Kansas Hospital ASSOCIATION

Inpatient PPS Final Rule for FY 2022

At A Glance

At Issue

The Centers for Medicare & Medicaid Services (CMS) Aug. 2 issued its hospital inpatient prospective payment system (PPS) and long-term care hospital (LTCH) PPS final rule for fiscal year (FY) 2022. In addition to finalizing a 2.5% increase in inpatient PPS payments for 2022 and other policy changes, the rule repeals the requirement to report certain payer- negotiated rates and makes changes to quality measurement and value programs.

Details of the final rule follow:

Key Takeaways

CMS' finalized policies will:

- Increase inpatient PPS payments by 2.5% in FY 2022.
- Repeal the requirement to report the median payer-specific negotiated rates for inpatient services, by Medicare Severity-Diagnosis-related Group (MS-DRG), for Medicare Advantage organizations.
- Use data from Worksheet S-10 in the FY 2018 cost report to determine the distribution of FY 2022 DSH uncompensated care payments.
- Extend New COVID-19 Treatments Add-on Payments for eligible COVID-19 products through the end of the fiscal year in which the public health emergency (PHE) ends.
- Change the Promoting Interoperability Program, including requiring a 180-day reporting period for CY 2024 and increasing the minimum required score to be considered a meaningful electronic health record (EHR) user.
- Suppress certain measures in hospital quality reporting and value programs, applying neutral payment adjustments under hospital value-based purchasing (VBP) for FY 2022, to account for the impact of the COVID-19 PHE.
- Adopt new measure reflecting COVID-19 vaccination coverage among health care personnel.

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Inpatient PPS Payment Update

The final rule will increase inpatient PPS rates by a net of 2.5% in FY 2022, compared to FY 2021, after accounting for inflation and other adjustments required by law. Specifically, the update includes an initial market-basket update of 2.7%, less 0.7 percentage points for productivity as required by the Affordable Care Act (ACA), and plus 0.5 percentage points to partially restore cuts made as a result of the American Taxpayer Relief Act (ATRA) of 2012. Table 1 below details the factors CMS includes in its estimate.

Impacts of FY 2022 Finalized Policies

Policy	Average Impact on Payments
Market-basket update	+ 2.7%
Productivity cut mandated by the ACA	- 0.7%
Partial restoration of documentation and coding cut mandated by ATRA	+ 0.5%
Total	**+ 2.5%**

The productivity and ATRA adjustments will 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 will 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 1.83%.
- Hospitals that were not meaningful users of EHRs in FY 2020 would be subject to a three-quarter reduction of the initial market basket and, thus, would receive an update of 0.48%.
- Hospitals that fail to meet both of these requirements would be subject to a full reduction of the initial market-basket rate and receive an update of - 0.20%.

FY 2020 vs. FY 2019 Data in Rate-setting

Typically, CMS uses the most recently available claims data source for rate setting, which for FY 2022 rate-setting purposes would be FY 2020 claims data. Similarly, CMS uses cost report data from the most recent release, which for FY 2022 would be FY 2019 cost report data. However, as noted by CMS, both the FY 2020 claims and the FY 2019 cost report data were impacted by the COVID-19 PHE and are highly unusual compared to past years. For example, there are significant impacts on the outlier fixed-loss amount, MS-DRG relative weights, and case mix. Accordingly, CMS finalized that it will use FY 2019 claims and FY 2018 cost report data in approximating expected FY 2022 inpatient hospital utilization for rate-setting purposes.

Rebasing and Revising Hospital Market Baskets

The hospital market basket describes the mix of goods and services used in providing hospital care and it commonly refers to the cost category weights and price proxies used to refer to the hospital input price index. CMS rebases and revises the market basket every four years so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase to furnish inpatient care. The last time the hospital market basket was rebased was for FY 2018 using 2014 data. As such, CMS finalized that it will rebase the hospital market basket for FY 2022 using 2018 data.

In addition, by law, CMS must adjust the proportion of the standardized amount that is attributable to wages and wage-related costs (known as the labor-related share) by a factor that reflects the relative difference in labor costs among geographic areas (known as the area wage index). For FY 2022, CMS finalized that it will recalculate the labor-related share using the 2018-based market basket. Specifically, CMS will 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 will not use a Puerto Rico-specific labor-related or non-labor-related share percentage.

CMS also finalized that it will rebase and revise the capital input price index (CIPI), which reflects the capital cost structure, to a 2018-based year.

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 finalized that the rate of increase percentage is 2.7% for FY 2022 for these hospitals based on the 2018-based market basket update.

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 finalized that it will increase the national capital federal rate for FY 2022 by 1.37% compared to the FY 2021 capital federal rate.

"Market-based" MS-DRG Data Collection and Weight Calculation

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

CMS finalized its repeal of the requirement that hospitals report their median payer-specific negotiated rates for inpatient services, by Medicare Severity-Diagnosis Related Group, for MA organizations. It also repealed the market-based MS-DRG

relative weight methodology CMS had planned to implement in FY 2024. Instead, CMS will continue using its existing cost-based methodology.

This policy was originally adopted for the stated purpose of better aligning fee-for-service Medicare payments with market rates. However, privately negotiated rates take into account a number of unique circumstances between a private payer and a hospital and are not an appropriate benchmark for fee-for-service Medicare payments.

Disproportionate Share Hospital (DSH) Payment Changes

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

FY 2022 DSH Payments

For FY 2022, CMS estimates that the total amount of Medicare DSH payments that would have been made under the former statutory formula is $13.985 billion. Accordingly, CMS estimates that hospitals would receive 25% of these funds, or $3.496 billion, as empirically justified DSH payments.

The remaining $10.488 billion will flow into the 75-percent pool, which is then adjusted to reflect changes in the percentage of uninsured. CMS determined that the percentage of uninsured for FY 2022 will be approximately 9.6%. Thus, after inputting that rate into the statutory formula, it will retain 68.57% – or $7.19 billion – of the 75-percent pool in FY 2022. This is a decrease of about $1.1 billion in uncompensated care payments in FY 2022 compared to FY 2021.

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

Worksheet S-10 Data

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

unaudited data, could “dilute” the effect of auditing and potentially lead to a “less smooth result.”

Specifically, CMS finalized its proposal to use data from the FY 2018 cost report to determine the distribution of uncompensated care payments in FY 2022. CMS indicates that the FY 2018 cost reports contain the most recently audited data (audit began in 2020). The FY 2018 data also reflect the revisions to Worksheet S-10 cost report instructions that were effective as of Oct. 1, 2017.

CMS recognized concerns about the impact of COVID-19 PHE in future years when using only one year of audited Worksheet S-10 data. The agency stated that it will consider this issue further in future rulemaking when FY 2020 and FY 2021 cost reporting data are more fully available to be analyzed.

Healthcare Cost Report Information System (HCRIS) Data. CMS used the HCRIS cost report data updated through Feb. 19, 2021 for the FY 2022 proposed rule. CMS considered using more recent data that may be available after March 2021 but before the development of the final rule. The agency finalized the use of the June 2021 extract of HCRIS data for the final rule.

Definition of Uncompensated Care

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

Interim Uncompensated Care Payments

CMS finalized the calculation for interim uncompensated care payments for FY 2022 in light of the COVID-19 PHE. The agency is using 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 three-year average that would include FY 2020 data. CMS will use the resulting two-year average of discharges to calculate the per

discharge payment amount for interim uncompensated care payments to each project DSH-eligible hospital.

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

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

Based on several court decisions, CMS is now required to count in the numerator of the "Medicaid fraction" those patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration, as well as the days of patients who receive premium assistance under a section 1115 demonstration program. Considering these court decisions, CMS proposed to modify its regulation to ensure that the days that are counted in the numerator of the Medicaid fraction are the days of patients for whom a section 1115 waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day. The agency stated that it continues to review the large number of comments on the proposed revisions, and it intends to address the public comment in separate rulemaking.

Additional DSH Policies

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

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

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

Puerto Rico Hospitals. CMS will continue to use a low-income patient proxy, rather than FY 2018 Worksheet S-10 data, to determine the share of uncompensated care provided by Puerto Rico hospitals for FY 2022. Specifically, CMS will utilize Medicaid days from FY

2013 and FY 2018 Supplemental Security Income (SSI) days. For Puerto Rico hospitals, SSI days would be equivalent to 14% of a hospital's Medicaid days, as finalized in the 2017 inpatient PPS/LTCH PPS final rule.

Indian Health Service (IHS) and Tribal Hospitals. For FY 2022, CMS will continue to use a low-income proxy for IHS and Tribal hospitals, which consists of Medicaid days from FY 2013 and the most recent update of SSI days.

CMS has published on its website a table listing uncompensated care payments and other DSH-related information for all hospitals it estimates would receive these payments in FY 2022.

Chimeric Antigen T-Cell (CAR-T) Therapy

CAR-T MS-DRG and Clinical Trial Adjustment

In its FY 2021 final rule, CMS developed a relative weight for a CAR-T T MS-DRG, which did not include claims determined to be clinical trials, as such cases do not account for the cost of therapy itself. In addition, CMS also finalized an adjustment to payments for clinical trial cases and expanded access immunotherapy cases. For FY 2022, CMS finalized that it will use a payment adjustment of 0.17 when calculating payment for clinical trial cases and expanded access cases assigned to MS-DRG 018. That is, the inpatient payment would be reduced by 83% 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 (QIDPs) and Limited Population Pathway for Antibacterial and Antifungal Drugs (LPADs)). These payments are not budget neutral.

NTAP Submissions and Approvals

CMS is continuing NTAPs in FY 2022 for ten technologies already approved for the payments that remain eligible. In light of the COVID-19 PHE, CMS finalized its proposal to allow a one-year extension of payments for thirteen new technologies for which the NTAP would otherwise have been discontinued in FY 2022 because the technologies would no

longer be considered new. Nineteen technologies were newly approved for NTAPs beginning in FY 2022. This includes nine technologies under the alternative pathway Breakthrough Devices Program, two technologies under the QIDP designation, one conditional approval under QIDP, and seven technologies under the traditional pathway.

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. In light of the COVID-19 PHE, and consistent with CMS' use of FY 2019 claims data for FY 2022 rate-setting, CMS will also use FY 2019 claims data to evaluate threshold amounts.

Alternative Pathways

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

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

In light of the COVD-19 PHE, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) for COVID-19 cases that meet certain criteria occurring on or after Nov. 2, 2020 until the end of the PHE. The established NCTAP paid hospitals the lesser of 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. CMS will extend NCTAP for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends. It did not finalize its proposal to discontinue NCTAP for discharges on or after Oct. 1, 2021 for a product that is approved for NTAPs beginning in FY 2022. Instead, CMS finalized that it 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 2022, CMS will use data from FY 2018 cost reports to determine the area wage index. In addition, for FY 2022, CMS will use the Office of Management & Budget (OMB) labor market delineations that it adopted beginning with FY 2015, with updates as reflected in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-04 and 20-01.

Area Wage Index Transition Policies

In FY 2021 final rule, CMS adopted updates in OMB bulletin 18-04. In connection with core-based statistical area (CBSA) modifications for FY 2021, CMS adopted a policy to cap any decrease in a hospital's final wage index in FY 2021 compared to its final wage index in FY 2020 at 5%. This was set to expire at the end of FY 2021. In light of the COVID-19 PHE, CMS is extending this cap through FY 2022 for hospitals that received it in FY 2021. Specifically, it will apply a 5% cap on any decrease in those hospitals' FY 2022 wage index compared to FY 2021. CMS is applying this 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 2016 Medicare Wage Index Occupational Mix Survey with the intent of computing the occupational mix adjustment for FYs 2019, 2020 and 2021. Accordingly, a new measurement of occupational mix is required for FY 2022. CMS finalized its proposal to calculate the FY 2022 occupational mix adjustment based on data from the 2019 Medicare Wage Index Occupational Mix Survey. CMS will apply the occupational mix adjustment to 100% of the wage index, as it has in the past.

Low-wage Hospital Wage Index Policy

CMS will continue its policy to increase wage index values for low-wage hospitals, which 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 will increase the hospital's wage index by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals. According to CMS, the 25th percentile wage index for FY 2022 will be 0.8437. The agency will continue to make this policy budget neutral by adjusting the national standardized amount for all hospitals.

Rural Floor Calculation

Per statute, the area wage index value of any urban hospital may not be less than the area wage index applicable to hospitals located in rural areas in the same state — this is known as the "rural floor" policy. As finalized in FY 2020, CMS will continue to exclude the wage data of urban hospitals that reclassify to rural areas when calculating the wage index for the rural floor. For FY 2022, CMS estimates that 269 hospitals will receive their state's rural floor wage index.

Imputed Floor Calculation

As required by the American Rescue Plan Act, CMS is permanently reinstating a minimum area wage index for hospitals in all-urban states, known as an "imputed rural floor" for FY 2022. This policy applies to states that have no rural hospitals or no rural areas to set a rural floor wage index for those states. The imputed floor policy had

been in effect from FYs 2005 through 2018, but for FYs 2019 through 2021, hospitals in all-urban states received a wage index without the application of an imputed floor.

Unlike the imputed floor in effect for FYs 2005 through 2018, this reinstated policy for FY 2022 is not budget neutral. Therefore, CMS will not apply 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 will define a rural hospital as one assigned the state's rural area wage index value, after all reclassifications. This is in contrast to prior adoption of the policy, where states did not qualify for "all-urban" status if hospitals geographically located in rural areas of the state were reclassified to receive an urban area wage index. However, a state will now qualify as all-urban state if all hospitals located in rural areas were reclassified to receive the urban area wage index.

Medicare Geographic Classification Review Board (MGCRB) Redesignations and Reclassifications

Hospitals may apply to the MGCRB for geographic reclassifications for purposes of inpatient PPS payment. In order to qualify, hospitals must be proximate to the labor market area to which they are seeking reclassification and meet certain wage thresholds. At the time the final rule, the MGCRB had completed its review of FY 2022 reclassification requests and 406 hospitals were approved for wage index reclassifications for FY 2022. Hospitals reclassified during FYs 2020 (243 hospitals) and 2021 (291 hospitals) will continue to be reclassified, because wage index reclassifications are effective for three years.

MGCRB Reclassification, Applications, Withdrawals and Terminations. CMS is finalizing its proposal to clarify a procedure for a hospital to request Administrator review of an MGCRB decision. The agency clarified that the hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. CMS believes that this proposed change will provide clarity and specificity by addressing changes to future technology platform for submission of the hospital's request. **Applications for hospital reclassifications for FY 2023 are due to the MGCRB by Sept. 1, 2021.**

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

Reclassification from Urban to Rural

In order for a hospital to be treated as rural in the wage index and budget-neutrality calculations for the coming FY, CMS currently stipulates that an application for rural

reclassification must be approved no later than 60 days after the public display date of the inpatient PPS proposed rule. This is known as the “lock-in date.” If an application were approved after the lock-in date, the rural wage index value would not include data for the hospital in the rate-setting calculation. As a result, CMS states that there exists an incentive for low-wage index hospitals to cancel their rural classification, and reapply again after the “lock-in date.”

CMS finalized its proposal that rural reclassification be in effect for at least one year before cancellation can be requested. Specifically, a hospital may cancel its rural reclassification not less than one calendar year after the effective date of the rural reclassification and not less than 120 days prior to the end of a federal fiscal year. CMS will continue to monitor rural reclassification applications and cancellation requests and, if necessary, will make additional proposal to address this issue further in future fiscal years.

Graduate Medical Education (GME)

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

CMS proposed to implement several provisions of the Consolidated Appropriations Act that affect Medicare direct GME and IME payments to teaching hospitals, including new Medicare-funded residency positions, the Promoting Rural Hospital GME Funding Opportunity, and adjustments of low per-resident amounts and low FTE resident caps for certain hospitals. The agency stated that due to the number and nature of the comments it received on the implementation of these programs, it would address these policies in future rulemaking.

Organ Acquisition Payment

CMS supports a number of organ acquisition services by providing payment for organ transplantations. CMS excludes organ acquisition costs from the inpatient PPS payment, and instead separately reimburses for organ acquisition on a reasonable cost basis. In the FY 2022 proposed rule, CMS proposed to codify into Medicare regulations some longstanding Medicare organ acquisition payment policies, as well as and some new policies, including clarifying definitions for “transplant hospital,” “transplant program” and “organs.” The agency also proposed to clarify when medical complications are considered organ acquisition costs. In addition, CMS proposed that transplant hospitals and organ procurement organizations count and report Medicare usable organs to ensure such organs are accurately allocated to Medicare. Lastly, the agency also proposed several

provisions for donor community hospitals, including reducing its customary charges to its costs. The agency stated that due to the number and nature of the comments it received on these payment policies, it would address these policies in future rulemaking.

Medicaid Enrollment of Medicare Providers

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

Therefore, CMS finalized its proposal to require, for the purposes of determining Medicare cost-sharing obligations, that state Medicaid programs accept enrollment of all Medicare-enrolled providers and suppliers if they meet all federal Medicaid enrollment requirements, even if the provider or supplier is not eligible to enroll in the state Medicaid program. State Medicaid programs must be in compliance in time to process cost-sharing claims for dually eligible beneficiaries with dates of service beginning Jan. 1, 2023.

Rural Provisions

Low-volume Hospitals

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

Add-on Percentage = (95 / 330) - (total discharges / 13,200)

To receive the enhanced payments beginning Oct. 1, 2021, a hospital must have made a written request for low-volume status that was received by its MAC by Sept. 1, 2021. However, if a hospital's written request is received after Sept. 1, 2021, and if the MAC approves the hospital's low-volume status, the rule states that the MAC will

apply the low-volume adjustment prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Hospitals Applying for Rural Referral Center (RRC) Status

One way in which a hospital can qualify for RRC status is based on a combination of discharge volume and case mix criteria, in comparison to other providers in the hospital's region. Specifically, a hospital must meet the minimum case-mix index (CMI) value during the most recent FY that ended at least one year prior to the beginning of the cost reporting period for which the hospital is seeking RRC status. For example, CMS typically uses data from the FY that is two years prior to the fiscal year for which the hospital is seeking RCC status. In light of the COVID-19 PHE, CMS finalized its proposal to use FY 2019 data to calculate CMI values rather than FY 2020 data.

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

Rural Community Hospital (RCH) Demonstration Program

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

Critical Access Hospitals and Frontier Program

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

and CMS finalized that the starting date of the extension period of the demonstration will begin Jan. 1, 2022. CMS expects to use the same methodology to assess budget neutrality during the extension period as the initial demonstration period, but may update or modify the FCHIP budget neutrality methodology once data is available.

Key Coding and MS-DRG Changes

FY 2022 MS-DRG Updates

CMS finalized the following changes to the MS-DRGs. CMS' analysis is based on claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file.

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 their clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In addition, CMS considers the number of patients who will have a given set of characteristics and notes it generally prefers not to create a new MS-DRG unless it would include a substantial number of cases.

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

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

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

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

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

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

CMS finalized their proposal to delay the application of the Non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023 or later, and are finalizing for FY 2022 to maintain the current structure of the 32 MS-DRGs that currently have a three-way severity level split. CMS announced their plan to perform and make publicly available a more detailed analysis in connection with any future proposed changes, consistent with their annual claims analysis for MS-DRG classification change proposals.

- **Pre-MDC**

  - *Chimeric Antigen Receptor (CAR) T-Cell Therapy*. CMS finalized their proposal to assign the procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS-DRG 018 and to modify the title to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies.

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

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

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

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

From	To
MS-DRGs 143, 144 and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)	○ MS-DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator); ○ MS-DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC); and ○ MS-DRGs 25, 26 and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, CC, and without CC/MCC, respectively)

- **MDC 4 (Diseases and Disorders of Respiratory System)**
  - *Major Chest Procedures*.
    - Laser Interstitial Thermal Therapy. CMS finalized their proposal with modification to reassign 31 procedure codes shown in Table 6P.2b of the final rule describing laser interstitial thermal therapy (LITT) from MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively) and MS-DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively) to various clinically appropriate MDC and MS-DRGs. The 31 procedure codes do not describe areas within the respiratory system and therefore are not consistent with the organ system, etiology or clinical specialty of the MDC to which the procedure code is currently assigned.

    - Repair of Esophagus. CMS finalized their proposal to remove five procedure codes describing repair of the esophagus from MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively). The codes are not clinically coherent with the other procedures in MS-DRGs 163, 164, and 165 that describe procedures performed on major chest structures.

    - Repair of Pulmonary or Thoracic Structures and Procedures Performed on the Sternum of Ribs. CMS finalized their proposal to reassign 26 procedure codes (9 procedure codes describing repair of pulmonary or thoracic structures, and 17 procedure codes describing procedures performed on the sternum or ribs) reflected in Table 6P.2c associated with this final rule as shown below

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

Data analysis by CMS shows that the average length of stay and average costs for these cases appear more consistent with cases in the proposed MS-DRGs. CMS believes further analysis of the procedures currently assigned to MS-DRGs 163, 164, 165, 166, 167, and 168 is warranted based on the creation of new procedure codes that have been assigned to these MS-DRGs in recent years for which 1) claims data are not yet available and 2) there is a need for additional time to examine the procedures by clinical intensity, complexity of service and resource utilization as additional claims data become available. CMS will continue to evaluate the procedures assigned to these MS-DRGs.

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

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

From	To
MS-DRG 215 (Other Heart Assist System Implant)	o MS-DRGs 216, 217 and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) and o MS-DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively)

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

  - *Type II Myocardial Infarction*. CMS finalized their proposal to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS-DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively) when reported with a listed procedure code, for clinical consistency with the other MS-DRGs describing myocardial infarction. Coding rules stipulate that diagnosis code I21.A1 must be reported as a secondary diagnosis. The code is currently one of the listed principal diagnoses in the GROUPER logic for MS-DRGs 222 and 223 but is not currently recognized in these same MS-DRGs when coded as a secondary diagnosis.

- *Viral Cardiomyopathy*. CMS finalized their proposal to reassign the diagnosis code B33.24 (Viral cardiomyopathy) from MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites) in MS-DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS-DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively).

- *Surgical Ablation*. CMS finalized their proposal to revise the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). Under this proposal, if a procedure code describing a coronary artery bypass graft (CABG) and a procedure code describing an open surgical ablation are present, the GOUPER logic would assign the CABG surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation as shown below:

  CMS also finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS-DRGs 233 and 234 and changing the titles of these MS-DRGs to "Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively."

- **MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)**

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

  CMS is also adding 11 additional code combinations that were identified by a commenter as inadvertently missing from the logic for MS-DRGs 628, 629 and 630.

- **MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunological Disorders)**

- *Cytokine Release Syndrome (CRS).* CMS finalized their proposal to assign diagnosis code T80.82XA (Complication of immune effector cellular therapy, initial encounter) to MS-DRGs 814, 815 and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively). CMS also finalized their proposal to revise the structure of MS-DRGs 814, 815, and 816 by removing the logic that includes a principal diagnosis of T80.89XA with a secondary diagnosis of any CRS code from MS-DRGs 814, 815, and 816.

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

Each year, CMS review cases assigned to MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 987, 988, and 989 (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 finalized their proposal to add three ICD-10-PCS procedure codes for control of bleeding in the cranial cavity to the following craniotomy MS-DRGs in MDC 01:

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

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

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

Drainage of Urethra, Open Approach	1

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

In the FY 2020 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 based on whether 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 public health emergency, CMS believed it might be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as CMS continues to develop their process and methodology. Therefore, CMS will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

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

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

Table 1: Procedures Changed from O.R. Procedures to Non-O.R. Procedure

Procedure Groups	Number of ICD-10-PCS Procedure Codes Affected
Open Drainage of Subcutaneous Tissue and Fascia	22
Diagnostic Drainage of Vestibular Gland	2
Insertion of Feeding Device into Stomach, Open Approach	1
Endoscopic Fragmentation and Extirpation of Matter of Urinary Tract	6

Non-O.R. Procedures to O.R. Procedures. CMS finalized their proposal to change the status of the procedure groups in table 2 below from Non-O.R. procedure to O.R. procedures.

Table 2: Procedures Changed from Non-O.R. Procedures to O.R. Procedure

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

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 Complications or Comorbidities (CC) and Major Complications or Comorbidities (MCC) lists for FY 2019. For FY 2020, CMS proposed but did not finalize a change in the severity level designation for 1,492 ICD-10-CM diagnosis codes.

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

For FY 2022, as another interval step in the comprehensive review of the severity designations of ICD-10-CM diagnosis codes, CMS solicited comments on adopting a change to 3,490 “unspecified” diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a Non-CC for FY 2022. Table 6P.2a of the proposed rule included the list of ICD-10-CM unspecified diagnosis codes with data for impact on resource use. If approved, the change would have affected the severity level assignment for 4.8% of the ICD-10-CM diagnosis codes. The net result of these potential changes to the Version 39 ICD-10 MS-DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD-10-CM classification, would be a decrease of 507 (3,278 – 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 – 11,696) codes designated as a CC, and an increase of 3,490 (58,154 – 54,664) codes designated as a Non-CC.

Fifty-eight ICD-10-CM diagnosis codes listed in Table 6P.2a of the proposed rule will not be included for consideration to change the severity level designation as part of the list of “unspecified” diagnosis codes. The 58 diagnosis codes include

malignant neoplasms, occipital fractures, spinal fractures, and other internal conditions that cannot be visualized externally.

For FY 2022 CMS is maintaining the severity level designation of all "unspecified" diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site. Instead, CMS finalized the proposed Unspecified Code Medicare Code Editor edit to provide additional time to educate coders on updated coding guidelines and offer assistance to providers on proper documentation while not affecting the payment the provider is eligible to receive. The list of codes subject to this edit is identified in Table 6P.3a associated with this final rule. The new edit is effective with discharges on and after April 1, 2022. Future information regarding an updated version of the *ICD-10 Medicare Severity Diagnosis Related Group (MS-DRG) GROUPER Software and Medicare Code Editor (MCE) ICD-10 Software* is expected to be released by Feb. 1, 2022 via the internet on the CMS website.

If, upon review, additional information to identify the laterality from the available medical record documentation by any other clinical provider is unable to be obtained or there is documentation in the record that the physician is clinically unable to determine the laterality because of the nature of the disease/condition, then the provider must enter that information into the remarks section in order to bypass the edit and allow the Medicare Administrative Contractor (MAC) to process the claim accordingly. Specifically, the provider may enter in the remarks section "UNABLE TO DET LAT 1" to identify that they are unable to obtain additional information to specify laterality or they may enter "UNABLE TO DET LAT 2" to identify that the physician is clinically unable to determine laterality." If there were no language entered into the remarks section as to the availability of additional information to specify laterality and the provider submits the claim for processing, the claim would then be returned to the provider.

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

CMS is adopting an April 1 implementation date for ICD-10-CM and ICD-10-PCS code updates, in addition to the annual Oct. 1 update, beginning with April 1, 2022. This April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process.

CMS also believes this earlier recognition diagnoses, conditions, and illnesses as well as procedures, services, and treatments in the claims data would be beneficial for purposes of reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions, and data interoperability.

Any new ICD-10 code updates finalized for implementation on the following April 1 would be announced in November of the prior year, which would provide a 4-month timeframe for the public to receive notice about the diagnosis and/or procedure code updates with respect to the codes, code descriptions, code designations (severity level for diagnosis

codes or O.R. status for procedure code) and code assignment under the ICD-10 MS-DRGs.

CMS indicated it would assign the codes approved for the April 1 update to an MS-DRG(s) using their established process for GROUPER assignments for new diagnosis and procedure codes which would be in effect from April 1 through Sept. 30 of that same calendar and fiscal year, along with the opportunity for members of the public to comment (during the public comment period in association with the proposed rule for the upcoming fiscal year), on any alternate suggestions should they not agree with the initial assignment.

CMS further noted that it would use a phased approach, such that initially, the number and nature of the code updates would be fewer and less comprehensive as compared to the existing Oct. 1 update. The process and/or criteria to determine which codes would be implemented in April versus October would include identifying the number of code requests received for consideration of each date, providing the Agenda and meeting materials which indicate the implementation date (April or October) being considered for each topic, using their established process for presenting the code proposal to members of the public participating in the ICD-10 Coordination and Maintenance Committee meeting process, allowing the opportunity for public comments to be submitted following the meeting, agency review of the public comments to determine if there is support for the code proposal, as well as, support for the proposed implementation date.

If updates to the guidelines are necessary, the necessary information would be incorporated into the appropriate section for all users of the classification accordingly. Coding guideline updates in response to April 1 code updates effective with discharges on and after April 1 are valid beginning on that April 1 date of that fiscal year. These April 1 coding guideline updates would be in addition to the coding guidelines that were effective at the beginning of that same fiscal year.

Medicare Shared Savings Program

Medicare Shared Savings Program

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

However, due to the uncertainty of the COVID-19 pandemic, CMS modified this "automatic advancement" policy in a May 8, 2020 interim final rule with comment period (IFC). This rule allowed BASIC track ACOs participating in the glide path the option to forgo automatic advancement and freeze their performance year (PY) 2020 participation for PY 2021. CMS finalized this policy in the Calendar Year 2021 Physician Fee Schedule final rule. ACOs that elected this option for PY 2021 will be automatically advanced for PY 2022 to the level at which they would have otherwise participated if they had not elected the deferral. In other words, an ACO that was participating at BASIC Level B in PY 2020 and froze its participation at BASIC Level B for PY 2021 would be automatically advanced to BASIC Level D in PY 2022.

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

Under this option, ACOs participating in the BASIC track's glide path will once again be permitted freeze their current level of risk for PY 2022. Thus, ACOs will be allowed to forgo automatic advancement and maintain their participation for PY 2022 at their PY 2021 level. ACOs that froze their participation for PY 2021 at their PY 2020 level will be permitted to freeze their participation a second time, thus remaining at their PY 2020 participation level for PY 2022. Any ACO that elects to remain at its current participation level for PY 2022 will be automatically advanced to the BASIC track level in which it would have participated during PY 2023 if it had advanced automatically in PY 2022 (unless the ACO chooses to advance more quickly). While many commenters opposed this automatic advancement policy, CMS declined to change it, noting that 75% of all ACOs participating in the BASIC track for PY 2021 are in a second or subsequent MSSP agreement period and have multiple years of operational experience.

As an example to illustrate the final policy, an ACO that participated in BASIC Level A for PY 2020 and did not freeze its participation level would have automatically advanced to BASIC Level B in PY 2021. If that ACO elects to remain at Level B for PY 2022, instead of advancing to Level C, it would automatically advance to Level D for PY 2023. Similarly, if an ACO participated in BASIC Level A for PY 2020 and did elect to freeze its participation level, it would have participated in BASIC Level A in PY 2021. If that ACO again elects to remain at Level A for PY 2022, it would automatically advance to Level D for PY 2023. CMS included a chart in the rule to illustrate the possible "freeze" scenarios ACOs could choose. The chart, reproduced below, is available on page 1967 of the display copy of the rule.

<table>
<tr><th colspan="4">BASIC TRACK'S GLIDE PATH "FREEZE" SCENARIOS</th></tr>
<tr><th>PY 2020</th><th>PY 2021</th><th>PY 2022</th><th>PY 2023</th></tr>
<tr><td rowspan="2">Level A</td><td rowspan="2">Maintained at Level A</td><td>Maintain at Level A</td><td rowspan="2">Progress to Level D</td></tr>
<tr><td>Progress to Level C</td></tr>
</table>

	Progressed to Level B	Maintain at Level B Progress to Level C	
Level B	Maintained at Level B	Maintain at Level B Progress to Level D	Progress to Level E
	Progressed to Level C	Maintain at Level C Progress to Level D	
Level C	Maintained at Level C	Maintain at Level C Progress to Level E	Progress/Maintain Level E
	Progressed to Level D	Maintain at Level D Progress to Level E	
Level D	Maintained at Level D	Maintain at Level D Progress to Level E	Progress/Maintain Level E
	Progressed to Level E	Maintain at Level E	

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

Promoting Interoperability Programs

EHR Reporting Period

The EHR reporting period in CY 2022 is a minimum of any continuous 90-day period for new and returning program participants. CMS will continue this policy for CY 2023. For CY 2024, CMS finalized its proposal to increase the reporting period to a minimum of any continuous 180-day period. CMS responded to concerns from commenters by asserting that the two-year notice provides adequate time for vendors and providers to meet the new requirement.

Changes to Objectives and Measures

CMS proposed a number of changes to measures and other requirements beginning in 2022. With the exception of the Provide Patients Electronic Access to their Health Information Measure, CMS finalized all proposed changes to measures and objectives.

- *Electronic Prescribing Objective: Query of Prescription Drug Monitoring Program (PDMP) Measure*. Acknowledging continued stakeholder concerns that PDMPs are not yet consistently integrated into EHR workflows, CMS will maintain this measure as optional for 2022 and increase the available bonus points from five points to 10. CMS believes at least one additional year is needed before potentially requiring the measure.
- *Health Information Exchange (HIE) Objective*. CMS finalized the addition of a new, optional HIE Bi-Directional Exchange measure for the 2022 reporting period as a yes/no attestation. Hospitals and CAHs can attest to this measure in place of reporting the two existing measures — Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and

Incorporating Health Information. The new optional measure is worth 40 points. CMS provides clarification in the final rule on a number of questions raised by commenters including the definition of "HIE," the scope of bi-directional exchange and examples of audit evidence to support attestation.

- *Provider to Patient Exchange Objective: Provide Patients Electronic Access to their Health Information Measure.* Beginning in 2022, CMS proposed to modify the measure to require eligible hospitals and CAHs to ensure that patient health information remains available indefinitely and using any application of the patient's choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR. This would have included all patient health information from encounters on or after Jan. 1, 2016. CMS did not finalize the proposed modifications to this measure.
- *Public Health and Clinical Data Exchange Objective*. CMS finalized its proposal to require reporting "yes" or requesting exclusions on four of the existing measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting and Electronic Reportable Laboratory Result Reporting).
    - *Syndromic Surveillance Reporting*. CMS further finalized its proposal to change the setting for which data is required to be submitted for this measure from urgent care to the emergency department (POS 23). A technical change to the first exclusion to the measure is made by eliminating a reference to urgent care.
    - *Scoring.* Beginning with the EHR reporting period in 2022, eligible hospitals and CAHs will receive 10 points for this objective if they report a "yes" response for each of the four required measures. They will also receive 10 points for the objective if they report a "yes" response for one or more of the measures and claim applicable exclusions for the remaining measures. Failure to report on any of the four measures, or reporting a "no" response for one or more of those measures, will result in a score of zero for the objective and a total score of zero for the Medicare Promoting Interoperability Program. If applicable exclusions are claimed for all four measures, CMS will redistribute the points for the objective to the Provider to Patient Exchange objective.
    - *Optional Measures*. The remaining two measures (Public Health Registry Reporting and Clinical Data Registry Reporting) are optional and available for a total of five bonus points if a "yes" response is reported for either measure (exclusions are eliminated).
- *Protect Patient Health Information Objective*. ONC originally developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, which provide recommended safety practices during planned or unplanned EHR unavailability, due to events like system disruptions, systems failures or natural disasters. CMS finalized its proposal to require hospitals and CAHs to attest (yes/no) as to whether they have completed an annual assessment of all nine guides (following completion of an initial self-assessment) in a new SAFER Guides measure. While the measure is required, it is not scored and CMS underscores that a "no" response is acceptable and will not result in a penalty.
- *Prevention of Information Blocking Attestation Requirement*. As part of the Promoting Interoperability Program, eligible hospitals and CAHs are required to attest to three statements indicating that they do not limit or restrict the

interoperability of certified EHR technology. CMS explains that the similarities between practices described in statements two and three, and the practices that could constitute information blocking under ONC's information blocking regulations, could create confusion for participating hospitals and CAHs. CMS finalized its proposal to remove attestation statements 2 and 3. Hospitals will continue to be required to attest to statement 1: "Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology."

Scoring Methodology

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

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

Performance-Based Scoring Methodology
EHR Reporting Period in CY 2022

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

	Report one of the following 2 measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (bonus)

Clinical Quality Measurement

CMS finalized several changes related to eCQM reporting that align with policies in the Hospital IQR Program. This includes requiring eligible hospitals and CAHs to use only technology certified to the 2015 Edition Cures Update to submit data for eCQMs, beginning with the 2023 reporting period. Additional details are included in the Hospital IQR Program section of the advisory.

Hospital Quality Reporting and Value Programs

CMS adopted a number of significant policy changes to account for the impact of the COVID-19 public health emergency (PHE) on its hospital quality reporting and value programs. The agency also added five new measures for the inpatient quality reporting (IQR) program, while removing three current IQR measures.

Measure Suppression Policy

In a September 2020 interim final rule, CMS announced that in light of the COVID-19 PHE, the agency will not use data from Q1 and Q2 of 2020 to calculate performance or make payment adjustments in any of its hospital quality measurement and value programs. This policy impacts CMS programs beginning in FY 2022, as described in subsequent sections of this advisory.

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

CMS will consider several factors in deciding whether to suppress hospital measure data, including:

1. Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years;

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

3. Rapid or unprecedented changes in (i) clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or (ii) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

4. Significant national shortages or rapid or unprecedented changes in: (i) healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.

Hospital Readmissions Reduction Program (HRRP)

The HRRP imposes penalties of up to 3% of base inpatient PPS payments for having "excess" readmissions rates for selected conditions when compared to expected rates. CMS uses six Medicare claims-based readmission measures to assess performance in the program — acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), chronic obstructive pulmonary disease (COPD), isolated coronary artery bypass grafts (CABG), and elective hip and knee arthroplasties (THA/TKA). In the final rule, CMS estimates that readmissions penalties across all eligible hospitals will total $521 million in FY 2022.

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

Performance Periods and Payment Adjustments. The policy adopted in CMS' September 2020 interim final rule means that CMS will not use data from Q1 and Q2 of 2020 to calculate performance in the HRRP in FYs 2022, 2023, and 2024. As a result, the FY 2022 HRRP performance period will be July 1, 2017 through Dec. 31, 2019. In this rule, CMS finalized its proposal to align the MedPAR data it uses to determine aggregate payment amounts and payment adjustments with the modified performance periods. In other words, the agency will not use MedPAR data from quarters 1 and 2 of 2020 in calculating payment adjustments in FY 2022 and subsequent years.

FY 2023 PN Measure Suppression. Using the measure suppression policy described in the previous section of this advisory, CMS will suppress the use of the HRRP's pneumonia readmissions measure in calculating FY 2023 performance and payment adjustments. CMS suggests that factor 2 — the "clinical proximity" of pneumonia to COVID-19 — is significant enough that including the measure in calculating HRRP performance could distort measure performance. The final rule includes an analysis indicating that a substantial proportion of the pneumonia measure cohort in 2020 had COVID-19 noted as a secondary diagnosis. In addition, the observed readmission rates for the pneumonia patient cohort were statistically significantly higher in September 2020 than during the same period in 2019 (i.e., before the pandemic).

As a result, CMS states its belief that "COVID-19 patients captured in the pneumonia readmissions measure cohort likely represent a distinct, severely ill group of patients for

whom it may be difficult to adequately ascertain appropriate risk adjustment." The agency further suggests that excluding from the measure those patients with COVID-19 as a secondary diagnosis would result in a measure that does not accurately reflect performance, especially given the uneven distribution of COVID-19 patients across hospitals during 2020. Therefore, the agency will suppress the measure entirely for FY 2023, while also indicating it will monitor the measure carefully to determine whether it should suppress the measure in future fiscal years.

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

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

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

- *Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).* CMS will suppress the HCAHPS measures under measure suppression factor 1 (i.e., significant deviation in national performance during the COVID-19 PHE). CMS conducted analyses that show statistically significant declines in HCAHPS scores during 2020 that are associated with the COVID-19 PHE. CMS believes this impact is likely to influence the entire 2020 performance period and result in non-representative data.

- *Medicare Spending per Beneficiary (MSPB).* CMS will suppress the MSPB under measure suppression factor 4. Specifically, the agency's analysis shows significant impact to hospitals patient mix and episode costs that are associated

with COVID-19 and span across a wide variety of MS-DRGs. Given the uneven distribution of COVID-19 cases across hospitals and time periods, CMS believes suppressing MSPB is the most appropriate approach.

- *Healthcare Associated Infections (HAIs).* Using measure suppression factor 1, CMS will 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 Methicilin-resistant staphylococcus aureus (MRSA). CMS cites data suggesting that there were statistically significant increases in the rates of all five HAI measures during Q3 and Q4 of 2020 and that change is likely due to the unique and unprecedented circumstances of the pandemic. For example, longer hospitals stays for sicker patients may make the chances of infection higher than normal. CMS also notes that the volumes for the SSI measure were significantly lower than normal due to the decline in surgical procedure volumes most hospitals experienced during 2020.

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

Therefore, CMS finalized its proposal to apply neutral payment adjustments to all hospital under the HVBP for FY 2022. CMS will 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 will be neutral. This approach is permissible given that the HVBP program is budget neutral.

FY 2023 Pneumonia Mortality Measure Suppression. CMS will suppress the pneumonia mortality measure for the FY 2023 HVBP program using suppression factor 2 (i.e., clinical proximity to COVID-19). The rule includes an analysis indicating that a substantial proportion of the pneumonia measure cohort in 2020 had COVID-19 noted as a secondary diagnosis. In addition, the observed mortality rates for the pneumonia patient cohort were statistically significantly higher in September 2020 than during the same period in 2019 (i.e., before the pandemic).

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

Exclusion of COVID-19 Patients from Mortality and Complication Measures beginning in FY 2023. In addition to the pneumonia mortality, the HVBP includes 30-day mortality measures

for AMI, HF, CABG and COPD and a THA/TKA complication measure. Similar to the HRRP, CMS finalized its proposal to update the measure specifications for these measures to exclude patients with COVID-19 from performance calculations. While the full details of these technical updates are not yet available, CMS indicates it will use various ICD-10 CM codes to remove patients with COVID-19 as a secondary diagnosis from each measure's denominator.

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

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

Hospital-Acquired Condition (HAC) Reduction Program

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

However, CMS will suppress performance data from the third and fourth quarters of 2020 in calculating HAC Reduction Program performance for FYs 2022 and 2023. The factors for suppressing performance are the same as those cited for suppressing HAI measure data in the HVBP (described above). In addition, the September 2020 interim final rule announced that CMS would not use data from Q1 and Q2 of 2020 to calculate performance or payment adjustments in the HAC Reduction program or any of its quality measurement programs. The resulting performance periods for FY 2022 and 2023 are provided in the table below. CMS believes these truncated performance periods will retain sufficient reliability for the program's measures, while excluding the timeframes most affected by the COVID-19 pandemic.

While CMS had not formally proposed to suppress Q3 and Q4 data from the FY 2024 HAC Reduction program, the agency adopted a policy to do so as a "logical outgrowth" of its finalized measure suppression policies for FYs 2022 and 2023. The previously finalized PSI 90 measure performance period for FY 2024 includes data from Q3 and Q4 2020. Thus, the agency believes extending its suppression policy to FY 2024 is consistent with both comments and the logical premise of its policy.

HAC Reduction Program Performance Periods, FYs 2022 - 2024

	FY 2022		FY 2023		FY 2024	
Measure	**Previously Finalized**	**Revised**	**Previously Finalized**	**Revised**	**Previously Finalized**	**Revised**
HAIs	Jan. 1, 2019 – Dec. 31, 2020	Jan. 1, 2019 – Dec. 31, 2019	Jan. 1, 2020 – Dec. 31, 2021	Jan. 1, 2021 – Dec. 31, 2021	Jan. 1, 2021 – Dec. 31, 2022	Unchanged
PSI 90	July 1, 2018 – June 30, 2020	July 1, 2018 – Dec. 31, 2019	July 1, 2019 – June 30, 2021	July 1, 2019 – Dec. 31, 2019 -AND- Jan. 1, 2021 – June 30, 2021	July 1, 2020 – June 30, 2022	Jan. 1, 2021 – June 30, 2022

Hospital IQR Program

The IQR program is CMS' 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 electronic clinical quality measures (eCQMs) using CMS-mandated reporting standards. The IQR eCQM reporting requirements align with the eCQM reporting requirements in the Promoting Interoperability Program.

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

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

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

- Employees (all persons receiving a direct paycheck from the reporting facility);
- Licensed independent practitioners affiliated with, but not directly employed by, the reporting facility (including post-residency fellows); or
- Adult students/trainees and volunteers.

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

To report this data, hospitals would use the CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework, which hospitals currently use to report the influenza coverage among HCP measure. Hospitals would submit data through NHSN for at least one self-selected week each month, and the CDC would calculate a summary measure of the data each quarter reflecting the average of the three monthly rates. If hospitals submit more than one week of data in a month, CDC would use the most recent week's data to calculate the rate.

CMS had proposed that when it had a full year of HCP measure data it would calculate a "rolling average" of those four quarters and display it on Care Compare. However, several public commenters noted that because the measure collects data at specific points in time, a rolling average could reflect outdated data. As a result, CMS will instead report only the most recent quarter of data on its Care Compare website.

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

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

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

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

on the measure. However, CMS indicates it will provide “additional education and clarifying detail.”

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

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

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

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

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

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

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

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

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

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

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

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

Measure Removals. CMS finalized the removal of three IQR program measures. The measure are described below:

- *PC-05 (Exclusive Breast Milk Feeding eCQM).* CMS will remove this measure from its menu of available eCQMs beginning with the FY 2026 IQR (CY 2024 reporting)

because it believes its new maternal morbidity structural measure is more strongly aligned with its focus on improving maternal health and reducing maternal morbidity.

- *ED-2 (Admit Decision Time to ED Departure Time eCQM).* Beginning with the FY 2026 IQR (CY 2024 reporting), CMS will remove this eCQM because it believes its costs outweigh its benefits. Specifically, the agency believes there is limited association between ED boarding times and patient mortality.

- *STK-06 (Discharged on Statin Medication).* CMS will remove this eCQMs effective with the FY 2026 IQR (CY 2024 reporting) because it believes its costs outweigh its benefits. CMS notes that the IQR includes other stroke measures that may overlap with STK-06.

CMS also had proposed to remove PSI-04 (Deaths Among Surgical Inpatients with Serious Treatable Conditions) and STK-03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter). However, in response to stakeholder feedback suggesting the measures continue to have value, the agency is retaining the measures in the IQR for now.

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

CMS previously finalized regulations permitting hospitals to report the eCQMs using either the 2015 Edition of certified EHR technology, or the 2015 Edition Cures update. The 2015 edition cures update was finalized in the Office of the National Coordinator (ONC) for Health Information Technology's 21st Century Cures Final rule in 2020. Beginning with the FY 2025 IQR (CY 2023 reporting), CMS will require hospitals to report eCQMs using EHR technology certified to the 2015 Edition Cures Update. CMS also will require EHR technology to be certified to report all eCQMs using the 2015 Edition Cures Update beginning with the CY 2023 reporting period (FY 2025 payment determination).