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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 Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals – Final Rule

September 11, 2020

Background & Summary

On Wednesday, September 2, the Centers for Medicare and Medicaid Services (CMS) released the Final Rule to update the fiscal year (FY) 2021 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and long-term care hospital (LTCH) prospective payment system (PPS). Vizient provided a summary of the proposed IPPS payment regulations and our comment letter to CMS on the Proposed Rule can be found here.

The final payment regulation is effective on October 1, 2020, except when noted otherwise.

Key Takeaways: Major Proposals Finalized & Changes from the Proposed Rule

In addition to the annual standard payment updates, CMS finalized other policy proposals that will impact hospitals and health systems. These include the disproportionate share hospital (DSH) payment methodology, disclosure of certain payer-negotiated rates, Chimeric Antigen Receptor T-cell (CAR T) therapy payment and new technology add-on payments. CMS also finalized several policies regarding quality incentive programs and the Medicare and Medicaid Promoting Interoperability (PI) Programs.

Final IPPS Payment Rate Updates for FY 2021

Policy	Average Impact on Payments (Rate)
Market Basket Percentage	2.4%
Multi-Factor Productivity Adjustment	0.0%
MS-DRG Documentation and Coding Adjustment	0.5%
Estimated payment rate update for FY 2021 (before applying budget neutrality factors)	**2.9%**

The Final Rule will increase payment rates by 2.9 percent in FY 2021, compared to FY 2020 (slightly reduced from the estimated 3.1 percent increase in the Proposed

Rule), for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users.

DSH Payment Adjustment and Additional Payment for Uncompensated Care

The Affordable Care Act (ACA) required changes, which started in 2014, to the way 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

In the Final Rule, CMS updated its estimates of the three factors used to determine uncompensated care payments for FY 2021. Due to the COVID-19 public health emergency (PHE), for Factor 2, CMS used an updated projection of the FY 2021 rate of uninsurance, which was derived from more recently available unemployment data. As a result, the uninsured rate CMS used was higher in the Final Rule than in the Proposed Rule. For Factor 3 in FY 2021, CMS used a single year of data on uncompensated care costs from Worksheet S-10 of the FY 2017 cost reports for most eligible hospitals. For Factor 3 for FY 2022 and all subsequent fiscal years, CMS also established a policy of using the most recent available single year for audited Worksheet S-10 data and made other methodological changes for purposes of calculating Factor 3.

In the Proposed Rule, CMS estimated the DSH payments would decrease by $1.1 billion compared to FY 2020. Based largely on changes to Factor 2, CMS now projects that the amount available to distribute as payments for uncompensated care for FY 2021 will decrease, but now by $60 million, as compared to CMS's estimated of FY 2020 uncompensated care payment distributions.

Market-Based MS-DRG Relative Weight Data Collection and Changes in Methodology for Calculating MS-DRG Relative Weights

CMS finalized a proposal (with modifications) to require that hospitals report the median payer-specific negotiated charge that the hospital has negotiated with its Medicare Advantage (MA) payers, by MS-DRG. Hospitals would be required to include this information in their Medicare cost report for cost reporting periods ending on or after January 1, 2021. Using data from this requirement and the Hospital Price Transparency Final Rule (84 FR 65524), CMS provided additional information to the new market-based MS-DRG relative weight methodology, beginning in FY 2024. CMS did not finalize a transition period to this market-based MS-DRG relative weight methodology but may consider this in future rulemaking prior to FY 2024. Notably, CMS did not finalize the proposal to publicly report third party payer rates.

The finalized market-based MS-DRG weight methodology involves the following steps:

- **Step One:** Standardize the median MA organization payer-specific negotiated charges
- **Step Two:** Create a single weighted average standardized median MA organization payer-specific negotiated charge by MS-DRG across hospitals
- **Step Three:** Create a single national weighted average standardized payer-specific negotiated charge across all MS-DRGs
- **Step Four:** Calculate the market-based relative weights
- **Step Five:** Normalize the market-based relative weights

In the Final Rule, CMS indicates it believes this policy will reduce the Medicare program's reliance on the hospital chargemaster and support the development of a market-based approach to payment under the Medicare fee-for-service (FFS) system. In addition, CMS notes that it estimates the data collection burden for each hospital (3,189) would be 20 hours per hospital. CMS indicated that once it has access to the payer-specific negotiated charge information at the MS-DRG level, it will be able to better estimate the impact of this policy for payments beginning in FY 2024.

Vizient's comments questioned the need for CMS to develop a new MS-DRG relative weight methodology and expressed concern related to the burden this policy would have on providers. Our comments also flagged the limitations in providing feedback on the proposed methodology given potential changes related to data collection.

Chimeric Antigen Receptor (CAR) T-Cell Therapies

CMS finalized a policy to assign cases reporting ICD-10-PCS procedure codes XW033C3 or XW043C3 to a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and to revise the title for MS-DRG 016 from "Autologous Bone Marrow Transplant with CC/MSS or T-cell immunotherapy" to "Autologous Bone Marrow Transplant with CC/MCC". CMS also finalized the proposal to exclude clinical trial claims that group to the new MS-DRG 018 when calculating the average cost for new MS-DRG 018 that is used to calculate the relative weight for this MS-DRG (with additional refinements).

CMS identifies CAR T-cell clinical trial cases by ICD-10 diagnosis code Z00.6 or standardized drug charges of less than $373,000. To improve accuracy and consistent with Vizient's comments, CMS adjusted its proposed policy for the payment adjustment for CAR T-cell clinical trial cases to address two other circumstances. These circumstances are where a CAR T-cell therapy product is used under an expanded access program and when the CAR T-cell therapy product is purchased in the usual manner but the case involves a clinical trial of another drug.

In addition, based on commenters' feedback, including Vizient's, regarding charges from revenue center 891 (a cost center for cell therapy products) which is typically excluded from rate-setting, CMS indicated it will consider the charges reported in revenue code 891 and include these charges in determining whether the case contains standardized drug charges of at least $373,000 and therefore should be

determined to be non-clinical trial case for purposes of this modified relative weight methodology.

Applying the finalized methodology, based on the March 2020 update of the FY 2019 MedPAR file, CMS estimates that the average costs of CAR T-cell therapy cases determined to be clinical trial cases ($46,0662) are 17 percent of the average costs of CAR T-cell therapy cases determined to be non-clinical trial cases ($276,042). Based on this information, CMS finalized an adjustment of 0.17 for cases determined to be CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations.

Changes to the New Technology Add-On Payment Policy for Certain Antimicrobial Products

In accordance with Vizient's comments, CMS is finalizing the proposal to expand the alternative new technology add-on payment (NTAP) pathway for qualified infectious disease products (QIDPs) to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathways). Under the finalized policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, and antimicrobial products approved under FDA's LPAD pathway, CMS provides a more streamlined NTAP approval process.

In addition, CMS is finalizing the proposals to provide for conditional new technology add-on payment approval for eligible antimicrobial products. Products that would receive the add-on payment sooner (since the product conditional NTAP approval) are either those designated as QIDPs that do not receive FDA approval by July 1 (of the fiscal year for which the applicant applied for NTAP, such as July 1, 2021), or products that do not receive FDA approval by July 1 through FDA's LPAD pathway but otherwise meet the applicable add-on payment criteria.

Hospital Readmissions Reduction Program

The Hospital Readmissions Reduction Program requires a reduction to hospital's base operating DRG payment to account for excess admissions of certain conditions (i.e., acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, elective primary total hop arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft surgery). In the Final Rule, CMS finalizes a policy to automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years. CMS also makes conforming regulatory changes to the definition of applicable period.

Hospital Value-Based Purchasing Program

Under the Hospital Value-Based Purchasing Program, value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In the Final Rule, CMS establishes new performance standards for certain measures for the FY 2023 – FY 2026 program years.

Hospital Inpatient Quality Reporting (IQR) Program

Hospitals are required to report data on certain measures each fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year. In the Final Rule, CMS finalizes several proposals to progressively increase the numbers of quarters of electronic clinical quality measure (eCQM) data reported, from one self-selected quarter of data, to four quarters of data over a three-year period. The progressive increase in reporting is as follows, however, hospitals will still be allowed to report three self-selected eCQMs and the Safe Use of Opioids eCQM:

- Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination
- Three quarters of data for the CY 2022 reporting period/FY 2024 payment determination
- Four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years

In addition, CMS finalized a policy to publicly display eCQM data starting with data reporting by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. CMS notes these policies align with policies under the Promoting Interoperability Program. Vizient's comments emphasized the importance of publicly displayed data having utility, and that requirements associated with providing and validating the data should not be unnecessarily burdensome. Also, CMS finalized the proposal to expand the requirement to use EHR technology certified to the 2015 Edition for submitting data on all hybrid measures in the Hospital IQR Program.

Lastly, CMS finalized several changes in efforts to streamline the Hospital IQR Program's validation process. Those changes include updating the quarters of data required for validation for both chart-abstracted measures and eCQMs, requiring electronic file submissions for chart-abstracted measure data and updating the educational review process to address eCQM validation results.

Hospital-Acquired Condition Reduction Program

To reduce the incidence of hospital-acquired conditions (HAC), low-ranking hospitals (worst performing 25 percent) of all applicable hospitals may have a 1 percent payment reduction imposed. In the Final Rule, CMS indicates it will automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years (and make conforming regulatory changes to the definition of applicable period). In addition, CMS makes refinements to the process for validation of HAC Reduction Program measure data in alignment with the finalized Hospital IQR Program measure validation policies.

Medicare and Medicaid Promoting Interoperability Program

In the final rule, CMS makes several changes to the Medicare Promoting Interoperability Program. Notably, these changes include progressively increasing the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar

quarters of data, over three year period, and to begin publicly reporting eCQM performance data beginning with eCQM data reported by eligible hospitals and CAHs for the repotting period in CY 2021. Consistent with Vizient's comments related to the Hospital IQR Program, Vizient voiced concern that the proposed policies could place unnecessary burden on providers and that the utility of the making the data publicly available is unclear.

Additional Resources

Jenna Stern, Sr. Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2673, and is monitoring regulatory developments that impact our members. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback these policies. We encourage you to reach out to our office if you have any questions or regarding any aspects of this final regulation – both positive reactions and provisions that cause you concern.