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2021 Hospital IPPS/LTCH PPS Proposed Rule

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May 11, 2020, CMS published its annual proposed rulemaking for the federal fiscal year 2021 inpatient prospective payment system (IPPS) and long-term care hospital (LTCH) payment system. The proposals summarized in this Alert, which generally fall into three categories, relate to the topics below:

A. Reimbursement Policy/Appeals: 1) Medicare Bad Debt – Retroactive Changes to Regulation; 2) GME/IME Payments – Change in "Displaced Residents" Definition; 3) MS-DRGs – Required Data Reporting on Negotiated Rates for 2024 Recalibration; 4) DSH – Reduction in Uncompensated Care Payment from 2020; 5) DSH – *Allina* Supreme Court Decision *Not* Addressed; 6) Wage Index – New Geographic Designations; 7) Wage Index – Continuation of Upward Adjustment for Lowest Quartile Hospitals; 8) LTCH – Transition Payment Base Year Change; and 9) PRRB Appeals – Authority for Mandatory Use of Electronic Filing System.

B. Performance/Data Reporting: 10) Inpatient Quality Reporting and Hospital Acquired Condition Reduction Programs – Unified Validation; 11) Hospital Readmissions Reduction Program –Permanent Three-Year Reporting Period; 12) Hospital Acquired Condition Reduction Program – Permanent Twenty-Four Month Reporting Period; 13) Hospital Value-Based Purchasing Program – Future Changes to Benchmarks; 14) Electronic Health Record Reporting – Choice of Reporting Period and Publication of Data; and 15) PPS-Exempt Cancer Hospital Quality Reporting Program – Revised Standards.

C. New Technology Add-On Payments: 16) New Technology Add-On Payment Pathway for Certain Antimicrobial Products; and 17) New MS-DRG for CAR-T.

Comments on these proposals are due to CMS by July 10, 2020. While CMS specifically requests comments from interested parties on specific sections, we recommend you to consider submitting comments on any provision potentially affecting your organization. Please feel free to reach out with any questions you may have about these proposals.

A. REIMBURSEMENT POLICY/APPEALS

1) Medicare Bad Debt Reimbursement– Retroactive Changes to Regulation. CMS proposes to codify retroactively effective for cost-reporting periods beginning before, on, or after the effective date of the rule, CMS's purported prior interpretation of many of the bad debt provisions currently contained in the Provider Reimbursement Manual. Among other things, the proposed rule would retroactively codify (1) the presumption of noncollectibility after 120 days of reasonable collection efforts (but provide that the 120-day period would restart if any payments are received on the account); (2) the requirement that providers use similar collection efforts for Medicare and non-Medicare patients, including a provision that amounts remaining at a collection agency, for whatever reason, may not be claimed for Medicare bad debt reimbursement; (3) that in making a determination of indigency, providers must evaluate a patient's "total resources," including, but not limited to, an analysis of the patient's assets, liabilities, income, expenses, and any extenuating circumstances; and 4) the requirement that for dual eligible beneficiaries, the provider submit a bill to the State Medicaid program and furnish a Medicaid remittance advice to the contractor (although CMS specifically solicits comments regarding potential other sources of documentation that may be furnished when a Medicaid remittance advice is not available). In addition, the proposed rule would prospectively provide that reasonable collection efforts require the issuance of a bill on or before 120 days after the later of (1) the date of the Medicare remittance advice or (2) the date of the remittance advice from the beneficiary's secondary payer. Finally, the proposed rule would provide for certain changes in accounting for Medicare bad debt, based on recent changes in national accounting standards.

2) GME/IME Payments – Change in "Displaced Residents" Definition. CMS proposes to change the definition of a "displaced resident" for purposes of the GME and IME payments when a teaching hospital closes. Hospitals are allowed to temporarily exceed the cap on their FTE count for GME and IME purposes when they take in displaced residents from a closed teaching hospital. The agency's current policy, not provided for in the regulations, defines displaced residents only as those physically present at the hospital training on the day prior to or the day of hospital program closure. CMS proposes to expand the existing definition of displaced residents to include those training on the date of the announcement of the program closure, rather than the date of the closure itself, and also to remove the physical presence requirement to include residents training at other facilities or residents that had intended to train at the closing facility.

3) MS-DRGs – Required Data Reporting on Negotiated Rates for 2024 Recalibration. CMS proposes to require every hospital to report the median charges that the hospital negotiated with all Medicare Advantage organizations and third-party payers, broken down by MS-DRG. The agency claims that hospitals are already required to report this data as a result of the 2019 final OPPS rule and that the reporting burden would be minimal. However, a number of hospitals have filed suit in the United States District Court for the District of Columbia challenging the relevant portion of that 2019 rule. The court heard oral arguments (by videoconference) earlier this month but has not yet issued a decision. If the proposal is finalized, the information would be required on the hospital cost report, with further guidance on that process forthcoming. CMS expects that this data could be ready to be used to recalibrate MS-DRG weights by fiscal year 2024, and the agency has indicated it could finalize the proposal to use the negotiated rates to recalibrate the MS-DRG weights beginning in 2024 as early as the final 2021 IPPS rule. The agency is specifically seeking comments on both the proposed data collection, and the proposed usage to recalibrate MS-DRG weights.

4) DSH –Reduction in Uncompensated Care Payment from 2020. CMS proposes to pay a total of $7.817 billion in disproportionate share hospital (DSH) uncompensated care payments to hospitals, down from the $8.350 billion in total payments made for 2020. The agency started with a baseline of DSH payments made in 2017, and then used largely the same assumptions and estimates as prior years, including estimates for the levels of Medicaid expansion and an assumption that expansion populations cost half as much as traditional Medicaid beneficiaries, to arrive at an estimated figure of DSH amounts that would be paid in 2021 (so called Factor 1). Similar to 2020, Factor 2 would use the same CMS actuary data to estimate that the ratio of the uninsured fell from 14% to 9.5% between 2013 and 2021, which by statute further reduced the pool of available funds to the proposed amount of $7.817 billion. The calculation for distributing the pool (Factor 3) will be based solely on the charity care figures from hospitals' FY 2017 cost report Worksheet S-10s. The agency used a February 19, 2020 HCRIS extract for the Worksheet S-10 data for the proposed rule, and proposes to use a March 31, 2020 extract in the final rule calculations. Hospitals noting any errors with their Factor 3 data have until July 10, 2020 to notify the agency by sending an email to the following account: Section3133DSH@cms.hhs.gov.

5) DSH– *Allina* Supreme Court Decision *Not* Addressed. CMS **does not** address the treatment of Part C days in the DSH calculation in this proposed rule. Last June, the Supreme Court issued its decision in *Azar v. Allina Health Services*, which held that the agency was required by the Medicare Act to undertake notice-and-comment rulemaking prior to readopting its previously vacated 2004 rule on the treatment of Part C days. Since that time, the government has indicated in court filings that it intends to undergo additional rulemaking to implement the decision. While not addressed in this proposed rule, CMS appears to be working on a separate proposed rule entitled "Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage," which has been at the Office of Management and Budget (OMB) for approval since March 12, 2020. OMB's standard review period is 90 days, but this period can be extended either by OMB or by request of the agency.

6) Wage Index – New Geographic Designations. In 2018, the OMB made updates to a number of geographical areas across the country, which in turn led to some areas changing from urban to rural and vice versa. CMS proposes to incorporate these new area designations in the calculation of the wage index for 2021. As a result, 34 counties that were previously considered part of an urban area are now located in a rural area, and 47 counties that were previously in rural areas would now be located in urban areas for wage index purposes. Additionally, some counties are being shifted from

one urban location to another urban location, which could also impact the wage index for the counties. While historically CMS has applied a two-year transition period to smooth changes in the labor markets, for this proposed rule, the agency instead proposes a 5% cap on the amount of a potential wage index decrease associated with a change geographical designation. Hospitals that wish to change their reclassification status as a result of these labor area changes are required to notify the MAC of their request within 45 days of the date this proposed rule is published in the Federal Register by emailing WageIndex@cms.hhs.gov. The Proposed Rule is scheduled to be published in the Federal Register on May 29, 2020.

7) Wage Index – Continuation of Upward Adjustment for Lowest Quartile Hospitals. In the fiscal year 2020 rulemaking, CMS enacted an upward adjustment to the wage indices for hospitals in the lowest wage index quartile. While the agency had initially proposed to achieve budget neutrality by reducing the wage indices of those hospitals in the upper quartile, ultimately the agency decided to achieve budget neutrality by applying a downward adjustment to the national standardized amount for all hospitals nationwide. CMS proposes to make this same adjustment in the same manner for the 2021 fiscal year as well.

8) LTCH – Transition Payment Base Year Change. Since 2017, CMS has calculated the LTCH PPS standard rate using market basket data from 2013. CMS proposes to rebase the standard rate to use updated market basket data from a 2017 base year. In 2013, Congress enacted a provision that required LTCHs to be paid at the lower, inpatient payment rate for patients CMS believed could be treated in a lower-cost setting. Instead of implementing this so-called "site neutral" policy immediately, CMS implemented a transition payment system whereby LTCHs were paid a blend of the IPPS and LTCH rates for such patients. CMS's proposed rule notes this transition payment system is no longer effective in 2021. CMS in turn estimates this decreases payments for these site-neutral services by 20%.

9) PRRB Appeals – Authority for Mandatory Use of Electronic Filing System. In August 2018, the PRRB launched a voluntary electronic filing system to manage its docket. CMS proposes to give the PRRB the power to make this filing system mandatory once the 2021 federal fiscal year begins on October 1, 2020, but is also requiring a 60-day notice period before the PRRB can make the electronic filing system mandatory. As a result, the earliest date the PRRB could make its filing system mandatory is November 30, 2020. CMS also proposes a host of amendments to the regulations governing filings with the PRRB to reflect that filings are no longer required to be in hardcopy, and can now be made electronically. Notably, CMS does not propose to change the regulation text providing for a presumed receipt date of five days after the issuance of any MAC or Board document.

B. PERFORMANCE/DATA REPORTING

10) Inpatient Quality Reporting and Hospital Acquired Condition Reduction Programs – Unified Validation. CMS proposes to create a unified validation process for the Inpatient Quality Reporting ("IQR") program and Hospital Acquired Condition ("HAC") Reduction Program. First, CMS proposes to increase the number of quarters for which hospitals are required to report electronic clinical quality measures ("eCQM") data from one self-selected quarter of data to all four quarters by 2023 (FY 2025). Beginning in 2023 (FY 2025) and for each subsequent year thereafter, hospitals would be required to report four calendar quarters of data, inclusive of three self-selected eCQMs and the Safe Use of Opioids eCQM. Next, CMS proposes to change the period for validation affecting the FY 2023 payment determination. In 2021 (FY 2023), only Q3 and Q4 chart-abstracted measurement data would be validated. Thereafter, chart-abstracted measures would be evaluated on a Q1 to Q4 basis within the same year (*i.e.*, Q1 – Q4 of 2021 for FY 2024), aligning the chart-abstracted measures and eCQM data reporting time frames. Finally, CMS proposes to evaluate up to 400 hospitals for both targeted and random selection for validation of chart-abstracted measures and eCQMs as of 2022 (FY 2024), down from 800 hospitals. Up to 200 hospitals would be validated randomly, and up to 200 would be validated using previously finalized targeting criteria. The hospitals selected would then be validated for both the inpatient quality reporting program and hospital-acquired condition reduction program. Hospitals that participate only in the HAC program and not in the IQR program would be excluded from the randomly selected hospitals in the revised validation process.

11) Hospital Acquired Condition Reduction Program – Permanent Twenty-Four Month Reporting Period. The HAC Reduction Program currently evaluates participating hospitals through six measurements: one CMS patient safety and adverse events measure and five CDC health care-associated infections measures. Since 2019, these measurements have been collected over two distinct 24-month periods, with the patient safety period spanning from January 1 to December 31, and the CDC infection reporting period spanning from July 1 to June 30. CMS proposes to make permanent the use of a 24-month measurement period for each set of measurements with automatic adjustment for subsequent fiscal years. Thus, for FY 2023, the applicable period for the CMS PSI 90 would be the 24-month period from July 1, 2019 through June 30, 2021, and the applicable period for CDC infection measures would be the 24-month period from January 1, 2020 through December 31, 2022. The period would advance by one year each year automatically thereafter.

12) Hospital Readmissions Reduction Program – Permanent Three-Year Reporting Period. The Hospital Readmission Reduction Program reduces payments to hospitals based on readmission rates. Traditionally, CMS has used three years of data for measuring readmissions, and the applicable period is announced with each rulemaking. CMS proposes to make permanent the three-year reporting period of readmission data for the Hospital Readmissions Reduction Program. The proposed change would take effect in 2021 (FY 2023), with the first reporting period spanning from July 1, 2018 through June 30, 2021, and advancing by one year each year automatically thereafter (e.g., July 1, 2019 – June 30, 2022 for FY 2024).

13) Hospital Value-Based Purchasing Program – Future Changes to Benchmarks. CMS proposes to establish performance standards in the hospital value-based purchasing program (the "VBP") for the FY 2023, 2025, and 2026 financial years, and is not making any proposals for FY 2021. The proposed rule would establish the safety domain CAUTI, CLASBI, CDI, MRSA, and Colon and Abdominal Hysterectomy SSI benchmarks for FY 2023 and the CMS PSI 90 benchmark for FY 2025. As of FY 2026, the safety domain would be eliminated from the VBP.

14) Electronic Health Record Reporting – Choice of Reporting Period and Publication of Data. CMS proposes to make a number of small changes to EHR reporting. Under the proposed rule, providers could choose any continuous 90-day period for EHR reporting for both CY 2021 and 2022. Further, CMS is seeking comment on the proposal to revise the IQR rule to publicly report eCQM data online, and to progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a three-year period, by requiring hospitals to report two quarters of data for the CY 2021 reporting period, three quarters of data for the CY 2022 reporting period, and four quarters of data beginning with the CY 2023 reporting period and for subsequent years. Providers could earn five bonus points under the meaningful use rules by conducting a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history for a prescription of a Schedule II opioid, but this is optional under the proposed rule.

15) PPS-Exempt Cancer Hospital Quality Reporting Program – Revised Standards. CMS proposes to revise two existing National Healthcare Safety Network (NHSN) quality reporting measures used by PPS-exempt cancer hospitals. CMS proposes to change the Catheter-associated Urinary Tract infection (CAUTI) and Central Line-associated Bloodstream Infection (CLABSI) measures to incorporate an updated calculation methodology developed by the CDC (SIR) that uses updated infection baseline data that is risk-adjusted to stratify results by patient location. CMS also proposes to begin to report publicly the updated versions of the CLABSI and CAUTI measures in the fall of CY 2022.

C. NEW TECHNOLOGY ADD-ON PAYMENTS

16) New Technology Add-On Payment Pathway for Certain Antimicrobial Products. CMS proposes to approve the nine technologies submitted through the FDA Breakthrough Devices and FDA Qualified Infectious Disease Product (QIDP) program and to continue the new technology add-on payments for 10 of the 18 technologies currently receiving the payment. CMS also proposes to make antimicrobial drugs approved under FDA's Limited Pathway for Antibacterial and Antifungal Drugs (LPAD) automatically considered "new and not substantially similar" to existing technology for purposes of qualifying for the add-on payment. The proposed rule would also allow for conditional approval for antimicrobial products that otherwise meet the add-on payment criteria but do not receive marketing authorization in

time, provided that the products receive marketing authorization by July 1 of the year in which the application for add-on payments was submitted. Additionally, the proposed rule would increase from 65 to 75 percent the maximum add-on payment for new products approved through the LPAD pathway. This add-on payment applies when the cost of the new product exceeds the amount paid by Medicare, and would be the lesser of 75% of the costs of the product or 75% of the amount by which the cost exceeds the Medicare payment rate.

17) New MS-DRG for CAR-T. CMS proposes to create a new MS-DRG (MS-DRG 018) specifically for cases involving Chimeric Antigen Receptor (CAR) T-cell therapies. CAR-T cell therapy currently is reimbursed under the MS-DRG associated with bone marrow transplant with a new-technology add-on payment. The standard rate for this MS-DRG would be $913,224, before any hospital-specific adjustments.