

May 20, 2021

Hospital Inpatient PPS Proposed Rule for FY 2022

At A Glance

At Issue

The Centers for Medicare & Medicaid Services (CMS) April 27 issued its hospital inpatient prospective payment system (PPS) and long-term care hospital (LTCH) PPS [proposed rule](#) for fiscal year (FY) 2022. The rule affects inpatient PPS hospitals, critical access hospitals (CAHs), LTCHs and PPS-exempt cancer hospitals. A summary of the proposals related to inpatient PPS hospitals, CAHs and PPS-exempt cancer hospitals is attached. Look for a separate AHA advisory on the LTCH PPS-related proposals soon. Comments on the proposed rule are due to CMS by June 28. The final rule will be published on or around Aug. 1 and take effect Oct. 1.

AHA Take

We applaud CMS' proposal to repeal the requirement that hospitals and health systems disclose privately negotiated contract terms with payers on the Medicare cost report. We have long said that privately negotiated rates take into account any number of unique circumstances between a private payer and a hospital and their disclosure will not further CMS' goal of paying market rates that reflect the cost of delivering care. We once again urge the agency to focus on transparency efforts that help patients access their specific financial information based on their coverage and care.

Key Takeaways

CMS proposes to:

- Increase inpatient PPS payments by 2.8% in FY 2022.
- Repeal the requirement to report the median payer-specific negotiated rates for inpatient services, by Medicare Severity-Diagnosis-related Group (MS-DRG), for Medicare Advantage organizations.
- Use data from Worksheet S-10 in the FY 2018 cost report to determine the distribution of FY 2022 DSH uncompensated care payments.
- Extend New COVID-19 Treatments Add-on Payments for eligible COVID-19 products through the end of the fiscal year in which the public health emergency (PHE) ends.
- Implement changes to the GME program and related payments, as required in the Consolidated Appropriations Act, 2021.
- Modify the Promoting Interoperability Program, including by requiring a 180-day reporting period for CY 2024 and increasing the minimum required score to be considered a meaningful EHR user.
- Suppress certain measures in hospital quality reporting and value programs, applying neutral payment adjustments under hospital value-based purchasing (VBP) for FY 2022, to account for the impact of the COVID-19 PHE.
- Add five new measures for the inpatient quality reporting (IQR) program.

What You Can Do

- ✓ **Participate in an AHA members-only webinar May 24** at 1:30 ET to share your questions about and feedback on this regulation for AHA's comment letter to CMS. To register for this 60-minute webinar, visit [here](#).
- ✓ **Share this advisory with your senior management team** and ask your chief financial officer to examine the impact of the proposed payment changes on your Medicare revenue for FY 2022. Hospitals may assess the impact of these provisions on their organizations by using AHA's calculators on readmissions, value-based purchasing and Medicare DSH: <https://www.aha.org/inpatient-pps>.
- ✓ **Verify CMS' [table](#) listing the factor used to calculate uncompensated care payments for Medicare Disproportionate Share Hospitals (DSH)**. Hospitals have until June 28 to review this table and notify CMS in writing of any inaccuracies.
- ✓ **Verify that you have attested to meaningful use**. Attestation status can be determined through CMS' [website](#).
- ✓ **If applicable, apply for low-volume hospital status** by written request to your Medicare Administrative Contractor (MAC) by Sept. 1 in order to receive the low-volume adjustment beginning Oct. 1.
- ✓ **Share this advisory with your billing, medical records, quality improvement and compliance departments, as well as your clinical leadership team** – including the quality improvement committee and infection control officer – to apprise them of the proposals around the diagnosis-related groups and quality measurement requirements.
- ✓ **Submit comments to CMS with your specific concerns by June 28 at www.regulations.gov**. The final rule will be published on or around Aug. 1 and take effect Oct. 1.

Further Questions

Please contact Shannon Wu, AHA senior associate director of policy, at 202-626-2963 or swu@aha.org if you have further questions.

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Inpatient PPS Payment Update

CMS' [proposed rule](#) would increase inpatient PPS rates by a net of 2.8% in FY 2022, compared to FY 2021, after accounting for inflation and other adjustments required by law. Specifically, the update includes an initial market-basket update of 2.5%, less 0.2 percentage points for productivity as required by the Affordable Care Act (ACA), and plus 0.5 percentage points to partially restore cuts made as a result of the American Taxpayer Relief Act (ATRA) of 2012. Table 1 below details the factors CMS includes in its estimate.

Impacts of FY 2022 Proposed Policies

Policy	Average Impact on Payments
Market-basket update	+ 2.5%
Productivity cut mandated by the ACA	- 0.2%
Partial restoration of documentation and coding cut mandated by ATRA	+ 0.5%
Total	+ 2.8%

The productivity and ATRA adjustments would be applied to all hospitals. However, inpatient PPS hospitals that do not submit quality data, or that failed to either meet meaningful use or qualify for hardship exemption for FY 2020 would be subject to market-basket penalties. Specifically:

- Hospitals not submitting quality data would be subject to a one-quarter reduction of the initial market basket and, thus, would receive an update of 2.18%.
- Hospitals that were not meaningful users of electronic health records (EHRs) in FY 2020 would be subject to a three-quarter reduction of the initial market basket and, thus, would receive an update of 0.93%.
- Hospitals that fail to meet both of these requirements would be subject to a full reduction of the initial market-basket rate and receive an update of 0.30%.

For more information related to the failure to either meet meaningful use or qualify for hardship exemption, including those that apply to CAHs, please review the Aug. 13, 2010 AHA [Regulatory Advisory](#) on meaningful use.

FY 2020 vs. FY 2019 Data in Rate-setting

Typically, CMS uses the most recently available claims data source for rate-setting, which for FY 2022 rate-setting purposes would be FY 2020 claims data. Similarly, CMS uses cost report data from the most recent release, which for FY 2022 would be FY 2019 cost report data. However, as noted by CMS, both the FY 2020 claims and the FY 2019 cost report data were impacted by the COVID-19 PHE and are highly unusual compared to past years. Specifically, there are significant impacts on the outlier fixed-loss amount, MS-DRG relative weights, and case mix. Accordingly, CMS proposes to use FY 2019 claims and FY 2018 cost report data wherever it would have ordinarily used FY 2020 claims and FY 2019 cost reports. CMS is considering, as an alternative, using the data it would have ordinarily used for purposes of FY 2022 rate-setting (i.e., FY 2020 claims and FY 2019 cost reports) and is soliciting comments on such an approach.

Rebasing and Revising Hospital Market Baskets

The hospital market basket describes the mix of goods and services used in providing hospital care and it commonly refers to the cost category weights and price proxies used to refer to the hospital input price index. CMS rebases and revises the market basket every four years so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase to furnish inpatient care. The last time the hospital market basket was rebased was for FY 2018 using 2014 data. As such, CMS proposes to rebase the hospital market basket for FY 2022 using 2018 data. As demonstrated by the table below, there are no differences in the market baskets for FY 2021 – FY 2024 when using the proposed 2018-based market basket compared to the 2014-based market basket.

Fiscal Year (FY)	2014-Based IPPS Market Basket Percent Change	Proposed 2018-Based IPPS Market Basket Percent Change
Historical data:		
FY 2017	2.6	2.5
FY 2018	2.5	2.5
FY 2019	2.4	2.4
FY 2020	2.0	2.0
Average FYs 2017-2020	2.4	2.4
Forecast:		
FY 2021	2.4	2.4
FY 2022	2.5	2.5
FY 2023	2.8	2.7
FY 2024	3.0	3.0
Average FYs 2021-2024	2.7	2.7

Source: IHS Global, Inc., 4th Quarter 2020 forecast.

In addition, by law, CMS must adjust the proportion of the standardized amount that is attributable to wages and wage-related costs (known as the labor-related share) by a factor that reflects the relative difference in labor costs among geographic areas (known as the area wage index). For FY 2022, CMS proposes to recalculate the labor-related share using the proposed 2018-based market basket. Specifically, CMS proposes to use a labor-related share of 67.6% for those hospitals with wage indices greater than 1.0 and 62% for those hospitals with wage indices less than or equal to 1.0. Similar to what it has previously done, CMS does not propose a Puerto Rico-specific labor-related or non-labor-related share percentage. As demonstrated by the table below, the proposed labor-related share is 0.7 percentage points lower than the current labor-related share of 68.3%.

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

Note: Detail may not add to total due to rounding.

CMS also proposes to rebase and revise the capital input price index (CIPI), which reflects the capital cost structure, to a 2018-based year. Rebasing the CIPI from 2014 to 2018 does not have an impact on the percent change in the capital update for FY 2022.

Rate-of-increase for Hospitals Excluded from the Inpatient PPS

Certain hospitals – including cancer hospitals, children’s hospitals, and hospitals located in U.S. territories – are excluded from the inpatient PPS and are paid based on reasonable costs. CMS estimates that based on the proposed 2018-based market basket update, the rate of increase percentage is 2.5% for FY 2022 for these hospitals.

Capital-related Costs

CMS uses a methodology for determining capital prospective payments using a federal rate for almost all acute care hospitals, including adjustments for outliers and geography, among other adjustments. CMS proposes to increase the national capital federal rate for FY 2022 by 1.22% compared to the FY 2021 capital federal rate.

“Market-based” MS-DRG Data Collection and Weight Calculation

In response to Executive Orders on price transparency and Medicare Advantage (MA), in its FY 2021 IPPS final rule, CMS stated it would begin collecting median payer-specific charges for MA organizations on the Medicare cost report in Jan. 1, 2021. CMS also finalized in its FY 2021 IPPS final rule using these data to calculate new relative MS-DRG weights beginning in FY 2024.

CMS now proposes to repeal the requirement that hospitals report their median payer-specific charges for MA organizations and to repeal its use in calculating new market-based MS-DRG relative weights. CMS proposes to continue using the existing cost-based methodology for calculating MS-DRG relative weights for FY 2024 and subsequent years.

Given the repeal of both market-based data collection and market-based MS-DRG relative weight methodology, CMS requests comments on alternative approaches or data sources that could be used for Medicare fee-for-service rate-setting for FY 2024 and subsequent years.

The AHA applauds CMS’ proposal to repeal the requirement that hospitals and health systems disclose privately negotiated contract terms with payers on the Medicare cost report. We have long said that privately negotiated rates take into account any number of unique circumstances between a private payer and a hospital and their disclosure will not further CMS’ goal of paying market rates that reflect the cost of delivering care. We once again urge the agency to focus on transparency efforts that help patients access their specific financial information based on their coverage and care.

Disproportionate Share Hospital (DSH) Payment Changes

Under the DSH program, hospitals receive 25% of the Medicare DSH funds they would have received under the former statutory formula (described as “empirically justified” DSH payments). The remaining 75% flows into a separate funding pool for DSH hospitals. This pool is reduced as the percentage of uninsured declines and is distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides.

FY 2022 DSH Payments

For FY 2022, CMS estimates that the total amount of Medicare DSH payments that would have been made under the former statutory formula is \$14.098 billion. Accordingly, CMS proposes that hospitals would receive 25% of these funds, or \$3.524 billion, as empirically justified DSH payments.

The remaining \$10.573 billion would flow into the 75-percent pool, which is then adjusted to reflect changes in the percentage of uninsured. CMS determined that the percentage of uninsured for FY 2022 would be 10.1%; thus, after inputting that rate into the statutory formula, it proposes to retain 72.14% – or \$7.628 billion – of the 75-percent pool in FY 2022. This would result in a decrease of about \$660 million in uncompensated care payments in FY 2022 compared to FY 2021.

As in previous years, to distribute the 75-percent pool, the agency would continue to use the share of uncompensated care provided by each DSH hospital. For example, if Hospital A accounts for 1% of the total uncompensated care provided by all DSH hospitals, it would receive 1% of what remains of the 75-percent pool.

Worksheet S-10 Data

In FY 2018, CMS began incorporating cost report Worksheet S-10 data on hospital charity care and bad debt into the determination of the amount of uncompensated care each hospital provides. CMS phased in the use of the S-10 data, using data from a rolling three-year period to estimate uncompensated care payments. However, as it did for FY 2021, CMS proposes for FY 2022 to use a single year of audited data to determine DSH payments. CMS continues to believe that averaging multiple years of data, and therefore mixing audited and unaudited data, could “dilute” the effect of auditing, and potentially lead to a “less smooth result.”

Specifically, CMS proposes to use data from the FY 2018 cost report to determine the distribution of uncompensated care payments in FY 2022. CMS indicates that the FY 2018 cost reports contain the most recently audited data (audit began in 2020) and that audited hospitals represent approximately 99.6% of proposed total uncompensated care payments for FY 2022. The FY 2018 data also reflect the revisions to Worksheet S-10 cost report instructions that were effective as of Oct. 1, 2017.

Healthcare Cost Report Information System (HCRIS) Data. CMS notes that, for the FY 2022 proposed rule, the agency uses HCRIS data updated through Feb. 19, 2021. However, the agency expects to use the March 2021 extract of HCRIS data for the final rule. CMS also may consider using more recent data that may be available after March 2021 but before the development of the final rule.

Definition of Uncompensated Care

CMS again proposes to continue defining uncompensated care costs as the amount on Line 30 of Worksheet S-10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

Statistical Trimming of Worksheet S-10 Data

CMS proposes to continue applying statistical trim methodologies to potentially aberrant cost-to-charge ratios (CCRs) and uncompensated care costs (UCC) reported on the Worksheet S-10. In addition to existing UCC trim methodology, CMS proposes to apply a new UCC trimming methodology to hospitals that are not projected to be DSH eligible and do not have an audited Worksheet S-10, but may have aberrant amounts of insured patients' charity care costs. CMS proposes to use a ratio threshold of greater than 60% of insured patients' charity care costs to total uncompensated care costs and a dollar threshold of the median total uncompensated care cost reported in FY 2018 cost reports (\$7 million). CMS believes that the new trim methodology more appropriately addresses aberrant insured patient charity care costs. For hospitals that are subject to this proposed trim but ultimately are DSH eligible at cost report settlement, the hospital's MAC would make a final determination of Medicare DSH payments based on its FY 2022 cost report.

Interim Uncompensated Care Payments

CMS proposes to modify the calculation for interim uncompensated care payments for FY 2022 in light of the COVID-19 PHE. The agency proposes to use the average of FY 2018 and FY 2019 discharge data to estimate the amount of a hospital's uncompensated care payment per discharge, rather than its traditional use of a 3-year average that would include FY 2020 data. CMS would use the resulting 2-year average of discharges to calculate the per discharge payment amount for interim uncompensated care payments to each project DSH-eligible hospital.

Additional DSH Policies

Newly Merged Hospitals. CMS proposes to continue its policy to treat hospitals that merge after the development of the final rule similar to new hospitals. Specifically, CMS proposes that the newly merged hospital's (i.e., the surviving hospital) current fiscal year cost report would be used to determine the hospital's DSH payment. If the newly merged hospital's cost reporting period is less than 12 months, CMS would annualize the data.

CMS also proposes to continue its policy that interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CMS Certification Number (CCN) available the time of the development of the final rule. For FY 2022, this would be the FY 2018 cost report for the surviving hospital's CCN. Per the

policy described above, CMS would then determine the final DSH payment for the newly merged hospital based on the FY 2022 during cost report settlement.

“New Hospitals.” CMS proposes to continue its policy for “new hospitals” finalized in FY 2020. Specifically, for those hospitals with a CCN established on or after Oct. 1, 2018, the hospital’s MAC would make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2022 cost report. New hospitals would not receive interim uncompensated care payments before cost report settlement because Worksheet S-10 data for FY 2018 would not be available.

Puerto Rico Hospitals. CMS proposes to continue to use a low-income patient proxy, rather than FY 2018 Worksheet S-10 data, to determine the share of uncompensated care provided by Puerto Rico hospitals for FY 2022. Specifically, CMS would utilize Medicaid days from FY 2013 and the most recent update of Supplemental Security Income (SSI) days. For Puerto Rico hospitals, SSI days would be equivalent to 14% of a hospital’s Medicaid days, as finalized in the 2017 inpatient PPS/LTCH PPS final rule.

Indian Health Service (IHS) and Tribal Hospitals. For FY 2022, CMS proposes to continue to use a low-income proxy for IHS and Tribal hospitals, which consists of Medicaid days from FY 2013 and the most recent update of SSI days. CMS continues to consult with IHS and Tribal hospitals and seeks comments regarding their uncompensated care reporting.

CMS has published on its [website](#) a table listing uncompensated care payments and other DSH-related information for all hospitals that the agency estimates would receive these payments in FY 2022. Hospitals will have 15 days from the date of public display of the FY 2022 final rule to review the accuracy of the table published in conjunction with the final rule and notify CMS in writing of any inaccuracies.

The AHA created a DSH calculator for member hospitals to assess the impact of the policy on their organizations. It is available at: <https://www.aha.org/inpatient-pps>. The calculator is designed so basic financial information regarding a hospital can be entered, including its CCN, and the dollar amount of the hospital’s DSH payment will be estimated.

Chimeric Antigen T-Cell (CAR-T) Therapy

CAR T MS-DRG and Clinical Trial Adjustment

In its FY 2021 final rule, CMS developed a relative weight for a CART T MS-DRG, which did not include claims determined to be clinical trials since such cases do not account for the cost of therapy itself. In addition, CMS also finalized an adjustment to payments for clinical trial cases and expanded access immunotherapy cases. Using FY 2019 data, CMS proposes a payment adjustment of 0.17 when calculating payment for clinical trial cases and expanded access cases assigned to MS-DRG 018 in FY 2022. That is, the inpatient payment would be reduced by 83% to account for the hospital not incurring the cost of the

therapy itself. CMS notes that an alternative approach of using FY 2020 data would yield an adjustment of 0.25.

New Technology Add-on Payments (NTAPs)

The inpatient PPS provides additional payments, known as NTAPs, for cases with relatively high costs involving eligible new medical services or technologies. Regulations specify three criteria for a new medical service or technology to receive additional payments: 1) newness criterion; 2) cost criterion; and 3) substantial clinical improvement criterion. NTAPs are allotted at a rate of 65% of the marginal cost of a case, up to 65% of the cost of the technology (75% for products designated as Qualified Infectious Disease Products (QIDPs) and Limited Population Pathway for Antibacterial and Antifungal Drugs (LPADs)). These payments are not budget neutral.

NTAP Submissions and Approvals

CMS proposes to continue NTAPs in FY 2022 for nine technologies already approved for the payments that remain eligible. In light of the COVID-19 PHE, CMS proposes to allow a one-year extension of payments for new technologies for which the NTAP would otherwise have been discontinued in FY 2022 because the technologies would no longer be considered new. Twenty-two applications for NTAPs are presented in the proposed rule, in addition to 16 products that meet the criteria for the “alternative pathway” for Breakthrough Devices and QIDPs.

Cost Criterion

According to regulation (42 CFR 412.87), CMS assesses the NTAP cost criterion by determining whether the product exceeds a certain cost threshold, which is based in part on payment associated with the product’s applicable MS-DRG. As finalized in FY 2021 final rule, beginning with FY 2022, CMS would use the threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for NTAPs and previously approved technologies that may continue to receive NTAPs. In light of the COVID-19 PHE, and consistent with CMS’ proposal to use FY 2019 claims data for FY 2022 rate-setting, CMS also proposes to use FY 2019 claims data to evaluate threshold amounts.

Alternative Pathways

CMS allows, beginning with applications for FY 2021 NTAPs, medical devices that are part of the Food and Drug Administration’s (FDA) Breakthrough Devices Program and products that are designated by the FDA as a QIDP to qualify for NTAPs under an alternative pathway. Beginning in FY 2022, it also would allow a drug that is approved by the FDA under LPAD to qualify under the alternative pathway. These products would be considered new and not substantially similar to an existing technology, and would not need to meet the requirement that they substantially improve diagnosis or treatment of patients, as long as they are approved by the FDA; they would only need to meet the cost criterion to be eligible for NTAPs.

As finalized in the FY 2021 final rule, CMS clarified that new technologies must receive FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. CMS also further clarified that for certain antimicrobial products that did not receive FDA marketing authorization by the July 1 deadline, these products would begin receiving NTAPs the quarter after FDA approval, provided FDA marketing authorization is received by July 1 of the year for which the applicant applied for NTAPs. CMS proposes that a product available only through an emergency use authorization would not be considered an FDA marketing authorization for the purposes of NTAPs.

New COVID-19 Treatments Add-on Payments (NCTAPs)

In light of the COVID-19 PHE, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) for COVID-19 cases that meet certain criteria occurring on or after Nov. 2, 2020 until the end of the PHE. The established NCTAP paid hospitals the lesser of 65% of the operating outlier threshold for the claim or 65% of the amount by which the costs of the case exceeded the standard DRG payment. CMS proposes to extend NCTAP for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends. In addition, CMS also propose to extend NCTAP for eligible products that are not approved for NTAPs through the end of the fiscal year in which the PHE ends, and to discontinue NCTAP for discharges on or after Oct. 1, 2021 for a product that is approved for NTAPs beginning in FY 2022.

Area Wage Index Modifications

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. For FY 2022, CMS proposes to use data from FY 2018 cost reports to determine the area wage index. In addition, for FY 2022, CMS proposes to use the Office of Management & Budget (OMB) labor market delineations that it adopted beginning with FY 2015, with updates as reflected in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-04 and 20-01.

Area Wage Index Transition Policies

In FY 2021 final rule, CMS adopted updates in OMB bulletin 18-04. In connection with core-based statistical area (CBSA) modifications for FY 2021, CMS adopted a policy to cap any decrease in a hospital's final wage index in FY 2021 compared to its final wage index in FY 2020 at 5%. (More details about the CBSA modifications can be found in AHA's FY 2021 inpatient PPS final rule [Regulatory Advisory](#)). This was set to expire at the end of FY 2021. In light of the COVID-19 PHE, CMS now seeks comments on the appropriateness of applying a transition to the FY 2022 wage index for hospitals that would be negatively impacted by the adoption of OMB Bulletin 18-04. For example, an extended transition could hold hospitals harmless of their FY 2022 wage index from any reduction relative to FY 2021 wage index. CMS also seeks comments on making such a transition, if adopted, budget neutral.

Occupational Mix

The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the calculation of 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. CMS collected data in the 2016 Medicare Wage Index Occupational Mix Survey with the intent of computing the occupational mix adjustment for FYs 2019, 2020 and 2021. Accordingly, a new measurement of occupational mix is required for FY 2022. CMS proposes to calculate the FY 2022 occupational mix adjustment based on data from the 2019 Medicare Wage Index Occupational Mix Survey. CMS also proposes to apply the occupational mix adjustment to 100% of the wage index, as has in the past.

Low-wage Hospital Wage Index Policy

CMS proposes to continue its policy to increase wage index values for low-wage hospitals that was finalized for FY 2020 to be effective for four years. Specifically, for hospitals with a wage index value below the 25th percentile, the agency would increase the hospital's wage index by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals. According to CMS, the 25th percentile wage index for FY 2022 would be 0.8418. The agency proposes to continue to make this policy budget neutral by adjusting the national standardized amount for all hospitals.

Rural Floor Calculation

Per statute, the area wage index value of any urban hospital may not be less than the area wage index applicable to hospitals located in rural areas in the same state – this is known as the “rural floor” policy. As finalized in FY 2020, CMS would continue to exclude the wage data of urban hospitals that reclassify to rural areas when calculating the wage index for the rural floor. For FY 2022, CMS estimates that 287 hospitals are expected to receive their state's rural floor wage index.

Imputed Floor Calculation

As required by the American Rescue Plan Act, CMS proposes to permanently reinstate a minimum area wage index for hospitals in all-urban states, known as an “imputed rural floor” for FY 2022. This policy applies to states that have no rural hospitals or no rural areas to set a rural floor wage index for those states. The imputed floor policy had been in effect from FYs 2005 through 2018, but for FYs 2019 through 2021, hospitals in all-urban states received a wage index without the application of an imputed floor.

Unlike the imputed floor in effect for FYs 2005 – 2018, this reinstated policy for FY 2022 is not budget neutral. Therefore, CMS proposes 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 imputed floor. In addition, CMS proposes to define a rural hospital as one assigned the State's rural area wage index value, after all reclassifications. This is in contrast to prior adoption of the policy,

where states did not qualify for “all-urban” status if hospitals geographically located in rural areas of the state were reclassified to receive an urban area wage index. However, a state will now qualify as all-urban state if hospitals located in a rural county were reclassified to receive the urban area wage index.

Medicare Geographic Classification Review Board (MGCRB) Redesignations and Reclassifications

Hospitals may apply to the MGCRB for geographic reclassifications for purposes of inpatient PPS payment. In order to qualify, hospitals must be proximate to the labor market area to which they are seeking reclassification and meet certain wage thresholds. At the time the proposed rule was drafted, the MGCRB had completed its review of FY 2022 reclassification requests and 496 hospitals were approved for wage index reclassifications for FY 2022. Hospitals reclassified during FYs 2020 (245 hospitals) and 2021 (317 hospitals) will continue to be reclassified, because wage index reclassifications are effective for three years.

MGCRB Reclassification, Applications, Withdrawals and Terminations. Hospitals with current reclassifications are encouraged to analyze the area wage indexes published in the proposed rule and confirm that the areas to which they have been reclassified still result in a higher wage index than their geographic area wage index. Hospitals may withdraw or terminate their reclassifications by contacting the MGCRB within 45 days of the issuance of the proposed rule.

CMS proposes to clarify a procedure for a hospital to request Administrator review of an MGCRB decision. The agency proposes to specify that the hospital’s request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. CMS believes that this proposed change would provide clarity and specificity by addressing changes to future technology platform for submission of the hospital’s request.

Applications for hospital reclassifications for FY 2023 are due to the MGCRB by Sept. 1, 2021.

Limitations on Redesignation by MGCRB. Concurrent with the inpatient PPS proposed rule, CMS also issued an [interim final rule](#) (IFR) with comment period in conjunction with its FY 2022 proposed rule to implement *Bates Co. v Azar*. Under this IFR, CMS will allow hospitals with a rural reclassification to use the rural area as the basis for its wage comparisons when seeking an MGCRB reclassification to another area. This would be effective with reclassifications beginning with FY 2023. The agency also would apply the policy when deciding timely appeals before the Administrator for reclassifications beginning with FY 2022 that were denied, which did not permit hospitals with rural redesignations to use the rural area’s wage data for purpose of reclassifying under the MGCRB.

Reclassification from Urban to Rural

In order for a hospital to be treated as rural in the wage index and budget-neutrality calculations for the coming FY, CMS currently stipulates that an application for rural reclassification must be approved no later than 60 days after the public display date of the inpatient PPS proposed rule. This is known as the “lock-in date.” If an application is

approved after the lock-in date, the rural wage index value would not include data for the hospital in the rate-setting calculation. As a result, CMS states that there exists an incentive for low-wage index hospitals to cancel their rural classification, and reapply again after the “lock-in date.”

Therefore, CMS proposes that requests to cancel rural reclassification cannot be submitted to the CMS regional office earlier than one calendar year after the reclassification effective date. For example, a hospital that was approved to receive rural reclassification effective Oct. 1, 2021 would not be eligible to request cancellation until Oct. 1, 2022. CMS also proposes that hospitals approved for rural reclassification would have its data included in the calculation for the rural wage index for at least one fiscal year before rural reclassification status can be canceled.

Graduate Medical Education (GME)

CMS provides payments to hospitals for the direct costs of approved GME programs. Generally, Medicare direct GME payments are based on the hospital’s per resident amount and the hospital’s Medicare share of total inpatient days. In addition, CMS also provides payment adjustments for hospitals for indirect medical education (IME) to account for higher indirect patient care costs of teaching hospitals. Generally, the IME adjustment is based on the ratio of the hospital’s number of full-time equivalent (FTE) residents to its number of inpatient hospital beds. CMS proposes to implement several provisions of the Consolidated Appropriations Act that affect Medicare direct GME and IME payments to teaching hospitals.

New Medicare-funded Medical Residency Positions

CMS proposes to distribute 1,000 new FTE residency positions. Specifically, beginning in FY 2023, it would phase in no more than 200 positions each year until 1,000 have been distributed. At least 10% of total residency positions would need to be distributed to each of the following four categories:

- Hospitals located in rural areas or that are treated as being located in rural areas for inpatient PPS purposes;
- Hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit;
- Hospitals in states with new medical schools; and
- Hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs).

To qualify under the rural status criterion, the hospital must be treated as such at the time of the application deadline for additional residency positions. To qualify under the “reference resident level” criterion, the hospital’s unweighted count of residents must be higher than its applicable resident cap as adjusted for participating in several programs, such as affiliated group arrangements and rural training tracks, among others. To qualify under the “new medical schools” category, CMS proposes a hospital would need to be located in one of 35 states or one territory for which the Liaison Committee on Medical

Education or Commission on Osteopathic College Accreditation has accredited a new medical school or additional location on or after Jan. 1, 2000 (a list of these locations can be found on p. 1080 – 1081 of the display copy of the proposed rule). Finally, to qualify under the HPSA criterion, CMS proposes that hospitals would need to be located in geographic primary care or mental health HPSAs. In addition, CMS proposes that at least 50% of the resident's training time must occur within the HPSA.

CMS proposes to prioritize applications for residency positions in programs serving underserved populations. The agency would further prioritize hospitals with residency programs that provide services to medically underserved populations in a population based HPSA and hospitals based on Health Resources and Services Administration's HPSA measure of severity of provider shortage in a geographic area. CMS proposes to also consider hospitals that qualify in more than one of the four statutory eligible categories.

By statute, there are limitations on the distribution of residency positions. For example, hospitals may not receive more than 25 additional FTE positions. CMS proposes to further limit the increase in the number of residency position to each individual hospital to no more than 1 FTE each year. Hospitals also must show a demonstrated likelihood of filling in additional positions. Hospitals can do this by demonstrating that they do not have sufficient room under their current FTE resident caps to accommodate a planned new program or expansion of an existing program.

CMS proposes that the application deadline will be January 31 of the fiscal year prior to the fiscal year the increase in FTEs becomes effective. The first application deadline would be Jan. 31, 2022. Application and instructions will be available on the CMS DGME [website](#) when the final rule is released.

Promoting Rural Hospital GME Funding Opportunity

CMS also proposes to implement the Promoting Rural Hospital GME Funding Opportunity, which would allow certain rural training hospitals to receive a GME cap increase. Specifically, in the past, to promote the training of residents in rural areas, urban hospitals with rural training tracks (RTTs) could see an increase in their cap of FTE residents. However, rural hospitals participating in RTTs may not have seen an increase in their cap of FTE residents, resulting in no funding going to the rural hospital for the rural portion of training. Additionally, cap adjustments were only awarded to an urban hospital that established separately accredited RTTs and may not have occurred for urban hospitals that added additional rural locations to already existing RTTs. To remedy these concerns, CMS proposes the following changes.

Urban and Rural Hospitals Participating in RTTs. CMS proposes to provide an adjustment to IME and direct GME FTE resident caps each time an urban and rural hospital establish a RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes. Previously, urban hospitals that established a rural track for the first time qualified for the FTE resident cap adjustments, even if the rural track was not new for Medicare payment purposes. However, rural hospitals that established a rural track would only receive a FTE resident cap adjustment if the program was new for

Medicare payment purposes. For example, if an urban hospital already had an accredited residency program, it could establish from that program a rural track for the first time and the urban hospital would receive IME and direct GME FTE resident cap adjustments. However, if a rural hospital established from an existing residency program a rural track for the first time, it would not receive the adjustment cap. The proposed change would now allow for the rural hospital to also receive adjustments to its resident caps.

Urban Hospitals Adding Additional RTTs. Previously, after establishing the first RTT, urban hospitals that established additional RTTs (beyond the first RTT) did not qualify for cap adjustment unless these additional RTTs were new for Medicare payment purposes. CMS proposes to change this policy and instead now adjust resident caps for an urban hospital creating additional RTTs after establishing its first RTT. Specifically, beginning on or after Oct. 1, 2022, if an urban hospital adds an additional RTT, that hospital, as well as the corresponding rural hospital participant may receive adjustments to their rural track FTE limitation. For example, consider an urban hospital that has an existing residency program and partnered with Rural Hospital 1 to create an RTT from its existing residency program. In 2023, the urban hospital partnered with Rural Hospital 2 to create an additional residency RTT. Both the urban hospital and Rural Hospital 2 would now receive adjustments to their resident caps. CMS believes that this would allow experienced and successful urban hospitals to branch out and partner with additional rural communities rather than relying on starting RTTs from scratch and is an efficient means of addressing rural healthcare workforce shortages. CMS would not allow increase to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT.

Separately Accredited RTTs. Previously, hospitals have not been able to seek additional funding opportunities for rural tracks developed in specialties other than family medicine because the Accreditation Council for Graduate Medical Education (ACGME) only separately accredited family medicine programs. CMS proposes that beginning on or after Oct. 1, 2022, as long as the program is entirely accredited by ACGME, regardless of specialty, and the residents spend more than 50% of the entire program in a rural area, except for family medicine, it may qualify as a RTT and the urban and rural hospitals may receive rural track FTE adjustments.

Adjustment of Low Per Resident Amounts and Low FTE Resident Caps

CMS proposes to implement changes to the determination of direct GME per-resident amounts and certain FTE resident limits for hospitals that host a small number of residents for a short duration. Previously, a hospital that served as a training site for a small number of residents would have had very low FTE caps. If they decided later to establish their own residency program, these hospitals would have found that their existing FTE caps would not have accommodated the number of residents in the new program. Therefore, CMS proposes to recalculate the per resident amount (PRA) if a hospital had a PRA of less than one FTE before Oct. 1, 1997 or if hospital has a PRA that was no more than three FTEs on or after Oct. 1, 1997 and before Dec. 27, 2020. The recalculation period would begin on Dec. 27, 2020 and end 5 years later.

CMS proposes to calculate the revised PRA as the lower of the hospital's actual cost per resident from Dec. 27, 2020 through Dec. 26, 2025, or the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area.

CMS proposes to use its existing regulations to calculate each qualifying hospital's FTE cap. Specifically, the cap would be determined in the fifth year of the new program based on the number of residents in training at that time. CMS also proposes to not set a FTE cap for any hospital that has trained fewer than one FTE resident on or after Dec. 27, 2020.

Organ Acquisition Payment

CMS supports a number of organ acquisition services by providing payment for organ transplantations. CMS excludes organ acquisition costs from the inpatient PPS payment, and instead separately reimburses for organ acquisition on a reasonable cost basis. CMS proposes to codify into Medicare regulations some longstanding Medicare organ acquisition payment policies, as well as and some new policies, including clarifying definitions for "transplant hospital," "transplant program" and "organs." The agency also would clarify when medical complications are considered organ acquisition costs. In addition, CMS proposes that transplant hospitals and organ procurement organizations count and report Medicare usable organs to ensure such organs are accurately allocated to Medicare. Lastly, the agency also proposes several provisions for donor community hospitals, including reducing its customary charges to its costs.

Medicaid Enrollment of Medicare Providers

Under existing Medicare and Medicaid law and regulations, state Medicaid programs are required to pay providers for Medicare cost-sharing on behalf of dually-eligible Medicare enrollees who are also enrolled in Medicaid. State Medicaid programs are permitted to limit payment for Medicare cost-sharing such that it is equal to the amount the state would have paid for the service under the Medicaid program. Providers may recover a portion of unpaid cost-sharing amounts as Medicare "bad debt." Before providers can claim any unpaid cost-sharing amounts as Medicare bad debt, the provider must bill the State (or the Medicaid managed care organization) and obtain from the state documentation of completed claims processing and the State's cost-sharing liability. However, some states have not recognized certain provider types under their Medicaid programs. Thus, some providers have been unable to obtain the necessary documentation from the state to allow them to claim Medicare bad debt. Other providers have encountered difficulty in the processing of certain cost-sharing claims under the State Medicaid program. .

Therefore, CMS proposes to require, for the purposes of determining Medicare cost-sharing obligations, that State Medicaid programs accept enrollment of all Medicare-enrolled providers and suppliers if they meet all Federal Medicaid enrollment requirement, even if the provider or supplier is not eligible to enroll in the State Medicaid program. CMS believes that this would reduce the number of future bad debt appeals, allow more

providers to claim Medicare bad debt, and allow certain providers to more easily treat or continue treating dually-eligible beneficiaries.

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

Some states extend medical coverage benefits under a section 1115(a) demonstration waiver to populations that could not have otherwise been made eligible for medical assistance under the Medicaid State plan. CMS then determines, on a case-by-case basis, if these expansion groups are included in the count of Medicaid inpatient days used in calculating the Medicare DSH patient percentage.

Based on several court decisions, CMS is now required to count in the numerator of the “Medicaid fraction” those patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration, as well as the days of patients who receive premium assistance under a section 1115 demonstration program. Considering these court decisions, CMS proposes to modify its regulation to ensure that the days that are counted in the numerator of the Medicaid fraction are the days of patients for whom a section 1115 waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day.

Rural Provisions

Low-volume Hospitals

For FYs 2019 through 2022, a low-volume hospital is defined as being located more than 15 road miles from the nearest subsection (d) hospital and having fewer than 3,800 total discharges. CMS provides these hospitals with a payment adjustment based on a continuous, linear sliding scale formula. Specifically, qualifying hospitals with 500 or fewer total discharges would receive a low-volume hospital payment adjustment of 25%. For qualifying hospitals with fewer than 3,800 total discharges, but more than 500 discharges, CMS proposes that the adjustment be calculated using the following formula:

$$\text{Add-on Percentage} = (95 / 330) - (\text{total discharges} / 13,200)$$

To receive the enhanced payments beginning Oct. 1, 2021, a hospital must make a written request for low-volume status that is received by its MAC by Sept. 1, 2021.

Hospitals Applying for Rural Referral Center (RRC) Status

One way in which a hospital can qualify for RRC status is based on a combination of discharge volume and case mix criteria, in comparison to other providers in the hospital’s region. Specifically, a hospital must meet the minimum case-mix index (CMI) value during the most recent FY that ended at least one year prior to the beginning of the cost reporting period for which the hospital is seeking RRC status. For example, CMS typically uses data from the FY that is two years prior to the fiscal year for which the hospital is seeking RCC

status. In light of the COVID-19 PHE, CMS proposes to, instead of using FY 2020 data, use FY 2019 data to calculate CMI values.

In addition, a hospital must meet the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. For example, CMS typically use the cost reporting periods that are 3 years prior to the FY for which a hospital is seeking RRC status to compute the regional median discharges. CMS proposes to, instead of using cost reporting periods beginning in FY 2019, use cost reporting periods beginning in FY 2018.

Rural Community Hospital (RCH) Demonstration Program

The Consolidated Appropriations Act of 2021 extended the RCH Demonstration for an additional five years. This program, which allows rural hospitals with fewer than 51 acute care beds to test the feasibility of cost-based reimbursement, was established under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The ACA and the 21st Century Cures Act extended the program each time for an additional 5 years, and CMS proposes to implement the 5-year extension period authorized this year to follow previous extensions. Specifically, CMS would provide an additional 5-year period under the cost-based reimbursement method for hospitals that were participating as of Dec. 30, 2019. For hospitals with a scheduled end date during 2021, 2022, and 2023, CMS propose that they would be eligible to elect to participate for an additional 5-year period after its end date under the 21st Century Cures Act extension. In addition, CMS proposes to permit hospitals that withdrew from the demonstration in February 2020 to elect to participate for an additional 5-year period.

Critical Access Hospitals and Frontier Program

The Frontier Community Health Integration Project (FCHIP) demonstration allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. Specifically, CMS waived certain Medicare rules for CAHs participating in the demonstration to allow for alternative reasonable cost-based payment methods in the areas of telehealth services, ambulance services, and skilled nursing facility and nursing facility beds expansion. The initial periods of the demonstration occurred from Aug. 1, 2016 to July 31, 2019. The Consolidated Appropriations Act of 2021 extends the demonstration project by 5 years beginning July 1, 2021.

Key Coding and MS-DRG Changes

FY 2022 MS-DRG Updates

CMS proposes the following changes to the MS-DRGs. CMS's analysis is based on claims data from the March 2020 update of the FY 2019 MedPAR file which contains hospital bills received from Oct. 1, 2018 through March 31, 2020, for discharges occurring through Sept. 30, 2019 and from the Sept. 2020 update of the FY 2020 MedPAR file which contains

hospital bills received from Oct. 1, 2019 through Sept. 30, 2020 for discharges occurring through Sept. 30, 2020.

In decisions to modify MS-DRGs, CMS considers whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG. CMS evaluates patient care costs using average costs and lengths of stay. CMS uses its clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In addition, CMS considers the number of patients who will have a given set of characteristics and notes it generally prefers not to create a new MS-DRG unless it would include a substantial number of cases.

CMS uses the criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted. In order to warrant the creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the following criteria:

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

In the FY 2021 final rule, CMS expanded the above criteria to include the Non-CC subgroup for a three-way severity level split. CMS believes that this will better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the Non-CC level MS-DRGs.

CMS' analysis applying the Non-CC subgroup criteria to all current MS-DRGs split into three severity levels found that it would delete 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) and create 58 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative rates and thus the payment rates. Table 6P.1c contains the list of the 96 MS-DRGs that would be subject to deletion and the list of the 58 new MS-DRGs that would be proposed if the Non-CC subgroup criteria were applied.

Because of the public health emergency (PHE), CMS has concerns about the impact of implementing these MS-DRGs changes and **requests comments on the following proposals:**

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

- **Pre-MDC**

- *Chimeric Antigen Receptor (CAR) T-Cell Therapy.* CMS is proposing to classify 16 new ICD-10-PCS procedure codes that describe the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies that will be effective with discharges on and after Oct. 1, 2021 as non-O.R. procedures affecting Pre-MDC MS-DRG 018.

CMS is also proposing to revise the title for Pre-MDC MS-DRG 018 from “Chimeric Antigen Receptor (CAR) T-cell Immunotherapy” 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 also be assigned to this MS-DRG in addition to CAR T-cell therapies.

- **Major Diagnostic Category (MDC) 3 (Diseases and Disorders of Ear, Nose and Throat)**

- *Major Head and Neck Procedures.* CMS is proposing to reassign three ICD-10-PCS procedure codes describing excision of subcutaneous tissue of chest, back, and abdomen as they do not describe major head and neck procedures as follows:

From	To
MS-DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively)	MS-DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)

CMS also is proposing to reassign these codes from Extensive O.R. procedures to Non-extensive procedures when any one of the codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis.

- *Other Ear, Nose, Mouth and Throat O.R. Procedures.* CMS proposes to reassign three procedure codes describing control of bleeding in the cranial cavity as follows:

From	To
MS-DRGs 143, 144 and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)	<ul style="list-style-type: none"> ○ MS-DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), ○ MS-DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and ○ MS-DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, CC and without CC/MCC respectively)

- **MDC 4 (Diseases and Disorders of Respiratory System)**

- *Major Chest Procedures.*

- Laser Interstitial Thermal Therapy. CMS is proposing to reassign 17 procedure codes shown in [Table 6P.2b](#) of this proposed rule describing laser interstitial thermal therapy (LITT) from MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively) and MS-DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to various clinically appropriate MDC and MS-DRGs. The 17 procedure codes do not describe areas within the respiratory system and therefore are not consistent with the organ system, etiology or clinical specialty of the MDC to which the procedure code is currently assigned. CMS is also proposing to reassign these codes from Extensive O.R. procedures to Non-extensive procedures when any one of the codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis.
 - Repair of Esophagus. CMS is proposing to remove five procedure codes describing repair of the esophagus from MS-DRGs 163, 164 and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) the codes are not clinically coherent with the other procedures in MS-DRGs 163, 164 and 165 that describe procedures performed on major chest structures. In addition, CMS is proposing to reassign three of these procedure codes from Extensive O.R. procedures to Non-extensive procedures when any one of the codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis.
 - Repair of Pulmonary or Thoracic Structures and Procedures Performed on the Sternum of Ribs. CMS is proposing to reassign 26 procedure codes (nine procedure codes describing repair of pulmonary or thoracic structures, and 17 procedure codes describing procedures performed on the sternum or ribs) reflected in [Table 6P.2c](#) associated with this proposed rule as shown below:

From	To
MS-DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)	MS-DRGs 163, 164 and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively)

Data analysis by CMS shows that the average length of stay and average costs for these cases appear more consistent with cases in the proposed MS-DRGs. CMS believes further analysis of the procedures currently assigned to MS-DRGs 163, 164, 165, 166, 167, and 168 is warranted based on the creation of new procedure codes that have been assigned to these MS-DRGs in recent years for which claims data are not yet available, and there is a need for additional time to examine the procedures by clinical intensity, complexity of service and resource

utilization as additional claims data become available. CMS will continue to evaluate the procedures assigned to these MS-DRGs.

- **MDC 5 (Diseases and Disorders of the Circulatory System)**

- *Short-term External Heart Assist Device.* CMS is proposing to reassign three procedure codes that describe the intraoperative insertion of a short-term external heart assist device as follows:

From	To
MS-DRG 215 (Other Heart Assist System Implant)	<ul style="list-style-type: none"> ○ MS-DRGs 216, 217, 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) and ○ MS-DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively)

CMS clinical advisors agreed that cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS-DRG 215. This reassignment would be more clinically homogenous, coherent and better reflect hospital resources while addressing concerns related to the relative weight of MS-DRG 215 at the same time.

- *Type II Myocardial Infarction.* CMS is proposing modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS-DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively) when reported with a listed procedure code, for clinical consistency with the other MS-DRGs describing myocardial infarction. The code is currently one of the listed principal diagnoses in the GROUPER logic for MS-DRGs 222 and 223 but is not currently recognized in these same MS-DRGs when coded as a secondary diagnosis.
- *Viral Cardiomyopathy.* CMS is proposing to reassign the diagnosis code B33.24 (Viral cardiomyopathy) from MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites) in MS-DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively).
- *Surgical Ablation.* CMS is proposing to revise the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). Under this proposal, if a procedure code describing a coronary artery bypass graft (CABG) and a procedure code describing an open surgical ablation are

present, the GOUPER logic would assign the CABG surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation.

- **MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)**
 - *Knee Joint Procedures*. CMS is proposing to add three ICD-10-PCS procedure code combinations describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to the MS-DRGs noted below:
 - MS-DRGs 461 and 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity with and without MCC, respectively), and
 - MS-DRGs 466, 467 and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) in MDC 08 and
 - MS-DRGs 628, 629 and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorder).

- **MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunological Disorders)**
 - *Cytokine Release Syndrome (CRS)*. CMS is proposing to assign diagnosis code T80.82XA (Complication of immune effector cellular therapy, initial encounter) to MS-DRGs 814, 815, and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively).

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

Each year, CMS review cases assigned to MS-DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS-DRGs. MS-DRGs 981 through 983 and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS-DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group.

CMS is proposing to add three ICD-10-PCS procedure codes for control of bleeding in the cranial cavity to the following craniotomy MS-DRGs in MDC 01:

- MS-DRGs 23 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator);
- MS-DRGs 24 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis without MCC); and
- MS-DRGs 25, 26 and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, CC and without CC/MCC, respectively).

Reassignment of Procedures among MS-DRGs 981 through 983 and 987 through 989

Each year, CMS reviews cases assigned to MS-DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to reassign any procedures among these MS-DRGs based on average costs and length of stay. MS-DRGs 981 through 983 and 987 through 989 are reserved for cases in which none of the O.R. procedures performed relate to the principal diagnosis. These MS-DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group.

CMS is proposing to reassign the procedures listed below from MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS-DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively).

Procedures	Number of ICD-10-PCS Procedure Codes Affected
Excision Of Subcutaneous Tissue And Fascia Of Chest, Back and Abdomen, Open Approach	3
Laser Interstitial Thermal Therapy of Various Body Parts	17
Repair of Esophagus, Percutaneous Approach, Via Natural or Artificial Opening, and Via Natural or Artificial Opening Endoscopic	3
Drainage of Urethra, Open Approach	1

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

In the FY 2020 Inpatient PPS/LTCH PPS proposed rule, CMS announced that given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, they planned to conduct a comprehensive, systematic review of the ICD-10-PCS procedure codes. This will be a multi-year project during which CMS also will review the process for determining when a procedure is considered an operating room procedure. For example, CMS notes it may leverage the detail that is now available in the ICD-10 claims data. CMS further indicates that determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD-10-PCS classification, as well as changes in medical practice.

CMS typically evaluates procedures on the basis of whether or not they would be performed in an operating room. CMS believes that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD-10. In the FY 2021 inpatient PPS/LTCH PPS final rule, CMS provided a summary of the comments received in response to their request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system for future consideration. In consideration of the public health

emergency, CMS believed it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as CMS continues to develop their process and methodology. Therefore, CMS will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

For FY 2022 CMS is addressing requests they received to change the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures, or change the designation from O.R. procedure to non-O.R. procedure.

O.R. Procedures to Non-O.R. Procedures. Under this proposal, the procedures below will no longer impact MS-DRG assignment. They do not require the resources of an operating room and they consume resources comparable to related ICD-10-PCS procedure codes that currently are designated as Non-O.R. procedures.

Procedures Proposed for Change from O.R. Procedures to Non-O.R. Procedure

Procedure Groups	Number of ICD-10-PCS Procedure Codes Affected
Open Drainage of Subcutaneous Tissue and Fascia	22
Diagnostic Drainage of Vestibular Gland	2

Non-O.R. Procedures to O.R. Procedures. CMS proposed changing the status of the procedure groups in table 2 below from Non-O.R. procedure to O.R. procedures.

Procedures Proposed for Change from Non-O.R. Procedures to O.R. Procedure

Procedure Groups	Number of ICD-10-PCS Procedure Codes Affected
Percutaneous Introduction of Substance into Cranial Cavity and Brain	1
Open Pleural Biopsy	2
Percutaneous Revision of Intraluminal Vascular Devices	5
Percutaneous Reposition of Sacroiliac Joint or Hip Joint with Internal Fixation	4
Open Insertion and Removal of Spacer into Shoulder Joint	8
Open/Percutaneous Extirpation of Jaw	4
Open Extirpation of Subcutaneous Tissue and Fascia	22

Extensive O.R. Procedures to Non-Extensive O.R. Procedures. CMS proposed changing the status of the procedure groups in the table below from Extensive O.R. procedures to Non-Extensive O.R. procedures.

Procedures Proposed for Change from Extensive O.R. procedures to Non-Extensive O.R. Procedures

Procedure Groups	Number of ICD-10-PCS Procedure Codes Affected
Open Drainage of Peritoneal Cavity	9

Comprehensive CC/MCC Analysis

In the FY 2018 inpatient PPS final rule, CMS provided public notice of their plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. For FY 2020, CMS proposed but did not finalize a change in the severity level designation for 1,492 ICD-10-CM diagnosis codes.

For FY 2021, CMS finalized nine guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. CMS plans to use a combination of mathematical analysis of claims data and the application of these guiding principles, to continue a comprehensive CC/MCC analysis and present the findings in future rulemaking.

For FY 2022, as another interval step in the comprehensive review of the severity designations of ICD-10-CM diagnosis codes, CMS is soliciting comments on adopting a change to 3,490 “unspecified” diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a Non-CC for FY 2022. Table 6P.2a of this proposed rule includes the list of ICD-10-CM unspecified diagnosis codes with data for impact on resource use.

If approved, the change would affect the severity level assignment for 4.8% of the ICD-10-CM diagnosis codes. The net result of these potential changes to the Version 39 ICD-10 MS-DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD-10-CM classification, would be a decrease of 507 (3,278 – 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 – 11,696) codes designated as a CC, and an increase of 3,490 (58,154 – 54,664) codes designated as a Non-CC.

As part of this request, CMS would be interested in comments regarding whether this modification might present operational challenges and how they might otherwise foster the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient’s health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

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

At the ICD-10 Coordination and Maintenance Committee meeting in March, CMS announced its consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current Oct. 1 annual update for ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. This April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process.

CMS also believes this earlier recognition diagnoses, conditions and illnesses as well as procedures, services, and treatments in the claims data would be beneficial for purposes of reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions and data interoperability. any new ICD-10 code updates finalized for implementation on the following April 1 would be announced in November of the prior

year, which would provide a 4-month timeframe for the public to receive notice about the diagnosis and/or procedure code updates with respect to the codes, code descriptions, code designations (severity level for diagnosis codes or O.R. status for procedure code) and code assignment under the ICD-10 MS-DRGs. CMS further noted that if an April 1 update were to be adopted, it could be through a phased approach, such that initially, the number and nature of the code updates would be fewer and less comprehensive as compared to the existing Oct. 1 update.

If this new April 1 implementation date is adopted, CMS would assign the codes approved for the April 1 update to an MS-DRG(s) using its established process for GROUPE assignments for new diagnosis and procedure codes. Specifically, CMS would review the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, CMS would consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition.

Medicare Shared Savings Program

When CMS redesigned the Medicare Shared Savings Program (MSSP) through the December 2018 “Pathways to Success” rule, it created a glide path to increasing levels of risk for MSSP accountable care organizations (ACOs). That glide path – called the BASIC track – has five levels of increasing risk, A through E. Under normal circumstances, ACOs are automatically advanced along the glide path at the start of each performance year over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, subject to limited exceptions.

However, due to the uncertainty of the COVID-19 pandemic, CMS modified this “automatic advancement” policy in a May 8, 2020 IFC with comment period. This rule allowed BASIC track ACOs participating in the glide path the option to forgo automatic advancement and freeze at their performance year (PY) 2020 level for PY 2021. CMS finalized this policy in the calendar year (CY) 2021 physician fee schedule final rule. ACOs that elected this option for PY 2021 were set to be automatically advanced for PY 2022 to the level at which they would have otherwise participated if they had not been frozen. In other words, an ACO that was participating at BASIC Level B in PY 2020, and froze its participation at BASIC Level B for PY 2021, would be automatically advanced to BASIC Level D in PY 2022.

In this rule, in recognition of the ongoing COVID-19 PHE, CMS proposes to once again offer the option for ACOs to freeze their participation level. Specifically, CMS believes that the impact of many unknowns on ACO expenditures – including the effects of cancelled or delayed services during the PHE, the emergence of new COVID variants and mutations, and resources needed to distribute vaccines to ACO beneficiaries – justifies providing additional flexibilities to ACOs so as to promote continued participation in the MSSP.

Under this proposal, ACOs participating in the BASIC track’s glide path would once again be permitted freeze at their current level of risk for PY 2022. Thus, ACOs would be allowed to forgo automatic advancement and maintain their participation for PY 2022 at their PY 2021 level. ACOs that froze their participation for PY 2021 at their PY 2020 level would be permitted to freeze their participation a second time, thus remaining at their PY 2020 participation level for PY 2022. Any ACO that elects to remain at its current participation level for PY 2022 would be automatically advanced to the BASIC track level in which it would have participated during PY 2023 if it had advanced automatically in PY 2022 (unless the ACO chooses to advance more quickly).

For example, an ACO that participated in BASIC Level A for PY 2020 and did not freeze its participation level would have automatically advanced to BASIC Level B in PY 2021. If that ACO elects to remain at Level B for PY 2022, instead of advancing to Level C, it would automatically advance to Level D for PY 2023. Similarly, if an ACO participated in BASIC Level A for PY 2020 and did elect to freeze its participation level, it would have participated in BASIC Level A in PY 2021. If that ACO again elects to remain at Level A for PY 2022, it would automatically advance to Level D for PY 2023. CMS included a chart in the rule to illustrate the possible “freeze” scenarios ACOs could choose. The chart, reproduced below, is available on page 1564 of the display copy of the rule.

BASIC TRACK’S GLIDE PATH “FREEZE” SCENARIOS			
PY 2020	PY 2021	PY 2022	PY 2023
Level A	Maintained at Level A	Maintain at Level A	Progress to Level D
		Progress to Level C	
	Progressed to Level B	Maintain at Level B	
		Progress to Level C	
Level B	Maintained at Level B	Maintain at Level B	Progress to Level E
		Progress to Level D	
	Progressed to Level C	Maintain at Level C	
		Progress to Level D	
Level C	Maintained at Level C	Maintain at Level C	Progress/Maintain Level E
		Progress to Level E	
	Progressed to Level D	Maintain at Level D	
		Progress to Level E	
Level D	Maintained at Level D	Maintain at Level D	Progress/Maintain Level E
		Progress to Level E	
	Progressed to Level E	Maintain at Level E	

CMS recognizes that the annual application and change request cycle for the MSSP will begin before this rule is finalized. To that end, CMS will give ACOs currently participating in upside-only levels of the BASIC track (Levels A and B) the opportunity to indicate during the change request cycle whether they are interested in maintaining their participation at Levels A or B. ACOs expressing such an interest would not be required to submit a repayment mechanism at that time.

Promoting Interoperability Programs

EHR Reporting Period

The EHR reporting period in CY 2022 is a minimum of any continuous 90-day period for new and returning program participants and CMS proposes to continue this policy for CY 2023. For CY 2024, CMS proposes to increase the reporting period to a minimum of any continuous 180-day period. CMS reiterates that the Medicaid Promoting Interoperability Program will end this year with Dec. 31, 2021 being the last date states may make payments to Medicaid-eligible hospitals.

Changes to Objectives and Measures

CMS proposes a number of changes to measures and other requirements beginning in 2022.

- *Electronic Prescribing Objective: Query of Prescription Drug Monitoring Program (PDMP) Measure.* Acknowledging continued stakeholder concerns that PDMPs are not yet consistently integrated into EHR workflows, CMS proposes to maintain this measure as optional for 2022, while increasing the available bonus from five points to 10 points. CMS seeks comment on the future direction of the measure, including what issues would need to be addressed before transitioning to a performance-based version of the measure and what exclusions, if any, should be made available.
- *Health Information Exchange (HIE) Objective.* CMS proposes to add a new, optional HIE Bi-Directional Exchange measure for the 2022 reporting period as a yes/no attestation. Hospitals and CAHs could attest to this measure in place of reporting the two existing measures – Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information. The new optional measure would be worth 40 points.
- *Provider to Patient Exchange Objective: Provide Patients Electronic Access to their Health Information Measure.* Beginning in 2022, CMS proposes to modify the measure to require eligible hospitals and CAHs to ensure that patient health information remains available indefinitely and using any application of the patient's choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR. This would include all patient health information from encounters on or after Jan. 1, 2016. CMS seeks comments on alternative encounter start dates for its proposal, including Jan. 1, 2012 and Jan. 1, 2019.
- *Public Health and Clinical Data Exchange Objective.* CMS proposes to require reporting “yes” or requesting exclusions on four of the existing measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting and Electronic Reportable Laboratory Result Reporting).
 - Syndromic Surveillance Reporting. CMS proposes to change the setting for which data is required to be submitted for this measure from urgent care to the emergency department (POS 23). It would make a technical change to the first exclusion to the measure by eliminating a reference to urgent care.
 - Scoring. Beginning with the EHR reporting period in 2022, eligible hospitals and CAHs would receive 10 points for this objective if they report a “yes”

response for each of the four required measures. They would receive 10 points for the objective if they report a “yes” response for one or more of these measures and claim applicable exclusions for the remaining measures. Failure to report on any of the four measures, or reporting a “no” response for one or more of those measures, would result in a score of zero for the objective and a total score of zero for the Medicare Promoting Interoperability Program. If applicable exclusions are claimed for all four measures, CMS proposes to redistribute the points for the objective to the Provider to Patient Exchange objective.

- Optional Measures. The remaining two measures (Public Health Registry Reporting and Clinical Data Registry Reporting) would be optional and available for a total of 5 bonus points if a “yes” response is reported for either of the two optional measures (exclusions would be eliminated).
- *Protect Patient Health Information Objective*. The Office of the National Coordinator for Health Information Technology (ONC) originally developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014 which provide recommended safety practices during planned or unplanned EHR unavailability, due to events like system disruptions, systems failures or natural disasters. CMS proposes to require hospitals and CAHs to attest to having completed an annual assessment of all nine guides in a newly proposed SAFER Guides measure.
- *Prevention of Information Blocking Attestation Requirement*. As part of the Promoting Interoperability Program, eligible hospitals and CAHs are required to attest to three statements indicating that they do not limit or restrict the interoperability of certified EHR technology. CMS explains that the similarities between practices described in statements 2 and 3, and the practices that could constitute information blocking under ONC’s information blocking regulations, could create confusion for participating hospitals and CAHs. Therefore, CMS proposes to remove attestation statements 2 and 3. Hospitals would continue to be required to attest to statement 1: “Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.”

Scoring Methodology

To be considered a meaningful user, eligible hospitals and CAHs must report on all required measures across all four objectives and report “yes” on all required yes/no measures, unless an exclusion applies. For 2022, CMS proposes to raise the minimum threshold score from 50 to 60 points citing that in 2019, performance results showed that 3,776 of 3,828 participating eligible hospitals and CAHs met the 50 point threshold.

The table below includes objectives and measures as proposed for 2022 with associated points available for each. The Security Risk Analysis measure, SAFER Guides measure and Prevention of Information Blocking attestations are required, but will not be scored.

**Performance-Based Scoring Methodology
EHR Reporting Period in CY 2022**

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Optional: 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	
	HIE 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:*	10 points
	<ul style="list-style-type: none"> • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting 	
	Report one of the following 2 measures:*	5 points (bonus)*
	<ul style="list-style-type: none"> • Public Health Registry Reporting • Clinical Data Registry Reporting 	

* New proposal for 2022

Clinical Quality Measurement

CMS proposes to make several changes related to electronic clinical quality measures (eCQMs) reporting that align with proposals in the Hospital IQR Program. This includes requiring eligible hospitals and CAHs to use only technology certified to the 2015 Edition Cures Update to submit data for eCQMs, beginning with the 2023 reporting period. Additional details are included in the Hospital IQR Program section of the advisory.

Requests for Information

CMS solicits feedback on the following topics:

- *Additional Objectives or Measures Adopting FHIR-based API Standards.* CMS indicates it intends to align the Health Information and Exchange and Public Health and Clinical Data Exchange objectives and measures with approaches using HL7 Fast Healthcare Interoperability Resources (FHIR) API functionality. CMS seeks comments on a range of issues including current stakeholder use of APIs, how technical approaches using FHIR could enhance existing data flows under the public health measures and policy and program changes that could reduce provider and health IT developer burden under these measures.
- *Patient Access Outcomes Measures.* CMS seeks comments on potential changes to the Promoting Interoperability Program to better target patient access outcomes related to the use of patient portals or third-party applications.

- *Clinical Notes.* CMS seeks input on changes that will better support the availability of clinical notes for patients. Areas of interest include changes to the Provide Patients Access to their Health Information measure, development of a mandatory measure to allocate points for the use of clinical note types and feedback on the types of clinical notes commonly requested by patients but not easily accessible to them.
- *Designating High Performance Hospitals.* CMS seeks comment on the development of, or support and adoption of, designating high performing hospitals in the context of EHR excellence. Areas of interest include availability and characteristics of current industry-based models of EHR excellence and whether there would be support for a CMS-led designation program.

Hospital Quality Reporting and Value Programs

CMS proposes a number of significant policy changes to account for the impact of the COVID-19 PHE on its hospital quality reporting and value programs. The agency also proposes to add five new measures for the IQR program, while removing five current IQR measures. The proposed rule also includes several requests for information (RFI) related to health equity, digital quality measurement and future measurement ideas.

Measure Suppression Policy

In a September 2020 interim final rule, CMS announced that in light of the COVID-19 PHE, the agency will not use data from the first and second quarters of 2020 to calculate performance or make payment adjustments in any of its hospital quality measurement and value programs. This policy impacts CMS programs beginning in FY 2022, as described in subsequent sections of this advisory.

In this rule, CMS proposes an additional policy to account for the impact of COVID-19 on its quality measurement and value policies beyond Q1 and Q2 of 2020. Specifically, CMS proposes a measure suppression policy that it would use across all of its hospital quality measurement and value programs for the duration of the PHE. Using the proposed policy, CMS could “suppress” (i.e., not use) measure data it believes have been affected by COVID-19 in calculating hospital performance. CMS proposes to suppress measure data across several programs, as described in subsequent sections of this advisory. The agency’s goal is to ensure hospitals are not rewarded or penalized for their performance based on non-representative quality data that have been affected by the pandemic.

CMS proposes several factors it would consider in deciding whether to suppress hospital measure data:

- 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;
- Clinical proximity of the measure’s focus to the relevant disease, pathogen or health impacts of the PHE for COVID-19;

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

While the suppression policy would apply to only the COVID-19 PHE, CMS invites comment on whether the suppression policy should be applied to future PHEs. The agency also asks for feedback on whether it should have the flexibility to suppress measure data without going through the notice-and-comment rulemaking process. Lastly, CMS invites comment on whether future measure suppression policies should permit the use of “regional adjustment” in which CMS would suppress data for hospitals in certain geographic regions rather than for all hospitals nationally.

Hospital Readmissions Reduction Program (HRRP)

The HRRP imposes penalties of up to 3% of base inpatient PPS payments for having “excess” readmissions rates for selected conditions when compared to expected rates. CMS uses six Medicare claims-based readmission measures to assess performance in the program – acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), isolated coronary artery bypass grafts (CABG), and elective hip and knee arthroplasties (THA/TKA). In the proposed rule, CMS estimates that readmissions penalties across all eligible hospitals will total \$553 million in FY 2022.

As required by the 21st Century Cures Act, CMS implemented a sociodemographic adjustment approach beginning with the FY 2019 HRRP in which CMS places hospitals into one of five peer groups based on the proportion of patients dually eligible for Medicare and Medicaid that they treat.

Performance Periods and Payment Adjustments. The September 2020 IFR means that CMS will not use data from Q1 and Q2 of 2020 to calculate performance in the HRRP in FYs 2022, 2023 and 2024. As a result, the FY 2022 HRRP performance period will be July 1, 2017 through Dec. 31, 2019. In this rule, CMS proposes to align the MedPAR data it uses to determine aggregate payment amounts and payment adjustments with the modified performance periods. In other words, the agency would not use MedPAR data from Q1 and Q2 of 2020 in calculating payment adjustments in FY 2022 and subsequent years.

FY 2023 Pneumonia Measure Suppression. Using the measure suppression policy described in the previous section of this advisory, CMS proposes to suppress the use of the HRRP’s pneumonia readmissions measure in calculating FY 2023 performance and payment adjustments. CMS suggests that factor 2 – the “clinical proximity” of pneumonia to COVID-19 – is significant enough that including the measure in calculating HRRP performance could distort measure performance. The proposed rule includes an analysis indicating that a substantial proportion of the pneumonia measure cohort in 2020 had

COVID-19 noted as a secondary diagnosis. In addition, the observed readmission rates for the pneumonia patient cohort were statistically significantly higher in September 2020 than during the same period in 2019 (i.e., before the pandemic).

As a result, CMS states its belief that “COVID-19 patients captured in the pneumonia readmissions measure cohort likely represent a distinct, severely ill group of patients for whom it may be difficult to adequately ascertain appropriate risk adjustment.” The agency further suggests that excluding from the measure those patients with COVID-19 as a secondary diagnosis would result in a measure that does not accurately reflect performance, especially given the uneven distribution of COVID-19 patients across hospitals during 2020. Therefore, the agency proposes to suppress the measure entirely for FY 2023, and indicates it will monitor the measure carefully to determine whether it should suppress the measure in future fiscal years.

Exclusion of COVID-19 Patients from Measures in FY 2023 and Beyond. To further account for the impact of COVID-19, CMS proposes to update the measure specifications for the remaining five readmission measures to exclude patients with COVID-19 from performance calculations. While the full details of these technical updates are not yet available, CMS indicates it would use various ICD-10 CM codes to remove patients with COVID-19 as a secondary diagnosis from each measure’s denominator.

Future Stratification of Readmission Measure Results. Please see the “Health Equity” section of this advisory for more information on CMS’s potential future expansion of stratified reporting – including public reporting – of the HRRP’s measures.

Hospital Value-based Purchasing (HVBP)

The ACA mandated that CMS implement the HVBP program, which ties a portion of hospital payment to selected measures of the quality, safety and cost of hospital care. CMS funds the program by reducing base operating diagnosis-related group payment amounts to participating hospitals by 2% to create a pool of funds to pay back to hospitals based on their measure performance. Hospitals may earn back some, all or more than the 2% withhold based on their measure performance. By statute, the program must be budget neutral – that is, the entire pool of dollars must be paid back to hospitals, and CMS may not hold back any portion of it to achieve savings to the Medicare program.

CMS proposes several significant changes to the HVBP program for FYs 2022 and 2023 to account for the impact of the COVID-19 PHE.

FY 2022 MeasureSuppressions. Using the measure suppression policy described earlier in this advisory, CMS proposes to suppress most of the HVBP program’s measures for FY 2022. CMS would calculate and publicly report measure scores where feasible and appropriate, but would not use the measures in determining performance. The measures CMS proposes to suppress and the agency’s rationale for each is described below.

- *Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)*. CMS proposes to suppress the HCAHPS measures under measure suppression factor 1 (i.e., significant deviation in national performance during the COVID-19 PHE). CMS conducted analyses that show statistically significant declines in HCAHPS scores during 2020 that are associated with the COVID-19 PHE. CMS believes this impact is likely to impact the entire 2020 performance period, and result in non-representative data.
- *Medicare Spending per Beneficiary (MSPB)*. CMS proposes to suppress the MSPB under measure suppression factor 4. Specifically, the agency's analysis shows significant impact to hospitals patient mix and episode costs that are associated with COVID-19, and span across a wide variety of MS-DRGs. Given the uneven distribution of COVID-19 cases across hospitals and time periods, CMS believe suppressing MSPB is the most appropriate approach.
- *Healthcare Associated Infections (HAIs)*. Using measure suppression factor 1, CMS proposes to suppress all five HAIs used in the HVBP – catheter-associated urinary tract infection (CAUTI), central-line associated blood stream infection (CLABSI), colon and hysterectomy surgical site infections (SSIs), Clostridium difficile infection (CDI) and Methicillin-resistant staphylococcus aureus (MRSA). CMS cites data suggesting that there were statistically significant increases in the rates of all five HAI measures during Q3 and Q4 of 2020, and that change likely is due to the unique and unprecedented circumstances of the pandemic. For example, longer hospitals stays for sicker patients may make the chances of infection higher than normal. CMS also notes that the volumes for the SSI measure were significantly lower than normal due to the decline in surgical procedure volumes most hospitals experienced during 2020.

FY 2022 Neutral Payment Adjustments. As a result of its measure suppression proposals, CMS indicates it would not have sufficient data to calculate FY 2022 performance on three of the HVBP's four measure domains – patient experience, safety and efficiency/cost reduction. Furthermore, the CMS states that it would not be appropriate to base hospital performance on only the remaining clinical outcomes measure domain, and that the agency cannot calculate fair HVBP scores.

Therefore, CMS proposes that all hospitals would receive neutral payment adjustments under the HVBP for FY 2022. CMS would continue to reduce base operating DRG payment amounts by two percent, as required by law. However, each hospital would receive a corresponding HVBP incentive amount equal to that reduction, thereby ensuring HVBP adjustments would be neutral. This approach is permissible given that the HVBP program is budget neutral.

FY 2023 Pneumonia Mortality Measure Suppression. CMS proposes to suppress the pneumonia mortality measure for the FY 2023 HVBP program using suppression factor 2 (i.e., clinical proximity to COVID-19). Prior to the pandemic, CMS established the FY 2023 mortality measure performance period as July 1, 2018 – June 30, 2021, a timeframe that includes the COVID-19 PHE. The proposed rule includes an analysis

indicating that a substantial proportion of the pneumonia measure cohort in 2020 had COVID-19 noted as a secondary diagnosis. In addition, the observed mortality rates for the pneumonia patient cohort were statistically significantly higher in September 2020 than during the same period in 2019 (i.e., before the pandemic).

Similar to the HRRP's pneumonia readmission measure, CMS suggests that excluding from the measure those patients with COVID-19 as a secondary diagnosis would result in a measure that does not accurately reflect performance, especially given the uneven distribution of COVID-19 patients across hospitals during 2020.

Exclusion of COVID-19 Patients from Mortality Measures beginning in FY 2023. In addition to the pneumonia mortality, the HVBP includes 30-day mortality measures for AMI, HF, CABG, COPD and THA/TKA. Similar to the HRRP, CMS proposes to update the measure specifications for these measures to exclude patients with COVID-19 from performance calculations. While the full details of these technical updates are not yet available, CMS indicates it would use various ICD-10 CM codes to remove patients with COVID-19 as a secondary diagnosis from each measure's denominator.

Removal of Patient Safety Indicator (PSI 90) beginning in FY 2023. As previously recommended by the AHA, CMS proposes to remove PSI 90 from the HVBP program beginning in FY 2023. CMS believes that the costs of including the measure in the HVBP outweigh the benefits. Specifically, CMS also uses the measure in the Hospital-Acquired Condition Reduction Program, which uses a different scoring approach from the HVBP. This means that hospitals have had to track two different results across the two programs, resulting in duplication of efforts and additional administrative costs.

Revised Baseline Periods for FY 2024. To account for the COVID-19 PHE, CMS proposes to alter the FY 2024 baseline periods for some HVBP measures. Specifically, for the HCAHPS, HAI and MSPB measures, CMS proposes to use CY 2019 as the baseline period instead of CY 2020. This would allow CMS to use data unaffected by the COVID-19 pandemic, while permitting CMS to use a full year of data to compare to the CY 2022 performance period. The proposed rule includes tables with the baseline and performance periods for all HVBP measures through FY 2027.

Hospital-acquired Condition (HAC) Reduction Program

The HAC Reduction Program imposes a 1% reduction to all Medicare inpatient payments for hospitals in the top (worst performing) quartile of risk-adjusted national HAC rates. The HAC Reduction Program's measure set and basic scoring methodology are unchanged.

However, CMS proposes to suppress performance data from the third and fourth quarters of 2020 in calculating HAC Reduction Program performance for FYs 2022 and 2023. The factors for suppressing performance are the same as those cited for suppressing HAI measure data in the HVBP (described above). In addition, the September 2020 IFR announced that CMS would not use data from Q1 and Q2 of 2020 to calculate performance or payment adjustments in the HAC Reduction program or any of its quality measurement programs. The resulting proposed performance periods for FY 2022 and 2023 are provided

in the table below. CMS believes these truncated performance periods would retain sufficient reliability for the program’s measures, while excluding the timeframes most affected by the COVID-19 pandemic.

Proposed HAC Reduction Program Performance Periods, FYs 2022 and 2023

Measure	FY 2022		FY 2023	
	Previously Finalized	Proposed Revision	Previously Finalized	Proposed Revision
HAIs	Jan. 1, 2019 – Dec. 31, 2020	Jan. 1, 2019 – Dec. 31, 2019	Jan. 1, 2020 – Dec. 31, 2021	Jan. 1, 2021 – Dec. 31, 2021
PSI 90	Jul. 1, 2018 – Jun. 30, 2020	Jul. 1, 2018 – Dec. 31, 2019	Jul. 1, 2019 – Jun. 30, 2021	Jul. 1, 2019 – Dec. 31, 2019 AND Jan. 1, 2021 – Jun. 30, 2021

Hospital IQR Program

The IQR program is CMS’s pay-for-reporting program in which hospitals must submit measures and meet other administrative requirements in order to avoid a payment reduction equal to one quarter of the annual market-basket update. The IQR program also includes a requirement to report on selected EHR-derived eCQMs using CMS-mandated reporting standards. The IQR eCQM reporting requirements align with the eCQM reporting requirements in the Promoting Interoperability Program.

CMS proposes to add five new IQR measures, while removing five existing measures. Most notably, CMS proposes a new measure reflecting COVID-19 vaccination coverage among health care personnel (HCP) that hospitals would be required to report starting on Oct. 1, 2021. Furthermore, CMS proposes that beginning in CY 2023, hospitals would be required to report the IQR’s electronic clinical quality measures using certified EHR technology consistent with 2015 Edition Cures Update.

New COVID-19 Vaccination Among HCP Measure. For the FY 2023 IQR program, CMS proposes to adopt a measure that calculates the cumulative number of HCP eligible to work in the hospital for at least one day during the reporting period who received a complete vaccination course. If finalized, hospitals would be required to submit data beginning Oct. 1, 2021.

The measure would exclude persons with contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC). For the purposes of this measure, “health care personnel” is defined — regardless of clinical responsibility or patient contact — as:

- Employees (all persons receiving a direct paycheck from the reporting facility);

- Licensed independent practitioners affiliated with, but not directly employed by, the reporting facility (including post-residency fellows); or
- Adult students/trainees and volunteers.

Facilities may include other contract personnel, but are not required to do so. Detailed specifications for this measure can be found on CDC's [website](#).

To report this data, hospitals would use the CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework, which hospitals currently use to report the influenza coverage among HCP measure. Hospitals would submit data through NHSN for at least one self-selected week each month, and the CDC would calculate a summary measure of the data each quarter. If hospitals submit more than one week of data in a month, CDC would use the most recent week's data to calculate the rate. This quarterly rate would be publicly reported on the *Care Compare* website.

The measure, which is also proposed for adoption in the quality reporting programs for all other post-acute and acute care settings, is not endorsed by the National Quality Forum (NQF). In its preliminary recommendations, the NQF's Measure Applications Partnerships (MAP) Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation; the mitigating factors included well-documented evidence, finalized specifications, testing and NQF endorsement. However, the MAP Coordinating Committee lent conditional support to the measure, asking CMS to bring the measure back to the MAP once specifications were further refined. The Coordinating Committee also asked for the denominator population to align closely with the influenza vaccination coverage measure. CMS contends in the proposed rule that the measure has undergone some validity testing using NHSN data, and believes the measure is sufficiently specified for use in the IQR.

New Maternal Morbidity Structural Measure. Beginning with the FY 2023 IQR program, CMS proposes that hospitals report a measure reflecting whether they participate in certain collaborative efforts related to reducing maternal morbidity. Specifically, hospitals would be asked to respond to the following question on the agency's QualityNet website:

“Does your hospital or health system participate in a statewide or national perinatal quality improvement program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has implemented patient safety practices or bundles related to maternal morbidity to address complications, including but not limited to hemorrhage, severe hypertension / preeclampsia or sepsis?”

Hospitals would be permitted to answer yes, no or not applicable (if the hospital does not provide inpatient labor/delivery services). For the FY 2023 program, CMS proposes a special shortened reporting period of Oct. 1 – Dec. 31, 2021. Data would be due to CMS by May 16, 2022. Beginning with the FY 2024 program reporting period would be January through December of the performance year. For example, for FY 2024, hospitals' responses would reflect participation in maternal morbidity improvement programs from Jan. 1 through Dec. 31, 2022. CMS provides limited information on its [website](#) about which

specific statewide and national programs or initiatives would enable hospitals to answer yes on the measure. However, CMS indicates it will provide “additional education and clarifying detail” if the measure is adopted.

NQF has not endorsed the proposed measure, and it received conditional support for use in the IQR by the MAP. However, CMS states that it is proposing the measure because it believes that reducing maternal morbidity is a national priority, and that the IQR program does not currently include measures directly related to maternal morbidity. CMS also suggests that the reporting of this measure would encourage hospitals to both participate in improvement efforts, and implement practices the agency believes would improve maternal care and reduce maternal morbidity.

New Hybrid Hospital-wide All-cause Mortality Measure. CMS proposes an all-cause, risk-standardized measure measuring mortality with 30 days of hospital admission for most conditions or procedures. The proposed measure is a “hybrid” measure in which hospitals submit certain “core clinical data elements” from EHRs to supplement the Medicare claims data used to calculate the measure. The reporting of the measure would be voluntary for the FY 2025 IQR program, with a reporting period of July 1, 2022 – June 30, 2023. However, it would become required beginning with the FY 2026 IQR program, with a reporting period of July 1, 2023 – June 30, 2024. Measure results would be publicly reported as part of the IQR program.

The measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service divisions (i.e., categories of admissions grouped based on similar discharge diagnoses or procedures). Hospitalizations can be counted in the measure if the patient was admitted to a non-federal, short-term acute care hospital. The measure’s inclusion and exclusion criteria are similar to those of the existing condition-specific, claims-based mortality measures in the IQR and HVBP programs. Detailed measure specifications are available on CMS’s [website](#). The core clinical data element reporting would be comparable to that of the hybrid hospital-wide readmission measure CMS adopted in prior rulemaking except that hospitals also would be asked to report data on patient platelet counts. Additional details on hybrid measure reporting requirements are available in AHA’s [Regulatory Advisory](#) on the FY 2020 inpatient PPS final rule.

CMS believes the adoption of a hospital-wide mortality measure would encourage hospitals to improve performance across a broader range of patients in their facilities. CMS also posits that the measure would further advance the use of the hybrid claims/EHR measurement approach, which the agency believes could ultimately enhance the reliability and accuracy of risk adjustment for measures like readmissions and mortality. The measure is endorsed by NQF.

New Glycemic Control eCQMs. Beginning with the FY 2025 IQR program (CY 2023 reporting period), CMS proposes to add two new eCQMs to the menu of available eCQMs from which choose to fulfill eCQM reporting requirements. The measures reflect the rates of severe hypoglycemia and hyperglycemia. While the measures can be reported

independently, they also can be used as “balancing measures” if a hospital chooses to report both measures. CMS believes that poor glycemic control is associated with poorer health outcomes, and notes that the IQR does not currently include any measures of glycemic control. Both measures are endorsed by NQF, and were conditionally supported for use in the IQR by the MAP.

The severe hypoglycemia measure reflects the proportion of inpatients who experience a hypoglycemic event within 24 hours of the administration of an anti-hyperglycemic agent, which CMS believes to be an adverse event. The measure defines a hypoglycemic event as a glucose test result of less than 40 mg/dL. The measure includes all patients 18 years or older during the measurement period that received at least one anti-hyperglycemic medication during their inpatient hospitalization. Emergency and observation patients who are subsequently admitted to the hospital would be included in the measure. The measure does not have any denominator exclusions, and is not risk-adjusted.

The severe hyperglycemia measure reflects the proportion of inpatient hospital days with a severe hyperglycemic event among the total qualifying hospital days for at-risk inpatient encounters. A severe hyperglycemic event is defined as either:

- A blood glucose result greater than 300 mg/dL; or
- A day in which the blood glucose value was not documented, and was preceded by two consecutive days where at least one glucose value is greater than or equal to 200 mg/dL.

The hyperglycemia measure’s denominator – “at-risk encounters” – includes discharges from an inpatient admission for all patients 18 years or older during the measurement period. It also includes certain other encounters that may take place during emergency department (ED) visits or observation stays. Specifically, it would include encounters with:

- A diagnosis of diabetes that starts before or during the encounter;
- Administration of at least one dose of insulin or any anti-diabetic medication during the encounter; or
- Presence of at least one blood glucose value greater than 200 mg/dL at any time during the encounter.

The denominator is calculated as the total number of eligible days across all encounters matching the inclusion criteria described above. However, the measure excludes the first 24 hours of admission to correct for hyperglycemia that may have been present upon admission. The measure numerator is the total number of days with a hyperglycemic event.

Proposed Measure Removal. CMS proposes to remove a total of five IQR program measures. The measure are described below:

- *PSI-04 (Deaths Among Surgical Inpatients with Serious Treatable Conditions).* For the FY 2023 IQR (CY 2021 reporting), CMS proposes to remove this measure because it overlaps with the proposed hybrid hospital-wide mortality measure.

- *PC-05 (Exclusive Breast Milk Feeding eCQM)*. CMS proposes to remove this measure from its menu of available eCQMs beginning with the FY 2026 IQR (CY 2024 reporting) because it believes its proposed maternal morbidity structural measure is more strongly aligned with its focus on improving maternal health and reducing maternal morbidity.
- *ED-2 (Admit Decision Time to ED Departure Time eCQM)*. Beginning with the FY 2026 IQR (CY 2024 reporting), CMS proposes to remove this eCQM because it believes its costs outweigh its benefits. Specifically, the agency believes there is limited association between ED boarding times and patient mortality.
- *STK-03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM) and STK-06 (Discharged on Statin Medication)*. CMS proposes to remove these two eCQMs effective with the FY 2026 IQR (CY 2024 reporting) because it believes their costs outweigh their benefits. CMS notes that the IQR includes other stroke measures, and removing these measures would alleviate provider burden.

Potential Future IQR Measures. CMS solicits comments on three potential future IQR program measures:

- *30-day risk-adjusted, all-cause mortality for patients admitted with COVID-19 infection*. The measure would be similar to other condition-specific mortality measures used in the IQR and HVBP, and would be calculated using Medicare claims data.
- *Patient-reported outcomes following elective primary total hip and/or total knee arthroplasty*. NQF recently endorsed this measure and the MAP supports its use in future IQR programs. The measure blends data from multiple sources – including some data that hospitals would collect from patients – to assess patient functional improvement following elective hip and knee replacement procedures. Detailed measure specifications are available on CMS’s [website](#).
- *Health equity structural measure*, which is described later in this advisory.

eCQM Reporting. The basic structure of CMS’s eCQM reporting requirements is largely unchanged. Hospitals must report data on four self-selected eCQMs. For the CY 2021 reporting periods (tied to FY 2023 payment), hospitals may choose any four eCQMs in the IQR program. Beginning with the CY 2022 reporting period, hospitals must report the Safe Use of Opioids eCQM, along with any three other eCQMs in the IQR program.

CMS previously finalized regulations permitting hospitals to report the eCQMs using either the 2015 Edition of certified EHR technology, or the 2015 Edition Cures update. The 2015 edition cures update was finalized in ONC’s 21st Century Cures final rule in 2020. In this rule, CMS proposes that, beginning with the FY 2025 IQR (CY 2023 reporting), hospitals would be required to report eCQMs using EHR technology certified to the 2015 Edition Cures Update. CMS also proposes to require EHR technology to be certified to report all eCQMs using the 2015 Edition Cures Update beginning with the CY 2023 reporting period (FY 2025 payment determination).

Request for Information – Health Equity

CMS includes in the proposed rule several RFIs asking for feedback on a range of ideas for advancing health equity using its quality measurement programs.

Facility Equity Score. CMS recently [developed](#) – but has not yet implemented – an equity summary score for MA plans, which aggregates results from multiple quality measures and then assess to what extent disparities in performance may exist among beneficiaries along the lines of race and dual-eligible status. This score, called the Health Equity Summary Score (HESS), calculates standardized and combined performance scores blended across the two social risk factors. The HESS also combines two assessments of disparities: *within-plan*, which calculates differences in measure outcomes between patients with and without social risk factors who are covered by the same plan while accounting for clinical risk factors, and *across-plan*, which allows for a comparison of disparities in outcomes for subgroups of patients (such as dual eligible patients) between and among multiple plans.

CMS is interested in building a HESS-like score for hospitals, but is in the preliminary stage of developing the concept. CMS envisions a facility equity score would supplement the measure data already reported on the *Care Compare* website and asserts that this summary score could provide easy-to-interpret information regarding disparities measured within individual facilities and across facilities nationally. CMS also states that the score “would decrease burden by minimizing the number of measure results provided and providing an overall indicator of quality,” suggesting that consumers would be interested in seeing a high-level “grade” of-sorts for how well a hospital treats patients with certain characteristics. In the RFIs, CMS states that the score, if created, would be provided at least initially to facilities in confidential reports. However, the agency does mention that this score could be publicly displayed on the *Care Compare* website.

CMS specifically seeks feedback on the feasibility of creating a facility equity score. The agency also solicits input on what interventions a facility could institute to improve a low facility equity score, and how improved demographic data could assist with these efforts.

Improving Demographic Data Collection. CMS notes that there are significant gaps in the availability of demographic and social risk data that prevent it from identifying the existence of disparities and tracking them over time. For that reason, the agency asks for feedback on how it could expand demographic data collection. This could include using certified information technology to collect such data, and possibly requiring hospitals to collect a “minimum set” of demographic, social, psychological and behavioral data elements by hospitals at the time of admission using structured, interoperable data standards.

Additional Reporting of Stratified Measure Data. CMS seeks input on the future potential stratification of individual quality measure results by dual-eligibility status—that is, calculating performance on quality measures for patients who were eligible for both Medicare and Medicaid and for patients who were not in order to determine if the hospital performed differently when caring for the former than for the latter. CMS

already provides hospitals with confidential reports of their HRRP performance stratified by dual-eligible status, but is interested in expanding this reporting to other measures and potentially displaying the performance publicly. CMS also is considering reporting results stratified by race/ethnicity.

Use of Indirect Estimation. CMS also recognizes that the collection and reporting of demographic data can be resource-intensive and would take time to ramp up. For that reason, the agency is considering other intermediate ways of producing analyses of health disparities using the data it currently has. Thus CMS asks for feedback on whether and to what extent it should use a statistical modeling technique called “indirect estimation.” That is, CMS could use data from existing sources like the U.S. Census and Medicare administrative data (e.g., first and last names, and the racial and ethnic composition of the patient’s neighborhood) to “impute” (i.e., infer) the demographic composition of hospitals’ patient populations. CMS states it would not use indirect estimation to infer the race and ethnicity of individuals; rather, the approach would be used for making hospital and population-level estimates. While CMS believes that indirect estimation is statistically reliable, the agency recognizes it could unintentionally introduce measurement bias, especially if the source data used to infer population-level race and ethnicity are inaccurate.

Health Equity Structural Measures in the IQR. CMS also is considering implementing a structural measure in the IQR that would ask hospitals whether they are implementing certain practices the agency believes reflect a hospital’s commitment to health equity. For example, the measure could ask questions about:

- The degree to which the hospital organization regularly examines existing algorithms for the presence of bias, and regularly shares these findings with the hospital organization’s leadership and board of directors;
- Whether the hospital has a disparities impact statement which identifies and prioritizes actionable steps towards addressing health disparities;
- The presence of an updated language access plan to competently care for individuals with limited English proficiency;
- The presence of an updated communication access plan to competently care for individuals who have visual or sensory disabilities;
- The degree to which the hospital’s electronic health record system has capabilities to collect demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status) in alignment with national data collection and interoperable exchange standards; and
- The degree to which the hospital conducts staff training on best practices in collection of demographic information.

Request for Information – Digital Quality Measurement and Use of Fast Healthcare Interoperability Standards

The proposed rule includes a wide-ranging request for comment on CMS' plans to advance the use of digital quality measures (dQMs) and expand the agency's use of FHIR standards and APIs for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025. Along those lines, CMS solicits comments on several policy concepts.

CMS asks for comment on a standardized definition of dQMs that it would use across its quality measurement programs:

"Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources."

CMS also asks for comment on a number of steps it is considering taking to enable a full transition to digital quality measures by 2025. This includes:

- Converting current CMS eCQMs to FHIR-based standards, thereby transitioning away from current quality data model (QDM) standards;
- Requiring the use of FHIR-based APIs for any measures that utilize EHR data, including eCQMs;
- Implementing dQMs that are "self-contained tools." That is, CMS is interested in promoting software solutions for dQMs that could, among other things:
 - Support the calculation of single or multiple quality measures;
 - Obtain data via automated queries from a broad range of digital sources (initially EHRs, but potentially also from claims data, patient-reported outcomes and patient-generated health data);
 - Generate measure score reports;
 - Be compatible with any data source;
 - Exist separately from data source systems;
 - Be tested and updated independently of data source systems;
 - Operate in accordance with health information protection laws and regulations;
 - Be deployable by hospitals, health IT vendors, health plans and/or CMS;
 - Be usable by non-technical end users; and
 - Have the ability to adopt to emerging advanced analytic approaches like natural language processing.
- Establishing and expanding policies for data aggregation by third-parties, including HIEs and clinical registries; and

- Developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector. The agency believes this would require a multi-stakeholder, joint federal, State and industry effort to align measure concepts, specifications and data elements.

Next Steps

The AHA will host a members-only webinar on Monday, May 24 at 1:30 ET to discuss the provisions of the proposed rule and gather input from the field for AHA’s comment letter and advocacy to CMS. To register for this 60-minute webinar, click [here](#).

Given the changes included in this year’s proposed rule, the AHA encourages hospital leaders to estimate the impact of the provisions on their facilities. To that end, the **AHA developed a readmissions penalty calculator, a VBP calculator and a DSH payment calculator for hospitals to assess the impact of these policies on their organizations.** The calculators are available at <https://www.aha.org/inpatient-pps>. They are designed so that you enter your hospital’s CCN (and some additional financial information for the DSH calculator) and the calculator will then estimate the dollar amount of your potential readmissions penalty, net VBP gain or loss, and DSH payment.

Hospitals that wish to apply for low-volume status for FY 2022 must make a written request that is received by its MAC by Sept. 1.

In addition, hospitals should verify whether they have attested to meaningful use. Attestation status can be determined through CMS’s EHR Incentive Program registration and attestation [website](#).

All comments are due to CMS by June 28 and may be submitted electronically at www.regulations.gov. Follow the instructions for “Comment or Submission” and enter the file code CMS-1752-P to submit comments on this proposed rule. You also may submit written comments to CMS.

By regular mail:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

By express or overnight mail:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
Mail Stop C4-26-05
7500 Security Boulevard
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Further Questions

For additional questions, please contact Shannon Wu, senior associate director of policy, at (202) 626-2963 or swu@aha.org.