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Regulatory Update: CMS Final Rule – Fiscal Year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS)

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Background & Summary

On Friday, August 2, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rule to update the fiscal year (FY) 2020 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). Vizient's detailed summary on the proposed IPPS payment regulation is on our Public Policy and Government Relations website and our comment letter to CMS on the proposed rule can be found here. This 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 also finalized various policy proposals that will impact hospitals and health systems. The major finalized policies address wage index disparities between high and low wage index hospitals, provide an alternative new technology add-on payment (NTAP) pathway for certain devices, and revise the calculation of the IPPS NTAP. CMS also finalized several new policies regarding quality reporting by various providers, including eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability (PI) Programs.

Final IPPS Payment Rate Update for FY 2020

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update	3.0%
ACA productivity adjustment	- 0.4%
Documentation & coding cut mandated by ATRA, altered by 21st Century Cures Act	0.5%
Payment rate update for FY 2020	**3.1%**

The final rule will increase payment rates for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users by 3.1 percent.

Proposals to Address Wage Index Disparities Between High and Low Wage Index Hospitals

In order to alleviate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications in the rural floor, CMS finalized their proposal to increase the wage index values for certain hospitals with low wage index values. However, rather than decreasing the wage index values for certain hospitals with high wage index values – for budget neutrality purposes – CMS finalized an adjustment to the standardized amount applied across all IPPS hospitals.

Beginning on October 1, 2020, this policy will be in effect for at least four years "in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation." Additionally, CMS finalized their proposal to remove urban to rural reclassifications from the calculation of the rural floor. CMS also finalized a transition for hospitals that will experience significant decreases in their wage index values as a result of these policies. For FY 2020, a 5 percent cap will be placed on any decrease in a hospital's wage index from the hospital's final wage index

in FY 2019. In other words, a hospital's final wage index for FY 2020 will not be less than 95 percent of its final wage index for FY 2019. No cap will be applied the second year.

Revision of the Calculation of the Inpatient Hospital New Technology Add-On Payment (NTAP)

Current statute specifies that a new medical service or technology may be considered for a new technology add-on payment (NTAP) if, based on the estimated costs incurred with respect to discharges involving the service or technology, the DRG prospective payment rate otherwise applicable is inadequate. Thus, the calculation of the new technology add-on payment is based on the cost to hospitals for the new medical service or technology. CMS has finalized their proposal to increase the maximum add-on amount from 50 to 65 percent of the costs of the new technology or medical service – except for medical products designated by the Food and Drug Administration (FDA) as Qualified Infectious Disease Products (QIDPs).

Beginning with discharges on or after October 1, 2019, if the costs of the discharge (determined by applying cost-to-charge-ratios or CCRs) exceed the full DRG payment – including payments for IME and DSH, but excluding outlier payments – Medicare will make an add-on payment equal to the lesser of:

1) 65 percent of the costs of the new medical service or technology; or
2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

CMS shares commenters concerns related to antimicrobial resistance due to its serious impact on Medicare beneficiaries and public health. Therefore, the agency has finalized its policy that for a new technology that is designated as a QIDP by the FDA, these products will receive a NTAP of 75 percent.

Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices & Antimicrobial Resistant Products

CMS finalized a proposal to develop an alternative pathway for transformative medical devices. The agency has created an alternative new technology add-on payment (NTAP) pathway for certain medical devices. Additionally, the agency has extended this payment pathway to a product that is designated by the FDA as a QIDP. This new pathway also includes any device that has received Premarket Approval (PMA), 510(k) clearance, or has been granted a De Novo classification request for FDA marketing authorization. Beginning in FY 2021 and for subsequent years, for applications CMS receives for NTAPs – if a medical device is part of the FDA's Breakthrough Devices Program or designated as a QDIP, and received FDA marketing authorization – it will be "considered new and not substantially similar to an existing technology" for NTAPs under the IPPS. Further, they will not be required to represent an "advance that substantially improves relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries."

In the final rule, CMS clarifies that this alternative inpatient NTAP pathway cannot be applied in situations where a "new drug designated for or approved under an FDA expedited program for drugs has received FDA marketing authorization." CMS believes that it is important and appropriate to distinguish between drugs and devices in this new alternative pathway, but will consider this issue in future rulemaking.

Chimeric Antigen Receptor (CAR) T-Cell Therapies

As expected, CMS finalized their proposal not to modify the MS-DRG assignment for cases reporting chimeric antigen receptor (CAR) T-cell therapies and also did not propose to create a new MS-DRG for these therapies. The agency did seek feedback, however, on "the most appropriate way to develop the relative weight if we were to finalize the creation of a new MS-DRG." The agency will consider comments received regarding CAR-T cell therapy payments in future rulemaking relating to the MS-DRG assignment for these cases. CMS continues to believe that given the "relative newness of CAR T-cell therapy", in addition to the agency's "consideration of approaches and authorities to encourage value-based care and lower drug prices, it would be premature to adopt structural changes" to existing payment mechanisms. However, CMS did finalize a maximum new technology add-on payment percentage of 65 percent of the costs of the technology for FY 2020. This increase to 65 percent will apply to all approved new technologies – including CAR T-cell therapy products.

Comprehensive CC/MCC Analysis

MS-DRG codes are defined as either a Complication or Comorbidity (CC) or a Major Complication or Comorbidity (MCC) when used as a secondary diagnosis. CMS proposed a multitude of changes to the classification of ICD-10 diagnosis codes to MCC/CC lists. As a result of CMS's review of the MCC/CC

lists – the agency proposed to change the severity level designation for 1,492 ICD-10 diagnosis codes[1]. Of these codes, 1,301 (87 percent) would have been shifted down in severity.

CMS noted that they received many comments on these proposed changes – the majority of commenters "requesting that the adoption of the proposed changes be delayed in order to provide additional time to evaluate given the broad scope" of the changes. After consideration of the public comments received, the agency agrees that "it would be premature to adopt broad changes to the severity designations at this time." Thus, CMS is not finalizing the proposed changes to the severity level designations for the ICD-10 diagnosis codes at this time – with the exception of changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a non-CC to a CC.

Additionally, in delaying comprehensive changes in severity level designations, CMS will have the opportunity to "incorporate review of additional ICD–10 claims data as it becomes available and to fully consider the technical feedback provided from the public on the proposed rule." Furthermore, the agency plans to "provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review, such as making a test GROUPER publicly available to allow for impact testing." CMS will examine if, in future rulemaking, it may be necessary to phase in any changes – rather than making them all at once.

Hospital Inpatient Quality Reporting (IQR) Program

CMS finalized several changes to the Hospital IQR Program – some differing slightly from the proposed rule. CMS finalized their proposal to adopt the eCQM Safe Use of Opioids – Concurrent Prescribing (NQF #3316e) beginning with the CY 2021 reporting period/FY 2023 payment determination. This measure is focused on the concurrent prescription of opioids and benzodiazepines at discharge to hopefully reduce preventable mortality and costs of adverse events associated with prescription opioid use. Additionally, CMS also finalized their proposal to adopt this eCQM for the Promoting Interoperability (PI) Program beginning with the reporting period in CY 2021. CMS is providing an updated version of the measure specifications, which can be found at the eCQI Resource Center's Pre-Rulemaking Eligible Hospital/Critical Access Hospital eCQMs website.

CMS finalized a change to the eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination. Hospitals will be required to report one, self-selected calendar quarter of data for three self-selected eCQMs and the Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. In other words, CMS is finalizing that all participating hospitals must report this measure as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination.

CMS is not finalizing their proposal to adopt the second opioid-related eCQM, the Hospital Harm – Opioid-Related Adverse Events eCQM, which was designed by CMS to reduce the rates of adverse events associated with opioid administration in the inpatient setting by utilizing the administration of naloxone as an indicator of harm.

CMS finalized their proposal to adopt the Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) measure (NQF #2879) in a "stepwise fashion." The two voluntary reporting periods will run from 1) July 1, 2021 through June 30, 2022; and 2) from July 1, 2022 through June 30, 2023. Required reporting of the measure will begin July 1, 2023 through June 30, 2024 – impacting the FY 2026 payment determination and for subsequent years. In the final rule, CMS also establishes reporting and submission requirements for the Hybrid HWR measure. In conjunction, CMS finalized their proposal to remove the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR claims-only measure) beginning with the FY 2026 payment determination.

Additionally, CMS finalized their proposal to continue requiring that electronic health records (EHRs) be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. These final eCQM policies under the Hospital IQR are aligned with finalized policies under the PI Program.

[1] FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246). Table 6.P.1c.

Medicare and Medicaid Promoting Interoperability (PI) Programs

CMS finalized several changes to the Promoting Interoperability (PI) Program. The agency is finalizing an electronic health record (EHR) reporting period of a minimum of any continuous 90-day period in CY 2021 for both new and returning eligible hospitals and critical access hospitals (CAHs) attesting to CMS. Measure actions must occur within the EHR reporting period beginning in CY 2021.

CMS finalized revisions to the Query of PDMP e-prescribing measure to remove exclusions associated with this measure, to convert the measure to a "yes/no attestation", and to make it an optional measure worth 5 bonus points in both CYs 2019 and 2020. In other words, if a hospital or CAH submits a "yes" for this measure, it will earn 5 bonus points in CY 2019 and 2020. Additionally, CMS is increasing the maximum points available for the electronic prescribing (e-Prescribing) measure from 5 points to 10 points beginning in CY 2020. CMS is removing the Verify Opioid Treatment Agreement measure beginning in CY 2020; however, the agency clarifies that this measure is still worth a full 5 bonus points in CY 2019.

Finally, CMS finalized the policy to eliminate the October 1, 2019 deadline for an eligible hospital that has not successfully demonstrated it is a meaningful EHR user in a prior year. Hospitals that have not met requirements to be a meaningful EHR user in the previous year will have the rest of CY 2019 to complete their respective minimum 90-day EHR reporting period for the FY 2020 payment adjustment year.

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 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.