensated care payment for an applicable fiscal year is divided by the hospital's historical 3-year average of discharges. For FY 2022, CMS proposes basing the average of discharges on two years of data (FY 2018 and 2019), rather than three years (FYs 2018-2020), because CMS believes including FY 2020 would underestimate discharges due to the decrease in discharges during the pandemic. For FY 2022, CMS again purposes to provide hospitals 15 days from the date of public display of the FY 2022 IPPS/LTCH final rule to review and submit comments on the accuracy of data CMS used for Factor 3. CMS invites

comments on its proposed methodology for calculating Factor 3 for FY 2022, including the agency's proposed use of FY 2018 Worksheet S-10 data.

Proposed Changes to Related Medicare Severity Diagnosis-Related Group (MS-DRG) and Relative Weights

Under the IPPS, the DRG classifications and relative weights are adjusted (at least annually) to account for changes in resource consumption. For FY 2022 rate-setting, CMS proposes to use claims data from the March 2020 update of the FY 2019 MedPAR file (hospital bills received from October 1, 2018 – March 31, 2020) in the agency's analysis of proposed MS-DRG classification changes. CMS notes it believes this is the best available data for overall for rate-setting.

For FY 2022, CMS accepted MS-DRG classification change requests by November 1, 2020 and, in the Proposed Rule, CMS addresses those requests. CMS also notes that interested parties should continue to submit any comments and suggestions for FY 2023 by November 1, 2021 via the CMS MS-DRG Classification Change Request Mailbox located at: MSDRGClassificationChange@cms.hhs.gov.

<u>Criteria to Create a New Complication or Comorbidity (CC) or Major Complication or</u> <u>Comorbidity (MCC) Subgroup within a Base MS-DRG</u>

In the Proposed Rule, CMS restates its FY 2021 IPPS final rule policy to expand the criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG to include the NonCC subgroup for a three-way severity level split. Notably, application of the finalized criteria results in some MS-DRGs that are split into three severity levels being split into two severity levels. For FY 2022, CMS received reclassification requests and analyzed the results, given the application of the new criteria. 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 and the creation of 58 new MS-DRGs. Due to the PHE, CMS noted it is concerned about implementing this volume of MS-DRG changes, and instead proposes to delay applying the updated criteria until FY 2023.

MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Therapy

In the FY 2021 IPPS/LTCH Final Rule, CMS finalized its proposal to create a Pre-MDC MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). For FY 2022, CMS proposes to classify several new procedure codes affecting Pre-MDC MS-DRG 018; a table in the <u>Proposed Rule</u> (pg. 73-74) lists the new procedure codes which involve both CAR T-cell and other immunotherapies. Since more types of immunotherapies are proposed to be included in the Pre-MDC MS-DRG 018, CMS proposes changing the MS-DRG name to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies".

Related to CAR T-cell clinical trial and expanded use immunotherapy cases, CMS proposes to continue a payment adjustment using the same methodology finalized in the FY 2021 IPPS/LTCH final rule. Notably, this methodology distinguishes cases for the purposes of rate-setting calculations based on whether they contain the ICD-10-CM diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program) or if the standardized drug charges are less than \$373,000. CMS proposes to use FY 2019 data for the FY 2022 rate-setting and, as a result, the adjustment factor would be 0.17 (the FY

2021 adjuster was also 0.17), which would then be used to determine the payment for clinical trial or expanded use access immunotherapy claims that group to MS-DRG 018.

CMS seeks comments on potentially using FY 2020 data which it would ordinarily use for purposes of the FY 2022 rulemaking. The proposed relative weight for MS-DRG 018 using FY 2019 MedPAR data is 37.4436. If FY 2020 MedPAR data is used the proposed relative weight is 34.9219. CMS highlighted that when using the FY 2020 MedPAR file the adjustment factor was 0.25. However, given the difference in relative weights, the reimbursement for clinical trials cases is higher if the 2019 MedPAR data is used to set the relative weight and the 2020 MedPAR file is used to set the adjustment factor.

Lastly, for FY 2022, CMS received applications for new technology add-on payments (NTAPs) for different CAR T-cell therapies. CMS invites comments on whether these products meet the NTAP criteria. More generally, related to MS-DRG 018, CMS notes there may no longer be a need for an NTAP and welcomes comment on this issue.

Recalibration of the FY 2022 MS-DRG Relative Weights

In the Proposed Rule, CMS details its methodology for calculating proposed FY 2022 relative weights, which due to the COVID-19 PHE, was done using the FY 2019 MedPAR claims data (as opposed to the FY 2020 MedPAR file) and the March 2020 update of the FY 2018 HCRIS file (as opposed to the December 2020 update of the FY 2019 HCRIS file). CMS invites public comments on its proposals to recalibrate the proposed FY 2022 relative weights and the changes in the relative weights from FY 2021.

Proposed Add-On Payments for New Services and Technologies for FY 2022

Under the IPPS, a service or technology may be considered for the new technology add-on payment (NTAP) if: (1) the medical service or technology is new; (2) the medical service or technology is costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient NTAP pathway.

Generally, CMS will extend 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 fiscal year. A table in the <u>Proposed Rule</u> (pgs. 304-305) provides the proposed extended NTAPs.

In addition, CMS generally limits the add-on payment window for new technologies for the first 2-3 years that a product comes to market as the costs of the new technology are not yet fully reflected in the DRG weights. However, due to the circumstances of FY 2022 rate-setting (e.g., using the FY 2019 MedPAR claims data), CMS proposes a one-year extension of the NTAPs for FY 2022 for those technologies listed in a table in the <u>Proposed Rule</u> (pgs. 309-312). CMS invites comments on this proposal.

For FY 2022, CMS received an NTAP application (among many other applications) for VEKLURY® (remdesivir), a treatment for patients with COVID-19. CMS invites comments on whether the remdesivir application and each other NTAP application meets the NTAP criteria.

New Technology Add-on Payment Newness Period for Products Available through an Emergency use Authorization (EUA) for COVID-19

In the FY 2021 IPPS/LTCH Final Rule, CMS finalized a technical clarification to indicate that a product must receive FDA marketing authorization (e.g., an emergency use authorization (EUA) is <u>not</u> considered FDA marketing authorization) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. However, CMS notes that data reflecting costs of products could become available from the data of the EUA. CMS requests comment on how data reflecting the costs of a product with an EUA should be considered for the purposes of the newness criteria for products with or expected to receive an EUA.

New COVID-19 Treatments Add-on Payment (NCTAP)

In response to COVID-19, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. The NCTAP became effective for discharges occurring on or after November 2, 2020 and runs until the end of the PHE. Since CMS anticipates COVID-19 inpatient cases after the end of the PHE, the agency proposes to extend the NCTAP for eligible products that are not approved for NTAPs through the end of the FY in which the PHE ends. In addition, CMS proposes to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for a NTAP beginning FY 2022. CMS invites comments on these proposals.

Proposed Repeal of the Market-Based MS-DRG Relative Weight Policy

In the FY 2021 IPPS/LTCH PPS final rule, CMS finalized a requirement for hospitals to include median payer-specific negotiated charges that are negotiated with Medicare Advantage (MA) organization payers, by MS-DRG, on their Medicare cost reports. In addition, CMS finalized another policy to use this reported median payer-specific negotiated charge data in the market-based MS-DRG relative weight methodology. In the Proposed Rule, CMS proposes repealing both of these policies. CMS notes the agency has further considered many contract arrangement hospitals use to negotiate rates with MA organization partners and questions the usefulness of the data for rate-setting purposes. CMS invites public comment on the proposal to repeal the market-based data collection requirement and market-based MS-DRG relative weight methodology. In addition, CMS seeks comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) rate-setting.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

Current law requires that the Secretary adjust the standardized amounts for area differences in hospital wages by a factor that reflects the relative hospital wage level in the geographic area of that hospital compared to the national average. Wage index values are based on data collected from Medicare cost reports submitted by hospitals. The wage index must be updated annually, and any updates or adjustments must be budget neutral – meaning the overall, aggregate payment to hospitals cannot change. CMS provides wage index tables (Tables 2, 3, and 4A and 4B) on the Proposed Rule website.

Proposed Core-Based Statistical Areas (CBSAs) for the FY 2022 Hospital Wage Index and Implementation Effects

Hospital labor markets are based on statistical areas established by the Office of Management and Budget (OMB) and the wage index is assigned to hospitals on the basis of the labor

market in which it is located. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). In the FY 2021 IPPS/LTCH final rule and beginning with the FY 2021 wage index, CMS adopted CBSA updates set forth in OMB Bulletin No. 18-04, which was released in September 2018.

For FY 2021, to minimize significant wage index fluctuations due to adoption of OMB Bulletin No. 1804, CMS finalized a policy to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020. Given the COVID-19 PHE, CMS seeks comment on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by the adoption of OMB Bulletin 18-04. CMS indicates an extended transition could potentially involve holding the FY 2022 wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. CMS also seeks comment on making this transition budget neutral (as was done for the FY 2021 transition).

On March 6, 2020, OMB issued another bulletin, <u>Bulletin No. 20-01</u>, which superseded Bulletin No. 18-04. CMS reviewed this bulletin and determined that the changes would not affect the Medicare wage index for FY 2022. Despite the lack of changes, CMS still proposes to adopt the OMB updates in Bulletin No. 20-01, consistent with long-standing policy.

Proposed Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

Any changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals and the Administrator's review process for FY 2022 will be incorporated into the wage index values – and published in the FY 2022 IPPS/LTCH PPS final rule. In the Proposed Rule, CMS outlines the process and timeline for requests for wage index data corrections.

Typically, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for payment purposes under IPPS. Due to the COVID-19 PHE, CMS extended the deadline for applications for FY 2022 to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule. In addition, CMS also notes that an <u>interim final rule with comment period</u> (IFC) was made available at the same time as the Proposed Rule. The IFC, which was effective May 10, 2021 amends CMS's regulations to allow a hospital with a rural redesignation to reclassify through the MGCRB using the rural reclassified areas as the geographic area in which the hospital is located.

In the FY 2021 IPPS/LTCH final rule, CMS allowed hospitals to submit materials required for Administrator review of MGCRB decisions electronically to the CMS Hospital and Ambulatory Policy Group. In the Proposed Rule, CMS proposes to clarify that the hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. CMS indicates hospitals will continue to be notified of the procedure for requesting Administrator review in the decision letters issued by the MGCRB.

Also, based on CMS's observances for the past two fiscal years, the agency believes it is necessary to adopt a measure to prevent rural reclassifications from being used purely as a mechanism for statewide wage index manipulation. CMS proposes that requests to cancel rural reclassifications must be submitted to the CMS Regional Office no sooner than calendar year after the reclassification effective date (e.g., if a hospital is approved for a rural

reclassification effective October 2, 2021, it would not be eligible to request cancellation until October 1, 2022). In addition, CMS proposes to make cancellation requests effective for the Federal fiscal year that begins in the calendar year after the calendar year in which the cancelation request is submitted (e.g., a cancelation request submitted on December 31, 2021 would be effective October 1, 2022; a cancelation request submitted January 1, 2022 would not be effective until October 1, 2023). CMS seeks feedback on this proposal.

Proposed Labor-Related Share for the Proposed FY 2022 Wage Index

The labor-related share is used to determine the proportion of the base payment rate to which the area wage index should be applied and includes a cost category if such costs are labor intensive and vary with the local market. For FY 2022, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.000, CMS proposes to apply the wage index to a labor related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2022, CMS proposes to apply the wage index to a proposed labor-related share of 67.6 percent of the national standardized amount.

Occupational Mix Adjustment

CMS uses an occupational mix adjustment to control for the effect of hospitals' employment choices on the wage index. To construct an occupational mix adjustment to the wage index, CMS is required to collect data every three years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program (e.g., CMS collected data in 2016 for the FY 2019-2021 wage indexes). Given the timing, a new measurement of occupational mix is required for FY 2022. In the Proposed Rule, CMS indicates the FY 2022 occupational mix adjustment is based on a new calendar year (CY) 2019 survey, which hospitals needed to submit to their Medicare Administrative Contractor (MAC) by September 3, 2020. CMS conducted an analysis to determine whether hospitals' wage indexes will increase or decrease under the 2019 survey data as compared to the prior 2016 survey data. A table in the Proposed Rule (pgs. 801-802) shows the results of this analysis. Those results show that the wage indexes for 49.3 percent of CBSAs will decrease due to the application of the 2019 occupational mix survey data as opposed to the 2016 occupational mix survey data. In addition, more urban areas (50.5 percent) than rural areas (40.4 percent) will benefit from the use of the 2019 occupational mix survey data compared to the 2016 data.

To compute the FY 2022 occupational mix adjustment, CMS is not proposing any changes to the methodology and plans on applying the occupational mix adjustment to 100 percent of the FY 2022 wage index. For the FY 2022 wage index, CMS used Worksheet S-3 wage data of 3,159 hospitals and occupational mix surveys of 2,955 hospitals.

CMS compared the proposed FY 2022 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. The results indicate a smaller percentage of urban areas (54.9 percent) would benefit from the occupational mix adjustment than would rural areas (57.4 percent).

Wage Index Adjustments

Currently, there are several policies in effect to address wage index disparities between high and low wage index hospitals. In the Proposed Rule, CMS implements a section of the

American Rescue Plan Act of 2021 (ARPA) (Pub. L. 117-2), to establish an "imputed floor" policy to address concerns from hospitals in all-urban states that are disadvantaged by the absence of rural hospitals to set a wage index floor for those states. For other wage index adjustments, CMS does not propose to modify these policies (e.g., "rural floor", Frontier Floor Wage Index, low wage hospital index, and out-migration policies).

CMS has included Wage Index Tables on the Proposed Rule website.

"Imputed Floor" Policy

From FYs 2005 - 2018, CMS utilized an imputed floor policy for hospitals in all-urban states, and it was considered as a factor in the national budget neutrality adjustment. CMS developed two methodologies, one in 2005 and another in 2018, to implement the imputed floor wage index.

Section 9831 of the ARPA requires that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban state may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology that was in effect for FY 2018. In the Proposed Rule, CMS implements this provision of the law. Based on the data available for the Proposed Rule, CMS lists the following eligible states as eligible to receive an increase in their wage index due to the application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut and Washington, D.C.

Unlike the imputed floor policy that was in effect from FYs 2005 – 2018, the ARPA provides that the imputed floor wage index shall not be applied in a budget neutral manner. Therefore, for FY 2022 and subsequent years, CMS proposes 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 policy.

CMS notes that since the ARPA was passed on March 11, 2021, there was not sufficient time available to incorporate changes required by this provision into the calculation of the provider wage index for the Proposed Rule. However, CMS will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule. CMS also highlights that at the same time this Proposed Rule was posted, the agency also posted estimated imputed floor values by state in a <u>file</u> on the <u>Proposed Rule website</u>.

Rural Floor Policy

The "rural floor" policy provides that wage indexes applied to urban hospitals in a state cannot be lower than the wage index for rural areas in that state. CMS does not propose changes to the rural floor policy for FY 2022. Based on the FY 2022 wage index in the Proposed Rule, CMS estimates 287 hospitals would receive an increase in their FY 2022 proposed wage index due to the application of the rural floor.

State Frontier Floor Policy

The ACA requires that the wage index for hospitals in low density states (known as the Frontier Floor Wage Index) cannot be below 1.0000. CMS does not propose changes to the Frontier Floor policy for FY 2022. In the Proposed Rule, CMS indicates 44 hospitals would receive the Frontier Floor adjustment so their FY 2022 wage index would be 1.0000. These hospitals are in Montana, North Dakota, South Dakota and Wyoming; although Nevada meets the definition of a frontier state, those hospitals' wage index is value greater than 1.0000.

Low Wage Index Hospital Policy

For FY 2022, CMS proposes to continue the low wage hospital index policy for hospitals whose wage index values are in the bottom quartile. Under the policy, CMS increases the wage index for each hospital by half the difference between the otherwise applicable final wage index value for a year for the hospital and the 25th percentile wage index value for that year across all hospitals. Based on the data for the Proposed Rule, the 25th percentile wage index value across all hospitals is 0.8418.

Out-Migration Adjustment

For FY 2022, CMS indicates the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the American Community Survey utilizing 2008 – 2012 (5-year) microdata. <u>Table 2</u> associated with the Proposed Rule includes the proposed out-migration adjustment for the FY 2022 wage index.

Proposed Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

CMS last rebased the hospital market basket cost weights effective for FY 2018, with 2014 data for the base period.¹ For FY 2022, CMS proposes to rebase the IPPS operating market basket to reflect the 2018 cost structure for IPPS hospitals. In doing so, the agency also proposes reviewing applicable cost categories and price proxies used to for the IPPS market basket, and to rebase and revise the Capital Input Price Index (CIPI) to a 2018 base year.

In addition, in the Proposed Rule, CMS details its proposed methodology for rebasing and revising the IPPS Market Basket and invites public comments. The below table provides a comparison of the 2014-based IPPS market basket with the proposed 2018-based IPPS market basket. In the Proposed Rule, CMS compares the average percent change in the 2014-based and the proposed 2018-based IPPS market basket over FY 2017- FY 2020. For FY 2022, CMS projects the increase to be 2.5 percent for both the 2014-based and proposed 2018-based IPPS market basket.

Major Cost Categories	2014-based IPPS Market Basket	Proposed 2018-based IPPS Market Basket
Wages and Salaries	42.1	39.7
Employee Benefits	12.0	11.3
Contract Labor	1.8	2.0
Professional Liability Insurance	1.2	1.0
Pharmaceuticals	5.9	7.1
Blood and Blood Products	0.8	0.6
Home Office/Related Org. Contract	4.2	5.9
Labor		
"All other" Residual	32.0	32.4

¹ CMS periodically updates the hospital market basket for operating costs. The percentage change in the market basket reflects the average change in the price of goods and services hospital purchase to provide inpatient care. The effects on total expenditure resulting from the changes in the mix of good and services purchased after the base period are not measured. Only when the index is rebased are changes in the quantity and intensity be captured; those changes are reflected in the cost weights.

Indirect and Direct Graduate Medical Education

Payments to hospitals for the direct costs of approved graduate medical education (GME) program are based on a methodology that determines a hospital-specific base-period per resident amount (PRA). In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. In addition, under IPPS, there is an indirect medical education (IME) adjustment for hospitals that have residents in an approved GME program. The hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds. The calculation of both direct GME payment and the IME payment adjustment is affected by the number of FTE residents that a hospital is permitted to count.

The Consolidated Appropriations Act of 2021 (CAA), contained three provisions affecting Medicare direct GME and IME payments to teaching hospitals. Specifically, the law: (1) makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year) to be distributed beginning in FY 2023, with priority given to certain types of hospitals; (2) changes the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT); and (3) changes the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. Additional information on each provision is included in the Proposed Rule, and the below provides additional information regarding the 1,000 new GME positions.

Distribution of Additional Residency Positions

For FY 2023, the CAA requires that the Secretary seek applications from hospitals to facilitate the distribution of 200 of the 1,000 new additional residency positions in accordance with the law's requirements. This application process would continue until all the positions are distributed. In the Proposed Rule, CMS notes that after a hospital's application is submitted and positions are distributed by the Secretary, the Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase. The increase would be effective July 1 of that fiscal year.

When selecting hospitals for an increase, the Secretary is required to consider the demonstrated likelihood of the hospital filling the positions made available within the first five training years. CMS proposes that a hospital would meet this requirement by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program. CMS proposes application materials for hospitals to show either criteria.

In addition, the law requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to a hospital in one the following four categories: (1) hospitals located in rural areas or that are treated as being located in a rural area; (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). In the Proposed Rule, CMS

elaborates on each category and indicates that hospitals would need to meet at least one category to be eligible. CMS then proposes a distribution method and seeks comment on an alternative method. Under the first proposed method, residency programs serving underserved populations would be prioritized (CMS would use a HPSA score). Under the alternative distribution method, hospitals qualifying in multiple categories would be given higher priority for FY 2023 and CMS would work with stakeholders to determine an alternative process for future years. CMS seeks comments on these proposals.

Proposed Indirect Medical Education (IME) Payment Adjustment Factor

Consistent with prior policy, for discharges occurring during FY 2022, the IME formula multiplier is 1.35. CMS estimates application of the multiplier results in an increase in the IPPS payment amount of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

<u>Counting Days Associated with Section 1115 Demonstration Projects in the Medicaid</u> <u>Fraction</u>

In the Proposed Rule, CMS proposes to revise the way it calculates the Medicaid fraction of the DSH calculation. In the Proposed Rule, CMS outlines various court decisions which have identified circumstances (e.g., hospital received payment for otherwise uncompensated inpatient hospital treatment; or the patient received certain types of premium assistance) where a patient is considered "eligible for inpatient hospital services"; this is has prompted CMS to clarify its policy. CMS proposes that patient days of individuals receiving benefits under a section 1115 waiver program would be counted in the numerator of the Medicaid fraction only if the patient directly receives inpatient hospital insurance coverage on the day the waiver was authorized. CMS invites comments on this proposal.

Hospital Readmissions Reduction Program (HRRP)

The HRRP requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The 21st Century Cures Act requires comparing peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. The HRRP currently includes six applicable conditions/procedures: acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

Due to the impact of COVID-19, CMS proposes to temporarily suppress the FY 2023 measure set for FY 2023 Hospital 30-day, all-cause, risk-standardized readmission rate (RDRR) following pneumonia hospitalization measure (NQF #0506). For FY 2023, CMS would weight the measure at 0 percent in the HRRP payment methodology. Also, CMS believes measure suppression would have a minimal negative impact on HRRP eligibility and the number of hospitals receiving payment reductions. However, CMS indicates it is not necessary to suppress this measure for the FY 2022 program year given the measure applicable period is July 1, 2017 – June 30, 2020 and CMS already indicated it would not use any Q1 or Q2 CY 2020 claims data to assess performance. CMS seeks comments on this suppression proposal.

Also due to the COVID-19 PHE, CMS proposes to update measure specifications by excluding patients diagnosed with COVID-19 for the five measure's denominators: (1) Hospital 30-day, all-cause RSRR following AMI hospitalization (NQF #0505); (2) Hospital 30-day, all-cause, unplanned, risk-standardized RSRR following CABG surgery (NQF #2515); (3) Hospital 30-day, all cause RSRR following COPD hospitalization (NQF #1891); (4) Hospital 30-day, all-cause RSRR following heart failure hospitalization (NQF #0330), and (5) Hospital-level 30-day, all-cause RSRR following elective primary THA/TKA (NQF 1551).

Extraordinary Circumstance Exception (ECE) Policy for the HRRP

For the COVID-19 PHE, in March 2020, CMS provided a nationwide Extraordinary Circumstances Exception (ECE) where qualifying claims would be excluded from the measure calculations for Q1 and Q2 2020 for the readmission measures. In September 2020, CMS updated the ECE to exclude any data submitted regarding care provided during Q1 and Q2 of CY 2020 from CMS's calculation of performance for FY 2022, 2023, and FY 2024. CMS clarifies that due to the nationwide ECE, the condition/procedure specific measures will use fewer than 12 months of data for risk adjustment for admissions between July 1, 2020 and June 30, 2021 during the FY 2023 applicable period (e.g., July 1, 2020 admissions will have a look back period of July 2, 2019 – December 31, 2019).

Proposed Flexibility for Changes that Affect Quality Measures during a Performance Period in the HRRP

In the Proposed Rule, CMS indicates it is concerned regional and temporal differences in COVID-19 prevalence during the FY 2022 HRRP applicable period, which includes data collected during the PHE, have affected hospitals' readmissions measure performance for the FY 2022 program year. As a result, for the duration of the COVID-19 PHE, CMS proposes to allow the agency to suppress the use of quality measures via adjustment to the HRRP's scoring methodology, if CMS determines that circumstances caused by the COVID-19 PHE have affected those measures and the associated "excess readmissions" calculations significantly. If the use of a measure is suppressed, the weighting of affected measures would be temporarily reduced to 0 percent in the program's scoring methodology until adjustments are made (e.g., 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 seeks feedback regarding this proposal.

CMS notes that as an alternative to the proposed measure suppression policy, it also considered waiving all data reporting requirements for Q3 and Q4 2020. However, CMS noted that the option would leave no comprehensive data available to the agency to provide confidential performance feedback and data would not be available for monitoring or to inform future programmatic changes. CMS invites comment on the proposed measure suppression policy for the duration of the COVID-19 PHE.

Measure Suppression Factors

Related to the different proposed measure suppression policies, the agency seeks feedback regarding "Measure Suppression Factors". CMS proposes Measure Suppression Factors throughout the Proposed Rule for the following programs: HRRP, Hospital VBP Program, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, or the End-Stage Renal Disease Quality Incentive Program. CMS would use the Measure

Suppression Factors to help the agency evaluate whether to suppress measures included in its programs. The proposed Measure Suppression Factors are:

- 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:
 - 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:
 - a. healthcare personnel;
 - b. medical supplies, equipment, or diagnostic tools or materials; or
 - c. patient case volumes or facility-level case mix.

CMS seeks feedback on the proposed Measure Suppression Factors. CMS also seeks feedback on whether it should consider adopting a measure suppression policy if there is a future national PHE, and whether measure suppression policies that have more granular effects (e.g., region-based measure suppression) should be considered.

Hospital Value-Based Purchasing (VBP) Program

The ACA established the Hospital VBP Program under which value-based incentive payments are made to hospitals that meet performance standards during specific performance periods. There are four Hospital VBP domains: Safety; Clinical Outcomes; Efficiency and Cost Reduction; and Person and Community Engagement. Typically, the applicable incentive payment percent is required by statute (e.g., 2 percent). CMS provides three key proposals for the FY 2022 program years which are described below, in addition to changes for the FY 2023 and 2024 program years.

First, CMS proposes a measure suppression policy for the duration of the COVID-19 PHE that is the similar to the HRRP measure suppression policy (including Measure Suppression Factors described above). CMS proposes to allow the agency to suppress the use of data for a number of measures if it determines the circumstances caused by the COVID-19 PHE have affected those measures and the resulting Total Performance Score (TPS) significantly. CMS invites comment on the adoption of a measure suppression policy for the duration of the PHE for COVID-19, and the Measure Suppression Factors.

Second, for the FY 2022 program year, CMS proposes suppressing all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains²

² For FY 2022, CMS proposes suppressing the following measures: Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166); Medicare Spending Per Beneficiary – Hospital (NQF #2158); National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); American College of Surgeons – Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant ;

and adopting a special scoring rule, where, due to the suppression of the so many measures, CMS would not calculate total performance scores (TPS) for hospitals. The agency would still provide confidential feedback reports to hospitals on their FY 2022 measure rates (not likely available until after August 1, 2021) and Q3 and Q4 data would be publicly reported with appropriate caveats noted. CMS welcomes comments on these proposals.

Third, related to payment, CMS proposes to reduce each hospital's base-operating DRG payment amount by 2 percent, as required under law; however, since no hospital would have a TPS, CMS proposes to assign each hospital a value-based payment percentage that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG. As a result, the net of these payment adjustments would be neutral for hospitals and the hospital's base operating DRG payment amount would remain unchanged for FY 2022. In the Proposed Rule, CMS outlines FY 2022 payment details if the proposal is not finalized. CMS welcomes comments on this proposal.

For the FY 2023 program year, CMS proposes to suppress only one measure, MORT-30-PN³ (because the COVID-19 PHE affected this measure significantly) and updates specifications to exclude patients diagnosed with COVID-19 from four condition-specific mortality measures and one procedure-specific complication measure.⁴ However, no special scoring would apply; scoring would revert to previous scoring rules. Although the FY 2024 and FY 2025 program years use CY 2020 data, CMS did not make proposals for those FYs in the Proposed Rule. CMS notes that it did not update these measures for FY 2022 program year because of the nationwide ECE.

Table V.H-4 (pgs. 1022-1023) and Table V.H-5 (pgs. 1023-1024) of the <u>Proposed Rule</u> provides a summary of measures for the FY 2022 – FY 2025 program year if the measure proposals are finalized.

Proposed Removal of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure from the Hospital VBP Program

For FY 2023 program year, CMS proposes to remove the CMS PSI 90 measure (NQF #0531) from the Hospital VBP Program. In the Proposed Rule, CMS describes burdens associated with tracking the measure in both the Hospital VBP Program and the HACRP since each program uses a different methodology. Since CMS proposes to remove CMS PSI 90 from the Safety Domain Hospital VBP Program, CMS does not provide estimated performance standard for this measure in the Proposed Rule. CMS welcomes comment on removal of the CMS PSI 90 measure beginning with FY 2023.

³ MORT-30-PN: Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure ⁴ CMS proposes changes the specifications for the following measures: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229); and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716); and the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

Baseline and Performance Periods for the FY 2024 Program Year

Under the nationwide ECE for the Hospital VBP program CMS waived reporting requirements for Q1 and Q2 2020. However, CMS recognizes the need for the program to have sufficient data for reliable baseline period scores. As a result, CMS proposes several updates to the baseline periods for the FY 2024 program year.

For the FY 2024 program year for the Person and Community Engagement Domain Measure (HCAHPS Survey), the previously finalized baseline period was January 1, 2020 to December 31, 2020. However, due to the nationwide ECE, which removed January-June data, there would only be six months of data which may be insufficient for accuracy and reliability. As a result, for FY 2024 scoring, CMS proposes to use a baseline period of January 1, 2019 - December 31, 2019 and notes that this baseline period would be paired with the previously finalized performance period (January 1, 2022 - December 31, 2022). Similarly, for the FY 2024 program year for the Safety Domain Measures and the Efficiency and Cost Domain measure, CMS proposes updating the baseline period to January 1, 2019 - December 31, 2019 for accuracy and reliability purposes. The corresponding performance periods would still be January 1, 2022 – December 31, 2022, as previously finalized.

Related to these proposed changes, <u>Table V.H-11</u> (pg. 1034) of the Proposed Rule provides previously established and estimated performance standards for the FY 2024 Program Year, including achievement thresholds. In addition, <u>Table V.H-12</u> (pg.1035) provides estimated performance standards for the FY 2024 Program Year for the person and community engagement domain. Both tables relied on CY 2019 data. CMS believes the previously established baseline periods for FY 2022, FY 2025 and FY 2026 are not impacted. <u>Tables V.H-6 through 10</u> (pgs.1028-32) depict a summary of baseline and performance periods for the FYs 2023 - 2027 Program Years.

Hospital-Acquired Conditions (HAC) Reduction Program

The ACA established the HAC Reduction Program (HACRP) to reduce the incidence of HACs by requiring hospitals to report on a set of measures (CMS PSI 90 and CDC NHSN HAI measures). Hospitals in the worst performing quartile (25 percent) would receive a one percent payment reduction. A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year will depend on several different factors. For the HACRP, CMS proposes a measure suppression policy for the duration of the PHE where the agency could suppress measures from the FY 2022 and FY 2023 Total HAC Score Calculations considering the same Measure Suppression Factors as other programs. CMS welcomes comments on the measure suppression policy.

In addition to waiving all data reporting requirements for Q1 and Q2, as noted in the HACRP ECE, CMS proposes suppressing CY 2020 Q3 and Q4 HAI and CMS PSI 90 measure data from the Total HAC Score calculation for FY 2022 and 2023. CMS seeks feedback regarding its suppression proposal.

In the Proposed Rule, CMS also clarifies aspects of the ECE provided or available in the HACRP in response to the COVID-19 PHE. Among the clarifications provided, CMS reiterates an approved individual ECE for the HACRP does not exempt a hospital from payment reductions under the HACRP.

Hospital Inpatient Quality Reporting (IQR) Program

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 authorized CMS to pay hospitals that successfully report designated quality measures a higher annual update to their payment rates. In order to receive the full payment increase, hospitals must report data on measures selected by the Secretary for each fiscal year. In the Proposed Rule, CMS proposes to adopt five new measures (as provided in the table below), remove five measures⁵, and seeks comment on two future potential measures (a mortality measure for patients admitted with COVID-19; and a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA)).

Proposed New Measure	Reporting period
Maternal Morbidity Structural Measure	October 1, 2021 – December 31, 2021 for the CY 2021 reporting period/FY 2023 payment determination (beginning with a shortened reporting period for CY 2021, in addition for CY 2021 only, the data submission period would be April 1, 2022-May 16, 2022)
Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure	Voluntary reporting: July 1, 2022 – June 30, 2023 Mandatory reporting: July 1, 2023 – June 30, 2024 (FY 2026 payment determination)
COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) measure	October 1, 2021 – December 31, 2021 for the CY 2021 reporting period/FY 2023 payment determination: Quarterly reporting beginning with FY 2024 payment determination
Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e)	Beginning with the CY 2023 reporting period/ FY 2025 payment determination
Hospital Harm Severe Hyperglycemia eCQM (NQF #3533e)	Beginning with the CY 2023 reporting period/ FY 2025 payment determination

Note: Measures for the FY 2023-FY 2026 Payment Determination can be viewed in tables in the Proposed Rule (pg. 1327-1331).

Use of Certified Technology

Beginning CY 2023 reporting period/FY 2025 payment determination, CMS proposes to require hospitals to use certified technology that is consistent with the 2015 Edition Cures Update. CMS clarifies that if this proposal is finalized, then all available electronic Clinical Quality Measures (eCQMs) used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination would need to be reported using certified technology updated to the 2015 Edition Cures Update. CMS also proposes to require that hybrid

⁵ The five measures CMS proposes to remove: Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI-04) beginning with the FY 2023 payment determination; Exclusive Breast Milk Feeding (PC-05) (NQF #0480) beginning with the FY 2026 payment determination; Admit Decision Time to ED Departure Time for Admitted Patients (ED-2) (NQF #0497) beginning with the FY 2026 payment determination; and two stroke-related eCQMs beginning with the FY 2026 payment determination; Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK-03) (NQF #0436); and Discharged on Statin Medication eCQM (STK-06) (NQF #0439).

measures comply with the same certification requirements (2015 Edition Cures Update) and timeline as eCQMs.

Overall Hospital Quality Star Ratings

In the Proposed Rule, CMS references the CY 2021 OPPS/ASC final rule where the agency finalized a methodology to calculate the Overall Hospital Quality Star Ratings but does not propose any modifications.

Medicare Promoting Interoperability Program

In 2011, the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were established to encourage eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology (CEHRT). More recently, CMS renamed the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to the "Medicare and Medicaid Promoting Interoperability Programs" or "Promoting Interoperability (PI) Programs". Regarding Medicaid providers and the Medicaid aspect of the Promoting Interoperability program, CMS previously established that Medicaid eligible hospitals cannot receive any incentives after CY 2021. Therefore, generally, December 31, 2021 is the last date that states could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals. Thus, the Proposed Rule focuses on the Medicare Promoting Interoperability Program.

Downward payment adjustments, under Medicare, were applied to eligible hospitals and CAHs that did not successfully demonstrate meaningful use of CEHRT for certain associated electronic health record (EHR) reporting periods. In addition, negative adjustments could be applied to monthly prospective payments for a qualifying Medicare Advantage organization if its affiliated eligible hospitals are not meaningful users of CEHRT.

EHR Reporting Periods

Since the EHR reporting period in CY 2015, to provide providers and health IT vendors flexibility, CMS has consistently established an EHR reporting period of any continuous 90-day period for eligible hospitals and CAHs for the Medicare Promoting Interoperability Program. For CY 2022, eligible hospitals and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2022 – December 31, 2022. For CY 2023, CMS proposes to continue the 90-day reporting period requirement. However, for CY 2024, CMS proposes an EHR reporting period of a minimum of any continuous 180-day period for new and returning participants. CMS believes this elongated reporting period would minimally increase the information collection burden. CMS seeks comment on this proposal.

Proposed Measure Changes

In the Proposed Rule and as described below, CMS proposes changes to several measures in the Electronic Prescribing Objective, Provider to Patient Exchange Objective, Health Information Exchange Objective, Public Health and Clinical Data Exchange Objective and Protect Patient Health Information Objective. CMS invites comments on these proposals. In the <u>Proposed Rule</u>, Table IX.F.-02 (pgs. 1471-1475) displays proposed objectives and measures for the Medicare Promoting Interoperability Program in 2022 and Table IX.F.-04 (pgs. 1478-1479) displays the performance-based scoring methodology EHR Reporting Period in CY 2022.

Electronic Prescribing Objective

CMS proposes to maintain optional reporting of the Electronic Prescribing Objective's Query of PDMP measure but to increase its associated bonus points from 5 points to 10 points, so the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022. CMS seeks comment on this proposal and future plans for requiring the Query of PDMP measure. CMS poses numerous, specific questions for comment on this topic in the <u>Proposed Rule</u> (pg. 1439).

Provider to Patient Exchange Objective

CMS proposes to modify the "Provide Patients Electronic Access to Their Health Information" measure to require eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely by using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital or CAH's CEHRT. The proposed requirement would apply beginning with the EHR reporting period in CY 2022 and would include all patient health information from encounters on or after January 1, 2016. CMS selected January 1, 2016 because it wants the date to align with the date of service start date (January 1, 2016) finalized in the Patient Access and Interoperability final rule. CMS seeks comment on this proposal.

Health Information Exchange Objective

To encourage participation, CMS proposes to add the following new measure to the Health Information Exchange Objective: Health Information Exchange (HIE) Bi-Directional Exchange Measure. The proposed new measure would be an optional alternative to the two existing measures (Support Electronic Referral Loops by Sending Health Information measure and Support Electronic Referral Loops by Receiving and Reconciling Health Information measure) and be worth 40 points. In addition, CMS proposes the HIE Bi-Directional Exchange measure be reported by attestation to certain information (listed in more detail on pg. 1446) and require a yes/no response. CMS seeks comments on this proposal, and also notes that it will continue to explore ways to provide further guidance so that the measure aligns with the use of health information networks that participate in the <u>Trusted Exchange Framework and Common</u> Agreement (TEFCA) in the future.

Public Health and Clinical Data Exchange Objective

Under this objective, eligible hospitals and CAHs must report on any two measures of their choice from six measures.⁶ Although CMS previously stated it intends to remove the Public Health and Clinical Data Exchange Objective, recent public health events (e.g., COVID-19) highlighted the need for comprehensive data exchange and CMS believes a more assertive approach is needed. In the Proposed Rule, CMS proposes to require the following four measures be reported beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. CMS proposes that, beginning with the EHR reporting period in CY 2022, an eligible hospital or CAH would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a "yes" response for each of the four required measures. CMS proposes making the other measures in this objective optional for up to 5 bonus points.

⁶ The six measures are: Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting

Protect Patient Health Information Objective

In the Proposed Rule, CMS describes ONC's Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) which help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs. CMS now proposes a new SAFER Guides Measure to the Protect Patient Health Information Objective beginning with the CY 2022 EHR reporting period.

Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

Eligible hospitals and CAHs must report on clinical quality measures (eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program. Since CMS proposes eCQM additions and removals for the Hospital IQR Program and continues to align requirements between the two programs, CMS proposes to adopt the severe Hypoglycemia and Severe Hyperglycemia CQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2023, and to remove STK-03, STK-06, PC-05, and ED-2 from the previously finalized set of eCQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2024. CMS welcomes feedback on these proposals.

Also consistent with the Hospital IQR Program, CMS proposes to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25667) to submit data for eCQMs, beginning with the reporting period in CY 2023.

Rural Community Hospital Demonstration Program

The Consolidated Appropriations Act, 2021 (CAA) extended the Rural Community Hospital Demonstration Program, which was established in 2003 and extended multiple times in different laws, for an additional five years. The demonstration program pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries.

In the Proposed Rule, CMS clarifies its interpretation of the CAA, including that the period of participation for the last hospital in the model under this most recent legislative authorization would extend until June 30, 2028. Also, in the Proposed Rule, CMS outlines the budget neutrality methodology for the extension period it proposes to apply. For FY 2022, CMS estimates approximately \$63.83 million would generally be paid if the program had not been implemented. As a result, CMS proposes to subtract this amount from the national IPPS rates for FY 2022.

Organ Acquisition Payment Policies

CMS proposes to change, clarify and codify Medicare organ acquisition payment policies relative to organ procurement organizations (OPOs), transplant hospitals and donor community hospitals. CMS proposes to clarify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries so that Medicare more accurately records and pays its share of organ acquisition costs.

Medicare Shared Savings Program

In the Proposed Rule, due to the COVID-19 PHE, CMS proposes amending the Medicare Shared Savings Program to provide eligible accountable care organizations (ACOs) participating in the BASIC track's glide path the opportunity to maintain their current level of participation for Performance Year (PY) 2022 ("freeze" option). In the Proposed Rule, CMS provides how ACOs would advance for PY 2023. For example, an ACO that decides to freeze it participation level for both PYs 2021 and 2022 would be automatically advanced for PY 2023 to the level of the BASIC track's glide path in which it would have participated in during PY 2023. A table (pg. 1564) in the <u>Proposed Rule</u> provides more information on the BASIC track's glide path "freeze" scenarios.

Request for Information (RFI): Advancing to Digital Quality Measurement for the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality programs

As part of CMS's efforts to modernize its quality measurement enterprise, in the Proposed Rule, the agency included a request for information (RFI) to inform CMS as it transitions to digital quality measurement. To advance digital quality measurement, CMS identifies four potential action in four areas it is considering:

- 1. Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs
- 2. Redesign CMS quality measure to be self-contained tools;
- 3. Better support data aggregation; and
- 4. Work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector, where appropriate.

CMS seeks comment on these potential actions and a complete list of questions is available in the <u>Proposed Rule</u> (pg. 1237-1239). CMS notes any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate notice and comment rulemaking.

RFI: Closing the Health Equity Gap in CMS Hospital Quality Programs

In recognition of persistent health disparities and the importance of closing the health equity gap, CMS identifies three potential future expansions of the <u>CMS Disparity Methods</u> which help show differences in readmission rates for patients with social risk factors, and seeks feedback. CMS also notes the responses to the RFI will not directly impact payment decisions and that the agency intends to release an additional RFI or rulemaking on this topic in the future. CMS also discusses previous public comments it has received related to two disparity methods, which illuminate outcome differences among patient groups within a provider's patient population. The two disparity methods are the Within-Hospital disparity method (promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors) and the Across-Hospital method (is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing a comparison among hospitals for their patients with social risk factors). CMS is considering expanding disparity methods to include two social risk factors (duality eligible and race/ethnicity).

In addition, CMS seeks comment on three potential future expansions of the CMS Disparity Methods, including:

- Future potential stratification of quality measure results by race and ethnicity: CMS is interested in learning more about the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.
- Improving demographic data collection (e.g., incorporation of demographic information into quality measure specifications): CMS is interested in current data collection practices by hospitals to capture demographic data elements (e.g., race, ethnicity, sex, sexual orientation, and gender identify, language preference, tribal membership and disability status). CMS is also interested in learning the potential challenges facing hospital collection, at the time of admission, of a minimum set of demographic data elements in alignment with national data collection standards (e.g., standards finalized by the ACA) and standards for interoperable exchange.
- Potential creation of a Hospital Equity Score to synthesize results across multiple social risk factors: CMS is considering developing a Health Equity Score that would be modeled after the equity score for Medicare Advantage contracts/plans, the Health Equity Summary Score, with the application to stratified reporting using two social risk factors (dual eligibility and race/ethnicity).

A complete list of questions is available in the <u>Proposed Rule</u> (pgs. 1259-1261). CMS clarifies that any data pertaining to these areas that are recommended for collection for CMS (e.g., measure reporting, posting on Care Compare) would be addressed through separate notice and comment rulemaking.

What's Next?

CMS is anticipated to publish the final IPPS regulation before August 1, 2021 and the changes are effective at the beginning of the federal fiscal year (October 1, 2021). The comment period closes on June 28, 2021.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to <u>Jenna Stern</u>, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.