American Hospital Association™
Advancing Health in America

Regulatory Advisory

May 19, 2022

Inpatient PPS Proposed Rule for FY 2023

The Centers for Medicare & Medicaid Services (CMS) April 18 issued its hospital inpatient prospective payment system (PPS) and long-term care hospital (LTCH) PPS proposed rule for fiscal year (FY) 2023. 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. The AHA will issue a separate advisory on the LTCH PPS-related proposals. Comments on the proposed rule are due to CMS by June 17. The final rule will be published on or around Aug. 1 and take effect Oct. 1.

The rule proposes a 3.2% rate increase for inpatient PPS payments in FY 2023. However, when accounting for proposed changes to disproportionate share hospital (DSH) payments, outlier payments, the Medicare-dependent hospital (MDH) and low-volume adjustment (LVA) programs, and other policies, CMS estimates that inpatient PPS hospitals would actually see a net decrease of 0.3% from FY 2022 to FY 2023.

KEY HIGHLIGHTS
CMS' proposed policies would:

- Increase inpatient PPS payment rates by 3.2% in FY 2023.
- Use FY 2018 and 2019 Worksheet S-10 data to determine the distribution of FY 2023 DSH uncompensated care payments. CMS also would use a three-year average of S-10 data for FY 2024 and beyond.
- Cut DSH payments by about $800 million, due partially to a projected decrease in the uninsured population.
- Decrease outlier payments by 1.8 percentage points, to return to the target of paying 5.1% of inpatient PPS funds as outlier payments.
- End the MDH and enhanced LVA programs, which expire on Sept. 30, 2022 under current law.
- Permanently apply a 5% cap on any decrease in a hospital's area wage index.
- Implement changes to the graduate medical education (GME) program, related to the calculation of full-time equivalent (FTE) caps.
- Apply measure suppressions to the Hospital Acquired-Condition (HAC) Reduction Program and most measures in the Hospital Value-based Purchasing (HVBP) program, resulting in neutral payment adjustments for FY 2023.
- Add 10 new measures to the inpatient quality reporting (IQR) program.
- Propose several policies intended to advance health equity.
- Seek several requests for information on measurement policy topics, maternal health, climate change and health equity, and payment adjustments for N95 respirators.

AHA TAKE

We remain extremely concerned with CMS' proposed payment update of only 3.2% for FY 2023. Hospitals and health systems continue to face an extraordinary inflationary environment and continued labor and supply cost pressures. Even worse, hospitals would actually see a net decrease in payments from FY 2022 to FY 2023 under this proposal because of proposed cuts to DSH and other payments. This is simply unacceptable for hospitals and health systems, and their caregivers, who have been on the front lines of the COVID-19 pandemic for over two years now. We urge the agency to support policies that help hospitals' and health systems' ability to continue caring for patients and providing essential services for their communities.

WHAT YOU CAN DO

- **Participate in an AHA members-only webinar May 25** at 1:00 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 2023. Hospitals may assess the impact of these provisions on their organizations by using AHA's calculators on readmissions and Medicare DSH. Please note that based on CMS proposals to the hospital acquired conditions (HAC) and value-based purchasing programs (VBP), the VBP and HAC calculators are not applicable for FY 2023 and will not be updated.
- **Verify CMS' table listing the factor used to calculate uncompensated care payments for Medicare Disproportionate Share Hospitals (DSH).** Hospitals have until June 17 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.
- **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 17 at www.regulations.gov.** The final rule will be published on or around Aug.1 and take effect Oct. 1.

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INPATIENT PPS PAYMENT UPDATE

CMS' proposed rule would increase inpatient PPS rates by a net of 3.2% in FY 2023, compared to FY 2022, after accounting for inflation and other adjustments required by law. Specifically, the update includes an initial market-basket update of 3.1%, less 0.4 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.

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 2.43%.
- 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 0.88%.
- Hospitals that fail to meet both of these requirements would be subject to a market-basket update of 0.10%.

Beginning in FY 2023, Puerto Rico hospitals also will be subject to penalty for not being meaningful users of EHR. Specifically, CMS proposes that Puerto Rico hospitals that are not meaningful EHR users will be subject to a two-third reduction of the 75% reduction of initial market basket.

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.

The proposed increase of 3.2% in payment rates is offset by a 1.8 percentage point decrease in outlier payments, as well as other proposed policies and program expirations (e.g. DSH, LVA, MDH) resulting in a net *decrease* of approximately $0.3 billion in inpatient PPS payments in FY 2023 compared to FY 2022. Table 1 below details the impact of proposed policies.

Table 1: Impacts of FY 2023 CMS Proposed Policies

Policy	Average Impact on Payments
Market-basket update	+ 3.1%
Productivity cut mandated by the ACA	- 0.4%
Partial restoration of documentation and coding cut mandated by ATRA	+ 0.5%
Sub-Total	**+ 3.2%**
DSH payment cut	- 0.8%
Outlier payment adjustment	- 1.8%
LVA / MDH expiration	- 0.6%
Other	- 0.3%
Total	**- 0.3%**

FY 2021 Data in Rate-setting. CMS proposes to use the most recently available claims data source for rate-setting, as it ordinarily would have done. Specifically, CMS proposes to use FY 2021 claims and FY 2020 cost report data for rate-setting. However, anticipating Medicare inpatient hospitalizations for COVID-19 will continue in FY 2023, the agency is also proposing several modifications to the usual rate-setting methodology (described below) to account for such cases. CMS is also considering, as an alternative, the use of FY 2021 data without the proposed modifications, and is soliciting comments on such an approach.

Specifically, CMS is proposing modifications to the calculation of FY 2023 MS-DRG relative weights and outlier fixed-loss amount. The agency proposes to determine the MS-DRG weights for FY 2023 by averaging the relative weights as calculated with and without COVID-19 cases. For example, 50% of the relative weights would come from all applicable cases and 50% would come from cases without COVID-19 as a principal or secondary diagnosis. CMS believes that this approach would reduce, but not entirely remove, the effect of COVID-19 cases, consistent with the agency's belief that COVID-19 hospitalizations will decline in FY 2023. Additionally, CMS is also proposing a permanent 10% cap on the reduction in a MS-DRG relative weight for a given fiscal year, which would be applied in a budget neutral manner.

Separately, CMS proposes to use FY 2018 and 2019 claims data, rather than FY 2020 and 2021, which it ordinarily would have done, to calculate the charge inflation factor for the outlier fixed-loss cost threshold. The agency states that the charge inflation factors using the two most recently available years of claims data are abnormally high as a result of the pandemic. Because the agency believes that there will be fewer COVID-19 cases in FY 2023 than in FY 2021, CMS proposes to use the one-year charge inflation factor from FY 2018 to FY 2019 to determine FY 2023 outlier thresholds.

Additionally, CMS proposes to adjust the cost-to-charge ratios used in the outlier calculation by the percentage change between March 2019 and March 2020 updates to the provider specific file, rather than the December 2020 and December 2021 updates, citing anomalies of COVID-19 cases in FY 2021. As a result of these proposed changes, the agency is proposing an outlier threshold of $43,214 for FY 2023. CMS stated that the FY 2023 outlier threshold would be 36% higher, or $58,798, if the policy adjustments described above were not applied.

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 proposes that the rate-of-increase for these hospitals be 3.1%, the market basket rate-of-increase, for FY 2023.

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 2023 by 1.63% compared to the FY 2022 rate.

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 2023 DSH Payments. For FY 2023, CMS estimates that the total amount of Medicare DSH payments that would have been made under the former statutory formula is $13.27 billion. Accordingly, CMS proposes that hospitals would receive 25% of these funds, or $3.32 billion, as empirically justified DSH payments. This would result in a decrease of about $176 million in empirically justified DSH payments in FY 2023 compared to FY 2022.

The remaining $9.95 billion would flow into the 75-percent pool, which is then adjusted to reflect changes in the percentage of uninsured. CMS estimates that the percentage of uninsured for FY 2023 would be 9.2%; thus, after inputting that rate into the statutory formula, it proposes to retain 65.71% — or $6.54 billion — of the 75-percent pool in FY 2023. This would result in a decrease of about $660 million in uncompensated care payments in FY 2023 compared to FY 2022.

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. For FY 2023, CMS is proposing to use the average of audited FY 2018 and audited FY 2019 data to determine the distribution of uncompensated care payments. CMS believes that this proposal would address concerns from stakeholders on the year-to-year fluctuations in uncompensated care payments. Additionally, CMS is proposing to use three years of audited data to determine uncompensated care payments, beginning in FY 2024. Specifically, the agency proposes to use the three-year average of the uncompensated care data from the three most recent fiscal years for which audited data are available. If a hospital does not have data for all three years, CMS would use the average of the hospital's available data.

Puerto Rico, Indian Health Service (IHS) and Tribal Hospitals. Previously, CMS has used a low-income patient proxy, rather than Worksheet S-10 data, to determine the share of uncompensated care provided by Puerto Rico, IHS and Tribal hospitals. For FY 2023, CMS is proposing to discontinue the use of low-income insured days as a proxy for uncompensated care costs provided by these hospitals and to use the same data as for other hospitals. Specifically, the agency proposes to use the average of uncompensated care data reported on Worksheet S-10 for FY 2018 and FY 2019 cost reports to determine payment distribution for Puerto Rico, IHS and Tribal hospitals. The agency is seeking comments on this proposal and how to best measure and define uncompensated care costs associated with these hospitals that may not be captured based on Worksheet S-10 data.

In addition, CMS recognizes that the proposal to discontinue the use of the low-income insured days proxy and to rely solely on Worksheet S-10 data could result in significant financial disruptions for these hospitals. Therefore, the agency is proposing to establish a new supplemental payment for Puerto Rico, IHS and Tribal hospitals under its exceptions and adjustments authority beginning in FY 2023.

Specifically, CMS proposes to calculate a new supplemental payment as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year. The base year amount would be calculated by using the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable year and FY 2022. For example, for FY 2023, the percent change between the proposed FY 2023 DSH uncompensated care pool and final FY 2022 is -9.1%. Therefore, a hospital's base year amount for FY 2023 would be its FY 2022 uncompensated care payments multiplied by 0.909 (1 minus 0.091). CMS is seeking comments on the establishment of this new supplemental payment for Puerto Rico, IHS and Tribal hospitals.

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. CMS also proposes to continue to apply its FY 2022 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 would continue 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). To conform with the use of multi-year cost report data, CMS is proposing to apply the threshold to identify potentially aberrant data for all cost reporting years that are used in determining uncompensated care. For hospitals that are subject to this proposed trim but ultimately are DSH eligible at cost report settlement, the hospital's Medicare Administrator Contractor (MAC) would make a final determination of Medicare DSH payments based on its FY 2023 cost report.

Interim Uncompensated Care Payments. CMS proposes to modify the calculation for interim uncompensated care payments for FY 2023 in light of the COVID-19 public health emergency (PHE). In FY 2022, the agency used 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. For FY 2023, CMS is proposing to once again exclude FY 2020 data and instead use FY 2018, 2019, and 2021 data to calculate a 3-year average.

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's) 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 at the time of the development of the final rule. For FY 2023, this would be the FY 2018 and FY 2019 cost reports 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 2023 during cost report settlement.

- **"New Hospitals."** CMS proposes to modify its "new hospitals" policy finalized in FY 2020 to be consistent with its proposal to use multiple years of cost reports. The agency is proposing to define new hospitals as hospitals that do not have cost report data for the most recent year of the data being used in

uncompensated care payment calculations. For example, for FY 2023, the FY 2019 cost reports are the most recent year for which Worksheet S-10 has been audited. Thus, hospitals with CCNs established on or after October 1, 2019 would be subject to the new hospital policy. Specifically, for those hospitals, 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 2023 cost report.

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 2023. Hospitals will have 15 days from the date of public display of the FY 2023 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 is in the process of updating its DSH calculator for member hospitals to assess the impact of the policy on their organizations and will notify members when it is available. The calculator is designed so basic information regarding a hospital can be entered, including its CCN, and the dollar amount of the hospital's DSH payment will be estimated.

SECTION 1115 DAYS IN THE MEDICAID FRACTION OF MEDICARE DSH ADJUSTMENT

CMS proposes to modify current regulations regarding the Medicaid fraction of the Medicare DSH adjustment. The agency proposes that only Medicaid patients who receive health insurance through a Section 1115 demonstration waiver, where state spending to provide health insurance is matched with Medicaid funds, can count for purposes of the Medicaid fraction. This proposal would specifically preclude the counting of days of patients that are associated with uncompensated care pools from the Medicaid fraction. CMS's justification is based on the belief that uncompensated care pool payments are not tied to care provided to a specific individual nor provides health insurance to a specific individual and therefore the patients associated with uncompensated care should not be regarded as eligible for Medicaid. CMS's previous attempts to limit how patients associated with uncompensated care pools are treated for purpose of the Medicare DSH adjustment has been met with legal challenges. However, CMS sites its current regulatory flexibility in making this proposed change.

The proposed rule would also clarify that patients receiving premium assistance to purchase health insurance through a Section 1115 demonstration waiver can be regarded as Medicaid for purposes of the Medicaid fraction. It specifically proposes that only premium assistance days that count in the Medicaid fraction are days of patients that purchased health insurance that provides Essential Health Benefits equal to 90 percent of the cost of health insurance. The agency further explains it chose this threshold because this level of benefits is similar to benefits provided to traditional Medicaid beneficiaries. If the premium assistance program provides benefits less than

what is provided to traditional Medicaid beneficiaries, those patient days would not count for purpose of the Medicaid fraction. These proposed changes would be effective on or after Oct. 1, 2021.

CHANGES TO MS-DRG CLASSIFICATIONS

FY 2023 MS-DRG Updates. CMS's analysis is based on claims data from the September 2021 update of the FY 2021 MedPAR file which contains hospital bills received from October 1, 2021 through September 30, 2021. Beginning with FY 2024 MS-DRG classification change requests, CMS is changing the deadline to request changes to the MS-DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. CMS is also changing the process for submitting requested updates to the MS-DRG classifications, beginning with the FY 2024 MS-DRG classification change requests. CMS is in the process of implementing a new electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), to submit new technology add-on payment applications, requests for ICD-10-PCS procedure codes, and other requests. CMS anticipates that beginning April 5, 2022, MEARIS will be available for users to begin gaining familiarity with this new approach for submitting MS-DRG classification change requests. Beginning with the FY 2024 MS-DRG classification change requests, CMS will only accept such requests submitted via MEARIS, and will no longer consider any such requests sent via email.

For this FY 2023 IPPS/LTCH PPS proposed rule, CMS is providing a test version of the ICD-10 MS-DRG GROUPER Software, Version 40, so that the public can better analyze and understand the impact of the proposals included in this proposed rule.

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 from 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;
- At least a 20% difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

For this FY 2023 IPPS/LTCH PPS proposed rule, using the September 2021 update of the FY 2021 MedPAR file, CMS analyzed how applying the non-CC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure beginning in FY 2023. Findings from CMS' analysis found that applying the non-CC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 123 MS-DRGs (41 MS-DRGs x 3 severity levels = 123) and the creation of 75 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases.

Because of the PHE, CMS continues to have concerns about the impact of implementing this volume of MS-DRG changes at this time. Therefore, CMS proposes **not** to apply the non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split for FY 2023, and to instead maintain the current structure of the 41 MS-DRGs that currently have a three-way severity level split (total of 123 MS-DRGs) that would otherwise be subject to these criteria. CMS intends to address this in future rulemaking.

Pre-MDC

MS-DRG 018 Chimeric Antigen Receptor (CAR) T-Cell Therapy and Other Immunotherapies. CAR T-cell therapy is a cell-based gene therapy. The CAR process genetically engineers a patient's T-cells, resulting in the addition of a chimeric antigen receptor that will bind to and attack a certain protein on the patient's cancerous cells. In the FY 2022 IPPS final rule, CMS finalized its proposal to create a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and revised its title "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies."

CMS described the process for code creation and proposed assignment to the most appropriate MS-DRG as being independent processes, regardless of whether there is an associated publication for new technology add-on payment for product or technology submitted for consideration in a given fiscal year. CMS has continued to assess the appropriateness of the therapies assigned to MS-DRG 018 and provided results of its data analysis. CMS is not proposing any changes for FY 2023 and will continue to consider issues and suggestions in connection with future rulemaking.

Major Diagnostic Category (MDC) 1 (Diseases and Disorders of the Nervous System)

Laser Interstitial Thermal Therapy. In the FY 2022 final rule, CMS finalized the reassignment of 31 procedure codes describing laser interstitial thermal therapy (LITT) of various body parts to more clinically appropriate MS-DRGs. The change included the reassignment of LITT of the brain and brain stem as noted below.

From	To
• MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) • MS-DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) • MS-DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively)	MS-DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively)

The two LITT procedures were also redesignated from extensive operating room (O.R.) procedures in MS-DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to non-extensive O.R procedures in MS-DRGs 987, 989, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

For FY 2023, CMS has received a proposal for reclassifying LITT from the Radiation Therapy section of the procedure classification to the Medical/Surgical section root operation Destruction, and a separate MS-DRG reclassification request on the existing procedure codes. CMS is providing the opportunity for public comment on possible MS-DRG assignments for the requested new procedure codes describing LITT that may apply based on the application if its established process and analysis in the event the new codes are finalized for FY 2023.

CMS is proposing to reassign the existing procedure codes describing LITT of the brain or brain stem as follows:

From	To
MS-DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively	MS-DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively)

CMS is also proposing to maintain the MS-DRG assignments for the existing procedure codes describing LITT of other anatomic sites as finalized and displayed in Table 6P.2b in association with the FY 2022 IPPS/LTCH PPS final rule, for FY 2023. In addition, CMS is also seeking public comment and feedback on other factors that should be considered in the potential restructuring of MS-DRGs 023 through 027.

Vagus Nerve Stimulation. CMS received a request to review the MS-DRG assignment for cases that identify patients who receive an implantable vagus nerve stimulation system for heart failure. After an extensive analysis, CMS is not proposing to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure.

For clinical consistency, CMS is proposing to add the 108 ICD-10-PCS code clusters listed in Table 6P.3a that describe the insertion of a stimulator generator, that is not differentiated by device type, and a neurostimulator lead to MS-DRG 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator).

MDC 4 (Diseases and Disorders of the Respiratory System): Acute Respiratory Distress Syndrome (ARDS)

CMS is proposing to reassign cases reporting ARDS (ICD-10-CM code J80) as a principal diagnosis from MS-DRG 204 (Respiratory Signs and Symptoms) to MS-DRG 189 (Pulmonary Edema and Respiratory Failure). The request for reclassification was partially based on ICD-10-CM Official Guidelines for Coding and Reporting, ICD-10-CM Tabular List instructions and *Coding Clinic for ICD-10-CM and ICD-10-PCS* advice which support that when acute respiratory failure is documented along with ARDS, only code J80 is reported to capture the highest level of severity. CMS' data analysis supports that cases reporting ARDS (code J80) are more appropriately aligned with the average length of stay and average costs of the cases in MS-DRG 189 in comparison to MS-DRG 204 when ARDS is reported as a principal diagnosis.

MDC 5 (Diseases and Disorders of the Circulatory System)

Percutaneous Transluminal Coronary Angioplasty (PTCA) Logic. CMS is proposing to remove procedure code 02UG3JE (Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach) from the list for PTCA procedures in the GROUPER logic for MS-DRGs 231 and 232. The change is proposed because the procedure is not clinically consistent a PTCA procedure and it was initially assigned to the list for PTCA procedures in the GROUPER logic as a result of replication in the transition from ICD-9 to ICD-10 based MS-DRGs. CMS is also proposing to maintain the MS-DRG assignment for procedure code 02UG3JE in MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively).

Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy). The BAROSTIM NEO™ System is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. The system consists of an implantable pulse generator, a stimulation lead and a wireless programmer system that is used to non-invasively program and adjust BAROSTIM NEO therapy via telemetry.

CMS received requests to reassign the ICD-10-PCS procedure codes for the implantation of the system and the placement of the implantable pulse generator alone. After performing a data analysis, CMS is not proposing a change. CMS noted it is difficult to detect patterns of complexity and resource intensity due to the low volume of cases.

During CMS' review of this issue, they found two diagnosis codes describing heart failure that were missing from the list of heart failure diagnoses. CMS is proposing to modify the GROUPER logic to allow cases reporting diagnosis code I97.130 or I97.131 (post-procedural heart failure following cardiac surgery, and following other surgery, respectively) as a principal 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 qualifying procedures.

Cardiac Mapping. CMS is proposing to reassign procedure code 02K80ZZ (Map conduction mechanism, open approach) to address a replication issue in the transition from ICD-9 to ICD-10 based MS-DRGs. Cardiac mapping is generally performed during open-heart surgery or performed via cardiac catheterization to create detailed maps of electrical signals to identify the location of rhythm disorders. The procedure is not clinically consistent with percutaneous cardiovascular procedures and CMS is therefore proposing its reassignment as follows:

From	To
• MS-DRG 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents) • MS-DRG 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC) • MS-DRG 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents) • MS-DRG 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC) • MS-DRG 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC) • MS-DRG 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC)	MS-DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively)

MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Laparoscopic Cholecystectomy with Common Bile Duct Exploration

For FY 2023, CMS is proposing to redesignate procedure code 0FC94ZZ (Extirpation of matter from common bile duct, percutaneous endoscopic approach) from a non-O.R. procedure to an O.R. procedure and add it to the logic list for common bile duct exploration (CDE) in MS-DRGs 411, 412 and 413 (Cholecystectomy with CDE with MCC, with CC, and without CC/MCC, respectively) to appropriately reflect when this procedure is performed and improve the clinical coherence of the patients assigned to these MS-DRGs.

CMS is requesting feedback to consider proposing to restructure MS-DRGs 411, 412 and 413, and MS-DRGs 417, 418 and 419 (Laparoscopic Cholecystectomy without CDE with MCC, with CC, and without CC/MCC, respectively). For example, CMS could consider proposing to restructure these cholecystectomy MS-DRGs to reflect the following two concepts, if supported by the data, and relatedly, to determine if severity levels are also supported according to the existing criteria:

- Open Cholecystectomy with or without CDE.; and
- Laparoscopic Cholecystectomy with or without CDE.

The due date for recommendations and/or options to further refine these MS-DRGs is outside of this proposed rule — October 20, 2022.

MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period): Normal Newborn

CMS is proposing to add 13 diagnosis codes that describe contact with and (suspected) exposure to communicable diseases to the “only secondary diagnosis” list under MS-DRG 795 (Normal Newborn). Under this proposal, cases with a principal diagnosis described by an ICD-10-CM code from category Z38 (Live born infants according to place of birth and type of delivery), followed by codes Z05.1 (Observation and evaluation of newborn for suspected infectious condition ruled out) and Z20.822 (Contact with and (suspected) exposure to COVID-19) will be assigned to MS-DRG 795.

In addition, CMS is proposing to reassign three ICD-10-CM diagnosis codes as listed below:

ICD-10-CM Code	Current MS-DRG	Proposed MS-DRG
P07.00, Extremely low birth weight newborn, unspecified weight	MS-DRGs 791 and 792 (Prematurity with and without Major Problems, respectively)	MS-DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome Neonate)
P07.20, Extreme immaturity of newborn,	MS-DRG 795 (Normal Newborn)	

unspecified weeks of gestation		
P07.26, Extreme immaturity of newborn, gestational age 27 completed weeks	MS-DRGs 791 and 792 (Prematurity with and without Major Problems, respectively	

Review of Procedure Codes in 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 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 move the procedures and/or principal diagnosis codes described below from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into one of the surgical MS-DRGs for the MDC into which the principal diagnosis is assigned.

Embolization of Portal and Hepatic Veins. CMS is proposing to add ICD-10-PCS procedure codes for embolization of a hepatic or portal vein to MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas). Under this proposal these procedures would group as noted below when reported in conjunction with a principal diagnosis code from MDC 7:

ICD-10-PCS Procedure Codes	Proposed MS-DRGs
• 06L43DZ, Occlusion of hepatic vein with intraluminal device, percutaneous approach • 06L83DZ, Occlusion of portal vein with intraluminal device, percutaneous approach • 06V43DZ, Restriction of hepatic vein with intraluminal device, percutaneous approach • 06V83DZ, Restriction of portal vein with intraluminal device, percutaneous approach	MS-DRGs 423, 424 and 425 (Other Hepatobiliary or Pancreas Procedures with MCC, with CC, and without CC/MCC, respectively)

Percutaneous Excision of Hip Muscle. CMS is proposing to remove four procedure codes describing percutaneous excision or biopsy of muscle from the O.R. procedures list. Under this proposal, these procedures would no longer impact MS-DRG

assignment. The procedures would group as noted below when reported in conjunction with a principal diagnosis code from MDC 6 (Diseases and Disorders of the Digestive System):

ICD-10-PCS Procedure Codes	Proposed MS-DRGs
• 0KBN3ZX, Excision of right hip muscle, percutaneous approach, diagnostic • 0KBN3ZZ, Excision of right hip muscle, percutaneous approach • 0KBP3ZX, Excision of left hip muscle, percutaneous approach, diagnostic • 0KBP3ZZ, Excision of left hip muscle, percutaneous approach	MS-DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively)

CMS is not proposing to move any cases reporting procedure codes from MS-DRGs 981 through 983 to MS-DRGs 987 through 989 or vice versa.

O.R. and Non-O.R. Issues. In the FY 2020 IPPS/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 will also review the process for determining when a procedure is considered an operating room procedure. For example, CMS notes they 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 has typically evaluated 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 IPPS/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 ongoing PHE, CMS continues to believe 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 its process and methodology. Therefore, CMS will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

For FY 2023 CMS addresses 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. CMS is not considering making a change to the designation of these codes at this time.

Comprehensive CC/MCC Analysis. In the FY 2018 IPPS 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. The nine guiding principles are as follows:

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

In the FY 2022 IPPS proposed rule, CMS solicited comments on adopting a change to the severity level designation of the 3,490 “unspecified” diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a non-CC for FY 2022. If approved, the change would have affected the severity level assignment for 4.8% of the ICD-10-CM diagnosis codes.

Instead, for FY 2022 CMS finalized effective beginning with discharges on or after April 1, 2022, a new Medicare Code Editor (MCE) code edit for “unspecified” codes, to provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. For FY 2023, CMS is **not** proposing to change the designation of any ICD-10-CM diagnosis codes, including the unspecified codes that are subject to the “Unspecified Code” edit, as CMS continues its comprehensive

CC/MCC analysis to allow stakeholders the time needed to become acclimated to the new edit.

CMS continues to solicit feedback regarding the guiding principles, as well as other possible ways it can incorporate meaningful indicators of clinical severity. CMS has made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019, FY 2020 and FY 2021 MedPAR files.

Social Determinants of Health Diagnosis Codes. CMS is soliciting public comments on how the reporting of diagnosis codes in categories Z55-Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) may improve CMS' ability to recognize severity of illness, complexity of illness, and/or utilization of resources. CMS is also interested in receiving feedback on how it might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

CMS cites references that support reporting social determinants of health codes (SDOH Z codes) in inpatient claims data could enhance quality improvement activities, track factors that influence people's health, and provide further insight into existing health inequities. CMS states that more routine collection of SDOH Z codes could also likely improve coordination within hospitals to utilize the data across their clinical care and discharge planning teams, including with post-acute partners. CMS has heard from stakeholders about a number of reasons for why there may be less routine documentation and reporting of SDOH in the inpatient setting.

The 96 diagnosis codes that describe the social determinants of health (SDOH) for which CMS is soliciting comments are shown in Table 6P.5a available on the CMS website. Specifically, CMS is soliciting comments on the following questions:

- How the reporting of certain Z codes — and which ones — may improve its ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS-DRGs?
- Whether CMS should require the reporting of certain Z codes — and if so, which ones — to be reported on hospital inpatient claims to strengthen data analysis?
- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.
- Whether codes in category Z59 (Homelessness) have been underreported and if so, why? In particular, CMS is interested in hearing the perspectives of large urban hospitals, rural hospitals and other hospital types in regard to their experience. CMS also seeks comments on how factors such as hospital size and type might impact a hospital's ability to develop standardized consistent protocols to better screen, document and report homelessness.

CMS notes that examining the severity level designation of diagnosis codes is just one area to possibly support documentation and reporting of SDOH in the inpatient setting. CMS is also interested in ideas from the public on how the MS-DRG classification can be utilized in agency wide efforts to advance health equity, expand access, drive high-quality, person-centered care, and promote affordability and sustainability in the Medicare program. Specifically, CMS invites public comment on ways the MS-DRG classification can be useful in addressing the challenges of defining and collecting accurate and standardized self-identified socioeconomic information for the purposes of reporting, measure stratification and other data collection efforts. CMS is interested in learning more about the potential benefits and challenges associated with the collection of SDOH data in the inpatient setting. Feedback on the limitations and barriers providers could experience as they consider documentation and reporting that is more robust would also help inform its development of appropriately tailored efforts that address and mitigate barriers for all hospital types across communities and patient mixes under the MS-DRGs.

Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems. At the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee meeting CMS announced it was changing the process for submitting requested updates to the ICD-10-PCS classification, beginning with the procedure code request submitted for consideration for the September 13-14, 2022 ICD-10 Coordination and Maintenance Committee Meeting. Effective March 1, 2022, the full release of MEARIS became active for ICD-10-PCS code request submissions. Moving forward, CMS will only accept ICD-10-PCS code requests submitted via MEARIS. Requests submitted through the ICD Procedure Code Request email will no longer be considered.

Because of the ongoing COVID-19 PHE, the CDC implemented three new diagnosis codes describing immunization status related to COVID-19 into the ICD-10-CM effective with discharges on and after April 1, 2022. In addition, CMS implemented nine new procedure codes describing the introduction or infusion of therapeutics, including vaccines for COVID-19 treatment, into the ICD-10-PCS effective with discharges on and after April 1, 2022. The nine procedure codes are designated as non-O.R. and do not affect any MDC or MS-DRG assignment.

As discussed in the FY 2022 IPPS/LTCH final rule, CMS adopted an April 1 implementation date for diagnosis and procedure code revisions, in addition to the annual October 1 update beginning with April 1, 2022. CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies).

Mechanisms to Address Rare Diseases and Conditions Represented by Low Volumes within the MS-DRG Structure. CMS is soliciting public comments involving how the reporting of certain diagnosis codes may improve its ability to recognize severity of illness, complexity of illness and utilization of resources

under the MS-DRGs, as well as feedback on mechanisms to improve the reliability and validity of the coded data as part of an ongoing effort across CMS to evaluate and develop policies to reduce health disparities for rare diseases and low volume conditions. In concert with that effort, CMS is also soliciting comments to explore possible mechanisms through which CMS can address rare diseases and conditions that are represented by low volumes in our claims data. In particular, CMS is seeking comment on potential issues related to patient access for patients diagnosed with rare diseases and conditions that are represented by low volumes in its claims data.

For the purposes of this comment solicitation, CMS described three selected requests received in the past relating to the MS-DRG classification of rare diseases and conditions that are represented by low volumes in its claims data:

- Porphyria, a group of rare disorders that interfere with the production of hemoglobin needed for red blood cells.
- Administration of ANDEXXA® coagulation factor Xa (recombinant) to rapidly reverse the anticoagulant effects of two direct oral anticoagulants, apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages and gastrointestinal bleeds.
- Administration of Zulresso® (brexanolone) for the treatment of postpartum depression in adults.

CMS notes that the MS-DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. However, cases involving treatment of rare diseases may involve more resource use than other cases in their respective MS-DRG. Section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.

CMS is soliciting feedback on the following for consideration in future policy development:

- Other mechanisms it can explore through which it could address concerns relating to payment for patients with rare diseases and conditions that are represented by low volumes in its claims data.
- Other meaningful ways in which it may potentially improve access to treatment for postpartum depression in certain populations, including through activities pursuant to Vice President Harris's Call to Action to Reduce Maternal Mortality and Morbidity.
- How to mitigate any unintended negative payment impacts to providers serving patients with rare diseases that are represented by low volumes in its claims data.
- Perspectives of large urban hospitals, rural hospitals and other hospital types in regard to their experience.

- How factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions.

CHIMERIC ANTIGEN T-CELL (CAR-T) THERAPY

In its FY 2021 final rule, CMS developed a relative weight for a CAR-T MS-DRG (MS-DRG 018), 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 use of immunotherapy cases (sometimes called "compassionate use"). Using FY 2021 data for FY 2023 rate-setting, CMS proposes a payment adjustment of 0.20 when calculating payment for clinical trial cases and expanded access cases assigned to MS-DRG 018 in FY 2023. That is, the inpatient payment would be reduced by 80% to account for the hospital not incurring the cost of the therapy itself.

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 and Limited Population Pathway for Antibacterial and Antifungal Drugs). These payments are not budget neutral.

NTAP Submissions and Approvals. CMS proposes to continue NTAPs in FY 2022 for 15 technologies already approved that remain eligible. In addition, for FY 2022, CMS finalized a policy to allow for a one-year extension of payments for 13 new technologies for which the NTAP would otherwise have been discontinued in FY 2022 due to the pandemic. CMS proposes to discontinue NTAP for these 13 technologies in FY 2023.

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. The threshold amounts for FY 2023 are presented in the FY 2022 final rule. Consistent with that final policy, CMS finalized its proposal to use the FY 2019 claims data to set the thresholds for applications for new technology add-on payments for FY 2023. For FY 2024 thresholds, CMS is proposing to use the FY 2021 claims data and to use the average of the charges with and without COVID-19 cases.

Proposal to Publicly Post NTAP Applications. CMS proposes to publicly post online future applications for NTAP to increase transparency, enable increased stakeholder engagement, and to further improve the agency's evaluation process. Specifically, beginning with the FY 2024 application cycle, CMS proposes to post online the completed application forms and certain related information, but not cost and volume information and copyrighted materials.

National Drug Codes (NDCs) for NTAPs. As part of public comments to the ICD-10 Coordination and Maintenance Committee meetings, CMS has received comments opposing the continued creation of new ICD-10-PCS Section X codes for the purpose of administering NTAPs for drugs and biologicals as the ICD-10-PCS classification system was not intended to represent unique drugs/therapeutic agents. The current process of creating and implementing new ICD-10-PCS frequently results in codes that are created unnecessarily when the drug/therapeutic agents do not receive approval for the NTAP, as the administration of drugs/therapeutic agents is not typically coded in the inpatient hospital setting. The majority of commenters, as well as the AHA, supported using National Drug Codes (NDCs), because it would avoid creating duplicate codes within the ICD-10-PCS and NDC code sets to identify the same technology/product, which would allow for predictive and efficient coding. CMS has previously used NDCs as an alternative code set in circumstances where an ICD-10-PCS code was not available to uniquely identify the use of the technology.

CMS is proposing to phase in utilizing NDC/ICD-10-PCS Section X codes as shown below for purposes of the NTAP application cycle involving the administration of therapeutic agents based on the fiscal year when the NTAP was newly approved. CMS anticipates that this proposal would reduce work for hospital coding professionals in becoming familiar with newly created ICD-10-PCS Section X codes to describe the administration of therapeutic agents and in searching for these codes within the documentation and within the classification in what may be non-intuitive locations.

Fiscal Year	**FY NTAP Approval**	**Codes Utilized for NTAP**
FY 2023 Transitional Period	Newly Approved FY 2023	Either NDC(s) or ICD-10-PCS procedure code(s)
	Newly Approved *prior* to FY 2023 still eligible for NTAP	Existing ICD-10-PCS procedure codes
Beginning FY 2024	Newly Approved FY 2024	Only NDC(s)
		Exception: ICD-10-PCS procedure codes for therapeutic agents that are not assigned an NDC by FDA (for example, blood, blood products, etc.)
	Newly Approved FY 2023 still eligible for NTAP FY 2024 or subsequent fiscal years	Either NDC(s) or ICD-10-PCS procedure code(s)
	Newly Approved *prior* to FY 2023 still eligible for NTAP	Existing ICD-10-PCS procedure codes

NEW COVID-19 TREATMENT ADD-ON PAYMENTS (NCTAPS)

In light of the COVD-19 PHE, CMS established 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 either 1) 65% of the operating outlier threshold for the claim; or 2) 65% of the amount by which the costs of the case exceeded the standard DRG payment.

In the FY 2022 final rule, CMS finalized that it would make NCTAPs through the fiscal year in which the PHE ends. CMS also finalized that for a product eligible for NCTAP that is also approved for NTAP, the agency will reduce NCTAP for an eligible case by the amount of any NTAPs. CMS believes that this would not create financial disincentive between technologies eligible for both NTAPs and NCTAPs compared to technologies eligible for NCTAP only.

AREA WAGE INDEX MODIFICATIONS

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. For FY 2023, CMS proposes to use data from FY 2019 cost reports to determine the area wage index. In addition, for FY 2023, CMS proposes to continue the 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.

Permanent Cap on Wage Index Decreases. In the FY 2020 final rule, CMS adopted a transition policy for FY 2020 to place a 5% cap on any decrease in a hospital's wage index due to the combine effects of policy changes in FY 2020. In FY 2021, CMS adopted updates in OMB bulletin 18-04 and adopted the same 5% cap policy for any decrease in a hospital's final wage index in FY 2021 compared to its final wage index in FY 2020 at 5%. Given the PHE, CMS continued the policy in FY 2022 but it only applied to hospitals that were affected by the OMB bulletin.

For FY 2023, CMS is proposing to adopt a permanent policy to place a 5% cap on all wage index decreases each year, regardless of the reason. CMS recognizes that significant year-to-year changes in the wage index can occur due to external factors beyond a hospital's control and that the proposed policy would increase the predictability of IPPS payments for hospitals. The agency proposes to implement this permanent policy in a budget neutral manner.

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 2019 Medicare Wage Index Occupational Mix Survey with the intent of computing the occupational mix adjustment for FYs 2022, 2023 and 2024.

Accordingly, CMS proposes to continue the use of 2019 survey for the FY 2023 occupational mix adjustment. CMS also proposes to apply the occupational mix adjustment to 100% of the wage index, as it 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 2023 would be 0.8401. The agency proposes to continue to make this policy budget neutral by adjusting the national standardized amount for all hospitals. However, a recent court ruling found that the Secretary did not have authority to adopt the low-wage policy. CMS stated that while it is proposing to continue the low-wage policy, the agency may take a different approach in the final rule depending on developments in court proceedings.

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. The rural floor is calculated without including the wage data of hospitals that have reclassified as rural. For FY 2023, CMS proposes to continue to calculate the rural floor under such method. As such, CMS estimates that 192 hospitals would receive their state's rural floor wage index. However, a recent court ruling found that the Secretary did not have authority to establish a rural floor lower than the rural wage index for a state. CMS stated that while it is proposing to continue the rural floor policy, the agency may take a different approach in the final rule depending on developments in court proceedings.

Imputed Floor Calculation. As required by the American Rescue Plan Act, CMS permanently reinstated a minimum area wage index for hospitals in all-urban states, known as an "imputed rural floor" for FY 2022. CMS proposes to continue the imputed floor policy for FY 2023.

This policy would apply 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 beginning in FY 2022 was not budget neutral. Therefore, CMS would 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 would define a rural hospital as one assigned the state's rural area wage index value, after all reclassifications.

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 2023 reclassification requests and 491 hospitals were approved for wage index reclassifications for FY 2023. Hospitals reclassified during FYs 2021 (288 hospitals) and 2022 (304 hospitals) will continue to be reclassified, because wage index reclassifications are effective for three years. **Hospitals with 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. **Applications for hospital reclassifications for FY 2024 are due to the MGCRB by Sept. 1, 2022.**

Labor-related Share. 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 rebased and revised the hospital market basket and finalized a labor-related share of 67.6% using the 2018-based IPPS market basket. For FY 2023, CMS is proposing to continue the use of a labor-related share of 67.6%. 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.

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, a weighted number of full-time equivalent (FTE) residents, 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 FTE residents to its number of inpatient hospital beds. In this rule, CMS proposes to make several modifications to GME that would affect Medicare direct GME and IME payments to teaching hospitals.

Direct GME Full-time Equivalent Caps. Medicare direct GME payments are determined, in part, using the number of FTE residents, and certain factors are applied to adjust this count of FTE residents. For example, resident are counted at 1.0 FTE for the period of their initial residency and at 0.5 FTEs when outside their initial residency period. For cost reporting periods beginning on or after October 1, 1997, a hospital's weighted FTE count of residents may not exceed the hospital's unweighted FTE count

in 1996 (known as the FTE cap). Thus, CMS established a method to bring each hospital's weighted FTE count within its unweighted FTE cap.

In a U.S. District Court ruling, the Court held that CMS' method improperly modified the weighting factors statutorily assigned to residents and fellows and ordered CMS to recalculate reimbursement owed. Specifically, it was found that CMS' method effectively reduced the weighting factor of 0.5 to an amount less than that, thus reducing the FTE amount that was entitled for residents outside their initial period.

CMS is now engaging in retroactive rulemaking to a new policy for cost reporting periods beginning on or after October 1, 2001. Specifically, it proposes to revise the instructions to Worksheet E-4, line 9 on the cost report to address situations for applying the FTE cap when a hospital's weighted FTE count is greater than its FTE cap, ensuring that it would not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. The rule provides detailed information on how the total allowable weighted FTE count (Worksheet E-4, Line 9, Column 3) would be reported.

Reasonable Cost Payment for Nursing and Allied Health Education Program. Medicare pays providers for Medicare's share of the costs that providers incur in connection with approved education activities, including nursing and allied health (NAH) programs. The costs of these programs are not included in the calculation of payment rates for hospitals paid under the IPPS; instead, they are separately paid on a reasonable cost basis. Hospitals that operate approved NAH programs and receive Medicare reasonable cost reimbursement also receive additional payments from Medicare Advantage (MA) organizations. The total spending for these programs are capped at $60 million for any calendar year. As such, direct GME payments are reduced by the amount paid for NAH MA payments.

In an August 1, 2000 interim final rule, CMS stated that it would publish the NAH MA rates and resulting reduction in direct GME payments every year in the IPPS. Instead, the agency published subsequent rates through Change Requests. In accordance to the interim final rule, CMS is proposing, beginning in FY 2023, to issue rates for the NAH MA add-on and the direct GME MA percent reductions in the annual IPPS rule. As such, for calendar years (CYs) 2020 and 2021, the statutory formula for distributing NAH payments will result in a reduction of 3.7% and 3.2%, respectively, to direct GME MA and NAH payments.

Medicare GME Affiliation within Rural Tracks. While there are hospital-specific direct GME and IME FTE caps, CMS does allow institutions that are members of the same affiliated group to apply their direct GME and IME FTE caps on an aggregate basis through a Medicare GME affiliation agreement. This allows hospitals to increase or decrease their resident caps to reflect the rotation of residents among affiliated hospitals for agreed upon years.

To encourage training of residents in rural areas, urban hospitals may establish training programs in rural areas (rural tracks). Caps associated with rural tracks are separate and distinct from a hospital's general FTE cap, and as a result, the rural track FTE caps are not part of the regular FTE caps that hospitals may aggregate in Medicare GME affiliation agreements.

CMS is now proposing to afford the same flexibility with cap sharing to urban and rural hospitals that together train residents in rural track programs as those afforded to teaching hospitals that share general FTE cap slots via Medicare GME affiliation agreements. This flexibility would allow the urban and rural hospitals to share their rural track FTE caps in a manner that best matches rotations occurring in those hospitals. Specifically, CMS is proposing to allow urban and rural hospitals jointly training residents to aggregate their respective IME and direct GME rural track FTE caps and enter into a "Rural Track Medicare GME Affiliation Agreement" to share those cap slots and facilitate the cross-training of residents. This would only apply to separately accredited family medicine programs in the "1-2" format (where the first year is at a core family medicine program and second year and beyond are at another site) and hospitals with such a program in place prior to October 1, 2022.

RURAL PROVISIONS

Low-volume Hospitals. Beginning in FY 2023, the low-volume hospital qualifying criteria and adjustment will revert to statutory requirements that were in effect prior to FY 2011. As such, CMS proposes that a low-volume hospital would be defined as one that is located more than 25 road miles from another subsection (d) hospital and has fewer than 800 total discharges. The payment adjustment would be based on the "empirical relationship" between the standardized cost-per-case and the total number of discharges and the amount of additional incremental costs associated with such discharges. The adjustment would be capped at 25%. CMS proposes to apply a 25% low-volume adjustment to all qualifying hospitals with less than 200 discharges while hospitals with between 200 and 799 discharges do not receive a low-volume adjustment. The agency states that this method, based on analysis conducted when the method was last effective (FYs 2005-2010), is most consistent with the statutory requirement to provide relief to low-volume hospitals where empirical evidence shows higher incremental costs are associated with low numbers of total discharges.

CMS is proposing to continue the past process for hospitals to apply for low-volume hospital status. **To request for low-volume hospital status, a hospital must make a written request for low-volume status that is received by its MAC by Sept. 1, 2022.** If a hospital qualified for low-volume status in FY 2022, it may continue to receive an adjustment for FY 2023 without reapplying, but the hospital must provide written verification to the MAC that it continues to meet the lower discharge criterion for FY 2023. **The AHA is currently working to extend the enhanced low-volume adjustment beyond the September 31, 2022 expiration date.**

Medicare-dependent, Small Rural Hospital (MDH) Program. The MDH program was established with the intent of supporting small rural hospitals for which Medicare patients make up a significant percent of inpatient days or discharges. The program provides special payments for these qualifying hospitals and under current law is set to expire at the end of FY 2022. Hospitals that previously qualified for MDH status will be paid based on the IPPS federal rate.

CMS reiterates its existing sole community hospital (SCH) policy that allows MDHs to apply for SCH status and be paid as such under certain conditions, following the expiration of the MDH program. Hospitals wishing to apply for SCH status must apply at least 30 days before the end of the MDH program, or by September 1, 2022, in order for SCH status to be effective upon expiration of the MDH program. **The AHA is currently working to extend the MDH program beyond the September 31, 2022 expiration date.**

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. 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.

In FY 2022, in light of the COVID-19 PHE, CMS used cost report data from FY 2018 and claims data from FY 2019 to calculate CMI and discharge values. For FY 2023, CMS is proposing to use FY 2021 claims data and FY 2020 cost report data, as it traditionally would have done, to calculate CMI and discharge values.

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. With the extension finalized in FY 2022, hospitals with a scheduled end date during 2021, 2022 and 2023 were eligible for an additional 5-year period. The period of participation for the last hospital in the demonstration under this most recent extension is now June 30, 2028.

For FY 2023, 26 hospitals are continuing their participation in the demonstration program. The program is enacted in a budget neutral manner. Therefore, CMS is proposing for FY 2023 that the budget neutrality offset be based on the sum of 1) the amount representing the difference between estimated reasonable cost amounts paid under the demonstration program and the estimated amounts that would have been paid had the demonstration been not implemented for FY 2023; and 2) the difference between the actual costs of the demonstration and the amount determined in FY 2017 since no budget neutrality offset was conducted in FY 2017.

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. In FY 2022, the program was extended for another 5-year period, with 5 CAHs participating in the telehealth intervention, 4 CAHs in the skilled nursing/nursing facility bed intervention, and 3 CAHs in the ambulance services intervention. CMS proposes that it would adopt the same budget neutrality methodology and analytical approach for the extension period as it did for the initial period; however, in the event the demonstration extension period is not budget neutral, the agency proposes to recoup any excess costs within one fiscal year, rather than a 3-year period as it was instituted in the initial demonstration.

PROMOTING INTEROPERABILITY PROGRAM

Changes to Measures and Objectives

CMS proposes several changes to the Promoting Interoperability Program's objectives and measures would begin starting with the CY 2023 reporting/FY 2025 payment year.

Query of Prescription Drug Monitoring Program Measure. CMS proposes to require the reporting of the Electronic Prescribing objective's Prescription Drug Monitoring Program (PDMP) measure. The measure would continue to have 10 points associated with its reporting, but would no longer be considered bonus points. In addition, CMS proposes to expand the measure to include Schedule II, III and IV drugs. CMS believes this expansion would facilitate more informed prescribing practices and improve patient outcomes. The proposal would require a "yes/no" response for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

Of note, CMS would exclude any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and any eligible hospital or CAH that cannot report on this measure in accordance with applicable law. CMS hopes to modify the measure in the future to be numerator/ denominator based once common standards for exchange between PDMP and EHRs have been advanced.

New Trusted Exchange Framework and Common Agreement (TEFCA) Measure in the Health information Exchange (HIE) Objective. CMS proposes to add a new Enabling Exchange under the TEFCA measure as an optional alternative to fulfill the

objective, beginning with the CY 2023 EHR reporting period. The measure is attestation based, and would require a "yes/no" response to two statements:

- Hospital is participating as a signatory to a TEFCA framework agreement and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department and all unique patient records stored or maintained in the EHR for those departments during the reporting period in accordance with applicable law and policy;
- Hospital is using the functions of Certified EHR Technology to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Antimicrobial Use and Resistance (AUR) Measure in the Public Health and Clinical Data Exchange Objective. CMS proposes to add a new required AUR measure to this objective. This "yes/no" measure would reflect whether hospitals are in active engagement with the Centers for Disease Control and Prevention's National Health Care Safety Network (NHSN) to submit AUR data and receives a report from NHSN indicating their successful submission of AUR data for the reporting period.

Levels of Active Engagement for Measures in Public Health and Clinical Data Exchange Objective. CMS proposes to consolidate the current options for "active engagement" from three to two levels:

- Option 1: Pre-production and validation (which combines current "Option 1," which reflects completed registration to submit data, and current "Option 2," which reflects testing and validation of data);
- Option 2: Validated data production (current "Option 3," production).

CMS does not make substantive changes to the individual options or requirements for selecting the individual options. CMS would also require the reporting of the level of active engagement for the measures under the objective beginning with the CY 2023 EHR reporting period.

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. CMS proposes several changes to the maximum number of points for each meaningful use objective. CMS would increase the points associated with the Electronic Prescribing objective from 10 to 20 points given that the Query of PDMP measure is being converted into a required measure. CMS also proposes to increase the number of points associated with the Public Health and Clinical Data Exchange objective from 10 to 25 points. CMS would reduce the points associated with the Health Information Exchange objective from 40 to 30 points, and the Provider to Patient Exchange objective from 40 to 25 points. These changes are summarized in the table below.

Proposed Performance-Based Scoring Methodology
CY 2023 EHR Reporting Period

Objective	**Measures (Reflects CY 2023 Proposals)**	**Current Maximum Points**	**Proposed Maximum Points**
Electronic Prescribing	e-Prescribing	10 points	10 points
	Query of PDMP	10 points (bonus)	10 points (required)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points	15 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points	15 points
	-OR-		
	HIE Bi-Directional Exchange	40 points	30 points
	-OR-		
	Enabling Exchange under TEFCA	N/A	30 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	25 points
Public Health and Clinical Data Exchange	<u>Report the following five measures</u>: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • AUR Surveillance Reporting	10 points (does not include AUR measure)	25 points (includes AUR measure)
	<u>Report one of the following 2 measures</u>: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (bonus)	5 points (bonus)

Clinical Quality Measurement. CMS proposes changes to the Promoting Interoperability Program's electronic clinical quality measures (eCQMs) measure set and reporting requirements that are aligned to changes proposed in the Hospital Inpatient Quality Reporting Program. See the IQR section of this advisory for further details.

Public Reporting. CMS proposes to begin publicly reporting hospital performance on the Medicare Promoting Interoperability Program. While CMS would report the aggregate scores of hospitals, the agency is considering reporting hospital scores on specific measures in the future. Reflecting the Promoting Interoperability program's scoring methodology, hospitals could receive a score of up to 105 points to highlight high performing hospitals. If finalized, hospitals' total scores would be made publicly available by fall 2024. Hospitals would be provided with a 30-day preview period before the data are posted publicly.

Request for Information: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA). CMS believes that health information exchange enabled by the TEFCA can advance CMS policy and program objectives related to care coordination, cost efficiency and patient-centered care. Notably, the Common Agreement includes an expanded set of Exchange Purposes that are supported by most nationwide exchanges today. These include Treatment, Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination.

As described above, CMS proposes to add a new measure to the Medicare Promoting Interoperability Program called "Enabling Exchange Under TEFCA." However, CMS is exploring additional levers to incentivize exchange under TEFCA through other programs which incentivize high quality care. CMS seeks public input on what use cases can be enabled through TEFCA, how CMS should approach incentivizing information exchange under TEFCA, and any barriers to or concerns about enabling exchange under TEFCA.

HOSPITAL QUALITY REPORTING AND VALUE PROGRAMS

CMS proposes several significant policy changes intended to account for the impact of the COVID-19 PHE on its hospital quality reporting and value programs. The agency also proposes to add 10 new measures to the IQR program, and to adopt several policies intended to advance health equity and perinatal care.

Hospital Readmissions Reduction Program (HRRP). The HRRP imposes penalties of up to 3% of base inpatient PPS payments for having "excess" readmission 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 (PN), 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 $400 million in FY 2023.

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.

Resumption of PN Readmissions Measure for FY 2024. In last year's inpatient PPS final rule, CMS adopted a COVID-19 measure suppression policy across its quality measure programs that permits the agency to not use quality measure data the agency believes have been affected by the pandemic and would result in distorted hospital performance. CMS used this policy to suppress the use of the PN readmissions measure from the FY 2023 HRRP because of data showing a substantial proportion of the measure cohort included admissions with a COVID-19 diagnosis. As a result, the measure's "clinical proximity" to COVID-19 was close enough to affect performance.

However, for the FY 2024 HRRP, CMS proposes to resume scoring hospitals on the PN readmissions measure that it suppressed for FY 2023. As it finalized for the other five readmission measures in last year's rule, CMS would remove patients with COVID-19 as a principle or secondary diagnosis from both index admissions and readmissions. CMS believes it can resume the use of the PN readmission measure because in January 2021 it adopted an ICD-10-CM code that captures pneumonia due to COVID-19 as a secondary diagnosis (J12.82). CMS indicates that hospitals have made increased use of this code, and includes data in the proposed rule indicating that patients with a COVID-19 diagnosis now make up a smaller proportion of PN admissions.

History of COVID-19 as a Risk Adjustment Co-variate. For all measures in the HRRP, CMS proposes to include patient history of COVID-19 in the 12 months prior to the index hospitalization as a co-variate in the measures' risk adjustment models starting in FY 2023. This change would be incorporated in the PN readmission measure when CMS resumes its use in FY 2024. CMS cites data indicating the long-lasting impacts that some COVID-19 patients have experienced that also may affect their risk of readmission for any of the six measures included in the program.

Potential Future Inclusion of Health Equity Performance in HRRP. The proposed rule includes a request for information on how CMS could encourage hospitals to improve health equity and reduce health care disparities through the HRRP. CMS is considering approaches that go beyond providing hospitals with confidential reports of their performance stratified by particular demographic or social risk data and that could potentially impact hospitals performance — and therefore, financial penalties — in the program. For example, CMS is considering approaches that "would account for a hospital's performance on readmissions for socially at-risk beneficiaries compared to other beneficiaries within the hospital, or its performance in treating socially at-risk beneficiaries compared to other beneficiaries, or a combination of these approaches."

CMS also seeks comment on what measures or indices of social risk — in addition to dual-eligibility — that it could use to assess hospital performance in achieving equity in the HRRP.

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 2023 and beyond to account for the continued impact of the COVID-19 PHE.

FY 2023 Measure Suppressions and Neutral Payment Adjustments. As it did for FY 2022, CMS proposes to use its COVID-19 PHE measure suppression policy to suppress most of the HVBP program's measures for FY 2023, including the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures and five health care associated infection measures**. As a result, CMS again believes it cannot calculate fair scores for hospitals nationally, and proposes that all hospitals would receive neutral payment adjustments under the VBP for FY 2023.** CMS would continue to reduce base operating DRG payment amounts by 2% 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.

Similar to last year, CMS also proposes to calculate and report HVBP measure scores publicly where feasible and appropriate. Below are additional details on CMS's rationale for suppressing the measures. CMS notes that its goal is to resume the use of measure data, scoring and payment adjustments for the FY 2024 VBP program year, but will continue to monitor the pandemic.

- *Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).* CMS proposes to suppress the HCAHPS measures using two of the suppression factors it adopted — factor 1 (i.e., significant deviation in national performance during the COVID-19 PHE) and factor 4 (significant national shortage or unprecedented changes in health care personnel). CMS conducted analyses that show a continuation in statistically significant declines in HCAHPS scores that started in Q2 2020 and have continued through Q3 2021. CMS believes this is likely to impact the entire 2021 performance period on which FY 2023 payment adjustments would be based and result in non-representative data. In addition, CMS cites data

showing the critical staffing shortages that hospitals experienced during 2021, and notes that these shortages are very likely to affect patient experience of care.

- *Healthcare Associated Infections (HAIs).* 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). In addition to the two measure suppression factors the agency applied to the HCAHPS measure, CMS also would use suppression factor 3 — that is, rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs or related protocols, or equipment or diagnostic tools. CMS cites data suggesting that hospitals generally experienced significant increases in the rates of CAUTI, CLABSI and MRSA during Q1-Q3 of 2021 likely is due to the unique and unprecedented circumstances of the pandemic such as longer hospitals stays for sicker patients that may make the chances of infection higher than normal. For SSIs, CMS notes that the volume of relevant procedures is still significantly lower than normal, which may affect its ability to calculate performance reliably. Of note, CMS's analysis shows the CDI measures experienced statistically significant decreases over the measured period, which the agency believes reflects pandemic-related improvements to hand hygiene, use of personal protective equipment, environmental cleaning and other factors.

Resumption of PN Mortality Measure for FY 2024. Similar to its proposal for the HRRP PN readmissions measure (described earlier in this advisory), CMS proposes to resume scoring hospitals on the PN mortality measure in the HVBP starting in FY 2024. As it finalized for the other mortality measures in last year's rule, CMS would remove patients with COVID-19 as a principle or secondary diagnosis from both index admissions and readmissions.

History of COVID-19 as a Risk Adjustment Co-variate. Similar to its proposal for the HRRP's readmission measures, CMS proposes to include patient history of COVID-19 in the 12 months prior to the index hospitalization as a co-variate in the measures' risk adjustment models for its HVBP mortality and complication measures starting in FY 2023. This change would be incorporated in the PN mortality measure when CMS resumes its use in FY 2024. For additional information, see the HRRP section of this advisory.

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 and HAI measures, CMS proposes to use CY 2019 as the baseline period instead of CY 2021. 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 2023

performance period. The proposed rule includes tables with the baseline and performance periods for all HVBP measures through FY 2028.

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.

FY 2023 Measure Suppressions and Payment Adjustments. Using its COVID-19 PHE measure suppression policy, CMS proposes to suppress all six measures in the HAC Reduction Program. **As a result, no hospitals would be penalized under the HAC Reduction Program for FY 2023.** However, similar to the HVBP, CMS would continue to give hospitals confidential preview reports of their performance, and publicly report measure data.

The factors for suppressing performance are the same as those cited for suppressing HAI measure data in the HVBP (described above). CMS also notes that because HAI data are collected at the hospital unit level rather than the patient level, it cannot feasibly use either risk adjustment or exclusions to account for COVID-19 diagnoses in calculating performance. For the claims-based patient safety indicator (PSI 90), CMS states that the comparability of performance on the measure has continued to be impacted by the PHE. In addition, if CMS were to suppress only data from CY 2021 in calculating PSI 90 performance, the only data that would remain to calculate the PSI would be from 2019.

CMS also notes that it considered three alternatives to its proposal. The agency considered scoring on only SSI, CDI and PSI 90, but opted against this proposal because it would base hospital performance on only half of the measures in the program and potentially be less statistically reliable and valid. It also considered adopting no measure suppressions at all, but the agency believes performance on the measures has been distorted by the pandemic, and that hospitals that were more heavily affected by COVID-19 could be at an unfair disadvantage. Finally, CMS considered basing FY 2023 performance on the performance periods of a previous program year (e.g., FY 2021 or FY 2021), but opted against this approach because it would penalize hospitals twice, and not reflect current performance.

FY 2024 Suppressions. Using two of the same measure suppression factors cited to suppress FY 2023 data (factors 1 and 4), CMS proposes to suppress the HAC Reduction Program's HAI measures for FY 2024. However, CMS proposes to retain the claims-based PSI measure with technical changes intended to risk-adjust for COVID-19 diagnoses.

PSI 90 Minimum Volume Threshold. In prior rulemaking, CMS adopted a sub-regulatory process to make technical measure specification updates in the HAC Reduction Program. CMS uses the proposed rule to announce an increase in the minimum volume threshold for receiving a PSI 90 score. Currently, CMS requires that hospitals only have

three or more eligible discharges for at least one component indicator in PSI 90 to receive a measure score. While CMS believes this lends an acceptable level of reliability, they note that "a small subset of hospitals have reliability close to zero." To improve measure reliability, CMS will now require hospitals to meet both of the following criteria to receive a PSI 90 score:

- Have one or more component PSI measures with at least 25 eligible discharges; and
- Seven or more component PSI measures with at least three eligible discharges.

CMS believes this charge would result in approximately 5% of hospitals no longer receiving a PSI 90 score, and half of those hospitals would no longer receive a total HAC score. Most of the hospitals no longer receiving a total HAC score would be small and rural hospitals. CMS also asserts the change would likely result in a smaller number of hospitals in the worst performing quartile for the HAC program.

The AHA is in the process of updating its readmissions penalty calculator for member hospitals to assess the impact of the policy on their organizations and will notify members when it is available. The calculator is designed so that basic financial information regarding a hospital can be entered, including its CCN, and the dollar amount of the hospital's readmissions penalty, if any, will be estimated.

Request for Information: Overarching Principles for Measuring Health Care Quality Disparities across CMS Quality Programs. CMS is considering ways of using its quality measurement and value programs to identify and address the underlying drivers of health disparities. The agency seeks public input on several methodologies and guiding principles the agency is considering for use in the future, including:

- **General approaches for disparity reporting and measure stratification.** This includes pairing stratified measure results with overall measure results to evaluate potential gaps in care and outcomes among groups of patients treated by a specific provider (i.e., within provider disparities), and comparison of care for a selected subgroup of patients across different hospitals (i.e., between hospital disparities).
- **What measures to prioritize for disparity reporting.** CMS indicates it would generally prioritize the stratification of existing clinical quality measures that have evidence of disparities in treatment and outcomes. CMS would also seek to prioritize measures that have sufficient sample size for reliable comparisons, as well as outcome and access measures.
- **What demographic and social risk factor data to use in disparity reporting.** CMS already uses dual-eligible status for generating confidential disparity reports for hospitals, but is interested in using a broader range of data elements. The agency asks for input on how it could use patient-level data from administrative sources and EHRs. CMS also asks for input on the use of imputed approaches to measuring social risk and demographic factors in cases where patient-level data are unavailable, such as the CDC's area deprivation index and the Agency for Health Care Research and Quality (AHRQ) socioeconomic status index.

- **Methodologies for reporting and publicly displaying disparities.** CMS asks for input on a variety of approaches, including tests of statistical significance, rank ordering and percentiles, threshold approaches and benchmarking against national or state-level averages.

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 10 new measures to the IQR program, three of which are focused on health equity and two of which are focused on maternal health. CMS also proposes a new maternal health designation for hospitals, and solicits input on approaches it could take to advance maternal health in its quality programs. In addition, CMS proposes changes to the IQR's eCQM reporting requirements that are aligned with the requirements of the Promoting Interoperability Program.

Hospital Commitment to Health Equity. CMS proposes to adopt an attestation-based structural measure beginning with the CY 2023 reporting / FY 2025 payment periods that assesses hospital leadership's commitment to health equity. Hospitals would be asked to attest to implementing a series of practices the agency believes would demonstrate organization's commitment to advancing health equity across five domains:

- *Domain 1: Equity is a Strategic Priority*, which reflects practices such as hospitals having strategic plans that include health equity goals and action steps;
- *Domain 2: Data Collection,* which includes whether hospitals collect demographic information — including race, ethnicity and/or social determinant of health information — on most of their patients;
- *Domain 3: Data Analysis*, which indicates whether hospitals are stratifying key performance indicators by demographic or social determinant of health indicators;
- *Domain 4: Quality Improvement,* which asks whether hospitals are participating in local, regional or national quality improvement activities focused on addressing health equity;
- *Domain 5: Leadership Engagement,* which assesses whether hospitals' senior leadership and board annually reviews the strategic plan and key performance indicators related to health equity.

Full detailed specifications on the proposed measure are available on CMS's QualityNet website. A hospital would receive a "score" out of five points based on how many domains are met. There is no "partial credit" — a hospital must affirmatively attest to all elements within each domain in order to earn the point.

CMS believes that this measure will incentivize providers to collect and utilize data to identify critical equity gaps, implement plans to address these gaps, and ensure that resources are dedicated toward addressing healthcare equity initiatives. Of note, the measure has not yet been endorsed by the National Quality Forum (NQF).

Screening for Social Drivers of Health. CMS believes that systematically screening patients for social needs that impact their short- and long-term health outcomes gives hospitals an opportunity to connect patients with supportive resources. As a result, CMS proposes a measure reflecting the extent to which hospitals conduct screenings for certain health-related social needs (HRSNs) that would be voluntary for the CY 2023 reporting/FY 2025 payment period and required starting for the CY 2024 reporting/FY 2026 payment period. Specifically, the measure assesses the percentage of patients admitted to the hospital who are 18 years or older at the time of admission and are screened for five domains of HRSNs: food insecurity, housing instability, transportation problems, utility difficulties and interpersonal safety. Detailed measure specifications are available on CMS's QualityNet website.

The proposed measure's numerator is the number of admitted patients screened for the HRSNs, while the denominator is number of patients 18 years or older admitted to the hospital, except those who meet the measure exclusion criteria. CMS would exclude from the denominator those patients who opt out of screening, or are unable to complete the screening and do not have a legal guardian or caregiver able to answer questions on their behalf during the inpatient stay.

CMS proposes flexibilities in how hospitals would implement the measure. That is, hospitals would be allowed to choose the screening tool and mode of data collection that they use. CMS indicates that hospitals could use data from administrative claims, EHRs, patient assessments, or patient-reported surveys. Hospitals simply would be expected to report the overall numerator and denominator once per year using a web-based data collection tool using CMS's Hospital Quality Reporting (HQR) System. While CMS does not specify a specific screening tool, CMS provides in the rule several examples of screening tools that hospitals could consider using. This includes the 10-item tool CMS developed as part of its Accountable Health Communities model. CMS also refers hospitals to the Social Interventions Research and Evaluation Network (SIREN) website for additional tools.

Similar to the proposed Hospital Commitment to Health Equity measure, this proposed measure has not yet been endorsed by NQF.

Screen Positive Rate for Social Drivers of Health. This proposed measure would assess the proportion of patients who screened positive on the date of hospital admission for one or more of the five HRSNs listed previously. Hospitals would be

required to report this measure as five separate rates for each of the five HRSNs. CMS believes the use of this measure could help promote linkages with relevant community-based services that would address those needs and support improvements in health outcomes following hospitalization. However, in the rule, the agency notes that "the measure is intended to provide information to hospitals on the level of unmet social needs among patients served, and not for comparison between hospitals." Data on the proposed screen positive rate measure also would be submitted once per year using a web-based tool on CMS's HQR System.

Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). This proposed measure blends data from multiple sources — including some data that hospitals would collect from patients and submit to CMS — to assess patient functional improvement following elective hip and knee replacement procedures. A version of this measure was implemented for voluntary reporting as part of CMS's Comprehensive Care for Total Joint Replacement (CJR) model. If finalized, it would be the first required patient-reported outcome measure (PROM) to be part of the IQR program. Initially, the reporting of the measure would be voluntary, with CMS implementing two voluntary data reporting periods of Jul. 1, 2023–Jun. 30, 2024 and Jul. 1, 2024–Jun. 30, 2025. Data submission would become required starting with the reporting period of Jul. 1, 2025–Jun. 30, 2026, affecting inpatient PPS payment in FY 2028.

The measure would calculate a risk-standardized improvement rate in PROs following elective primary THA/TKA procedures for Medicare beneficiaries aged 65 years and older. Improvement would be measured by the proportion of patients that achieve a pre-defined improvement in score on joint-specific PRO instruments that measure hip or knee pain and functioning between the pre-and-post operative periods. Hospitals would be required to collect and submit to CMS PRO data in the pre-operative (i.e., 90 to 0 days before surgery), and post-operative (300-435 following surgery) periods. CMS will combine these PRO data with Medicare claims, Medicare beneficiary and enrollment database and U.S. Census Bureau Survey data to calculate hospital performance. Claims data would be used to identify eligible procedures, and to identify certain clinical risk variables. Of note, to account for potential non-response bias, the measure's risk model would use race, dual-eligible status and the AHRQ SES Index score. Detailed measure specifications are available on CMS's website.

Hospitals would be required to collect PRO data from each eligible patient using either the Hip Dysfunction and Osteoarthritis Score for Joint Replacement (HOOS, JR) or Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) PRO instruments. For risk adjustment purposes, CMS would also ask hospitals to use one of two other PRO instruments to capture pre-operative mental health status — the Patient-Reported Outcome Measurement Information System (PROMIS)-Global Mental Health subscale, or all of the items in the Veterans RAND 12-item Health Survey (VR-12) Mental Health subscale. The pre-operative

assessment also would need to include self-reported health literacy, and this information would be used in the measure risk model. Hospitals also would be required to collect and submit certain other pre-and-post operative assessment variables, described below.

THA/TKA Patient Reported Outcome Measure — Pre-Operative and Post-Operative Assessment Variables to be Submitted by Hospitals

Pre-Operative	Post-Operative
• Medicare provider number • Medicare health insurance claim (HIC) number / Medicare beneficiary identifier • Date of birth • Date of procedure • Date of PRO data collection • Procedure type • Mode of collection • Person completing survey • Date of admission to anchor hospitalization • Generic PROM version • PROMIS-Global or VR-12 scores • HOOS, JR or KOOS, JR scores • Single-item Health Literacy Screening (SILS2) questionnaire • BMI or weight (kg)/height (cm) • Chronic narcotic use • Total painful joint count (patient-reported in non-operative lower extremity joint) • Quantified spinal pain (paint-reported back pain, Oswestry index question)	• Medicare provider number • Medicare health insurance claim (HIC) number / Medicare beneficiary identifier • Date of birth • Date of procedure • Date of PRO data collection • Procedure type • Mode of collection • Person completing survey • Date of admission to anchor hospitalization • HOOS, JR or KOOS, JR scores

In response to stakeholder feedback, CMS proposes to permit hospitals to submit the PRO and other assessment variables to CMS directly, or to utilize an external entity such as a vendor or registry to submit the data on their behalf. Regardless of whether the hospital submits the data itself or uses an external entity, the data would be submitted via the HQR System. Detailed instructions on how to submit data would be provided using CMS's QualityNet website and listservs. The proposed voluntary and mandatory reporting periods, data collection windows and data submission deadlines are described in the table below.

THA/TKA Patient Reported Outcome Measure — Pre-Operative and Post-Operative Data Collection Periods and Deadlines

Reporting Period	Performance Period	Pre-Operative Data Collection Window	Pre-Operative Data Submission Deadline	Post-Operative Data Collection Window	Post-Operative Data Submission Deadline
Voluntary Period 1	Jan. 1, 2023-Jun. 30, 2023	Oct. 3, 2022-Jun. 30, 2023	Oct. 2, 2023	Oct. 28, 2023-Aug. 28, 2024	Sep. 30, 2024
Voluntary Period 2	Jul. 1, 2023-Jun. 30, 2024	Apr. 2, 2023-Jun. 30, 2024	Sep. 30, 2024	Apr. 26, 2024-Aug. 29, 2025	Sep. 30, 2025
Mandatory Reporting	Jul. 1, 2024-Jun. 30, 2025	Apr. 2, 2024-Jun. 30, 2025	Sep. 30, 2025	Apr. 27, 2025-Aug. 29, 2026	Sep. 30, 2026

Medicare Spending per Beneficiary (MSPB). CMS proposes an updated version of the MSPB measure that includes three key changes. First, CMS would permit readmissions to trigger new episodes that could count in calculating a hospital's MSPB performance. Second, CMS would add a new variable to the MSPB risk model indicating whether a patient had an inpatient stay in the 30 days prior to an episode start date. Lastly, CMS would change one step in the calculation of the measure from the ratio of sums (i.e., sub of observed costs divided by sum of expected costs) to the mean of ratios (mean of observed costs divided by expected costs). CMS believes these changes will improve measure reliability and accuracy.

CMS also signals in the rule that it intends for the proposed version of MSPB to eventually be proposed for use in the HVBP program. By law, CMS must put measures intended for the HVBP program into the IQR program for at least one year.

THA/TKA Complications. Similar to the MSPB measure, CMS proposes methodology updates to its THA/TKA complications measure, and intends for the updated version of the measure to eventually replace the version used in the HVBP program. The measure would now include 26 additional mechanical complication ICD-10-CM codes.

eCQM Reporting Requirements. CMS proposes to increase the number of eCQMs required for reporting from four to six measures starting with the CY 2024 reporting

period, which would affect payment in FY 2026. Hospitals would be required to report the two proposed perinatal eCQMs (described below) and the previously adopted Safe Use of Opioids eCQM, while self-selecting three other eCQMs.

In addition, starting with the CY 2023 reporting/FY 2025 payment years, CMS would increase eCQM validation requirements by requiring hospitals to submit 100% of requested medical records rather than just 75%.

Lastly, for "hybrid" measures that combine EHR and claims data (e.g., hospital-wide readmissions), CMS proposes to remove zero denominator and case threshold exemptions starting with FY 2026. Zero denominator and case threshold exemptions have been available for eCQM reporting. However, CMS believes these exemptions are not necessary for hybrid measures because CMS itself identifies the patients for which hospitals need to extract relevant EHR and claims-based data.

Global Malnutrition Composite eCQM. This proposed measure is intended to assess whether hospitals are screening for, documenting and developing plans to address malnutrition identified among elderly patients. Specifically, the measure assesses adults age 65 and older admitted to inpatient hospital services who received care appropriate to their level of malnutrition risk and diagnosis. It is a composite that averages the individual scores of four component measures:

- Completion of malnutrition screening at admission;
- Completion of a nutrition assessment for patients identified as at-risk for malnutrition;
- Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings; and
- Nutrition care plan completed for patients identified as malnourished following an assessment.

Patients whose inpatient stays are less than 24 hours would be excluded from the measure denominator. Hospitals would receive a score of 0 to 100% based on an unweighted average of each component score.

Cesarean Birth eCQM. CMS proposes to adopt this measure for voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period (except for those hospitals that do not perform deliveries). The measure assesses the rate of nulliparous, term, singleton, vertex (NTSV) live born deliveries via C-section at greater than 37 weeks gestation.

CMS believes that the adoption of this measure "may ultimately reduce the occurrence of non-medically indicated C-sections." C-sections have higher morbidity and mortality than vaginal deliveries, but existing literature does not distinguish whether these inferior outcomes are driven by the procedure itself or by patient-level risk (i.e. higher-risk patients may be more likely to undergo C-

sections). In addition, CMS notes that C-sections receive higher reimbursement than vaginal deliveries.

The measure excludes patients with abnormal presentations or placenta previa, but is not risk adjusted. CMS believes that the population included in the measure (NTSV pregnancies) is homogenous and low risk, and including a comprehensive set of additional medical exclusions "would add data collection burdens without commensurate benefit." The measure is designed to be informed by the hospitals' CEHRT using patient-level data, which would be submitted by hospitals to CMS; the chart-abstracted version of this measure is endorsed by NQF, but the eCQM is still under review.

Severe Obstetric Complications eCQM. CMS proposes to adopt this measure for voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period. The measure assesses the proportion of patients with severe obstetric complications that occur during the inpatient delivery hospitalization. Severe obstetric complications are defined as certain severe maternal morbidity conditions that are not present on admission but diagnosed during the delivery hospitalization, certain procedures performed during the hospitalization, and death. The measure reports two rates per 10,000 deliveries: the total rate of severe complications, and the rate of complications excluding instances where blood transfusion is the only complication.

The denominator of the measure includes hospitalizations for patients between eight and 65 years of age who undergo a delivery procedure in the inpatient setting at greater than or equal to 20 weeks' gestation. Patients with confirmed diagnosis of COVID-19 and related respiratory conditions are excluded. Risk adjustment variables include patient age, certain preexisting conditions and pregnancy characteristics, lab tests and vital signs upon hospital arrival, long-term anticoagulant medication use, and social risk indicated by the presence of economic/housing instability.

Hospital Harm — Opioid-related Adverse Events eCQM. CMS proposes to adopt this measure that hospitals can self-select beginning with the CY 2024 reporting period. The measure assesses the proportion of inpatient hospital encounters were adult patients have been given an opioid medication and are administered naloxone within twelve hours of receiving that medication. In other words, the measure seeks to determine whether hospital staff administered the wrong medication dose, improperly monitored the patient, or failed to recognize medication interactions when providing a patient an opioid during the inpatient stay, resulting in a preventable adverse event that must be mitigated with naloxone. The measure excludes naloxone administration occurring in the operating room. The measure is not risk-adjusted, as CMS believes that opioid-related adverse events in the hospital should be avoidable regardless of patient risk.

The measure has undergone updates since it was previously proposed (but not finalized) for adoption in the FY 2020 IPPS proposed rule. Specifically, the denominator of the measure was refined to only include patients who received at least one opioid during the hospitalization in a twelve-hour window in order to ensure that hospital administration of the opioid was the cause for naloxone administration (as opposed to ingestion prior to hospitalization). In addition, the measure's value set was updated with the most current codes to harmonize across other eCQMs in CMS programs. The measure was re-tested and received NQF endorsement in 2021.

Refinements to Existing IQR Measures. CMS proposes updates to two of its existing IQR measures:

- *Excess Days in Acute Care after Hospitalization for AMI.* Beginning with the FY 2024 payment year, CMS proposes to increase the minimum case count needed to report the measure from 25 to 50 cases to improve measure reliability.
- *Elective THA/TKA Payment Measure.* Similar to THA/TKA complication measure described earlier in this section, CMS proposes to include 26 additional mechanical complication ICD-10-CM codes in calculating the measure.

Maternal Health Designation. As part of the Administration's Maternal Health Action Plan to reduce maternal morbidity and mortality, CMS proposes to establish a publicly reported hospital quality designation specifically focused on maternal health. Hospitals would be awarded this designation based on their attestation of submission of the Maternal Morbidity structural measure that was adopted in the FY 2022 IPPS final rule. The designation would be listed on "a CMS website" beginning in the fall of 2023.

The structural measure asks whether hospitals currently participate in a structured state or national Perinatal Quality Improvement Collaborative and are implementing patient safety practices as part of these initiatives (a summary of the measure can be found in AHA's FY 2022 IPPS Regulatory Advisory). CMS notes that it intends to propose a more robust set of criteria, including additional measures that may be added to the IQR (such as the Severe Obstetric Complications and Cesarean Birth eCQMs proposed for adoption in this rule) for awarding this designation in future notice and comment rulemaking.

In addition to this proposal, CMS seeks comment on other details related to the designation. Among several specific questions, CMS requests feedback on:

- A name for the designation;
- Other future sources of quality measurement data, particularly on patient experience;
- How CMS can address the U.S. maternal health crisis through policies and programs, including, but not limited to, the Conditions of Participation and quality reporting programs;

- Best practices or quality improvement initiatives used in hospitals;
- Services and staff training hospitals without inpatient maternity services should have in place in preparation for patients in labor;
- Hospitals' community-based engagement and outreach related to maternity care improvement and disparity reduction;
- How hospitals can review and monitor aggregate data on maternal health risks of their patient population, as well as challenges to collecting data;
- Hospital reviews of maternal deaths that occur within the facility;
- Relationships between hospitals and other obstetrical providers, including primary care physicians, certified nurse midwives, and doulas; and
- How hospitals evaluate perinatal customer experience.

Request for Information: Digital Quality Measurement and Use of Fast Healthcare Interoperability (FHIR) Standards. Similar to last year's inpatient PPS proposed rule, this 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 has previously stated its intention to move to "fully to digital quality measurement" by 2025. Along those lines, CMS solicits comments on several policy concepts.

CMS asks for comment on an updated definition of dQMs that it would use across its quality measurement programs. Specifically, CMS would define dQMs as "quality measures, organized as self-contained measure specifications and code packages, that use *one or more sources of health information that are captured and can be transmitted electronically via interoperable systems."* The data sources for a dQM could continue to include administrative systems, laboratory systems, prescription drug monitoring programs, 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 feedback on potential considerations for harvesting data from non-EHR data sources, specific FHIR implementation guides under consideration, and transitioning to FHIR-based eCQM reporting. Future notice-and-comment rulemaking must take place to change specific program requirements related to how hospitals provide data for quality measurement and reporting.

HOSPITAL INFECTIOUS DISEASE DATA REPORTING CONDITION OF PARTICIPATION FOR COVID-19 AND FUTURE PUBLIC HEALTH EMERGENCIES

In 2020, CMS adopted a condition of participation (CoP) requiring hospitals and CAHs to submit certain data related to COVID-19 and other acute respiratory illnesses (i.e., influenza) to HHS. While the CoP was written to expire at the conclusion of the COVID-19 PHE, CMS suggests its need to monitor the impact of the pandemic could extend beyond the current PHE. In addition, the agency states

that it and its federal partner agencies want a more permanent policy allowing it to collect data in the event of future PHEs involving infectious diseases.

As a result, CMS proposes to revise the COVID-19 hospital data reporting CoP it adopted in 2020 so that hospital COVID-19-related reporting would continue after the conclusion of the current PHE through April 30, 2024, unless the Secretary establishes an earlier end date. The broad data reporting categories proposed in the rule align with current reporting requirements.

In addition, CMS proposes to establish a new CoP for future public health emergencies that would require hospitals and CAHs to report certain data to the CDC in the event of a PHE declaration for an infectious disease. CMS proposes several broad categories of data that it could ask hospitals to report, including:

- Suspected and confirmed cases of the relevant infectious disease pathogen among patients and staff;
- Total deaths attributed to the relevant infectious disease pathogen among patients and staff;
- Levels of personal protective equipment and other relevant supplies in the facility;
- Capacity and supplies in the facility relevant to the immediate and long-term treatment of the infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies;
- Total hospital bed and intensive care unit census, capacity and capability;
- Staffing shortages;
- Vaccine administration status of patients and staff if a vaccine is applicable;
- Relevant therapeutic inventories and or usage;
- Isolation capacity, including airborne isolation capacity;
- Key co-morbidities and/or exposure risk factors of the patients being treated for the relevant infectious disease pathogen.

CMS also proposes that it would generally require hospitals to report person-level information on each applicable infection (confirmed and suspected) and if applicable, vaccination data at the person-level. This person-level data would need to include a medical record identifier, race, ethnicity, age, sex, residential county, zip code and relevant co-morbidities for affected patients. Finally, CMS would generally require hospitals to report request data to the CDC on a daily basis. However, the Secretary of HHS would retain discretion over the format of data reported (including whether to ask for person-level data), as well as the frequency of data reporting.

REQUEST FOR INFORMATION: CLIMATE CHANGE AND HEALTH EQUITY

As a byproduct of Executive Order 14008 on Tackling the Climate Crisis at Home and Abroad, the proposed rule includes a request for information (RFI) on how hospitals and other health care providers can better prepare for the impact of climate change on beneficiaries and consumers and how CMS can best support

that work. The RFI specifically seeks comments on what HHS and CMS can do to help hospitals determine the impacts of climate change on their patients. Further, the agency seeks comment on how it can help providers better understand the threats of climate change on their health care operations, as well as what steps they can take to reduce emissions and track their progress.

CODIFICATION OF THE COSTS INCURRED FOR QUALIFIED AND NON-QUALIFIED DEFERRED COMPENSATION PLANS

Certain costs incurred on behalf of deferred compensation plans may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred by the provider submitting the cost report. CMS is proposing to codify and clarify policies related to deferred compensation plans. Specifically, the agency provides additional details and specifies requirements related to arrangements involving physicians, recognition of contributions and allowable costs for these compensation plans, documentation in the Medicare cost report, and the treatment of certain administrative and other costs.

RFI ON IPPS AND OPPS PAYMENT ADJUSTMENTS FOR WHOLLY DOMESTICALLY MADE NIOSH-APPROVED SURGICAL N95 RESPIRATORS

As part of the President's Executive Order 13987, "Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID-19 and To Provide United States Leadership on Global Health and Security," CMS is seeking comments and feedback on the appropriateness of a payment adjustment to recognize the additional resource costs associated with acquiring NIOSH-approved surgical N95 respirators that are wholly domestically made. Specifically, the agency is seeking feedback on two possible frameworks — lump-sum payment to hospitals to be reconciled at cost report or MS-DRG add-on to each applicable IPPS or OPPS encounter. The agency is considering the payment adjustment for FY 2023 and beyond.

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.