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Regulatory Update: CMS Proposed Rule – Fiscal Year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) & Long Term Acute Care Hospital (LTCH) Prospective Payment System

May 7, 2018

On Tuesday, April 24, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the 2019 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). Comments are due June 25, 2018 and Vizient looks forward to working with members to help inform our letter to the Agency.

Background & Summary

After accounting for inflation and other adjustments required by law, the proposed rule would increase IPPS rates by 1.75 percent in fiscal year (FY) 2019. The chart below details factors CMS includes in their estimate.

Proposed IPPS Payment Rate Update for FY 2019

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update	2.8%
ACA productivity adjustment	- 0.8%
ACA market-basket cut	- 0.75%
Documentation & coding cut mandated by ATRA, altered by 21st Century Cures Act	0.5%
Estimated payment rate update for FY 2019	**1.75%**

The proposed rule includes an initial market-basket update of 2.9 percent, minus 0.8 percentage points for productivity, and minus 0.75 percentage points mandated by the Affordable Care Act (ACA). Additionally, CMS proposes an increase of 0.5 percentage points to partially restore cuts as a result of the American Taxpayer Relief Act (ATRA). The ACA and ATRA payment adjustments would be applied to all hospitals.

Medicare DSH Payment Changes (DSH Payment Adjustment and Additional Payment for Uncompensated Care)

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

- **Factor 1:** Office of the Actuary estimated of 100% of Medicare DSH payments.
- **Factor 2:** Change in the percentage of uninsured
- **Factor 3:** Proportion of total uncompensated care each Medicare DSH hospital provides

CMS continues to use the National Health Expenditure Accounts (NHEA) to calculate the number of uninsured (Factor 2), as finalized in last year's IPPS/LTCH PPS rulemaking. In using NHEA data, the total amount (in the 75 percent pool) available to Medicare DSH hospitals increases – thus increasing overall Medicare DSH payments to hospitals. The proposed FY 2019 uncompensated care payment (total available) is $8.25 million. CMS projects that the proposed estimated Medicare DSH payments and additional payments for uncompensated care made for FY 2019 would increase payments overall by approximately 1.3 percent as compared to FY 2018.

To determine Factor 3 for FY 2019, CMS is proposing to continue implementing the second year of a three-year phase-in of incorporating data from Worksheet S-10 in the calculation of hospitals' share of the aggregate amount of uncompensated care. Consistent with FY 2018, CMS is proposing to advance the time period of the data used to calculate Factor 3 by one year and using data from FYs 2013, 2014, and 2015 cost reports. CMS will continue to incorporate data from Worksheet S-10 by combining data on uncompensated care costs from Worksheet S-10 for FYs 2014 and 2015 with proxy data regarding a hospital's share of low-income insured days for FY 2013 to determine Factor 3 for FY 2019.

The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the total uncompensated care for all hospitals eligible for Medicare DSH payments – and the payment amount is not directly tied to a hospital's number of discharges.

The estimated impact of the proposed changes to Factors 1, 2, and 3 on uncompensated care payments (UCP) across all hospitals projected to be eligible for DSH payments in FY 2019, by hospital characteristic, is presented in the following table (excerpted from Table 18 of the proposed rule, which provides further detail).

Modeled Uncompensated Care Payments for Estimated FY 2019 DSHs by Hospital Type: Model UCP $ (in millions) from FY 2018 to FY 2019

Hospital Characteristics	Number of Estimated DSHs (FY 2019)	FY 2018 Final Rule CN Estimated UCP $ (in millions)	FY 2019 Proposed Rule Estimated UCP $ (in millions)	Dollar Difference FY 2018 – FY 2019 (in millions)	Percent Change
All hospitals	2,485	$6,767	$8,25	$1,484	21.93%
Geographic location					
Urban	1,962	$6,422	$7,793	$1,371	21.35%
Rural	522	$345	$457	$112	32.50%
Teaching Status					
Non-Teaching	1,545	$2,020	$2,522	$503	24.90%
Fewer than 100 residents	695	$2,246	$2,695	$448	19.96%
100 or more residents	244	$2,501	$3,033	$532	21.27%

The changes projected for FY 2019 uncompensated care payments (compared to FY 2018) are driven by increases in Factor 1 (from $11.665 to $12.221 billion) and Factor 2 (from 58.01 to 67.51 percent) – as well as an increase in the number of hospitals eligible to receive DSH payments in FY 2019. Due to the increases in these two factors, the proposed impact analysis found that FY 2019 uncompensated care payments, across all projected DSH eligible hospitals, are estimated at approximately $8.250 billion, an increase of 21.9 percent from FY 2018 ($6.767 billion).

Proposed Methodology for Calculating Factor 3 for FY 2019

A hospital's Factor 3 determines the proportion of the aggregate amount available for uncompensated care payments that a Medicare DSH eligible hospital will receive under section 3133 of the ACA. Since the publication of the FY 2018 IPPS/LTCH PPS final rule, CMS has continued to monitor the reporting of Worksheet S-10 data in anticipation of using Worksheet S-10 data from hospitals' FY 2014 and FY 2015 cost reports in the calculation of Factor 3.

CMS continues to "believe it is inappropriate to use Worksheet S–10 data for periods prior to FY 2014." Rather, for cost reporting periods prior to FY 2014, CMS believes it is appropriate to continue to use low-income insured days. With a time period that includes 3 cost reporting years consisting of FY 2015, FY 2014, and FY 2013,

CMS is proposing to use Worksheet S–10 data for the FY 2014 and FY 2015 cost reporting periods and the low-income insured days proxy data for the earliest cost reporting period to determine Factor 3 for FY 2019.

CMS will draw three sets of data (1 year of Medicaid utilization data and 2 years of Worksheet S–10 data) from the most recent available Health Care Provider Cost Report Information System (HCRIS) extract. CMS expects to use the March 2018 update of HCRIS for the final rule. However, due to the hurricanes and the extension of the deadline to resubmit S-10 data, CMS may consider using data updated through May 31, 2018, in the final rule, if necessary.

In addition to the Worksheet S–10 data for FY 2014 and FY 2015, CMS is proposing to use Medicaid days from the FY 2013 cost report and FY 2016 SSI ratios for FY 2019. In calculating Factor 3, CMS has adopted a policy under which they annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S-10 if a hospital's cost report does not equal 12 months of data. CMS is still not proposing to annualize SSI days because the agency does not obtain these data from hospital cost reports in HCRIS.

CMS is not proposing any changes to their definition of "uncompensated care". For FY 2019, for purposes of calculating Factor 3 and uncompensated care costs, "uncompensated care" is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

CMS is proposing to discontinue the policy finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year. For FY 2019, CMS is proposing to eliminate the additional step of combining data across multiple cost reports if a hospital filed more than one cost report beginning in the same fiscal year. CMS is proposing to use the data from the cost report that is equivalent to 12 months or, if no such cost report exists, the cost report that is closest to 12 months and annualize the data. In rare cases, a hospital may have multiple cost reports beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year such that the hospital has no cost report for that fiscal year. In these cases, CMS is proposing to use "data from the cost report that spans both fiscal years in the Factor 3 calculation for the latter fiscal year as the hospital would already have data from the preceding cost report that could be used to determine Factor 3 for the previous fiscal year."

CMS is also proposing to continue to apply statistical trim methodologies to potentially aberrant cost-to-charge ratios (CCRs) and potentially aberrant uncompensated care costs reported on the Worksheet S-10 (as finalized in FY 2018). Statute provides that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (i.e., the CCR "ceiling"). CMS recalculates the CCR ceiling annually and publishes it in the proposed and final IPPS rules.

CMS has instructed the Medicare Administrative Contractors (MACs) to review situations with hospitals where they have an extremely high ratio of uncompensated care costs to total operating costs. CMS does not intend to make the MACs' review protocols public. Additionally, hospital cases with extremely large dollar increases or decreases in uncompensated care costs when it resubmits its FY 2014 or FY 2015 Worksheet S-10 data, or when the data previously submitted were reprocessed by the MAC, could undergo further review. Although CMS does not make their review protocols public – they note that it might "be appropriate to review hospitals with increases or decreases in uncompensated care costs in the top 1 percent of such changes." The agency has instructed MACs to review these situations with each hospital.

Therefore, for FY 2019, CMS is proposing to compute Factor 3 for each hospital by:

- **Step 1:** Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio
- **Step 2:** Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;
- **Step 3:** Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and
- **Step 4:** Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

CMS is not making any proposals regarding the development of Factor 3 for FY 2020 and subsequent fiscal years, but notes that this proposed methodology would have the effect of fully transitioning the incorporation of

data from Worksheet S-10 into the calculation of Factor 3 if used in FY 2020. If CMS's proposed methodology is finalized both in FY 2019 and 2020, the use of low-income insured days would be phased out by FY 2020. However, CMS notes that it is also possible that when examining the FY 2016 Worksheet S-10 data, they could determine that the use of multiple years of Worksheet S-10 data is no longer necessary in calculating Factor 3 for FY 2020.

CMS is seeking comments on the proposed methodology for calculating Factor 3 for FY 2019, including, but not limited to, the proposed use of the FY 2013 low-income insured days proxy data, and the FY 2014 and FY 2015 Worksheet S-10 data.

Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet

In prior rulemaking, per ACA requirements, CMS established guidelines that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry.

In this proposed rule, CMS states they still have concerns that patients are unfairly challenged due to insufficient price transparency including being surprised by out-of-network bills for physicians, facility fees and physician fees for emergency room visits. The agency is also concerned that chargemaster data are not helpful to patients in determining what they will likely pay and is considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under current law.

CMS is proposing that effective January 1, 2019, current guidelines will be updated to "require hospitals to make available a list of their current standard charges via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could be in the form of the chargemaster itself or another form of the hospital's choice, as long as the information is in machine readable format."

CMS is considering other potential actions to further their objective of having more consumer-friendly communication of their charges so patients can better understand their financial liabilities and is seeking comment on the following:

- Defining "standard charges";
- What types of information would be most beneficial to patients, and how hospitals can best enable patients to use charge and cost information in their decision-making;
- Should health care providers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service?;
- What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of-pocket obligations will be?; and
- Should CMS require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers?

Furthermore, CMS is considering making information regarding hospital noncompliance with current price transparency law public, and intends to consider this as well as additional enforcement mechanisms in future rulemaking. Thus, CMS is seeking comment on a wide variety of proposals regarding the most appropriate mechanism for enforcing price transparency requirements and penalizing hospitals that are not in compliance.

Proposed Changes to the Medicare and Medicaid EHR Incentive Programs

In 2011, the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were established to encourage eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology (CEHRT). In this rule, CMS is proposing to overhaul the Medicare and Medicaid Electronic Health Record Incentive Programs (also known as the "Meaningful Use" program).

CMS is proposing to rename the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs as the "Medicare and Medicaid Promoting Interoperability Programs", or "Promoting Interoperability (PI) Programs".

CMS is increasing focus on interoperability and improving patient access to health care information and believes that the change in name better reflects this focus. Last year, CMS changed a previously finalized policy and provided flexibility for hospitals to use the 2014 Edition certification criteria, the 2015 Edition certification criteria, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination. However, CMS is proposing that for the EHR reporting period beginning in CY 2019, use of 2015 Edition CEHRT is required.

CMS is proposing changes to requirements pertaining to the clinical quality measurement of eligible hospitals and CAHs participating in the PI Programs. For FY 2019, depending on whether a hospital submits quality data under the rules established (referred to as a hospital that submits quality data) and is a meaningful EHR user under statute (referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount as specified in the following table.

Proposed Payment Updates for FY 2019

FY 2019	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 Adjustment for Failure to Submit Quality Data	0	0	-0.7	-0.7
Proposed Adjustment for Failure to be a Meaningful EHR User	0	-2.1	0	-2.1
Proposed Applicable Percentage Increase Applied to Standardized Amount	**1.25**	**-0.85**	**0.55**	**-1.55**

IPPS hospitals and CAHs that did not achieve meaningful use of EHRs under the Medicare EHR Incentive Program for 2017 can apply for a hardship exception to avoid a payment adjustment in FY 2019. IPPS hospitals must request the hardship exception by July 1, 2018 and CAHs by Nov. 30, 2018.

CMS is proposing EHR reporting periods in 2019 and 2020 for both new and returning participants attesting to CMS or their State Medicaid agency to be a minimum of any continuous 90-day period within each of the calendar years 2019 and 2020. CMS notes that the "applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2019 and 2020, as well as the deadlines for attestation and other related program requirements" would not change. CMS is seeking comment on these proposals.

Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

CMS has placed regulatory reform and reducing regulatory burden as top priorities. In October 2017, the agency launched the Meaningful Measures Initiative to reduce the regulatory burden on the health care industry. The goals of this initiative are to foster operational efficiencies and reduce costs while producing quality measures that are easier to collect and report and are more focused on meaningful outcomes. CMS has identified a list of measure priority areas, and is using them to review measures in its quality and value programs.

CMS has undertaken efforts to review the existing measure sets in the Hospital Readmissions Reduction Program (HRRP), the Hospital Value-Based Purchasing (HVP) Program, and the Hospital-Acquired Conditions (HAC) Reduction Program. Under CMS's review of existing measures as part of the Meaningful Measures Initiative, the agency is evaluating the appropriateness of the measures, and views the three hospital value-based purchasing programs together as a collective set. The agency, in accordance with the Meaningful Measures Initiative, offers significant proposals in the FY 2019 IPPS/LTCH PPS rulemaking.

The agency is engaging in efforts to ensure that all quality program measure sets continue to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with each program. CMS notes that they believe these costs are multifaceted – including not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program.

CMS has identified several different types of "costs" – including but not limited to the following:

- Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS;
- The provider and clinician cost associated with complying with other quality programmatic requirements;
- The provider and clinician cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs;
- The CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and
- The provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable).

Hospital Readmissions Reduction Program – Proposed Updates and Policy Changes

The Hospital Readmissions Reduction Program (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.

For FY 2018 and subsequent years, the payment reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for six applicable conditions/procedures: acute myocardial infarction (AMI); heart failure (HF); pneumonia; total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG).

CMS notes that within the Meaningful Measures Initiative, the HRRP focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination. The agency believes the HRRP incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them. Under CMS's review of existing measures as part of the Meaningful Measures Initiative, the agency determined that the six readmission measures in the HRRP (which are proposed for removal from the Hospital Inpatient Quality Reporting (IQR) Program) are nevertheless appropriately included as part of HRRP, and are not proposing to adopt any new measures at this time.

CMS proposes that the FY 2019 "applicable period" for the HRRP would be the 3-year period from July 1, 2014 through June 30, 2017. The agency proposes subsequent 3-year periods for FY 2020 and FY 2021. For the FY 2019 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2019 applicable period before they are made public under existing policy regarding reporting of hospital-specific information; this period is to review the program calculations, and not the underlying data.

Per 21st Century Cures Act requirements, CMS finalized policies in last year's rulemaking to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. CMS is not proposing any changes to the payment adjustment methodology for FY 2019 or subsequent years. For FY 2019, a hospital subject to the HRRP would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

Hospital Value-Based Purchasing (VBP) Program – Proposed Updates and Policy Changes

The ACA established a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. The applicable percent for the FY 2019 program year as required by statute is 2.00 percent. CMS estimates that the total amount available for value-based incentive payments for FY 2019 is approximately $1.9 billion, based on the December 2017 update of the FY 2017 MedPAR file.

CMS published proxy value-based incentive payment adjustment factors in Table 16 of the proposed rule. The proxy factors are based on the Total Performance Score (TPS) from the FY 2018 program year; these performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. CMS intends to update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2018 update to the FY 2017 MedPAR file. CMS will also update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2019 will continue to be based on historic FY 2018 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2019 program year until after the FY 2019 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2019, the agency will add Table 16B (which will be available on the CMS website in the fall of 2018) to display the actual value-based incentive payment adjustment factors.

Retention and Proposed Removal of Quality Measures

In prior rulemaking, CMS finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. CMS is proposing to revise the regulation text to clarify that hospital VBP measures will be selected from the measures specified under the Hospital Inpatient Quality Reporting (IQR) Program – but the Hospital VBP Program measure set will not necessarily be a subset of the Hospital IQR Program measure set (i.e., the statute does not require that the measure continue to remain in the Hospital IQR Program). CMS states this will allow the agency to remove duplicative measures from the Hospital IQR Program that are retained in the Hospital VBP Program. Additionally, CMS is proposing to adopt the Hospital IQR Program measure removal factors for use in determining whether to remove Hospital VBP Program measures. In alignment with proposals being made for other quality reporting and value-based purchasing programs, CMS is proposing to adopt the one additional factor to consider when evaluating measures for removal from the Hospital VBP Program measure set: “Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.”

The agency is engaging in efforts to ensure that the Hospital VBP Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. CMS states that when these costs outweigh the evidence supporting the continued use of a measure it may be appropriate to remove the measure from the Hospital VBP Program. The agency is proposing that they would remove measures based on this factor on a case-by-case basis. Additionally, to further align with the Hospital IQR Program, CMS is proposing that if they believe continued use of a measure in the Hospital VBP Program poses specific patient safety concerns, the agency may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal and the reasons through routine communication which could include (but is not limited to) memos, emails, and online notices.

CMS is seeking feedback on the proposals to adopt for the Hospital VBP Program the measure removal factors adopted in the Hospital IQR Program, and a measure removal factor for when costs outweigh the benefit beginning with FY 2019. The agency is also seeking feedback on the proposal to allow the Hospital VBP Program to promptly remove a measure without rulemaking if CMS believes the measure poses specific patient safety concerns.

Proposed Removal of Ten Measures from the Hospital VBP Program

Under CMS’s review of existing measures as part of the Meaningful Measures Initiative, the agency believes the Hospital VBP Program should focus on the measurement priorities not covered by the HRRP or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) the clinical outcomes, such as mortality and complications; (2) patient and caregiver experience, as measured using the HCAHPS survey; and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure.

CMS is proposing to remove the following 10 measures previously adopted for the Hospital VBP Program:

1) Elective Delivery (NQF #0469) (PC-01);
2) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
3) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);

4) American College of Surgeons-Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
5) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia);
6) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) (CDI);
7) Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90);
8) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
9) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
10) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

Measures 1 through 6 above would be effective with the FY 2021 program year with data collection ending with Dec. 31, 2018 discharges. Measures 7 through 10 would be effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

CMS seeks feedback on the proposals to remove these measures, including specific feedback on individual measures. CMS is also requesting feedback on whether there are reasons to retain any of these measures in the Hospital VBP Program. Additionally, they are seeking comments on whether the removal of the five healthcare-associated infections (HAIs) measures from this program and their retention in the HAC Reduction Program would continue to provide a strong incentive for performance on these patient safety measures.

In the FY 2018 IPPS/LTCH PPS final rule CMS finalized the measure set for the Hospital VBP Program for the FY 2020 program year; they are not proposing any changes (new measures) to be added in this proposed rule.

Measures for the FY 2021 – FY 2023 Program Years if Proposals for Removal of Measures are Finalized
For the FY 2021 program year, CMS is proposing to remove six measures from the Safety domain (PC-01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) – which, because the Safety domain consists only of six measures, means they are proposing to remove the entire Safety domain itself. All of the HAI measures will be retained in the HAC reduction program. Additionally, CMS is proposing to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment).

CMS is proposing to change the name of the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year. If the proposals to remove all of the current Safety domain measures are adopted – beginning in the FY 2021 program year, CMS is proposing to increase the weight of the three remaining domains to the following: Clinical Outcomes (50%), Person and Community Engagement (25%) and Efficiency and Cost Reduction (25%). CMS is not proposing changing the previously adopted minimum number of cases for these measures required for hospitals in the Hospital VBP Program for the FY 2021 program year and subsequent years. In this proposed rule, CMS is not proposing any changes to the length of any of the performance or baseline periods. Additionally, CMS is seeking comment on the proposed performance standards for the FY 2021 through FY 2024 program years.

CMS is seeking feedback on all of these proposals – including whether they should keep the Safety domain along with one or more of its measures, and alternatively weighting the three domains equally, meaning that each would be weighted as one-third (1/3) of a hospital's TPS.

Hospital-Acquired Condition (HAC) Reduction Program – Proposed Updates and Policy Changes

The 1-percent payment reduction established by the ACA for the Hospital Acquired Conditions (HAC) program applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. A hospital's Total HAC score and its ranking in comparison to other hospitals in any given year will depend on several different factors.

The HAC Reduction Program focuses on patient safety measures which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. Measures in the

HAC Reduction Program generally represent “never ever” events and assess preventable conditions. Therefore, under CMS’s review of existing measures as part of the Meaningful Measures Initiative, the agency determined that the Patient Safety and Adverse Events Composite (PSI 90) and the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures (NHSN HAI measures) are most appropriately included as part of the HAC Reduction Program. CMS is proposing to remove these measures from the Hospital IQR and VBP Programs, and notes that they believe this will enable hospitals and patients to gather meaningful information about hospital performance, while streamlining the measure sets.

CMS is proposing that the HAC Reduction Program formally adopt analogous processes and independently manage these processes to receive CDC NHSN data and begin validation seamlessly with January 1, 2019 infections events. However – this proposal is contingent upon finalizing the proposal to remove NHSN HAI measures from the Hospital IQR Program. CMS notes that if that Hospital IQR Program proposal is not finalized, they would subsequently not finalize HAC Reduction Program proposals to manage the associated administrative processes.

The HAC Reduction Program currently utilizes five NHSN measures, with their full names in the following table:

HAC Reduction Program Measures for FY 2019 and Subsequent Years

Short Name	Measure Name	NQF #
Domain 1		
CMS PSI 90	Patient Safety and Adverse Events Composite	0531
Domain 2		
CAUTI	NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measures	1716

For measures adopted in the HAC Reduction Program, CMS will continue to use rulemaking to adopt substantive updates, and a subregulatory process to make non-substantive updates.

Proposed Data Collection Beginning CY 2019

CMS is proposing to adopt data collection processes for the HAC Reduction Program to receive CDC NHSN data beginning with January 1, 2019 infection events. This proposal corresponds with the Hospital IQR Program’s calendar year reporting period and maintains the HAC Reduction Program’s annual performance period start date. Current Hospital IQR Program reporting requirements would not change – which would aid continued hospital reporting through “clear and consistent” requirements. Additionally, CMS notes their proposed start date aligns with the effective date of the Hospital IQR Program’s proposed removal of these measures beginning with CY 2019 reporting period/FY 2021 payment determination to hopefully allow for a seamless transition.

In order to calculate a Total HAC Score, CMS is required to collect claims-based and chart-abstracted data from the CMS PSI 90 and NHSN HAI measures, respectively. The CMS PSI 90 measure is a claims-based measure calculated using data submitted to CMS by hospitals, and therefore does not impose additional administration or reporting requirements on participating hospitals – and does not require an additional collection mechanism. If the proposal to remove the NHSN HAI measures from the Hospital IQR Program is finalized, CMS is proposing to adopt the HAI data collection process established in the Hospital IQR Program. Thus, hospitals would continue to submit data through the CDC NHSN portal, and the HAC Reduction Program would receive the NHSN data directly from the CDC instead of through the Hospital IQR Program as an intermediary. Additionally, CMS is proposing to adopt the Hospital IQR Program's exception policy to reporting and data submission requirements for the CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI measures. If a hospital does not have adequate locations or procedures, it should submit the Measure Exception Form to the HAC Reduction Program beginning on January 1, 2019.

Beginning in FY 2019, the HAC Reduction Program would provide the same NHSN HAI measures quarterly reports that providers are familiar with under the Hospital IQR Program. However, hospitals that do not participate in the Hospital IQR Program may be unfamiliar with them. CMS notes that these hospitals will need to register for a QualityNet Secure Portal Account to access their reports, and anticipates the "transition to occur without interruption" with the only change being that hospitals would "receive reports from both the HAC Reduction Program and the Hospital IQR Program for the respective measures adopted in each program." CMS is not proposing any changes to the current administrative policies regarding the submission, review, and correction of claims data or of chart-abstracted HAI data.

Proposed Changes to Existing Validation Processes

CMS is proposing to adopt processes to validate the NHSN HAI measure data used in the HAC reduction Program (if the Hospital IQR Program proposals are finalized). CMS states that although the HAC Reduction Program cannot adopt the Hospital IQR Program's process, the agency intends for the processes to reflect, to the greatest extent possible, the current processes previously established the Hospital IQR Program.

CMS is proposing to adopt the validation processes into the HAC Reduction Program as previously established by the Hospital IQR Program – with some exceptions (detailed below) regarding: proposed measures subject to validation section; proposed provider selection; proposed targeting criteria; proposed calculation of the confidence period; proposed educational review process; proposed application of validation penalty; and proposed validation period. CMS is seeking feedback on all of these proposals.

- CMS is proposing that chart-abstracted NHSN HAI measures submitted via NHSN would be subject to validation in the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022.
- CMS is proposing to include all subsection (d) hospitals in the provider sample for validation beginning with the Q3 2019 discharges for FY 2022.
- CMS is proposing the following targeting criteria for the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022: any hospital that failed validation the previous year; any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed; any hospital that not been randomly selected for validation in the past 3 years; any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; and any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.
- CMS is proposing that beginning in FY 2022: (1) the agency would score hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol; (2) the agency would compute a confidence interval; (3) if the upper bound of this confidence interval is 75 percent or higher, the hospital would pass the HAC Reduction Program validation requirement; and (4) if the upper bound is below 75 percent, the hospital would fail the HAC Reduction Program validation requirement.
- CMS is proposing an educational review process beginning with Q3 2019 data validation, such that hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review (the same as the Hospital IQR Program). However, unlike the Hospital IQR Program educational review process – CMS is proposing that if an educational review is timely requested and an error is identified in the 4th quarter of review, the agency would use the corrected quarterly score to compute the final confidence interval.

- CMS is proposing that if a hospital does not meet the overall validation requirement, the agency would penalize hospitals that fail validation by assigning the maximum Winsorized z-score only for the set of measures CMS validated.
- CMS is we are proposing that the performance period would remain 2 calendar years and that the validation period would include the four middle quarters in the HAC Reduction Program performance period (i.e., third quarter through second quarter). The agency is proposing that the HAC Reduction Program would begin validation of NHSN HAI measures data with July 2019 infection event data.

CMS is proposing to adopt the Hospital IQR Program's Data Accuracy and Completeness Acknowledgment (DACA) for the HAC Reduction Program (if the Hospital IQR Program proposals are finalized). The agency is proposing the initial HAC Reduction Program annual DACA signing and completing period to be April 1 through May 15, 2020 for calendar year 2019 data. CMS is not proposing any changes to the review and correction procedures for FY 2019 – however, they are proposing to rename the annual 30-day review and correction period to the "Scoring Calculations Review and Correction Period."

CMS is proposing to maintain the current policy of reporting data under the Hospital IQR Program as soon as it is feasible on CMS websites (e.g., *Hospital Compare*), after a 30-day preview period. In other words, CMS is proposing to make the HAC Reduction Program data available in the same form and manner as currently displayed under the Hospital IQR Program.

Proposed Changes to the HAC Reduction Program Scoring Methodology

In order to allow the scoring methodology to continue to fairly assess all hospitals, CMS examined alternative scoring options. CMS offers discussion and proposals on two alternative scoring methodologies for calculating hospitals' Total HAC Scores – "Equal Measure Weights" and "Variable Domain Weights." CMS proposes their preferred approach, the Equal Measure Weights policy, which involves removing domains and applying an equal weight to each measure for which a hospital has a measure score in Total HAC Score calculations. However, CMS is also seeking comment on an additional approach: applying a different weight to each domain depending on the number of measures for which a hospital has a measure score (Variable Domain Weights).

Estimated Impact of Scoring Approaches on Percentage of Hospitals in Worst-Performing Quartile by Hospital Group

Hospital Group*	Equal Measure Weights	Variable Domain Weights
Teaching hospitals: 100 or more residents (N=248)	2.4%	1.6%
Safety-net** (N=644)	0.6%	0.8%
Urban hospitals: 400 or more beds (N=360)	2.2%	1.1%
Hospitals with 100 or fewer beds (N=1,169)	-1.8%	-0.9%
Hospitals with a measure score for:		
Zero Domain 2 measures (N=188)	0.0%	0.0%
One Domain 2 measure (N=269)	-4.2%	-1.9%
Two Domain 2 measures (N=225)	-0.8%	-0.4%
Three Domain 2 measures (N=198)	-2.5%	-2.5%
Four Domain 2 measures (N=253)	-0.4%	0.4%
Five Domain 2 measure (N=2,022)	1.0%	0.5%

* The number of hospitals in the given hospital group for FY 2018 is specified in parenthesis in this column (for example, N=248)
** Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent

CMS is seeking comment on both the agency's proposed preferred change to the HAC Reduction Program scoring methodology (Equal Measure Weights) and the alternative (Variable Domain Weights). Additionally, CMS is proposing the applicable period for the FY 2021 HAC Reduction Program for the CMS PSI 90 as the 24-

month period from July 1, 2017 through June 30, 2019, and the applicable period for NHSN HAI measures as the 24-month period from January 1, 2018 through December 31, 2019.

Request for Comments on Additional Measures for Potential Future Adoption

As CMS has done in previous rulemaking, the agency continues to seek comments and suggestions from stakeholders on the adoption of additional Program measures. CMS is also specifically seeking comments on whether electronic clinical quality measures (eCQMs) would benefit the program at some point in the future. CMS states that that they "believe eCQMs will allow for the improved measurement of processes, observations, treatments and outcomes". The agency invites comments and suggestions on future measures, including eCQMs, for the HAC Reduction Program.

Hospital Inpatient Quality Reporting (IQR) Program – Proposed Updates and Policy Changes

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

CMS is proposing a number of changes and new policies for the Hospital IQR Program. CMS believes that the Hospital IQR Program should focus on measure topics not covered in the other programs' measures. With CMS's review of existing measures, the agency is proposing to add a new measure removal factor, and to remove a total of 39 measures from the Hospital IQR Program (over calendar years (CY) 2018 – 2021). Additionally, CMS notes that these proposals reflect efforts to improve the usefulness of data that is publicly reported in the Hospital IQR Program.

CMS acknowledges that while some overlap may exist between the Hospital IQR Program measure set and the Hospital VBP measure set, their proposals to allow removal of duplicative measures from the Hospital IQR Program once they have been adopted into the Hospital VBP Program would further their efforts towards the goals of reducing costs, increasing efficiencies and improving patient experience. CMS is not proposing any changes to policies on the quality measure maintenance process or the public display of quality measures for the Hospital IQR Program.

Additionally, CMS is proposing for the CY 2019 reporting period/FY 2021 payment determination to:

1) Require the same eCQM reporting requirements that were adopted for the CY 2018 reporting period/FY 2020 payment determination (i.e., hospitals submit one, self-selected calendar quarter of 2019 discharge data for 4 eCQMs in the Hospital IQR Program measure set); and
2) Require that hospitals use the 2015 Edition certification criteria for CEHRT.

CMS notes that these proposals are aligned with both current policies and proposals in this regulation under the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) – and is seeking comments from stakeholders.

Removal Factors for Hospital IQR Program Measures

CMS's current policy for the Hospital IQR Program is to adopt Program measures beginning with a particular payment determination, and automatically readopt them for subsequent payment determinations unless they propose to remove, suspend, or replace the measures.

CMS currently has seven measure removal and retention factors, which they are not proposing to change:

Factor 1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, "topped-out" measures): statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤ 0.10.
Factor 2) A measure does not align with the current clinical guidelines or practice.
Factor 3) The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic).
Factor 4) Performance or improvement on a measure does not result in better patient outcomes.
Factor 5) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

Factor 6) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
Factor 7) It is not feasible to implement the measure specifications.

CMS is proposing to adopt an additional factor: **Factor 8)** The costs associated with a measure outweigh the benefit of its continued use in the program.

CMS states that when publicly reported data (including payment determination data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers, that removing measures from the IQR program may better accommodate the cost of the program and compliance without compromising health outcomes and beneficiary choice. In alignment with the proposals to the Hospital VBP Program, CMS is also proposing that they would remove measures from the Hospital IQR Program based on this factor on a case-by-case basis, beginning with the effective date of the final FY 2019 IPPS/LTCH PPS rule. The agency is seeking comment on the proposed eighth factor.

Proposed Removal of Hospital IQR Program Measures

CMS is proposing to remove a total of 39 previously adopted measures from the Hospital IQR Program across the FYs 2020, 2021, 2022, and 2023 payment determinations. Of the 39 measures, CMS is proposing to remove 18 measures that are "topped out", no longer relevant, or where the burden of data collection outweighs the measure's ability to contribute to improved quality of care. CMS is also proposing to "de-duplicate" 21 measures to "simplify and streamline measures across programs"; these measures remain in one of the four other hospital quality programs.

- Beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years, CMS is proposing to remove 17 claims-based measures and two structural measures.
- Beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years, CMS is proposing to remove eight chart-abstracted measures and two claims-based measures.
- Beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years, CMS is proposing to remove one chart-abstracted measure, one claims-based measure, and seven eCQMs.
- Beginning with the CY 2021 reporting period/FY 2023 payment determination, CMS is proposing to remove one claims-based measure.

The complete, detailed list of the 39 measure names and removal rationale can be found on the CMS website. CMS is seeking comment on the removal of each individual measure.

Possible New Quality Measures, Measure Topics, and Other Future Considerations

CMS developed two versions of a hospital-wide, all-cause, risk-standardized mortality measure: one calculated using only claims data (referred to as the "Claims-Only HWM measure"); and a hybrid version that uses claims data to define the measure cohort and a combination of data from EHRs and claims for risk adjustment (referred to as the "Hybrid HWM measure).

CMS developed a Hybrid HWM measure in addition to a Claims-Only HWM measure in response to stakeholder feedback on the importance of using clinical data in outcome measures, and to move toward greater use of EHR data for quality measurement. The Hybrid HWM measure is harmonized with the Claims-Only HWM measure – both use the same cohort definition, outcome assessment, and claims-based risk variables. The agency notes that they are currently collecting data from hospitals on a voluntary basis for the Hybrid HWM (NQF #2879) and are considering proposing it as a required measure in the Hospital IQR Program as early as the FY 2023 payment determination. CMS plans to submit both measures to the National Quality Forum (NQF) for endorsement proceedings as part of the Patient Safety Committee as early as FY 2019, after the measures have been fully specified for use with ICD-10 data. Additional information on the development of both the Claims-Only and Hybrid versions of the HWM measure can be found on the CMS website.

CMS is seeking comment on the possible future inclusion of one or both hospital-wide mortality measures in the Hospital IQR Program simultaneously. The agency is also considering possible future inclusion of the Hybrid HWM measure in the Medicare and Medicaid Promoting Interoperability Programs for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs. Additionally, CMS is seeking comment on other aspects of the measure including structure and validity testing.

CMS has developed and is proposing the Hospital Harm – Opioid-Related Adverse Events eCQM to reduce adverse events in surgical and non-surgical patients receiving opioids. This outcome measure assesses, by hospital, the proportion of patients who had an opioid-related adverse event. The agency believes that by measuring the adverse rates of these events at each hospital in a systematic, comparable way, they can better assess them, as well as the variation in rates among hospitals. The measure uses the administration of naloxone, an opioid reversal agent. This measure was reviewed by the NQF Measure Applications Partnership (MAP) Hospital Workgroup in December 2017 and received the recommendation to refine and resubmit for consideration for programmatic inclusion. CMS plans to submit the measure for NQF endorsement as part of the Patient Safety Committee in November 2018.

CMS is seeking comment on the possible future inclusion of the Hospital Harm – Opioid-Related Adverse Events eCQM in the Hospital IQR Program. The agency is seeking feedback specifically on 1) whether to introduce the measure as voluntary, initially; 2) adopting the measure into the existing eCQM measure set; or 3) adopting the measure as mandatory for all hospitals to report. Furthermore, CMS is seeking feedback on ways to address any potential unintended consequences that may result from implementation of this measure. CMS is also considering future adoption of this measure in the Medicare and Medicaid Promoting Interoperability Programs for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs.

Additionally, CMS is seeking comment on the potential future development and adoption of electronic clinical quality measures (eCQMs) generally. They note that the implementation of eCQMs can be a significant source of cost for providers for a variety of reasons. CMS is seeking feedback on ways they could address the challenges related to eCQM use. Specifically, CMS poses the following questions for comment:

1) What aspects of the use of eCQMs are most costly to hospitals and health IT vendors?
2) What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM costs?
3) What are the most significant barriers to the availability and use of new eCQMs today?
4) What specifically would stakeholders like to see CMS do to reduce costs and maximize the benefits of eCQMs?
5) How could CMS encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
6) How could CMS encourage hospitals and health IT vendors to engage in testing new eCQMs?
7) Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?
8) What ways could CMS incentivize or reward innovative uses of health IT that could reduce costs for hospitals?
9) What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The proposed rule would streamline the measure removal and retention process for the PCHQR Program following the same factors outlined in the IQR above. Thus, CMS is proposing to remove four web-based, structural measures from the PCHQR Program beginning with the FY 2021 program year because they are topped-out:

- Oncology: Radiation Dose Limits to Normal Tissues (PCH-14/NQF #0382);
- Oncology: Medical and Radiation – Pain Intensity Quantified (PCH-16/NQF #0384);
- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH-17/NQF #0390);
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH-18/NQF #0389).

CMS is also proposing to apply the newly proposed measure removal factor to two National Healthcare Safety Network (NHSN) chart-abstracted measures and, if that factor is finalized, to remove both measures from the PCHQR Program beginning with the FY 2021 program year because they have concluded that the costs associated with these measures outweigh the benefit of their continued use in the program.

- NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH-5/NQF #0138);
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH-4/NQF #0139).

In an effort to expand the PCHQR Program measure set to include measures that are less burdensome to report to CMS, but provide valuable information for beneficiaries, CMS is proposing to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years. CMS states that this measure aligns with the Promote Effective Communication and Coordination of Care domain of the Meaningful Measures Initiative and would fill an existing gap area of risk-adjusted readmission measures in the PCHQR Program.

Accounting for Social Risk Factors in Quality Programs

Following their request for information in FY 2018 rulemaking, the agency continues to seek public comment on whether they should account for social risk factors in quality programs, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. In this proposed rule, CMS is continuing to consider options to "improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures." The agency notes that they plan to continue working with stakeholders to look for policy solutions that will lead to health equity among all beneficiaries while minimizing unintended consequences and that they will continue to look for options to address equity and disparities in VBP programs.

In this proposed rule, CMS is only considering specific policies pertaining to social risk factors for the Hospital IQR Program. The agency is considering implementing two methods that would promote health equity and health care quality for patients with social risk factors. The first method – a hospital-specific disparity method – would calculate differences in outcome rates among patient groups within a hospital, taking into account their clinical risk factors. CMS notes that this would allow for a comparison of those differences, or disparities, across hospitals – so that hospitals could assess how well they are closing disparities gaps compared to other hospitals. The second methodological approach is complementary to the first, and would assess hospitals' outcome rates for subgroups of patients (e.g., dual-eligibles) across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors.

CMS acknowledges "the complexity of interpreting stratified outcome measures." CMS indicated in the FY 2018 IPPS/LTCH PPS final rule that prior to any future public reporting, they planned to stratify the Pneumonia Readmission measure (NQF #0506) data by providing both hospital-specific disparities and readmission rates specific for dual-eligible beneficiaries across hospitals in hospitals' confidential feedback reports beginning Fall 2018. In this proposed rule, CMS states that for simplicity's sake, they are planning to provide confidential feedback reports for the Pneumonia Readmission measure using both methodologies.

For the future, CMS is considering 1) expanding efforts to provide stratified data in hospital confidential feedback reports for other measures; 2) including other social risk factors beyond dual-eligible status in hospital confidential feedback reports; and 3) eventually, making stratified data publicly available on the *Hospital Compare* website. Additionally, a Technical Expert Panel (TEP) – contracted by CMS – will be convened in the spring of 2018 to solicit feedback from stakeholders on approaches to consider for stratification for the Hospital IQR Program. CMS anticipates receiving additional input from hospitals when they receive confidential feedback reports of the stratified results and will encourage stakeholders to submit comments. The agency is further considering how these methodologies may be adapted in the future to apply to other CMS quality programs.

Implementation of Recent Legislation

Low-Volume Hospitals

The Bipartisan Budget Act of 2018 (BiBA) retroactively extended the enhanced low-volume payment adjustment for FY 2018, which CMS addresses in a separate notice (CMS-1677-N).

For FYs 2019 through 2022, BiBA modifies the definition of a low-volume hospital and the methodology for calculating the payment adjustment. Specifically, section 50204 of BiBA amended the qualifying criteria for low-volume hospitals to specify that, for FYs 2019 through 2022, a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital; and has fewer than 3,800 total discharges during

the fiscal year. For qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, CMS is proposing the low-volume hospital payment adjustment for FYs 2019 through 2022 and how it will be calculated. Additionally, for FY 2019, a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and new total discharge criteria. Consistent with prior practice, a hospital's written request must be received by its MAC no later than September 1, 2018 in order for the enhanced low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2018.

Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011.

Medicare Dependent Hospital (MDH) Program

BiBA extended the MDH program for FYs 2018 through 2022 (that is, for discharges occurring before October 1, 2022). Consistent with previous extensions of the MDH program, a provider that was classified as an MDH as of September 30, 2017 was reinstated as an MDH effective October 1, 2017, with no need to reapply for MDH classification. Further details on this extension are addressed in a separate notice (CMS-1677-N).

Post-Acute Care Transfer Policy

BiBA required that beginning in FY 2019, discharges to hospice care will also qualify as a post-acute care transfer and be subject to payment adjustments. Accordingly, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS-DRGs subject to the post-acute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge would be subject to payment as a transfer case. CMS is proposing that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice - Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) would be subject to the post-acute care transfer policy.

Proposed Application of the Rural and Imputed Floors

Proposed Expiration of Imputed Floor Policy

In the FY 2005 IPPS final rule, CMS implemented an "imputed floor" policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban states that they are disadvantaged by the absence of rural hospitals to set a wage index floor. CMS has extended the imputed floor policy eight times, the last of which was finalized in the FY 2018 IPPS/LTCH PPS rulemaking. The imputed floor is set to expire effective October 1, 2018, and in this FY 2019 proposed rule, CMS is not proposing to extend the imputed floor policy. That is, hospitals in New Jersey, Delaware, and Rhode Island (and in any other all-urban state) would receive a wage index that is calculated without applying an imputed floor for FY 2019 and subsequent years. Thus, only states containing both rural areas and hospitals located in such areas would benefit from the rural floor.

Proposed Rural Floor

Statute requires that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state – a provision referred to as the "rural floor." Based on the proposed FY 2019 wage index (available on the CMS website), CMS estimates that 255 hospitals would receive an increase in their FY 2019 proposed wage index due to the application of the rural floor.

Proposed Changes Relating to Medicare GME Agreements for New Urban Teaching Hospitals

CMS is proposing to provide new urban teaching hospitals with greater flexibility under the regulation governing Medicare Graduate Medical Education (GME) affiliation agreements. Currently, if a new urban teaching hospital participates in a Medicare GME affiliation agreement, it can only receive an increase in its cap(s) as part of that agreement.

CMS is proposing to allow new urban teaching hospitals to be permitted to loan slots to other new urban teaching hospitals beginning July 1, 2019. CMS would continue to prohibit these hospitals from loaning their cap slots to other "existing teaching hospitals," which CMS defines as hospitals whose GME caps were set in the 1996 base year. CMS believes the proposal will help facilitate more physician training in local, smaller communities.

Proposed Revision – Hospital Inpatient Admission Orders Documentation Requirements

CMS is proposing to remove the requirement that written inpatient admission orders are a specific requirement for Medicare Part A payment. Specifically, CMS is proposing to revise the inpatient admission order policy to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment. CMS notes that they are not proposing any changes with respect to the "2 midnight" payment policy.

Proposed Changes to Regulations Governing Satellite Facilities

Under current statute, "a satellite facility is defined as part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital." The current separateness and control policies for satellite facilities were originally aimed to mitigate concerns that the co-location of a satellite facility and a host hospital could potentially lead to inappropriate patient shifting. However, CMS now believes that prior concerns where IPPS-excluded satellite facilities are co-located with IPPS-excluded host hospitals have been sufficiently mitigated. Thus, CMS is proposing to revise current regulations to only require IPPS-excluded satellite facilities that are co-located with IPPS hospitals to comply with the separateness and control requirements.

Specifically, CMS is proposing to specify that, "effective on or after October 1, 2018, a satellite facility that is part of an IPPS-excluded hospital that provides inpatient services in a building also used by an IPPS-excluded hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS-excluded hospital, is not required to meet the criteria" of current satellite facility requirements in order to be excluded from the IPPS. CMS is proposing to revise the regulation so that it also specifies "that a satellite facility that is part of an IPPS-excluded hospital which is located in a building also used by an IPPS hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS hospital, is still required to meet the criteria in order to be excluded from the IPPS."

CMS is proposing that, for cost reporting periods beginning on or after October 1, 2019, an IPPS excluded hospital would no longer be precluded from having an excluded psychiatric and/or rehabilitation unit. Consistent with the proposed changes to the regulations governing satellite facilities, CMS is proposing to specify "that an IPPS-excluded satellite facility of an IPPS-excluded unit of an IPPS-excluded hospital would not have to comply with the separateness and control requirements so long as the satellite of the excluded unit is not co-located with an IPPS hospital."

All hospitals must comply with the hospital conditions of participation (CoPs) – and CMS notes that payment rules never waive or supersede CoP requirements. All hospitals must demonstrate separate and independent compliance with the hospital CoPs – even if a part of a hospital is located in a building used by another hospital. Additionally, CMS notes that this proposal would not affect IPPS-excluded satellite facilities that are co-located with IPPS hospitals that are currently grandfathered under statute. Grandfathered satellite facilities would continue to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as all applicable requirements in the statute are met.

Proposed Elimination of the "25-Percent Threshold Policy" Adjustment for LTCHs

CMS is proposing to eliminate the 25-percent threshold policy, which is a per-discharge payment adjustment in the LTCH PPS. Currently, implementation of the 25-percent threshold policy is under a regulatory moratorium until Oct. 1, 2018. CMS acknowledges that original concerns that led to the policy originally "have been ameliorated" and that implementing it would place a regulatory burden on providers. Therefore, CMS believes it is appropriate to propose the removal of this payment adjustment policy. CMS proposes to eliminate the 25-percent threshold policy in a budget neutral manner – the LTCH PPS standard federal payment rate would be adjusted by a factor (-0.9 percent) to maintain aggregate LTCH PPS payments at the estimated levels they would be, absent the proposed change. CMS is seeking comment on their proposal to permanently eliminate the 25-percent threshold policy in a budget neutral manner – or, an alternative proposal of an additional 1-year delay on implementation with a budget neutrality adjustment. Additionally, the agency is seeking comment on whether the 25-percent threshold policy should be retained in FY 2019 and subsequent years.

Proposed Changes to Regulations Governing Excluded Units of Hospitals

Under current regulations, “an excluded psychiatric or rehabilitation unit cannot be part of an institution that is excluded in its entirety from the IPPS.” Prospective payment systems exist for both inpatient rehabilitation facilities (IRFs) and psychiatric hospitals and units (IPFs), and under this proposal, a long-term care hospital (LTCH) operating a psychiatric unit would receive payment under the IPF PPS for discharges from the psychiatric unit, and payment under the LTCH PPS for the discharges that are not from the psychiatric unit.

CMS proposes to revise existing regulations to specify that the requirement “that an excluded psychiatric or rehabilitation unit cannot be part of an IPPS-excluded hospital is only effective through cost reporting periods beginning on or before September 30, 2019.” Under this proposal, effective with cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would be permitted to have an excluded psychiatric and/or rehabilitation unit. CMS is also proposing to revise current regulations so that an IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an IRF may not have an IRF unit). CMS notes that this proposed change would be consistent with the current preclusion that prevents one hospital from having more than one of the same type of IPPS-excluded unit.

Request for Information (RFI) on Promoting Interoperability

CMS is requesting information to obtain stakeholder feedback on ways to better achieve interoperability between providers. With the increased adoption of EHRs and availability of health information exchange infrastructure among hospitals, CMS is seeking feedback from stakeholders on how they could “use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers.”

CMS states that they might consider revisions to the current CMS CoPs for hospitals that include: “requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.”

The agency notes that in responding to the RFI, commenters should “provide clear and concise proposals that include data and specific examples.” Although CMS will not respond to RFI comment submissions in the final rule, they will be actively considering all input in developing future regulatory proposals or future sub-regulatory guidance related to inpatient and long-term care hospitals.

What’s Next?

CMS publishes the final IPPS regulation around Aug. 1, 2018 and the changes are effective at the beginning of the federal fiscal year (Oct. 1, 2018). The 60-day comment period closes on June 25, 2018. Vizient’s Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in August.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient’s Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.