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Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

May 28, 2020

Background & Summary

On April 30, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Fiscal Year (FY) 2021 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). The proposed rule includes several potential changes, including a new MS-DRG for CAR T-cell therapy, expansion of the New Technology Add-on Payment (NTAP) pathway for certain antimicrobial products and additional electronic clinical quality measure (eCQM) reporting requirements. In addition, CMS proposes to modify the methodology to calculate MS-DRG relative weights by considering market-based information and implement changes impacting identification of labor market areas in which a hospital is located for purposes of calculating the wage index.

In a summary released by CMS, the agency indicated this proposed rule does not include an anticipated update to the Overall Hospital Star Rating methodology. According to CMS, due to COVID-19, it has limited annual rulemaking to changes required by statute and proposals that reduce provider burden and may help in the COVID-19 response. CMS stated it will return to this issue in future rulemaking.

Comments are due **July 10, 2020**. Due to COVID-19, CMS has indicated there will likely be a 30-day delay in the publication of the final rule, but the effective date of the final rule is still expected to be October 1, 2020. Vizient looks forward to working with members to help inform our letter to the agency.

Proposed IPPS Payment Rate Updates for FY 2021

After accounting for inflation and other adjustments required by law, the proposed rule would increase IPPS operating rates by 3.1 percent in FY 2021 for hospitals that successfully report quality measures and are meaningful users of electronic health records (EHR). The proposed rule includes an initial market-based update of 3.0 percentage points, minus 0.4 percentage points for productivity mandated by the Affordable Care Act (ACA). Regarding the MS-DRG Documentation and Coding

Adjustment, which partially restores cuts as a result of the American Taxpayer Relief Act (ATRA), CMS proposes a 0.5 percentage point positive adjustment. These changes are reflected in the following table and would be applied to all hospitals.

Proposed IPPS Payment Rate Updates for FY 2021

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update	3.0%
Multi-Factor Productivity Adjustment	-0.4%
MS-DRG Documentation and Coding Adjustment	0.5%
Estimated payment rate update for FY 2021 (before applying budget neutrality factors)	**3.1%**

In addition, CMS proposes four applicable percentage increases that can be applied to the standardized amount, as demonstrated in the below table. To determine the proposed applicable percentage increase, CMS applies adjustments to the proposed market-basket rate-of-increase. Two of these adjustments are dependent on two factors: (1) whether a hospital submits quality data; and (2) whether a hospital is a meaningful electronic health record (EHR) user. In addition, there is a 0.4 percentage point reduction for the multifactor productivity adjustment.

Proposed FY 2021 Applicable Percentage Increases for the IPPS

FY 2021	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 Multi-Factor 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**

Proposed Changes to the Methodologies for Determining Medicare Disproportionate Share Hospital (DSH) Payments and the Additional Payments for Uncompensated Care

The ACA required changes, which started 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 uninsured 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
- **Factor 3:** Proportion of total uncompensated care each Medicare DSH provides

For FY 2021, CMS estimates DSH payments will be $11.6 billion, a decrease of $1.1 billion compared to FY 2020. Of the $11.6 billion, $7.8 billion is for uncompensated care payments. The payments have redistributive effects, 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.

In addition, while CMS does not propose changes to Factors 1, the agency provides proposals for Factors 2 and 3. For Factor 2, for FY 2021, CMS proposes to use the same methodology as in FY 2020, where it uses a weighted average approach to estimate the rate of uninsurance. Using this methodology, CMS finds Factor 2 would be 67.86 percent.

For Factor 3, for FY 2021, CMS proposes to use a single year of Worksheet S–10 data from FY 2017 cost reports (audited) and apply that data in their methodology for all eligible hospitals (except Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals). CMS proposes that "uncompensated care" would continue to be defined as the amount on Line 30 of Worksheet S-10, which is consistent with FY 2020. However, in FY 2020, CMS relied on data from Worksheet S-10 for FY 2015. For purposes of the proposed rule, CMS used a Healthcare Cost Reporting Information System (HCRIS) extract from February 2020 (available on the CMS website), which contains cost report data but CMS intends to use the March 2020 update of HCRIS when finalizing policies for FY 2021 (so that updated information would be used to determine Factor 3 in the final rule). However, CMS believes that hospitals will have sufficient time during the proposed rule's comment period to provide information about recent or pending mergers or to report upload discrepancies. CMS seeks comment on the use of March 2020 HCRIS data.

In addition, for FY 2021 and subsequent fiscal years, CMS proposes to change the methodology for calculating Factor 3 as related to the agency's treatment of the

following: merger multiplier for acquired hospital data; newly merged hospitals; annualization and long cost reports; new hospitals; IHS and Tribal hospitals, Puerto Rico hospitals, all-inclusive rate providers; proposed CCR trim methodology; and uncompensated care data trim methodology.

For Factor 3, for FY 2022 and subsequent years, CMS proposes to use the most recent single year of cost report data that has been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments in its calculation for all hospitals (except IHS, Tribal hospitals and Puerto Rico hospitals). CMS invites comments and may revisit this proposal for FY 2022.

Proposed Changes to Related Medicare Severity Diagnosis-Related Group (MS-DRG) and Relative Weights

As noted in more detail below, CMS proposes a new process to determine if a subgroup within a base MS-DRG is warranted, provides guiding principles regarding severity level changes and proposes to change the methodology for calculating MS-DRG relative weights.

In addition, CMS proposes to change the deadline to request changes to the MS-DRG classifications to October 20 of each year as opposed to November 1, to provide more time for CMS to review and evaluate requests. Comments and suggestions for FY 2022 should be submitted by October 20, 2020 via the CMS MS-DRG Classification Change Request Mailbox located at: MSDRGClassificationChange@cms.hhs.gov.

Expanding the Criteria Used to Determine if a Subgroup Within a Base MS-DRG is Warranted

In the FY 2008 IPPS/LTCH PPS final rule, CMS established the following five criteria to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted. All five criteria must be met for a CC or MCC subgroup within a base MS-DRG to be created.

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

For FY 2021, CMS proposes to include the Non-Complication or Comorbidity (NonCC) subgroup in the five criteria, to better reflect resource stratification and promote stability in relative weights by avoiding low volume counts for the NonCC level MS-DRGs. The following table illustrates the proposed criteria and evaluation framework for FY 2021. As proposed, CMS would first consider if a 3-way split (MCC vs. CC vs. NonCC) is warranted and if those criteria are not satisfied, CMS would determine if a 2-way split (e.g., MCC vs. (CC +NonCC) or (MCC+CC) vs. NonCC) is warranted.

If all criteria for the 2-way split options are not met, then a CC subgroup would generally not be warranted for that base MS-DRG. In the proposed rule, for MS-DRG reclassification requests for FY 2021 that CMS received by November 1, 2019, CMS applied the expanded criteria to each of the MCC, CC and NonCC subgroups.

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	500+ cases for (MCC+CC) group; AND 500+ cases for NonCC group
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	5%+ cases for (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

Guiding Principles for Making Changes to Severity Levels

In 2019, CMS gained stakeholder feedback and relied on internal specialists and analysts to determine a set of principles related to making changes to severity levels. In the proposed rule, CMS indicates it plans to use those guiding principles and

mathematical analysis of claims data to continue a comprehensive CC/MCC analysis and will present findings in future rulemaking.

The proposed guiding principles that would be considered meaningful indicators of expected resource use by a secondary diagnosis are:

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

CMS seeks feedback regarding the guiding principles and encourages an explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects the resource use for any diagnosis code.

Market-Based MS-DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS-DRG Relative Weights

In 2019, CMS finalized a rule regarding price transparency that, effective January 1, 2021, requires hospitals to establish, update, and make public a list of their standard charges for the items and services they provide. CMS looks to build from this price transparency rule by requiring additional data to be reported and to develop a new market-based MS-DRG relative weight methodology.

Reporting Certain Market-based Payment Rate Information on the Medicare Cost Report

CMS proposes to require hospitals to report additional information on their Medicare cost report. Specifically, for cost reporting periods ending on or after January 1, 2021, CMS proposes that hospitals' Medicare cost reports include, by MS-DRG, the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) payers and the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers (including MA organizations).

Regarding the methodology for calculating the IPPS MS-DRG relative weights which is described below, CMS noted the use of payer-specific negotiated charges would replace the current use of gross charges that are reflected on a hospital's chargemaster and cost

information from Medicare cost reports. CMS is requesting comment on the proposed use of hospitals' reported median payer-specific negotiated charge data.

Potential Market-Based MS-DRG Relative Weight Methodology Beginning FY 2024

Using a cost-based methodology, CMS relies on MedPAR claims data and cost report data from the Healthcare Cost Report Information System (HCRIS) to calculate MS-DRG relative weights. Payment for a case under IPPS is determined by multiplying a hospital's geographically adjusted standardized amount per case by the relative weight for the case's MS-DRG.

In the proposed rule, CMS reviews different studies and concludes that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payments rates. In addition, CMS found payer-specific charges negotiated between hospitals and other commercial payers are generally not as well correlated with Medicare IPPS rates.

Based on CMS's findings and interest to develop a market-based approach to payment under the Medicare fee-for-service (FFS) system, the agency proposes to change the methodology for calculating the IPPS MS-DRG relative weights, beginning in FY 2024. CMS indicates the additional Medicare cost report data the agency proposes to collect (e.g., median payer-specific negotiated charges) would be used in determining potential market-based MS-DRG relative weights.

The methodology for calculating MS-DRG relative weights CMS is proposing includes the following steps:

- **Step 1.** Standardize the median Medicare Advantage (MA) organizations payer-specific negotiated charges.
- **Step 2.** Create a single weighted average standardized median MA payer-specific negotiated charge by MS-DRG across hospitals (use each hospital's Medicare transfer-adjusted case count for each MS-DRG).
- **Step 3.** Create a single national weighted average standardized payer-specific negotiated charge across all MS-DRGs (based on the national Medicare transfer adjustment case counts by MS-DRG).
- **Step 4.** Calculate the market-based relative weights (the ratio of Step 2 average to the Step 3 average).
- **Step 5.** Normalize the market-based relative weights using an adjustment factor so the average case weight is the same before and after recalibration.

For Step 1, CMS seeks comment on appropriate standardization for the median MA organization payer-specific negotiated charges, and any differences that should be considered in standardizing the median payer-specific negotiated charges for all third-party payers.

For Step 2, CMS indicates it would weight the standardized payer-specific negotiated charge for each MS-DRG for each hospital using that hospital's Medicare transfer-adjusted case count for that MS-DRG, with transfer adjusted case counts calculated exactly the same way as under the current MS-DRG relative weight methodology. CMS

may also consider alternative approaches (e.g., using unadjusted Medicare case counts). CMS seeks comment on the most appropriate weighting factor for purposes of calculating a single weighted average standardized median MA organization payer-specific negotiated charge across hospitals.

Regarding the methodology, CMS requests comments on alternatives to the current use of hospital charges in determining other inpatient hospital payments, including outlier payments and new technology add-on payments, to the extent permitted by law. In addition, CMS seeks feedback on whether the agency should provide a transition to any new market-based MS-DRG methodology, and, if so, on the appropriate design of any such transition.

Also related to the methodology, CMS asks whether hospitals' median payer-specific negotiated charges across all types of payment methodologies should be included in the determination of the median payer-specific negotiated charge for the conditions and procedures that are classified under the MS-DRG system and, if so, how the proposed definitions should be modified to encompass these other types of negotiation strategies or methodologies.

In addition, CMS invites responses regarding the appropriateness of using MS-DRGs or MS-DRG equivalents for this methodology, as well as whether it should potentially collect this information for payers that use MS-DRGs separately from payers that use other DRG systems.

While CMS provides significant information regarding its proposed methodology, the agency also requests stakeholders suggest alternative approaches that would capture market-based information for the potential use in Medicare FFS payments or other hospital payments (e.g., outlier payments and new technology add-on payments).

COVID-19 Coding

As of April 1, 2020, a new ICD-10-CM diagnosis code (U07.1) was implemented for the reporting of COVID-19. CMS assigned this code to the following MS-DRGs which are grouped to Major Diagnostic Categories (MDCs):

- MDC 04 (Respiratory System) in MS-DRGs 177 and 178 and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively).
- MDC 15 (Newborn and Other Neonates (Perinatal Period) in MS-DRG 791 and 793 (Prematurity with Major Problems) and (Full Term Neonate with Major Problems).
- MDC 25 (Human Immunodeficiency Virus (HIV) Infection) in MS-DRGs 974, 975 and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively).

As with other new diagnosis codes and MS-DRG assignments, CMS solicits public comments on the most appropriate MDC, MS-DRG and severity level assignments for these codes for FY 2021.

Chimeric Antigen Receptor (CAR) T-Cell Therapies

In the FY 2020 IPPS/LTCH PPS Final Rule, CMS declined to create a new MS-DRG for Chimeric Antigen Receptor (CAR) T-cell therapies because the agency believed it did not have enough comprehensive clinical and cost data to create relative weights for the new MS-DRG. In the proposed rule, CMS indicates it believes it has enough data from the September 2019 update of the FY 2019 MedPAR data file. CMS also performed an analysis on the updated data and provides the agency's findings in the proposed rule.

To perform the analysis, CMS identified clinical trial cases as claims with ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) which is reported only for clinical trial cases, or with standardized drug charges of less than $373,000, which is the average sales price of KYMRIAH and YESCARTA (the two CAR T-cell medicines approved to treat relapsed/refractory diffuse large B-cell lymphoma).

CMS also distinguished between clinical trial and non-clinical trial cases in this analysis because the agency believed it is appropriate to distinguish cases where the CAR T-cell product was provided without cost as part of a clinical trial so that the analysis appropriately reflects the resources required to provide CAR T-cell therapy outside of a clinical trial. CMS also included cases that would have been identified as statistical outliers under their usual process when examined as part of MS-DRG 016 (Autologous Bone Marrow Transplant or T-cell Immunotherapy) due to the extreme cost differences between the CAR T-cell therapy claims and other claims in MS-DRG 016. The findings of CMS's analysis are below:

MS-DRG	Description		# Cases	Average length of stay	Average Costs
016	All cases		2,212	18.2	$55,001
	ICD-10-PCS codes XW033C3 or XW043C3	All cases	262	16.3	$127,408
		Non-clinical trial cases	94	17.2	$275,952
		Clinical trial cases	168	15.8	$44,853

Based on CMS's findings, the agency proposes to create an MS-DRG 018 for CAR T-cell therapies and any cases reporting ICD-10-PCS procedure codes XW033C3 (Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3) or XW043C3 (Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3) would be assigned to the proposed new MS-DRG 018. In Table 5, CMS indicates the proposed relative weight for the new MS-DRG 018 is 37.1214. In determining the relative weight, CMS proposes to modify their existing relative weight methodology to ensure the relative weight for the proposed new MS-DRG appropriately reflects the relative

resources required for providing CAR T-cell therapy, while still accounting for clinical trial cases in the overall average cost for all MS-DRGs.

In addition, CMS proposes a differential payment for cases where the CAR T-cell product is provided without cost as part of a clinical trial. For this differential payment, CMS proposes to apply an adjustment to the payment amount for clinical trial cases that would group to the proposed new MS-DRG 018. The adjustor CMS proposes to apply is 0.15 (e.g., if the relative weight of MS-DRG 018 is 37.1214 then CMS would multiply 37.1214 by 0.15 as part of the calculation for the payment for clinical trial claims assigned to MS-DRG 018). It is important to note that CMS expects to recalculate this adjustor for the CAR T-cell therapy clinical trial cases for the final rule based on the updated MedPAR data.

Regarding surgical hierarchy sequence for this new MS-DRG, CMS proposes to place the Proposed New Pre-MDC MS-DRG 018 above the Pre-MDC MS-DRGs 001 and 002.

In addition, CMS proposes to discontinue the new technology add-on payment (NTAP) for FY 2021 for KYMARIAH and YESCARTA. If CMS finalizes the proposed new MS-DRG 018 then ICD-10-PCS procedure codes XW033C3 or XW043C3 would no longer group to MS-DRG 016. CMS would also modify the name of MS-DRG 016 to remove “or T-cell immunotherapy”.

CMS invites public comment on these proposals.

Proposed Changes to Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

The Further Consolidated Appropriations Act, 2020 required CMS to make changes related to cost reporting and payment to hospitals for allogeneic hematopoietic stem cell acquisition. Such changes must be budget neutral. To implement the law, CMS proposes that payment to certain hospitals for allogeneic hematopoietic stem cell acquisition be made on a reasonable cost basis and clarifies which items are included in allogeneic hematopoietic stem cell acquisition costs.

CMS indicated the following would be included in allogeneic hematopoietic stem cell acquisition costs: registry fees from certain national donor registries; tissue typing of donor and recipient; donor evaluation; physician preadmission/pre-procedure donor evaluation services; costs associated with the collection procedure such as, general routine and special care services, procedure/operating room and other ancillary services, and apheresis services; post-operative/post-procedure evaluation of donor; and the preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells. CMS seeks feedback on this proposal.

In addition, CMS proposes to require that hospitals formulate a standard acquisition charge that is based on costs reasonably expected to be incurred in the acquisition of hematopoietic stem cells. CMS also proposes that the standard acquisition charge would be billed and paid on an interim payment basis as a “pass-through” item.

Alternative Inpatient New Technology Add-on Payment (NTAP) Pathway

In the FY 2020 IPPS/LTCH Final Rule, CMS finalized an alternative pathway for transformative medical devices. The agency created two alternative NTAP pathways for certain medical devices and qualified infectious disease products (QIDPs). As a result, beginning with applications for NTAPs for FY 2021, certain transformative new devices and QIDPs may qualify under these alternative pathways. In the proposed rule, CMS indicates nine products were submitted through an alternative pathway and that the agency plans to approve all nine of these products.

In addition, CMS proposes to expand the QIDP pathway to include products approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). The proposed maximum NTAP percentage for a product under FDA's LPAD pathway is 75 percent, which is 10 percent higher than the default maximum NTAP percentage but consistent with the QIDP percentage.

CMS also proposes a conditional NTAP for products designated as QIDPs that do not receive FDA marketing authorization by the annual July 1 deadline to be considered in the final rule but otherwise meet applicable NTAP criteria. These products would begin receiving the NTAP effective for discharges the quarter after FDA marketing authorization is granted. Those granted conditional approval would still need to apply for the NTAP in the next fiscal year.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

Current law requires that the Secretary adjust 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 must be updated annually and any updates or adjustments must be budget neutral – meaning the overall, aggregate payment to hospitals cannot change.

CMS is proposing a wage index transition policy given the proposed changes which would be relevant to hospitals that experience a significant decrease in their FY 2021 wage index compared to their final FY 2020 wage index. Under the policy, in FY 2021, there will be a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year (FY 2020). No cap would be applied in the second year the new policies are in effect.

Proposed Core-Based Statistical Areas (CBSAs) for the FY 2021 Hospital Wage Index and Implementation Effects

Hospital labor markets are based on statistical areas established by the Office of Management and Budget (OMB) and the wage index is assigned to hospitals on the basis of the labor market in which it resides. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs).

CMS is proposing, effective October 1, 2020, to implement revised labor market area delineations, particularly those provided for in OMB No. 18-04 (released September 14,

2018). The new delineations would result in 34 counties and county equivalents (including 10 hospitals) that were once considered to be part of an urban CBSA to now be considered as in a rural area, and 47 counties and county equivalents (including 17 hospitals) that were in rural areas would now be in urban areas. In addition, eligibility for Lugar status, which makes certain hospitals eligible for increased Medicare payments, would also be impacted.

Given these changes, impacted hospitals may be interested in making status-related requests to CMS (e.g., reassignment to another CBSA, urban status reinstatement, waive or reinstate Lugar status). Requests must contain certain information (e.g., type of request, documentation supporting the request, hospital-specific information such as the address) and generally be made within 45 days of official publication of the proposed rule and may be sent to wageindex@cms.hhs.gov.

Looking to FY 2022, CMS noted that OMB Bulletin 20-01 (related to revising delineations of certain statistical areas) was released on March 6, 2020 and not in time for development of the proposed rule. CMS will propose any updates from this bulletin in future rulemaking.

Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

Any changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2021 will be incorporated into the wage index values – and published in the FY 2021 IPPS/LTCH PPS final rule. In the proposed rule, CMS outlines the process for requests for wage index data corrections.

CMS noted hospitals may withdraw or terminate their FY 2021 reclassifications by contacting the Medicare Geographic Classification Review Board (MGCRB) by July 17.

Regarding appeals of an MGCRB decision, CMS proposes to eliminate the prohibition on submitting a request by facsimile or other electronic means. As a result, hospitals may submit requests for Administrator review of MGCRB decisions electronically. Requests must be received by the Administrator 15 days after the date the MGCRB issues its decision. CMS is also proposing to require that hospitals submit an electronic copy of their requests for review to CMS's Hospital and Ambulatory Policy Group via email to wageindex@cms.hhs.gov.

Proposed Labor-Related Share for the Proposed FY 2021 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 2021, 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 2021, CMS proposes to apply the wage index to a proposed labor-related share of 68.3 percent of the national

standardized amount. Tables 1A and 1B, available on the CMS website, include the proposed national labor-related share.

Occupational Mix Adjustment

To compute the FY 2021 occupational mix adjustment, CMS is not proposing any changes to the methodology and plans on applying the occupational mix adjustment to 100 percent of the FY 2021 wage index. CMS used Worksheet S-3 wage data of 3,196 hospitals and used occupational mix surveys of 3,113 hospitals to calculate the proposed wage index. For FY 2022, CMS indicates a new measurement of occupational mix is required and will be based on a CY 2019 survey (OMB No. 0938-0907). This survey must be submitted to Medicare Administrative Contractors (MACs) by August 3, 2020 (CMS is granting an extension due to COVID-19, the original deadline was July 1, 2020).

CMS compared the proposed FY 2021 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. The results indicate a larger percentage of urban areas (57.8 percent) would benefit from the occupational mix adjustment than rural areas (44 percent).

Wage Index Adjustments

Currently, there are several policies in effect to address wage index disparities between high and low wage index hospitals. CMS does not propose to modify these policies (e.g., “rural floor” policy, Frontier Floor Wage Index, low wage hospital index, out-migration) as noted below.

The “rural floor” policy provides that wage indexes applied to urban hospitals in a state cannot be lower than the wage index for rural areas in that state. In the proposed rule, CMS indicates 255 hospitals would receive an increase in their wage index due to the application of the rural floor budget neutrality factor.

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 45 hospitals would receive the Frontier Floor adjustment so their FY 2021 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.

CMS proposes to continue the FY 2020 low wage hospital index policy in FY 2021 for hospitals whose wage index values are in the bottom quartile. Under the 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. Based on the data for the FY 2021 proposed rule, the 25th percentile wage index value across all hospitals would be 0.8420.

Regarding the out-migration adjustment, for FY 2021, CMS indicates this adjustment will continue to be based on the data derived from the custom tabulation of the American Community Survey utilizing 2008 – 2012 (5-year) Microdata. For future fiscal years, CMS

may consider determining out-migration adjustments based on data from the next Census or other available data. The areas affected by these adjustments for the proposed FY 2021 wage index are identified in the FY 2021 Proposed Rule Wage Index Tables (available on the CMS website).

For FY 2021, CMS proposes to continue providing for a transition of a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year, which would be FY 2020.

Payments for Indirect and Direct Graduate Medical Education Costs

In response to stakeholders' concerns regarding the circumstances where medical residents transfer to other hospitals after a hospital or program closure, CMS proposes several changes.

To address administrative burdens, CMS proposes to expand the definition of "displaced resident" so that certain groups of residents at closing hospitals/programs can have their residencies continue to be funded by Medicare.

In addition, CMS proposes to change the how the day of closure is determined so that it is the date the closure was publicly announced rather than the actual date of closure. As a result, medical residents could be granted the status of "displaced residents" sooner. Currently, Medicare provides temporary funding to hospitals that accept "displaced residents" that is effective on the day prior to or on the date of a program or hospital closure. CMS is now proposing that hospitals can receive this temporary funding on the day the closure was publicly announced (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)) and not the actual date of closure. CMS believes these changes will help medical residents transfer sooner, while the hospital operations or residency program are winding down, rather than later, such as the last day of hospital or program operations.

Regarding funding transfers, due to the proposed change related to the day of closure, CMS proposes to also allow funding to be transferred temporarily for residents who are not physically at the closing hospital/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital/closing program. Also to streamline the process, CMS proposes that the letter the receiving hospital would normally send to the MAC before training the resident, would now include the names and last four digits of each displaced resident's social security number (as opposed to the whole number).

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. Currently, the payment reduction is based on a hospital's risk-adjusted readmission rate during a three year period for six applicable

conditions/procedures. For FY 2021, CMS is not proposing to remove or adopt any additional measures.

In the proposed rule, for FY 2021, a hospital subject to the HRRP would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

Also, CMS reiterated that in the FY 2020 IPPS/LTCH Final Rule, it updated the definition of "dual-eligible" and this updated definition is applicable in FY 2021. According to that final rule, "Dual eligible" is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.

Although CMS restated the previously finalized applicable periods to calculate the readmission payment adjustment factor for FY 2021 (July 1, 2016–June 30, 2019) and FY 2022 (July 1, 2017–June 30, 2020), the agency proposes to automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. For example, under this policy, beginning FY 2023, the applicable period for the HRRP would be July 1, 2018 – June 30, 2021.

In addition, CMS proposes to determine aggregate payments for excess readmissions (the numerator), and aggregate payments for all discharges (the denominator) using the most recently available full year data from MedPAR claims (this would be the March update) with discharge dates that align with the FY 2021 applicable period. CMS proposes to continue to exclude admissions for patients enrolled in Medicare Advantage (MA), as identified in the enrollment database. Hospitals will have the opportunity to review and correct calculations (not the data) based on the proposed FY 2021 applicable period of July 1, 2016 – June 1, 2019, before they are made public.

As noted in the FY 2020 IPPS/LTCH PPS Final Rule, confidential hospital-specific reports will include data, stratified by patient dual-eligible status, for the six readmissions measures included in the HRRP in the Spring of 2020. This data will include two disparity methodologies ("Within-Hospital Disparity Method and "Dual Eligible Outcome Method") designed to highlight potential disparities. CMS noted that this data will not be publicly reported or used in payment adjustment factor calculations.

Hospital Value-Based Purchasing (VBP) Program

The ACA established a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made to hospitals that meet performance standards during specific performance periods. The applicable percent for the FY 2021 program year as required by statute is 2.00 percent, or $1.9 billion in total amount available.

CMS published proxy value-based incentive payment adjustment factors in Table 16 associated with the proposed rule (available on the CMS Website). The proxy factors are

based on the Total Performance Scores (TPSs) from the FY 2020 program year. 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 2020 update to the FY 2019 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 2021 will continue to be based on historic FY 2020 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2021 program year until after the FY 2021 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2021, the agency will add Table 16B (which will be available on the CMS website in Fall of 2020) to display the actual value-based incentive payment adjustment factors.

CMS is not proposing to add new measures or remove measures from the Hospital VBP Program and is not proposing changes to the length of performance or baseline periods, such as those associated with the clinical outcomes domain, safety domain, and efficiency and cost reduction domain. A chart and summaries of previously adopted measures for the FY 2022 and FY 2023 program years are available in the proposed rule.

Every year, performance standards for measures under the Hospital VBP Program must be established for a performance period for the applicable fiscal year. In accordance with this requirement CMS provides several tables describing previously established and estimated performance standards for FY 2023-2024. In the Safety and Person and Community Engagement domains for the FY 2023 program year, CMS provides estimated performance standards and indicates it intends on updating these values the FY 2021 IPPS/LTCH PPS final rule. In addition, CMS provides previously established and newly established performance standards for the FY 2025 Program Year. Also, while CMS is unable to provide numerical equivalents for the performance standards, it does provide a table detailing the newly established performance standards for the FY 2026 program year.

Hospital-Acquired Condition (HAC) Reduction Program

The ACA established the HAC Reduction Program 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. In this proposed rule, CMS is not proposing to add or remove any measures.

CMS proposes to automatically adopt applicable periods (and update the regulatory definition of "applicable period" to align with this change) beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the secretary. For FY 2023, applicable periods are as follows:

- CMS PSI 90: July 1, 2019 – June 30, 2021
- CDC NHSN HAI: January 1, 2020 – December 31, 2022

In the proposed rule, CMS provides several changes to the process for validation of HAC Reduction Program measure data to align with the proposed changes to the Hospital Inpatient Quality Reporting (IQR) Program's processes. These changes focus on aligning submission quarters to Hospital IQR submissions and updating the hospital selection process.

Regarding submissions, for the FY 2023 program year, CMS proposes to only use measure data from the third and fourth quarters of 2020. CMS would use measure data only from these quarters for the random and targeted validation pools. For the FY 2024 program year and subsequent years, CMS proposes to use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program. Data submission deadlines for chart-abstracted measures would be in the middle of the month, the fifth month following the end of the reporting quarter. CMS invites comments on the proposal to align submission quarters and deadlines with the Hospital IQR Program.

CMS is not proposing to update the hospital selection process for validation for FY 2023 (as in previous years, the validation pool would be up to 400 randomly hospitals and up to 200 hospitals selected using targeted criteria). However, for the validation for the FY 2024 program year and subsequent years, CMS is proposing to reduce the total validation pool from up to 600 hospitals to up to 400 hospitals. As a result, the HAC Reduction Program and Hospital IQR Program would have up to 400 hospitals for inclusion for validation purposes across both programs. CMS invites comment on the proposal to align hospital selection with the Hospital IQR Program for the FY 2024 payment determination and subsequent years.

In addition, CMS proposes to require the use of digital submissions for medical records requests and to discontinue the option of sending CD, DVD or flash drives containing digital images of patient charts. This would be effective beginning with Q1 for FY 2024 program year validation. Hospitals would be required to submit PDF copies of medical records using a CMS-approved secure file transmission process. CMS indicates it would continue to reimburse hospitals at $3.00 per chart. Based on CMS's monitoring, it believes almost two-thirds of providers use the option to submit PDF copies of medical records as electronic files. CMS invites comments on this proposal.

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. In order to receive the full payment increase, hospitals must report data on measures selected by the Secretary for each fiscal year. CMS is not proposing to adopt any new measures in the proposed rule but does propose changes to reporting and submission requirements, among other changes.

Reporting and Submission Requirements Related to eCQMs

CMS proposes to progressively increase, over a three-year period, the number of quarters that hospitals are required to report eCQM data. Currently, hospitals are

required to report one self-selected quarter of data and CMS proposes to increase this to four quarters of data, as described below.

- CY 2021 reporting period/FY 2023 payment determination: hospitals report two, self-selected calendar quarters of data for each of the four self-selected eCQMs.
- CY 2022 reporting period/FY 2024 payment determination: hospitals report three self-selected calendar quarters of data for the three self-selected eCQMs and the Safe Use of Opioids eCQM.
- CY 2023 reporting period/FY 2025 payment determination and beyond: hospitals report four calendar quarters of data for subsequent years the three self-selected eCQMs and the Safe Use of Opioids eCQM.

Also, CMS proposes to begin publicly reporting eCQM data beginning with the eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. Hospitals would have the opportunity to review the data before they are made public.

In addition, CMS proposes to add "EHR Submitter ID" (which is either assigned by QualityNet or the hospital's CCN) to the other four elements that must be listed to identify Quality Reporting Document Architecture (QRDA) I files; this would begin with the CY 2021 reporting period/FY 2023 payment determination.

CMS invites feedback on these proposals.

Hybrid Hospital-Wide Readmission (HWR) Measure

To help increase the use of electronic health record (EHR) data in quality measurement, CMS developed the Hybrid Hospital-Wide Readmission (HWR) measure (NQF #2879). CMS proposes to continue requiring hospitals to use EHR technology certified to the 2015 Edition when submitting data on the Hybrid HWR measure. CMS also proposes expanding this requirement to apply to any future hybrid measure adopted into the Hospital's IQR Program's measure set.

In addition, CMS clarified that core clinical data elements linking variables must be submitted using the QRDA I file format for future hybrid measures in the program.

Validation of Hospital IQR Program Data

To streamline the validation process, CMS is proposing to incrementally combine the validation processes for chart-abstracted measure data and eCQM data (and related policies) in a stepwise process, affecting FY 2023 and FY 2024 payment determinations, as described in the following table. Generally, CMS proposes to update the quarters of data required for validation, expand target criteria to include hospital selection for eCQMs, reduce the size of the validation pool from 800 to 400 hospitals, remove current exclusions for validation selection and align scoring so there is one combined validation score.

Proposed Process for Validation Affecting FY 2023 Payment Determination		
	Quarters of Data Required for Validation	**Scoring**
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020 4Q 2020	At least 75% validation score
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 - 4Q 2020	Successful submission of at least 75% of requested medical records
Proposed Process for Validation Affecting FY 2024 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 - 4Q 2021	Chart-abstracted Measures: At least 75% validation score (weighted at 100%) And eCQMs: Successful submission of at least 75% of requested medical records

As depicted in the above table, CMS proposes to provide one combined validation score starting with validation affecting the FY 2024 payment determination and for subsequent years. The single score would reflect a weighted combination of a hospital's validation performance for chart-abstracted measures (100 percent weight) and eCQMs (0 percent weight since eCQMs are not currently validated for accuracy). In the Proposed Rule, CMS noted that should this proposal be finalized, it will determine when eCQM measure data are ready for accuracy scoring for validation and that the agency anticipates increasing eCQM weighting. CMS also clarified that hospitals would continue to receive their total validation score annually and would still be required to successfully submit at least 75 percent of the requested medical records for eCQM validation.

CMS also proposes expanding the educational review process to incorporate eCQMs. As proposed, a hospital would have 30 calendar days to contact the validation support contractor to solicit a written explanation of the validation performance following the date that the validation results were provided to the hospital. Once a year, hospitals would have the opportunity to request an educational review following receipt of their results.

CMS seeks feedback on these proposals.

Overall Hospital Quality Star Rating Methodology

While not specifically included in the proposed rule, CMS indicated in their brief summary that this proposed rule would not include a proposed update to the Overall Hospital Quality Star Rating methodology. CMS previously indicated such information would be included in the proposed rule, but due to the impact of the COVID-19 public health emergency, CMS decided to limit annual rulemaking. CMS is expected to return to this issue in future rulemaking.

Medicare and Medicaid Promoting Interoperability 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). More recently, CMS finalized renaming the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs as the "Medicare and Medicaid Promoting Interoperability Programs", or "Promoting Interoperability (PI) Programs".

CMS proposes an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. To do this, CMS would change the regulatory definition of "EHR reporting period for a payment adjustment year" because the current regulations are applicable to CY 2021.This change is not being proposed for the Medicaid Promoting Interoperability Program because it will end with CY 2021.

CMS proposes to maintain the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure as an option and worth 5 bonus points in CY 2021. CMS indicated more time is needed prior to requiring a Query of PDMP measure for performance-based scoring.

Consistent with CMS's proposal for the Hospital IQR Program as described above, CMS proposes to increase the number of quarters for which eligible hospitals and CAHs are required to report eCQM data (shifting from one self-selected calendar quarter of data to four calendar quarters of data, over a 3-year period). CMS's proposed progressive approach is noted below:

- CY 2021 reporting period: two self-selected calendar quarters of data, for four self-selected eCQMs from the set of available eCQMs for CY 2021.
- CY 2022 reporting period: three self-selected calendar quarters of data, for each required eCQMs (three self-selected eCQMs from the set of available CQMs for CY 2022; and the Safe Use of Opioids-Concurrent Prescribing eCQM)
- CY 2023 reporting period and subsequent years: four calendar quarters of data from CY 2023 reporting period and each subsequent year for three self-selected eCQMs from the set of available eCQMs for CY 2023 and each subsequent year; and the Safe Use of Opioids—Concurrent Prescribing eCQM.

Beginning with CY 2023 reporting period, all eligible hospitals and CAHs are required to submit their eCQM data electronically through Hospital IQR Program reporting methods. The submission period for the Medicare Promoting Interoperability Program would be 2 months following the close of the respective calendar year (e.g., 2 months following the close of CY 2023, ending February 28, 2024).

CMS proposes to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021. Data would be on the *Hospital Compare* and/or data.medicare.gov websites (or successor website), and potentially available to the public as early as the Fall of 2022.

CMS is interested in comments that provide information on how these proposals might affect existing incentives and burdens under the PI Programs, as well as the benefit and utility of such data being publicly available.

Medicare Bad Debt Policy Clarifications

Currently, Medicare may reimburse deductible and coinsurance amounts for Medicare beneficiaries that remain unpaid after the provider has made a reasonable effort to collect and certain other conditions are met. For hospitals, the amount of Medicare bad debt reimbursement is 65 percent of the uncollectible amount (the amount varies by provider type). CMS proposes to clarify existing bad debt policies related to the following terms: Non-Indigent beneficiaries; Issuance of a bill; 120-day collection effort; Similar collection effort; and Reasonable collection effort as related to non-Indigent beneficiaries, beneficiaries determined indigent by provider using required criteria, dual eligible beneficiaries, and the Medicaid remittance advice). CMS indicates these changes would be effective before, on and after the effective date of the rule as they align with longstanding Medicare bad debt principles.

What's Next?

The IPPS tables for this FY 2020 proposed rule are available on the CMS website. CMS is anticipated to publish the final IPPS regulation before September 1, 2020 and the changes are effective at the beginning of the federal fiscal year (October 1, 2020). The comment period closes on July 10, 2020.

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. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.