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Vizient Office of Public Policy and Government Relations

Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes for Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

May 2, 2024

Background & Summary

On April 10, the Centers for Medicare & Medicaid Services (CMS) issued the <u>annual proposed rule</u> to update the Fiscal Year (FY) 2025 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS) ("Proposed Rule") (fact sheet available <u>here</u>). CMS proposes to increase the inpatient payment rate for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users by 2.6 percent. Based on various policy changes and circumstances described in the Proposed Rule, CMS anticipates hospital payments will increase by \$3.2 billion in FY 2025.

The Proposed Rule contains several policy proposals, including delaying implementation of the "three-way split criteria" as related to MS-DRGs, refinements to wage index-related policy, and increasing the outlier cost threshold for outlier payments. In addition, CMS proposes additional measures in the Hospital IQR Program and the Medicare Promoting Interoperability (PI) Program, as well as a modified Condition of Participation for Acute Respiratory Illness Surveillance. CMS also provides several requests for information, including on maternity care and public health data collection.

Comments are due **no later than 5PM on June 10, 2024**, with most policies going into effect on October 1, 2024. Vizient looks forward to working with our provider customers to help inform our letter to the agency.

Proposed IPPS Payment Rate Updates for FY 2025

After accounting for adjustments required by law, the Proposed Rule increases IPPS operating payment rates by 2.6 percent in FY 2025 for hospitals that successfully participate in the Hospital IQR Program and are meaningful EHR users. The Proposed Rule includes an initial market basket update of 3.0 percentage points, minus 0.4 percentage points for productivity as mandated by the Affordable Care Act (ACA). Consistent with the FY 2024 IPPS final rule, for calendar year (CY) 2025, there is no MS-DRG documentation and coding adjustment, as these cuts were in effect from CY 2018-2023 per the American Taxpayer Relief Act.

Table 1. Proposed IPPS Payment Rate Updates for FY 2025

Proposed Policy	Average Impact on Payments (Rate)
Estimated market basket update	3.0%
Productivity Adjustment*	-0.4
Estimated payment rate update for FY 2025 (before applying budget neutrality factors)	2.6%

*In the Proposed Rule, CMS notes that the U.S. Department of Labor's Bureau of Labor Statistics (BLS) replaced the term multifactor productivity adjustment (MFP) with total factor productivity (TFP). CMS notes that the data and methods are unchanged and that the agency refers to this as the productivity adjustment.

In addition, CMS proposes four applicable percentage increases applied to the standardized amount,¹ as demonstrated in the below table. To determine the proposed applicable percentage increase, CMS adjusted the proposed market basket rate-of-increase by considering (1) whether a hospital submits quality data; and (2) whether a hospital is a meaningful EHR user. CMS also applies a 0.4 percentage point reduction for the productivity adjustment. For the final payment calculation, hospitals may be subject to other payment adjustments under the IPPS which are not reflected in the below table (e.g., reductions under the pay for performance programs). In the Proposed Rule, CMS also provides a table (pg. 613) that displays changes from FY 2024 standardized amounts to the proposed FY 2025 standardized amounts.

Table 2. Proposed FY 2025 Applicable Percentage Increases for the IPPS

FY 2025	Hospital submitted quality data and is a Meaningful EHR User	Hospital submitted quality data and is not a Meaningful EHR User	Hospital did not submit quality data and is a Meaningful EHR User	Hospital did not submit quality data and is not a meaningful EHR user
Proposed market basket rate-of-increase	3.0	3.0	3.0	3.0
Proposed adjustment for not submitting quality data	0	0	-0.75	-0.75
Proposed adjustment for not being a Meaningful EHR User	0	-2.25	0	-2.25
Proposed Productivity Adjustment*	-0.4	-0.4	-0.4	-0.4
Proposed applicable percentage increase applied to standardized amount	2.6	0.35	1.85	-0.4^

^{*}In the Proposed Rule, CMS notes that the U.S. Department of Labor's Bureau of Labor Statistics (BLS) replaced the term multifactor productivity adjustment (MFP) with total factor productivity (TFP). CMS notes that the data and methods are unchanged and that the agency refers to this as the productivity adjustment.

<u>Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSH) for FY 2025</u>

The ACA required changes, which began in 2014, regarding the way disproportionate share hospital (DSH) payments are made to hospitals. Under this payment formula, hospitals receive 25 percent of the Medicare DSH funds that they would have received under the prior formula ("empirically justified"). The other 75 percent flows into a separate pool that is reduced relative to the number of

[^] Section 1886(b)(3)(B)(xi) of the Social Security Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

¹ Table 1A-1E on the Proposed Rule website provide the proposed FY 2025 Operating and Capital National Standardized Amounts.

uninsured who received care and then distributed based on the proportion of total uncompensated care each Medicare DSH provides. This pool is distributed based on three factors:

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

CMS estimates the empirically justified Medicare DSH payments for FY 2025 to be approximately \$3.486 billion. Also, for FY 2025, CMS estimates total Medicare DSH and uncompensated care payments will increase by approximately \$560 million compared to FY 2024, according to a CMS fact sheet.

The uncompensated care payments have redistributive effects, which are based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments. The calculated payment amount is not directly tied to a hospital's number of discharges.

To calculate Factor 1 and model the impact of this Proposed Rule, CMS describes the various data sources it utilized, including the Office of the Actuary's (OACT's) January 2024 Medicare DSH estimates (based on data from the December 2023 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2024 IPPS final rule Impact File). For FY 2025, CMS provides that Factor 1 would be approximately \$10.457 billion (\$13.943 billion minus \$3.486 billion) and notes it will use more recent data in the FY 2025 IPPS final rule.

For Factor 2, CMS proposes to use a methodology similar to the methodology applied in rulemaking for FYs 2018-2024. To calculate Factor 2, CMS used various data sources to project the change in the national uninsured rates in both CY 2024 and CY 2025. CMS notes that projected rates of growth in enrollment for private health insurance and the uninsured are based largely on the OACT's models and that greater detail is available on the CMS website. Notably, OACT estimated the uninsured rate to be 8.5 percent for CY 2024 and 8.8 percent in CY 2025. Using a weighted average approach to estimate the rate of uninsurance, CMS finds Factor 2 would be 62.14 percent. The proposed FY 2025 uncompensated care amount, if equivalent to proposed Factor 1 multiplied by proposed Factor 2, equals approximately \$6.498 billion.

For FY 2025, to calculate Factor 3, CMS proposes to use the three most recent years of audited cost report data (i.e., FY 2019, 2020, and 2021 cost reports). CMS further clarifies that for the Proposed Rule, the agency used reports from the December 2023 HCRIS extract, but intends to use the March 2024 update of HCRIS to calculate the final Factor 3 for the FY 2025 IPPS final rule.

In the FY 2024 IPPS final rule, CMS also finalized changes related to the per discharge amount of interim uncompensated care payments. Since FY 2014, CMS has made interim uncompensated care payments during the FY on a per discharge basis. Traditionally, CMS used a three-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. However, due to the COVID-19 public health emergency (PHE) potentially leading to discharge underestimations, beginning with FY 2024, CMS excluded FY 2020 from the three-year average (CMS similarly excluded FY 2020 data in the FY 2023 IPPS final rule). Beginning with FY 2025, CMS proposes to calculate the per-discharge amount for interim uncompensated care payments using the average of the most recent 3 years of discharge data. For FY 2025, that will include FY 2021, FY 2022, and FY 2023.

CMS welcomes comments on the proposals noted above. In addition, CMS provides a FY 2025 IPPS Proposed Rule Medicare DSH supplemental data file on the <u>Proposed Rule website</u>.

<u>Withdrawal of Regulation that Applied Prior to 2005 to Determine a Hospital's DSH</u> Adjustment

In the Proposed Rule, CMS addresses how it will interpret a portion of the Medicare statute when calculating a hospital's DSH adjustment, if there is a properly pending claim in a DSH appeal or open cost report where a pre-FY 2005 regulation would have applied. As a result of a Supreme Court decision² which found that a pre-FY 2005 regulation conflicts with the plain meaning of the Medicare statute, CMS effectively proposes to no longer rely on an older version of a regulation (42 CFR 412.106) when reviewing claims in a DSH appeal or open cost report where the older regulation would have otherwise applied.³ Instead, CMS indicates that for those limited circumstances, the agency will apply the interpretation of the Medicare statute, as provided in the FY 2005 IPPS final rule, to mean that the Medicare fraction includes non-covered days in the SSI ratio. CMS clarifies that this proposal will not serve as a basis to reopen a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, or a decision by the Provider Reimbursement Review Board or the Administrator.

<u>Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications</u> <u>and Relative Weights</u>

Under the IPPS, the DRG classifications and relative weights are adjusted (at least annually) to account for changes in resource consumption. Relative weight adjustments aim to reflect changes in treatment patterns, technology and other factors that may alter the relative use of hospital resources. To calculate proposed MS-DRG relative weights for FY 2025, CMS proposes to use the FY 2022 MedPAR claims file⁴ and FY 2021 HCRIS dataset, which are the most recently available datasets for FY 2024 ratesetting. For FY 2025, CMS has not proposed any modifications to the agency's usual ratesetting methodologies to account for the impact of COVID-19 on the ratesetting data.

CMS proposes several updates to MS-DRGs (i.e., adding and removing MS-DRGs) as described in the Proposed Rule (pg. 44-218). Also, the proposed 19 national average cost-to-charge ratios (CCRs) for FY 2025 are provided in the Proposed Rule (pg. 217). These CCRs are used in the methodology CMS uses to determine the proposed relative weights. Table 5, as found on the Proposed Rule website, provides information on proposed MS-DRGs, relative weighting factors, and geometric and arithmetic mean lengths of stay. CMS welcomes comments on each of the MS-DRG classifications and relative weight proposed changes, including the proposed changes further detailed below.

Application of the Non-Complication or Comorbidity (NonCC) Subgroup Criteria to Existing MS-DRGs with a Three-Way Severity Level Split

In the Proposed Rule, CMS restates its FY 2021 IPPS final rule policy to expand the criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG to include the NonCC subgroup for a three-way severity level split. In the FY 2022 IPPS final rule, due to the volume of MS-DRG changes associated with

² Becerra v. Empire Health Foundation, for Valley Medica Center, 597 U.S. 424 (2022)

³ CMS proposes to formally withdraw 42 CFR 412.106 as it existed prior to the effective date of the FY 2005 IPPS final rule to the extent it included only covered days in the SSI ratio.

⁴ CMS also notes that for the Proposed Rule, the agency's initial MS-DRG analysis was based on ICD-10 claims data from the September 2022 update of the FY 2022 MedPAR file, which contains hospital bills received from October 1, 2021, through September 30, 2022.

implementing this policy and the COVID-19 PHE, CMS delayed applying the updated criteria until FY 2023 or in future rulemaking. In the FY 2023 IPPS final rule, CMS again delayed application of the NonCC subgroup criteria due to the COVID-19 PHE and until additional analyses could be performed to assess the impacts of the policy. For FY 2025, CMS proposes to continue to delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split and does not propose an alternative date to apply the criteria. **The agency is still reviewing the feedback from FY 2024 but encourages interested parties to continue to submit feedback for future rulemaking.**

In the agency's analysis of MS-DRG classification requests for FY 2024 and FY 2025, CMS applied the FY 2021 IPPS final rule criteria, as described in Table 3, to each of the MCC, CC, and NonCC subgroups. Tables 6P.1a-6P.2h, as found on the <u>Proposed Rule website</u>, detail the potential changes with application of the NonCC subgroup criteria.

CMS indicates it continues to apply the FY 2021 criteria to create subgroups in the annual analysis of MS-DRG classification requests.

Table 3. FY 2021 IPPS Final Rule Criteria for a Three-Way Severity Level Split

Criteria	3-way split (MCC vs. CC vs. NonCC)	2-way split MCC vs (CC + NonCC)	2-way split (MCC+CC) vs. NonCC
Step 1: 500+ cases in the MCC/CC/NonCC group	500+ cases for MCC group; AND 500+ cases for CC group; AND 500+ cases for NonCC group	500+ cases for MCC group; AND 500+ cases for (CC+NonCC) group	(MCC+CC) group; AND 500+ cases for
Step 2: 5%+ of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; AND 5%+ cases for CC group; AND 5%+ cases for NonCC group	5%+ cases for MCC group; AND 5%+ cases for (CC+NonCC) group	(MCC+CC) group; AND 5%+ cases for
Step 3: 20%+ difference in the average cost between groups	20%+ difference in average cost between MCC group and CC group; AND 20%+ difference in average cost between CC group and NonCC group 20%+ difference in average cost between MCC group and (CC+NonCC) group		CC) group and
Step 4: \$2,000+ difference in average cost between subgroups	\$2,000+ difference in average cost between MCC group and CC group; AND \$2,000+ difference in average cost between CC group and NonCC group	\$2,000+ difference in average cost between MCC group and (CC+NonCC) group	between (MCC+
Step 5: The R ² of the split groups is greater than or equal to 3	R ² > 3 for the three-way split within the base MS-DRG	R ² > 3 for the two-wa split (MCC vs (CC+NonCC)) within the base MS-DRG	way split
Criteria	3-way split (MCC vs. CC vs. 2-way split MCC vs. (CC + NonCC)		2-way split (MCC+CC) vs. NonCC
Step 1: 500+ cases in the MCC/CC/NonCC group	500+ cases for MCC group; AND 500+ cases for CC group; AND 500+ cases for NonCC group	500+ cases for MCC group; AND	500+ cases for (MCC+CC) group; AND 500+ cases for NonCC group

Step 2: 5%+ of the	5%+ cases for MCC group;	500+ cases for (CC+NonCC) group 5%+ cases for	5%+ cases for
patients are in the MCC/CC/NonCC group	AND 5%+ cases for CC group; AND 5%+ cases for NonCC group	MCC group; AND 5%+ cases for (CC+NonCC) group	(MCC+CC) group; AND 5%+ cases for NonCC group
Step 3: 20%+ difference in the average cost between groups	20%+ difference in average cost between MCC group and CC group; AND 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
Step 4: \$2,000+ difference in average cost between subgroups	\$2,000+ difference in average cost between MCC group and CC group; AND \$2,000+ difference in average cost between CC group and NonCC group	\$2,000+ difference in average cost between MCC group and (CC+NonCC) group	\$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
Step 5: The R ² of the split groups is greater than or equal to 3	R ² > 3 for the three-way split within the base MS-DRG	R ² > 3 for the two- way split (MCC vs (CC+NonCC)) within the base MS- DRG	R ² > 3 for the two-way split ((MCC+CC) vs NonCC) within the base MS-DRG

Comprehensive CC/MCC Analysis

In the FY 2008 IPPS final rule, CMS provided a process for subdividing diagnosis codes into three different levels of CC severity (i.e., MCC, CC, or NonCC). In the FY 2021 IPPS final rule, given significant diagnosis code changes had occurred since 2008, CMS indicated it would continue plans for a comprehensive CC/MCC analysis, using a combination of claims data analysis and application of nine guiding principles (as provided in the FY 2021 IPPS final rule). Since the publication of the FY 2023 final rule, CMS has not received feedback or comments on the guiding principles. Therefore, for FY 2025, **CMS proposes to finalize the nine guiding principles.** Under this proposal, CMS affirms the use of both mathematical analysis and the nine guiding principles when evaluating the extent to which a diagnosis code that is included as a secondary diagnosis result in increased hospital resource use.

Proposal to Change the Severity Level Designation for Housing-Related Z-Codes

In the FY 2024 IPPS final rule, CMS finalized changes to the severity level for diagnosis codes Z.59.00 (homelessness, unspecified) and Z.29.02 (unsheltered homelessness) from NonCC to CC. CMS notes that housing instability encompasses several challenges that may negatively impact physical health and make it harder to access healthcare. Therefore, for FY 2025, CMS proposes to change the severity level designation from NonCC to CC for Z59.10 (inadequate housing,

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⁵ The nine guiding principles are: 1. Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility; 2. Denotes organ system instability or failure; 3. Involves a chronic illness with susceptibility to exacerbations or abrupt decline; 4. Serves as a marker for advanced disease states across multiple different comorbid conditions; 5. Reflects systemic impact; 6. Post-operative/post-procedure condition/complication impacting recovery; 7. Typically requires higher level of care; 8. Impedes patient cooperation or management of care or both; 9. Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

unspecified), Z59.11 (inadequate housing environmental temperature), Z59.12 (inadequate housing utilities), Z59.19 (other inadequate housing), Z59.811 (housing instability, housed, with risk of homelessness), Z59.812 (housing instability, housed, homelessness in past 12 months), and Z59.819 (housing instability, housing unspecified). **CMS also requests any additional feedback on how the agency can foster the use of diagnosis codes describing social and economic circumstances to advance health equity.**

<u>Proposed Payment Adjustment for MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies)</u>

In the FY 2021 IPPS final rule, CMS created MS-DRG 018 for cases that include procedures describing Chimeric Antigen Receptor (CAR) T-cell therapies. In the FY 2024 IPPS final rule, CMS finalized a policy to exclude claims from the calculation of the average cost for MS-DRG 018 if the claims (1) contain ICD-10-CM diagnosis code Z00.6⁶ and do not include payer-only code "ZC" or (2) contain condition code "ZB" or condition code "90." For FY 2025, CMS proposes to continue to apply an adjustment to the payment amount for expanded use of immunotherapy and applicable clinical trials that would group to MS-DRG 018.

Proposed Add-On Payments for New Services and Technologies for FY 2025

Under the IPPS, a service or technology may be considered for a new technology add-on payment (NTAP) if: (1) the medical service or technology is new ("newness" criterion); (2) the medical service or technology is costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate ("cost" criterion); and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies ("substantial clinical improvement" criterion). However, certain transformative new devices and antimicrobial products may qualify under an alternative NTAP pathway. NTAPs are not budget neutral. Overall, CMS estimates a decrease of \$94 million from changes in the NTAPs in FY 2025.

Table II.E.-01 (pg. 237 of the <u>Proposed Rule</u>) provides a list of 24 technologies for which CMS proposes to continue NTAPs because the three-year NTAP anniversary date will occur on or after April 1, 2025. Table II.E.-02 (pg. 239 of the <u>Proposed Rule</u>) lists the 7 technologies for which CMS proposes to discontinue NTAPs because the three-year NTAP anniversary date will occur prior to April 1, 2025. Estimates for NTAPs proposed to continue for FY 2025 are available in a table (pg. 1794) in the <u>Proposed Rule</u>.

Under the traditional pathway for NTAP applications, CMS indicates that it received 16 applications for NTAPs for FY 2025. However, 4 applications were withdrawn or deemed ineligible prior to the issuance of the Proposed Rule. In the Proposed Rule, CMS addresses the 12 remaining applications but notes that it has not yet determined whether these technologies will meet the criteria for NTAPs for FY 2025. Under the alternative NTAP pathways, CMS received 23 applications for FY 2025, but 9 applications were withdrawn or deemed ineligible before the Proposed Rule was released. CMS addresses the remaining applications in the Proposed Rule (pg. 384-445) and proposes to approve all 14 alternative pathway applications submitted for the FY 2025 NTAP.

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⁶ Diagnosis code Z00.6: Encounter for examination for normal comparison and control in clinical research program.

Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2024 IPPS final rule, CMS provided that new technologies must receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

Currently, NTAPs are made to medical services and technologies for the first 2-3 years that a product comes on the market.⁷ CMS generally uses a 6-month window before and after the start of the FY to determine whether to extend the NTAP for an additional FY.

In the FY 2024 IPPS final rule, CMS also provided that beginning with certain NTAP applications⁸ for FY 2025, applicants must have a complete and active FDA marketing authorization request at the time of the NTAP application submission and must provide documentation of FDA acceptance to CMS with the application. In the Proposed Rule, CMS acknowledges commenters' feedback that this change would prevent a 3-year NTAP duration for almost all applicants, as only those technologies that receive FDA marketing authorization in April would be eligible for 3 years of NTAPs, based on the agency's 6-month guideline for determining fiscal year NTAP eligibility.

After consideration of stakeholder feedback, CMS proposes to modify the 6-month guideline for determining eligibility for a third year of NTAP payments. Specifically, CMS proposes that beginning with FY 2026 NTAPs, the agency will extend the add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry into the U.S. market occurs on or after October 1 of the fiscal year. This proposal will be effective beginning with those technologies that are initially approved for NTAPs in FY 2025 to allow additional flexibility for those applications that were subject to the change in the deadline for FDA marketing authorization finalized in the FY 2024 IPPS final rule. CMS seeks comment on this proposal.

Proposed Changes to the FDA Marketing Application Requirements

As discussed in the FY 2024 IPPS final rule, CMS finalized a requirement that applicants must provide documentation of FDA acceptance or filing to CMS at the time of NTAP application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA.

Based on the variability of the FDA process for approval through various pathways, CMS proposes that, beginning in FY 2026, NTAP applications that are on hold with the FDA will no longer be considered inactive for purposes of eligibility for the NTAP. **CMS seeks comment on this proposal and notes that, because of the variety of circumstances for which a technology may be in a hold status, the agency may reassess this policy in future years.**

⁷ CMS most commonly uses the FDA marketing authorization date as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRG weights but may recognize a later date in certain circumstances.

⁸ In the Proposed Rule, CMS indicates that the FY 2024 IPPS final rule policy would apply to new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application.

⁹ Technologies approved prior to FY 2025 will still be subject to the April 1 deadline for determining whether a technology would still be considered "new" for NTAP payments for the upcoming fiscal year.

<u>Proposed Changes to New Technology Add-on Payments for Gene Therapies Indicated for Sickle Cell Disease</u>

If a medical service or technology is approved for NTAPs, the payment will be limited to the full MS-DRG payment plus 65 percent of the estimated costs of the new technology or medical service, or 75 percent for a medical product designated by the FDA as a Qualified Infectious Disease Product (QIDP) or approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). CMS also describes that it has, in the past, increased the NTAP percentage for a challenge (i.e., antimicrobial resistance) that is a public health challenge and disproportionately impacts Medicare beneficiaries.

CMS notes continued concern about the inadequacy of NTAPs for cell and gene therapies to treat sickle cell disease, which substantially improve the health of beneficiaries but are among the costliest treatments to date. Accordingly, CMS proposes to increase the add-on payment for gene therapies approved under NTAP that are indicated to treat sickle cell disease to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. This policy, if finalized, would apply to certain sickle cell gene therapies approved for a NTAP in the FY 2025 final rule (i.e., effective for discharges on or after October 1, 2024), and conclude at the end of the 2-3-year newness period. CMS seeks comment on this proposal and whether it should apply only to applicants that meet certain additional criteria, such as participating in behaviors that promote access to these therapies at a lower cost, or attesting to offering and/or participating in outcome-based pricing arrangements with purchasers.

Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

CMS proposes to establish separate payments (biweekly or lump sum at cost report settlement) under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of at least one essential medicine (for cost reporting periods beginning on or after October 1, 2024). A more detailed summary of this proposal is available here. **CMS seeks comments on this proposal.**

Outlier Payments

Costs incurred by a hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS-DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount. On March 28, 2024, CMS issued Change Recommendation (CR) 13566 that expands the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. The goal of these instructions is to expand the scope of cost reports used for outlier reconciliation approval to increase the accuracy of outlier payments.

For FY 2025, generally, CMS proposes to use the same methodology from FY 2020 to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed-loss cost threshold with modifications to reflect the expansion of outlier reconciliations under CR 13566. Also, CMS proposes to continue to aim to pay 5.1 percent of aggregate payments under IPPS as outlier payments. CMS ultimately proposes an outlier fixed-loss cost threshold for FY 2025 to be \$49,237, an increase from FY 2024, which was \$40,732.

Proposed Changes to the Core-Based Statistical Areas (CBSAs)

The wage index is calculated and assigned to hospitals based on the labor market area in which the hospital is located. CBSAs are based on delineations from the Office of Management and Budget (OMB), which updates delineations based on the results of the census. In 2023, OMB finalized a schedule for future updates.

CMS proposes to implement the revised OMB delineations of CSBAs to calculate wage indexes beginning with the FY 2025 IPPS wage index. Based on these changes, CMS believes that, starting in FY 2025, 53 counties and 33 hospitals that were once considered part of a Metropolitan Statistical Area (MSA) will now be in a rural area, and 54 counties and 24 hospitals that were in a rural area would now be in an MSA. More information on county codes for CBSAs, including the revised CBSA delineations, is available on the Proposed Rule website (supplemental file 8) as well as in the Proposed Rule (p. 460-474). CMS recognizes that this may have a negative impact on certain hospitals' IPPS payments and previously finalized transition policies in the FY 2015 final rule to mitigate these impacts and provide stability. CMS also finalized a 5 percent cap on reductions from OMB CBSA changes in the FY 2020 IPPS final rule.

Additionally, CMS notes that these delineations may impact a hospital's eligibility for urban- and rural-specific programs, such as the low volume hospital adjustment. Hospitals moving from urban to rural areas may wish to consider reclassification to retain eligibility for rural only programs. CMS encourages all hospitals to examine the labor market changes and determine whether they need to mitigate any potential impacts to payments or programs, such as DSH or GME, or any rural-only programs. A hospital's ability to request changes based on the labor market changes must be made within 45 days of when the Proposed Rule was posted for public display.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

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

The proposed FY 2025 wage index values are based on Medicare cost report data for cost reporting periods beginning October 1, 2020 through September 30, 2021 (FY 2021). CMS reiterates its ongoing practice for the wage index to generally use the most current data and information available, which is usually data that is nearly of four years old.

Based on the agency's analysis of FY 2021 data,¹¹ CMS states that it is not readily apparent whether any changes due to the COVID-19 PHE impacted the wages paid by individual hospitals. In

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¹⁰ See p. 465 and 467 of the Proposed Rule.

¹¹ Based on the agency's analysis of the FY 2021 wage data compared to prior data periods, CMS found the following: Approximately 91 percent of hospitals had an increase in their average hourly wage from FY 2020 to FY 2021, compared to a range of 76-86 percent of hospitals for the most recent 3 year periods; Approximately 97 percent of all CBSA average hourly wages increased from FY 2020 to FY 2021, compared to a range of 84-91 percent of all CBSAs for the most recent 3 year periods; Approximately 51 percent of all urban areas had an increase in their area wage index from FY 2020 to FY 2021, compared to a range of 36-43 percent of all urban areas for the most recent 3 year periods; Approximately 55 percent of all rural areas have an increase in their wage index from FY 2020 to FY 2021, compared to a range of 31-46 percent of all rural areas for the most recent 3 year periods; The unadjusted national average hourly wage increased by

addition, CMS notes that even if the COVID-19 PHE did differentially impact individual hospitals, it is not clear how to isolate those changes from other changes that might have occurred during this same time. Because the agency finds no other substantive issues with the data, such as those related to the impact of the COVID-19 PHE, it proposes to use the FY 2021 wage data for FY 2025. **CMS invites comment on this proposal.**

Proposed Occupational Mix Adjustment to the FY 2025 Wage Index

CMS uses an occupational mix adjustment to control for the effects of hospitals' choices to employ different combinations of staff to provide care services. There is also a statutory requirement that CMS collect data every three years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program and to measure the earnings and paid hours of employment for such hospitals by occupational category. Based on this requirement, CMS indicates it is required to provide a new measurement of occupational mix for FY 2025. To determine the FY 2025 occupational mix adjustment, CMS used a calendar year (CY) 2022 survey, which hospitals needed to submit to their Medicare Administrative Contractor by July 1, 2023. Also, in the Proposed Rule, CMS provides additional information regarding the survey results and notes that it is unclear how changes due to the COVID-19 PHE differentially impacted the occupational mix adjusted wages paid in each CBSA and that the agency believes the CY 2022 occupational mix data is the best available data to use for FY 2025. As a result, CMS proposes to use the CY 2022 occupational mix data for FY 2025.

For the FY 2025 wage index, CMS used Worksheet S-3 wage data of 3075 hospitals and occupational mix surveys of 2950 hospitals. CMS notes it had a "response" rate of 96 percent and will apply proxy data for hospitals that did not reply, for new hospitals, and for hospitals that submitted erroneous or aberrant data, as done in prior years. To compute the FY 2025 occupational mix adjustment, CMS is not proposing any changes to the methodology. In applying this methodology, the proposed FY 2025 occupational mix adjusted national average hourly wage is \$54.73, compared to \$50.27 in FY 2024. A table comparing the FY 2025 proposed occupational mix adjusted wage indexes to the proposed unadjusted wage indexes by CBSA is found in the Proposed Rule (pg. 501). The table indicates that 60.19 percent of urban areas and 59.57 percent of rural areas have a wage index that is increasing.

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

Rural Floor Policy

The "rural floor" policy provides that area wage indexes applied to any hospital that is located in an urban area of a state cannot be lower than the area wage index for hospitals in rural areas in that state. In addition, CMS applies a national budget neutrality adjustment when implementing the rural floor policy. Based on the FY 2025 wage index used in the Proposed Rule, CMS estimated that 494 hospitals would receive the rural floor adjustment in FY 2025.

a range of 2.4-5.4 percent per year from FY 2017 to FY 2020. For FY 2021, the unadjusted national average hourly wave increased by 8.7 percent from FY 2020.

"Imputed Floor" Policy

In the FY 2022 IPPS final rule, CMS adopted the American Rescue Plan Act (ARPA) requirements¹² to implement the "imputed floor" policy. For FY 2025, CMS proposes to continue to apply the FY 2022 "imputed floor" policy. Based on available data for the Proposed Rule, CMS indicates that hospitals in the following states and territories would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2025: Connecticut, Washington, D.C., New Jersey, Rhode Island, and Puerto Rico.

State Frontier Floor Policy

The ACA requires that the wage index for hospitals in low density states (known as the Frontier Floor Wage Index) cannot be below 1.0000. In the Proposed Rule, CMS indicates 43 hospitals would receive the Frontier Floor adjustment so their FY 2025 wage index would be 1.0000. These hospitals are in Montana, North Dakota, South Dakota, and Wyoming. Although Nevada meets the definition of a frontier state, all hospitals in Nevada currently receive a wage index value greater than 1.0000.

Low Wage Index Hospital Policy

In the FY 2022 IPPS final rule, CMS finalized a policy that provides certain low wage index hospitals with the opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index. CMS achieved this by temporarily increasing the wage index values for certain hospitals with low wage indexes and providing an adjustment to the standardized amount for all hospitals so that the policy was budget neutral. CMS notes that when it established the low wage index hospital policy, the intention was that it would be in effect for at least four fiscal years, beginning October 1, 2019. However, due to the complications of the COVID-19 PHE, which ended in May 2023, CMS believes that more data is needed to determine whether low wage hospitals have been provided a sufficient opportunity to increase employee compensation under the policy. Therefore, beginning with FY 2025, CMS proposes that the low wage index hospital policy and the related budget neutrality adjustment would be effective for at least three more years.

CMS also proposes to apply a budget neutrality adjustment factor to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value. The FY 2025 proposed 25th percentile wage index value across all hospitals is 0.8615.

Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

Beginning in FY 2005, CMS provided a process to make an "out-migration adjustment" to the hospital wage index based on commuting patterns of hospital employees. For FY 2025 and subsequent years, CMS proposes that the out-migration adjustment will be based on the data derived from the custom tabulation of the American Community Survey (ACS) utilizing 2016 through 2020 (5-year) microdata. All other out-migration adjustments will continue to be based on the same policies, procedures, and computations that were used for the FY 2012 out-migration adjustment. Table 2 associated with the Proposed Rule includes the proposed out-migration adjustment for the

¹² From FYs 2005–2018, CMS utilized an imputed floor policy for hospitals in all-urban states, and it was considered as a factor in the national budget neutrality adjustment. Section 9831 of the American Rescue Plan Act (ARPA) requires that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban state may not be less than the minimum area wage index for the fiscal year for hospitals in that state established using the methodology that was in effect for FY 2018. Unlike the imputed floor policy that was in effect from FYs 2005–2018, the ARPA provided that the imputed floor wage index shall not be applied in a budget neutral manner.

¹³ Under the FY 2020 policy, CMS increases the wage index for each hospital by half the difference between the otherwise applicable final wage index value for a year for the hospital and the 25th percentile wage index value for that year across all hospitals.

FY 2025 wage index and Table 4A provides a list of counties eligible for the out-migration adjustment, and the number of years adjustments will be in effect.

Proposed Labor-Related Share for the FY 2025 Wage Index

The labor-related share is used to determine the proportion of the base payment rate to which the area wage index should be applied and includes a cost category if such costs are labor intensive and vary with the local market. For FY 2025, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.000, CMS proposes to apply the wage index to a labor related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2025, CMS proposes to apply the wage index to a proposed labor-related share of 67.6 percent of the national standardized amount.

CMS notes that the IPPS market basket will likely be rebased and revised in the FY 2026 IPPS proposed rule.¹⁴

Proposed Payment Adjustment for Low-Volume Hospitals

Beginning in FY 2005, an additional payment to each qualifying low-volume hospital (LVH) under the IPPS was made (referred to as the LVH adjustment). ¹⁵ Additional changes to temporarily expand eligibility for the LVH adjustment and the payment methodology were provided in the ACA and the Bipartisan Budget Act of 2018 (BBA, 2018) (Pub. L. 115-123). The BBA, 2018, also provided that the adjustment would apply only for discharges occurring in FYs 2019-2022. However, the Consolidated Appropriations Acts (CAA), of 2023 and 2024 extended the provisions from FY 2019-2022 through FYs 2024 and the portion of FY 2025 occurring before January 1, 2025.

In the Proposed Rule, CMS proposes to extend the changes to the qualifying criteria for low-volume hospitals in accordance with the provisions of the CAA, 2024. These proposals would be in effect for discharges made during FY 2025 on or before December 31, 2024.

For discharges occurring on or after January 1, 2025, CMS proposes that the qualifications for the LVH will revert back to the policies in effect prior to the amendments made by the Affordable Care Act (ACA) and other legislation. Specifically, to qualify as an LVH, a subsection (d) hospital must be more than 25 miles from another subsection (d) hospital and have fewer than 800 total discharges during the fiscal year. A 25-percent low-volume adjustment to all qualifying hospitals with fewer than 200 discharges per fiscal year will also apply. CMS notes that if other legislation extends the lowvolume hospital changes, the agency will adjust the rules accordingly.

For FY 2025, CMS proposes that a hospital must submit a written recommendation request to its Medicare Administrative Contractor (MAC) with sufficient documentation that it meets the mileage and discharge criteria. For the portion of FY 2025 beginning October 1, 2024 through December 31, 2024, the deadline will be September 1, 2024. For the portion of FY 2025 beginning January 1, 2025, the deadline will be December 1, 2024. Hospitals may submit a single written request documenting both sets of criteria or may submit the requests separately. A hospital that met the criteria in FY 2024 may continue to receive a LVH payment adjustment for FY 2025 without reapplying if it meets both the discharge and mileage criteria for both segments of FY 2025.

¹⁴ Although this summary does not contain a full analysis of the LTCH proposed policies, it should be noted that CMS proposed a rebased and revised the LTCH PPS market basket for the FY 2025 proposed rule.

15 The LVH adjustment is based on total per discharge payments (e.g., capital, DSH, IME and outlier payments).

Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program

Medicare-Dependent Hospital (MDH) designations are available to hospitals that have a disproportionately high Medicare patient mix. The MDH program was originally set to expire on September 30, 2022. However, laws enacted in 2022 restored the program retroactive to October 1, 2022. Also, the CAA, 2024 extended the MDH program through December 31, 2024. In the Proposed Rule, CMS clarifies that a provider that is classified as an MDH will not have to reapply and will continue to be classified as an MDH until December 31, 2024. Beginning January 1, 2025, the MDH program will no longer be in effect unless Congress extends the program and, as a result, all hospitals that qualified as MDH providers will be paid based on the federal IPPS rate.

In the FY 2013 IPPS final rule, CMS revised the sole community hospital (SCH) policy to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. These policies allow for an effective date of an approval of SCH status that is the day following the expiration date of the MDH program. To receive SCH status effective January 1, 2025, the MDH must apply for SCH status by December 2, 2024, and request that, if approved, the status would be recognized on January 1, 2025. CMS will make regulatory modifications to the MDH program if legislation passes extending the program.

Rural Community Hospital Demonstration Program

The Rural Community Hospital Demonstration Program, which was established in 2003, and was extended by the CAA, 2021 for an additional five years, pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. In the Proposed Rule, CMS summarizes the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality. Based on the agency's analysis, the budget neutrality factor for FY 2024 is 0.999513.

Indirect and Direct Graduate Medical Education

Payments to hospitals for the direct costs of an approved graduate medical education (GME) program are based on a methodology that determines a hospital-specific base-period per resident amount (PRA). In general, Medicare GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and non-provider sites, when applicable), and the hospital's Medicare share of total inpatient days.

In addition, under IPPS, there is an indirect medical education (IME) adjustment for hospitals that have residents in an approved GME program. A hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds. The calculation of both direct GME payment and the IME payment adjustment is affected by the number of FTE residents that a hospital is permitted to count. Consistent with prior policy, for discharges occurring during FY 2025, the IME formula multiplier is 1.35. CMS estimates application of the multiplier results in an increase in the IPPS payment amount of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

Distribution of Additional Residency Positions Under Provisions of the CAA, 2023

In 2021, the CAA authorized Medicare payments for more than one thousand additional GME resident slots. The CAA, 2023 required the distribution of additional residency positions to hospitals for FY 2026, 200 of which will go to psychiatry or psychiatry subspecialty residency training programs.

CMS is proposing several policies and procedures for the application cycle of these 200 residency slots, including deadlines and what hospitals must demonstrate to qualify for these additional slots. The hospital will also need to meet specific criteria based on whether the slots will be used for a new residency program or to expand an existing program.¹⁶

<u>Proposed Modifications to the Criteria for New Residency Programs and Requests for Information</u>

A new medical residency training program must meet certain criteria for CMS to create a new cap on slots for a previously non-teaching hospital. The three primary criteria are whether: (1) the residents are new; (2) the program director is new; and (3) the teaching staff are new. The agency notes that over the years it has received questions about whether a program could be considered new if any of the three criteria were only partially met. CMS seeks to establish in rulemaking additional criteria for establishing newness, but the agency seeks more information prior to establishing these changes.

Generally, CMS provides guidance that new residency programs should ensure that the "overwhelming majority" of residents are new residents, as opposed to residents that have transferred into a program and have previous residency training experience. Specifically, CMS seeks information on some proposals to clarify guidelines on newness, including information on the threshold of new residents in a program, how to designate staff and program directors as new to a residency training program, and information on commingling in residency programs and how that might impact small residency programs.

Reminder of CBSA Changes and Application to GME Policies

As <u>noted previously</u>, CMS is proposing to adopt new OMB delineations for statistical areas beginning with FY 2025. As a result, some teaching hospitals may be redesignated from rural to urban and urban to rural. CMS clarifies that it will continue using the guidance developed in the <u>FY 2015 IPPS final rule</u> regarding the effect of FTE caps of a hospital that is impacted by these new delineations (e.g., a hospital with a five year residency program that was designed for a rural CBSA, and three years in is redesignated to an urban CBSA).

Hospital Readmissions Reduction Program (HRRP)

The HRRP requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The 21st Century Cures Act requires comparing peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. The HRRP currently includes six applicable conditions/procedures: acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery. **CMS does not propose any changes to the HRRP in the Proposed Rule.**

Hospital Value-Based Purchasing (VBP) Program

The ACA established the Hospital VBP Program under which value-based incentive payments are made to hospitals that meet performance standards during specific performance periods. There are

¹⁶ Specific criteria are provided on p. 645-669 of the Proposed Rule.

four Hospital VBP domains: Safety; Clinical Outcomes; Efficiency and Cost Reduction; and Person and Community Engagement. Typically, the applicable incentive payment percent is required by statute (e.g., 2 percent). In the Proposed Rule, CMS proposes changes to measures and changes to the HCAHPS Survey scoring methodology to align with proposed changes in the HCAHPS survey for the Hospital IQR Program.

Proposed Updates to the Performance Standards for the Hospital VBP Program

CMS proposes to make substantive changes to the HCAHPS survey in the Hospital IQR program, as discussed in more detail <u>below</u>. To accommodate these changes, and the transition to the new survey, CMS proposes to modify the scoring of the HCAHPS survey in the Hospital VBP Program for the FY 2027-2029 program years. Scoring would be modified to only score hospitals on the six Hospital VBP Program dimensions of the HCAHPS survey that would remain unchanged from the current version, which include: communication with nurses, communication with doctors, communication about medicines, discharge information, cleanliness and quietness, and overall rating, excluding the sections that will be modified in future iterations of the survey. Therefore, **CMS proposes to exclude the responsiveness of hospital staff and care transition dimensions in scoring for FY 2027 through FY 2029 program years. CMS also proposes to adopt the updated version of the HCAHPS survey measure for use in the Hospital VBP Program beginning in FY 2030.**¹⁷

Previously Adopted Performance Periods

Table 4 outlines previously adopted and baseline performance periods for the FY 2026 Program Year. Also, Tables V.L.-03-07 of the <u>Proposed Rule</u> (p. 730) provide previously established and newly estimated performance standards for the FY 2026 – FY 2029 PYs.

Table 4. Previously Adopted and Baseline Performance Periods for the FY 2027 Program Year

Measure		Baseline Period for FY 2026 PY	Performance Period for the FY 2026 PY
Person and Community Engagement Domain	HCAHPS*	1/1/2023 – 12/31/2023	1/1/2025 – 12/31/2025
Clinical Outcomes Domain	Mortality measures (MORT-30-AMI, MORT-30- HF, MORT-30-COPD, MORT-30-CABG, MORT- 30-PN (updated cohort))	1/1/2017 — 6/30/2020	1/1/2022 – 6/30/2025
	COMP-HIP-KNEE	4/1/2017 - 3/31/2020	4/1/2022 - 3/31/2025
Safety Domain	NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	1/1/2023 – 12/31/2023	1/1/2025 — 12/31/2025
	SEP-1	1/1/2023 - 12/31/2023	1/1/2025 - 12/31/2025
Efficient and Cost Reduction Domain	Medicare Spending Per Beneficiary (MSPB)	1/1/2023 – 12/31/2023	1/1/2025 – 12/31/2025

*CMS is proposing changes to HCAHPS for FY 2027 which include only scoring for 6 dimensions of the HCAHPS survey that are unchanged from the previous version.

¹⁷ The full calculation is available on p. 888-889 of the <u>Proposed Rule</u>. Table IX.B.2.03 on p. 893 shows the full timeline for implementation of each dimension in the Hospital VBP Program.

Hospital-Acquired Conditions (HAC) Reduction Program

The ACA established the HAC Reduction Program (HACRP) to reduce the incidence of HACs by requiring hospitals to report on a set of measures (CMS PSI 90 and CDC NHSN HAI measures). Hospitals in the worst performing quartile (25 percent) would receive a one percent payment reduction. A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year will depend on several different factors. **CMS does not propose any changes to the HACRP for FY 2025.**

Hospital Inpatient Quality Reporting (IQR) Program

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 authorized CMS to pay hospitals that successfully report designated quality measures a higher annual update to their payment rates. To receive the full payment increase, hospitals must report data on measures selected by the Secretary for each fiscal year.

Proposal to Adopt New Measures and Remove Measures from the Hospital IQR Program

In the Proposed Rule, CMS proposes to adopt seven new measures (as provided in Table 5), modify two current measures, and remove five current quality measures. CMS proposes to adopt two new electronic Clinical Quality Measures (eCQMs), one claims-based measure, and two healthcare-associated hospital infection measures. CMS is also proposing to modify two current measures, including modifications to the HCAHPS survey measure. CMS is also proposing an increase in the total number of mandatory eCQMs reported by hospitals. **CMS seeks comment on these proposals.**

Table 5. Proposed Changes to the Hospital IQR Program

Measure		Proposed Changes	Timeline (starting with most imminent changes)
Changed	Global Malnutrition Composite Score eCQM	Add patients ages 18-64 to the current cohort of patients 65 years or older	Beginning with the CY 2026 reporting period/FY 2027 payment determination
measures	HCAHPS Survey	See below for information on the HCAHPS proposed changes	Beginning with the CY 2025 reporting period/FY 2027 payment determination
New Measures	Hospital Harm – Falls with Injury eCQM	N/A	Inclusion in the measure set beginning with the CY 2026 reporting period/FY 2028 payment determination
	Hospital-Harm—Post-Op Respiratory Failure eCQM	N/A	Inclusion in the measure set beginning with the CY 2026 reporting period/FY 2028 payment determination
	Thirty-day Risk- Standardized Death Rate among Surgical Inpatients with Complications (Failure to Rescue) claims-based measure	N/A	Inclusion in the measure set beginning with the Jul. 1, 2023- Jun. 30, 2025 reporting period, impacting the FY 2027 payment determination
	Patient Safety Structural Measure (more information below)	N/A	Inclusion in the measure set beginning with the CY 2025 reporting period/FY 2027 payment determination

	Age Friendly Hospital Structural Measure (more information below)	N/A	Beginning with the CY 2025 reporting period/FY 2027 payment determination
	Catheter-Associated Urinary Tract Infection Standardized Infection Ratio Stratified for Oncology Locations (more information below)	N/A	Beginning with the CY 2026 reporting period/FY 2028 payment determination
	Central Line-Associated Bloodstream Infection Ratio Stratified for Oncology Locations (more information below)	N/A	Beginning with the CY 2026 reporting period/FY 2028 payment determination
	Hospital-level, Risk- Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction (AMI Payment) (more information below)	CMS will permanently remove this measure from the Hospital IQR Program	Remove beginning with the Jul. 1, 2021-Jun. 30, 2024 performance period/FY 2026 payment determination
	Hospital-level, Risk- Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure (HF Payment) (more information below)	CMS will remove this measure from the Hospital IQR Program	Remove beginning with the Jul. 1, 2021-Jun. 30, 2024 performance period/FY 2026 payment determination
Existing measures being removed	Hospital-level, Risk- Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia (PN Payment) (more information below)	CMS will remove this measure from the Hospital IQR Program	Remove beginning with the Jul. 1, 2021-Jun. 30, 2024 performance period/FY 2026 payment determination
	Hospital-level, Risk-Standardized Payment Associated with a 30-day Episode of Care for Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA Payment) (more information below)	CMS will remove this measure from the Hospital IQR Program	Remove beginning with the Apr. 1, 2021-Mar. 31, 2024 performance period/FY 2026 payment determination
	CMS PSI-04 Death Among Surgical Inpatients with Serious Treatable Conditions	CMS will remove this measure from the Hospital IQR Program	Remove beginning with the FY 2027 payment determination, associated with the July 1, 2023-Jun. 30, 2025 reporting period

Proposal to Adopt the Patient Safety Structural Measure

The Patient Safety Structural measure is an attestation-based measure that assesses whether hospitals demonstrate a structure, culture, and leadership commitment that prioritizes safety. The measure includes five domains, which CMS has identified as capturing a systems-based approach to safety best practices. These domains include (1) leadership commitment to eliminating preventable harm; (2) strategic planning and organizational policy; (3) culture of safety and learning health systems; (4) accountability and transparency; and (5) patient and family engagement. A hospital would evaluate its work and attest to whether it meets the statements of each domain,

which are scored from 0 to 5 points. CMS states that this measure is part of a larger strategy to address patient safety in hospitals and is complimented by the other safety measure proposals in the Proposed Rule.

This measure was endorsed with conditions for inclusion in the Hospital IQR program at the meeting of the Pre-Rulemaking Measure Review (PRMR) committee meeting of the Consensus-Based Entity (CBE) Partnership for Quality Management (PQM). CMS proposes that hospitals would be required to submit information for the Patient Safety Structural measure once annually using the data submission and reporting procedures set forth by the Centers for Disease Control & Prevention (CDC) for the National Healthcare Safety Network (NHSN). The agency proposes adopting the measure in the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 program year, and to start publicly reporting the performance score on *Care Compare* beginning in fall 2026. **CMS invites public comment on this proposal.**

Proposal to Adopt the Age Friendly Hospital Measure

With CMS being the largest provider of healthcare coverage for those 65 years and older, the agency seeks to ensure that hospitals are prioritizing patient-centered care for aging populations with multiple chronic conditions. The Age Friendly Hospital measure is an attestation-based measure to help hospitals ensure they are using a framework comprised of a set of four evidence-based elements of high-quality care to older adults, called the "4 Ms": what matters, medication, mentation, and mobility. CMS proposes to adopt the Age Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment determination.

The Age Friendly Hospital measure consists of five domains that address essential aspects of patient care, which include (1) eliciting patient healthcare goals; (2) responsible medication management; (3) frailty screening and intervention; (4) social vulnerability; and (5) age-friendly care leadership. Similar to the Patient Safety Structural measure, hospitals will evaluate their work on each of these domains and attest yes or no to the statements as provided. When presented with this measure, the PRMR committee of the CBE did not reach consensus and therefore did not endorse adding this measure. CMS feels, however, that this measure is important for establishing a foundation for future health outcome measures and provides a framework of best practices for providing care to older adults. **CMS seeks comment on these proposals.**

Proposal to Adopt Two Healthcare-Associated Infection Measures

CMS proposes to adopt two healthcare-associated infection (HAI) measures into the Hospital IQR program beginning with the CY 2026 reporting period/FY 2028 payment determination. Both the Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI) measures were adopted into the Hospital IQR Program in the FY 2012 IPPS final rule but were moved into the HAC Reduction program and then the Hospital Value-Based Purchasing program in subsequent years. The current measures capture data in many inpatient care wards at acute care hospitals, but locations mapped as oncology wards have not been included. The CAUTI-Onc and CLABSI-Onc measures would be limited to inpatients at acute care hospitals in oncology wards.

The agency notes that patients with cancer are particularly vulnerable to developing HAIs, and that the Administration has increased its focus on cancer care through a variety of initiatives.²⁰ The CAUTI-Onc and CLABSI-Onc measures will encourage the use of best practices to prevent HAIs

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¹⁸ https://www.ihi.org/initiatives/age-friendly-health-systems

¹⁹ See p. 906-907 of the <u>Proposed Rule</u> for more information on the five domains.

²⁰ https://www.whitehouse.gov/cancermoonshot/

and capture more data to compare rates between inpatient cancer care settings and PPS-exempt cancer hospitals (PCHs). CMS proposes to collect data for these measures consistent with the current approach for HAI reporting for the HAC Reduction and Hospital VBP programs. CMS notes that the PRMR committee of the CBE voted to recommend adoption of these measures into the Hospital IQR Program.

Proposal to Remove Four Clinical Episode-Based Payment Measures

CMS proposes to remove four clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2026 payment determination. These include the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction, the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure, the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia, and the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty. CMS is proposing to remove these measures under removal factor 3, the availability of a more broadly applicable measure – specifically, the Medicare Spending per Beneficiary measure, which was adopted into the Hospital VBP Program in the FY 2024 IPPS final rule. **CMS seeks comment on these proposals.**

Proposal to Modify the HCAHPS Survey Measure

For FY 2025, CMS proposes modifications to the substantive questions on the <u>HCAHPS</u> survey. Specifically, the proposed update would change the number of questions from 29 to 32, modifying and removing certain measures and sub-measures. The proposed updated version of the HCAHPS survey would include three new sub-measures: care coordination, restfulness of hospital environment, and information about symptoms (see Table 6 for more information). The proposed updates would remove the existing care transition sub-measure and modify the existing responsiveness of hospital staff sub-measure, resulting in seven new questions and the removal of four existing questions. CMS provides a crosswalk of the updated HCAHPS survey questions and sub-measures in the <u>Proposed Rule</u> on p. 872-874.

CMS proposes a transitional timeline for implementation of the new HCAHPS survey, consistent with the transition period proposed for the Hospital VBP Program. Beginning with discharges on January 1, 2025, CMS proposes that the updated HCAHPS survey measure would be implemented in the Hospital IQR Program. Reporting of responses from the updated HCAHPS Survey measure for patients discharged between January 1, 2025 and December 31, 2025 would be used for the CY 2025 reporting period/FY 2027 payment determination for the Hospital IQR Program. Currently, HCAHPS Survey sub-measures are publicly reported on a quarterly rolling basis. Accordingly, CMS notes that there will be a period of time when the publicly reported HCAHPS data would only reflect the eight unchanged sub-measures. CMS outlines the transition of how the sub-measures would be reported on p. 880 of the Proposed Rule. More detail on the proposed added, modified, and removed sub-measures is available in Table 6. **CMS seeks comment on these proposals.**

Table 6. Proposed Changes to the HCAHPS Survey

Table 6. Proposed C	Changes to the HCAHPS S	urvey
	Sub-Measure	Description
New Sub- Measures	Care Coordination	The Care Coordination sub-measure is comprised of three questions that ask patients how often hospital staff were informed and up-to-date about the patient's care, how often hospital staff worked well together to care for the patient, and whether hospital staff worked with the patient and family or caregiver in making plans for the patient's care post-hospitalization.
	Restfulness of Hospital Environment	The Restfulness sub-measure is a newly developed multi-question sub-measure comprised of three survey questions: two new questions that ask how often patients were able to get the rest they needed, and whether the hospital staff helped the patient to rest and recover. It retains a current question that asks how often the area around the patient's room was quiet at night.
	Information about Symptoms	The Information about Symptoms sub-measure is a newly developed single-question sub-measure that asks whether the care team gave the patient's family or caregiver enough information about symptoms or health problems to watch out for after the patient left the hospital.
Modified Sub- Measures	Responsiveness of Hospital Staff	The revisions to the Responsiveness of Hospital Staff sub-measure entail adding a new question and removing a current question under this sub-measure. CMS proposes to remove the "call button" question because call buttons have largely been replaced with other forms of communication. The revised sub-measure would ask how often patients received help in getting to the bathroom as soon as they wanted and how often patients got help as soon as they needed it when they asked for help right away.
	About You	CMS Proposes changes to the About You section including: replacing the existing "Emergency Room Admission" question with a new, "Hospital Stay Planned in Advance" question; reducing the number of response options for the "Language Spoken at Home" question; and alphabetizing the response options for the race and ethnicity questions
Removed Sub- Measures	Care Transition	This sub-measure will be removed and replaced with the Care Coordination sub-measure

Reporting and Submission Requirements for eCQMs

CMS is proposing a progressive increase in the number of mandatory eCQMs a hospital must report beginning with the CY 2026 reporting period/FY 2028 payment determination. Under current eCQM reporting policies, hospitals must report four calendar quarters of data for each required eCQM and allow hospitals to report on three self-selected eCQMs. For the CY 2026 reporting period/FY 2028 payment determination, CMS proposes to increase the number of mandatory eCQMs from 3 to 6, adding in the Hospital Harm eCQMs, in addition to the 3 self-selected eCQMs. Accordingly, hospitals would report a total of 9 eCQMs in the CY 2026 reporting period. CMS also proposes to increase the number of mandatory eCQMs in the CY 2027 reporting period/FY

2029 payment determination, from 6 mandatory eCQMs to 8 mandatory eCQMs, in addition to the 3 self-selected eCQMs. For the CY 2027 reporting period, hospitals would report a total of 11 eCQMs, 8 which are mandatory and 3 which are self-selected. **CMS seeks comment on these proposals.** See Table 7 for the proposed timeline and changes to the measures.

Table 7. Proposed Changes to the Total Number of eCQMs Reported

Reporting Period/Payment Determination	Total Number of eCQMs Reported	Mandatory eCQMs Reported
CY 2024/FY 2026 and CY 2025/FY 2027	Six (3 mandatory; 3 self-selected)	(1) the Safe Use of Opioids – Concurrent Prescribing eCQM;(2) the Cesarean Birth eCQM; and(3) the Severe Obstetric Complications eCQM.
CY 2026/FY 2028 (proposed)	Nine (6 mandatory; 3 self-selected)	 Hospital Harm – Severe Hypoglycemia eCQM; Hospital Harm – Severe Hyperglycemia eCQM; Hospital Harm – Opioid-Related Adverse Events eCQM. the Safe Use of Opioids – Concurrent Prescribing eCQM; the Cesarean Birth eCQM; and the Severe Obstetric Complications eCQM.
CY 2027/FY 2029 (proposed)	Eleven (8 mandatory; 3 self-selected	 Hospital Harm – Pressure Injury eCQM; Hospital Harm – Acute Kidney Injury eCQM. Hospital Harm – Severe Hypoglycemia eCQM; Hospital Harm – Severe Hyperglycemia eCQM; Hospital Harm – Opioid-Related Adverse Events eCQM. the Safe Use of Opioids – Concurrent Prescribing eCQM; the Cesarean Birth eCQM; and the Severe Obstetric Complications eCQM.

Advancing Patient Safety and Outcomes Across Hospital Quality Programs

CMS is seeking information on ways to build on current measures in several quality reporting programs that account for unplanned patient hospital visits to encourage hospitals to improve discharge processes. The agency notes that while the HRRP program, as well as other measures within various quality reporting programs, aim to lower the rates of patient readmissions, the measures do not comprehensively capture unplanned patient returns to inpatient or outpatient care settings after discharge. Therefore, **CMS seeks public comment on how these programs could further encourage hospitals to improve discharge processes, such as by introducing measures currently in quality reporting programs into value-based purchasing to link outcomes to payment incentives.** The agency is specifically interested in input on adopting measures that better represent the range of outcomes of interest to patients, including unplanned returns to the emergency department and receipt of observation services within 30 days of a patient's discharge from an inpatient stay.

Proposal to Modify eCQM Data Validation

Under the existing eCQM data validation policy, the accuracy of eCQM data has not affected a hospital's validation score. Hospitals are currently scored on the completeness of the eCQM medical record data that were submitted for the validation process. The agency notes that it has worked with hospitals to validate data, and those hospitals that have been selected for validation have performed well above a passing threshold of 75 percent. Therefore, CMS proposes to implement an eCQM validation scoring based on the accuracy of eCQM data beginning with the CY 2025 eCQM data affecting the FY 2028 payment determination. CMS notes that there is no additional burden to hospitals associated with this proposal to begin scoring the submitted records.

CMS also proposes to change the requirements for eCQM medical records for validation. Currently, hospitals must submit 100 percent of the requested eCQM medical records to pass the validation requirement. CMS proposes to remove this requirement and proposes that missing eCQM medical records would be treated as mismatches, beginning with the validation of the CY 2025 eCQM data. Under this proposal, eCQM validation scores would be determined using the same methodology that is currently used to score chart-abstracted measure validation, requiring a minimum score of 75 percent accuracy for the hospital to pass the eCQM validation requirement. **CMS invites comment on this proposal and notes that the agency may consider raising the 75 percent threshold in future years.**

CMS is also proposing to remove the combined eCQM and chart-abstracted data validation score and replace it with two separate validation scores – one for chart-abstracted measures and one for eCQMs. CMS proposes that the new validation scores would go into effect for the FY 2028 payment determination and subsequent years. Hospitals would be required to receive passing scores for each type of measure (a 75 percent validation score on the chart-abstracted measures and a 75 percent validation score on the eCQMS validation measure) or the hospital will not receive the full annual payment update.

Medicare Promoting Interoperability Program

In 2011, the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were established to encourage eligible professionals, eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified EHR technology (CEHRT). In recent years, the Medicare and Medicaid EHR Incentive Programs have evolved and are now known as the Medicare Promoting Interoperability (PI) Program.

Under the Medicare PI Program, downward payment adjustments are applied to eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated EHR reporting periods. For FY 2025, CMS proposes several updates to the PI program, including separating the Antimicrobial Use and Resistance (AUR) surveillance measure into two measures, adopting two new eCQMs, and increasing the performance-based scoring threshold for hospitals reporting to the Medicare PI program.

Proposal to Change the Antimicrobial Use and Resistance Surveillance Measure

In the FY 2023 IPPS final rule, CMS finalized a requirement for hospitals and CAHs to report the AUR Surveillance measure beginning in CY 2024. Under the AUR Surveillance measure, hospitals report data for Antimicrobial Use (AU) and Antimicrobial Resistance (AR). Since finalizing this measure, CMS states that hospitals and CAHs have sought clarity on whether qualifying under one of the allowable exclusions prevented the hospitals from reporting any data under the measure. Under current criteria, if the hospital or CAH meets the exclusion criteria for either AU or AR reporting, it does not have to report any data under the AUR Surveillance measure.

After collaborating with CDC, the agencies believe that separating the AUR Surveillance measure into the two measures that comprise the AUR Surveillance measure (the AU and AR measures) will incentivize greater data reporting from eligible hospitals and CAHs and clarify reporting requirements. CMS proposes that, beginning with the EHR reporting period in FY 2025, eligible hospitals and CAHs will now report two measures: (1) the AU Surveillance measure and (2) the AR Surveillance measure. These measures will be reported separately to CDC's NHSN, and eligible hospitals and CAHs will report a "yes" response or claim an exclusion for both measures separately. Further, CMS proposes a related policy applying the current exclusions separately to each measure should a hospital or eligible CAH request an exclusion.

Proposal to Change the Scoring Methodology

The current performance-based scoring threshold for eligible hospitals and CAHs reporting under the Medicare PI program is 60 points. CMS proposes an increase in the minimum scoring threshold from 60 points to 80 points beginning with the EHR reporting period in CY 2025 and subsequent years. The agency notes that 81.5% of eligible hospitals and CAHs exceeded the 80-point threshold in the CY 2022 EHR reporting period. **CMS invites comment on this proposal.**

Proposed Changes to Clinical Quality Measures in Alignment with the Hospital IQR Program

CMS proposes to align the eCQM reporting requirements for the Medicare PI Program with the requirements under the Hospital IQR Program when feasible. Accordingly, CMS proposes to add two proposed Hospital IQR eCQMs: (1) the Hospital Harm – Falls with Injury eCQM; and (2) the Hospital Harm – Postoperative Respiratory Failure eCQM. CMS also proposes to modify the Global Malnutrition Composite Score eCQM to align with the modifications proposed in the Hospital IQR Program. These proposals would take effect beginning with the CY 2026 EHR Reporting period. CMS also proposes that, if this proposal is finalized, these measures would be available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2026 reporting period and subsequent years. **CMS invites comment on this proposal.**

Information Blocking

In November 2023, HHS issued a proposed rule entitled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" (hereinafter, Information Blocking proposed rule). If finalized, the proposed rule would establish certain disincentives for providers found to have participated in information blocking, including financial penalties applied through CMS payments. One proposal would revise the definition of "Meaningful EHR User" in the Medicare PI program to provide that an eligible hospital or CAH is not a meaningful EHR user in an EHR reporting period if a determination is made that the eligible hospital or CAH committed information blocking. This would result in a reduced payment for facilities paid under the IPPS by three-quarters of the annual market basket update applied to the payment year that occurs two years after the year in which the determination of information blocking is made.²¹

CMS notes that if the Information Blocking proposed rule is finalized, the revised definition of Meaningful EHR User would become effective when the Information Blocking final rule takes effect.

Request for Information Regarding Public Health Reporting and Data Exchange

CMS notes that HHS is undertaking an agency-wide effort to address and evolve public health data standards, particularly after the COVID-19 pandemic. These efforts offer an opportunity for CMS to consider how best to evolve the Medicare PI program and the agency seeks information on ways to improve both the overall program and more specifically, the Public Health and Clinical Data Exchange. CMS believes that decision-making and prioritization of policy change should adhere to four goals that the meaningful use of CEHRT enables, including timeliness, quality, and completeness of data; the flexibility to respond to new public health threats; mutual data sharing between public health and healthcare providers, and a reduced reporting burden on eligible hospitals and CAHs. **CMS seeks comment on these four goals through several questions, which are available on pages 1065-1069 of the Proposed Rule**.

²¹ For CAHs, the payment reduction would occur in the year that the determination of information blocking is made.

<u>Conditions of Participation (CoP) Requirements for Hospitals and CAHs to Report Acute</u> <u>Respiratory Illness</u>

Conditions of Participation (CoPs) set out the patient health and safety protections that providers must meet to participate in the Medicare or Medicaid programs. Currently, the CoPs require that hospitals and CAHs have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases. The programs must adhere to nationally recognized infection prevention and control guidelines.

In the FY 2023 IPPS final rule, CMS required hospitals to continue electronically reporting information about cases of COVID-19, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection until April 30, 2024. As this hospital reported data continues to provide important information on respiratory illness burden, CMS proposes to modify the hospital and CAH infection prevention and control and antibiotic stewardship program CoPs to extend a modified form of the current requirements for COVID-19 and influenza reporting requirements. Specifically, hospitals and CAHs would be required to report data on RSV, COVID-19, and influenza, including confirmed infections, hospital bed census and capacity, and limited patient demographic information including age. The proposed changes, which would go into effect October 1, 2024, aim to include data for RSV and reduce the frequency of reporting for hospitals and CAHs. **CMS welcomes** feedback on this proposal, including ways to minimize reporting burden and feedback on the challenges of collecting and reporting this data.

CMS notes that as the current regulations expire on April 30, 2024, there will be a 5-month gap between the current regulations and the beginning of new requirements, if finalized. The agency encourages hospitals and CAHs to continue voluntarily reporting data in the interim, and requests feedback on strategies to mitigate challenges and support this transition.

Soliciting Input on Collecting Data by Race and Ethnicity

CMS notes that COVID-19 disproportionately impacted socially vulnerable populations. However, while the agency is committed to addressing inequities, CMS notes that data standards for the collection of race and ethnicity data are still evolving, which may make it burdensome for facilities to accurately capture this data. **Therefore, CMS seeks comment on whether race and ethnicity demographic information should be included as part of the requirements for the modified CoP.** CMS is specifically interested in the ways that this additional data could be used to better protect patient safety and how to protect patient privacy within demographic groups.

Proposal to Collect Additional Data Elements during a Public Health Emergency

Based on the experiences from the COVID-19 PHE, CMS proposes several changes to the routine collection of data during a public health emergency. Specifically, CMS proposes that, during a PHE for an infectious disease, the Secretary could require daily data collection without notice and comment rulemaking on data elements such as confirmed infections, facility structure and infrastructure and operational status, hospital/ED diversion status, staffing, supply inventory shortages, and medical countermeasures, among others. CMS further proposes that if the Secretary determines that an event is likely to become a PHE for an infectious disease, the Secretary may require hospitals to report daily data without notice and comment rulemaking.

CMS invites comment on whether there should be limits on what data can be collected during a PHE, limits on the duration of additional reporting, how the Secretary can solicit stakeholder feedback on additional elements during a PHE, and how HHS should notify hospitals of new required infectious disease data. The agency also invites comment on what evidence HHS should provide to demonstrate (1) that an event is "significantly likely to

become a PHE"; or (2) that the increased scope of required data will be used to protect patient and community health and safety. Finally, CMS seeks comment on whether hospitals should be incentivized to report this data if the burden of reporting reaches a certain threshold of cost or time.

Collaboration with Other Agencies

CMS notes that it will work with other agencies such as the CDC, the Assistant Secretary for Strategic Preparedness and Response (ASPR), and ONC to establish national standards and interoperability requirements that reduce burden and promote standardization. If finalized, CMS, CDC, and ASPR will work to streamline data reporting across federal, state, and local requirements, and leverage ONC and the USCDI for data exchange. The agency requests feedback on the existing data systems – specifically what has worked well and what has been a challenge.

Request for Information on Health Care Reporting to the National Syndromic Surveillance Program

CDC's National Syndromic Surveillance Program (NSSP) is a collaboration among CDC, other federal agencies, state and local health departments, and academic and private sector partners who have formed a Community of Practice. They collect and share data to analyze data and respond to events of public health concern. Currently, CDC receives data from 78% of the non-federal emergency departments across the US, and CDC hopes to close the participation gap by ensuring that acute care hospitals and CAHs are represented in the NSSP.

The goal of this RFI is to determine how CMS can support CDC in this effort by facilitating hospital and CAH participation in the NSSP. **CMS seeks feedback specifically on potential incentives or requirements for hospital participation in the NSSP, the potential burdens for facilities in creating partnerships with state and local public health jurisdictions without established syndromic reporting programs, and whether this data could be used to inform clinical practice.**

Maternity Care Requestion for Information

As part of CMS's efforts to address the maternal health crisis, the agency seeks to gather information on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients as compared to non-Medicare patients. CMS also seeks information on whether non-Medicare payers use IPPS as a basis for determining their payment rates for inpatient pregnancy and childbirth services and the effect this may have on maternal health outcomes. The RFI seeks information on these practices, including the extent to which payers, such as Medicaid specifically, may use the IPPS for determining payment rates. A full list of questions is available on page 1408 of the Proposed Rule.

Request for Information on Obstetrical Services Standards for Hospitals, CAHs, and REHs

Currently, there are no baseline care requirements for hospitals, CAHs, and rural emergency hospitals (REHs) that are specific to maternal-child health services, or for care for pregnant and postpartum women in other departments of an inpatient facility. Given the ongoing concerns about maternal health care and outcomes, CMS plans to propose baseline health and safety standards for obstetrical services in the CY 2025 Outpatient Prospective Payment System (OPPS) proposed rule.

CMS plans to use this RFI, as well as comments received in the FY 2023 IPPS proposed rule RFI to design proposals in the CY 2025 OPPS proposed rule. **Specifically, CMS seeks comment on what the overarching requirement, scope, and structure should be for an obstetrical services CoP, what types of facilities a CoP should apply to, and other information related to**

requirements and best practices for high quality obstetric care. A full list of questions can be found on pages 1415-1425 of the <u>Proposed Rule</u>.

Transforming Episode Accountability Model (TEAM)

In conjunction with the release of the Proposed Rule, on April 10, the Innovation Center announced a new mandatory 5-year, episode based alternative payment model known as the Transforming Episode Accountability Model (TEAM). Generally, the TEAM would test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories (i.e., coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion). In the Proposed Rule, CMS proposes to implement several general provisions which are consistent with other Innovation Center models and TEAM-specific provisions, which are further detailed below.

A more detailed summary of the TEAM is available here.

What's Next?

CMS is anticipated to publish the final IPPS regulation around August 1, 2024, with the changes being effective at the beginning of the federal fiscal year (October 1, 2024). The comment period closes on June 10, 2024.

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