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CMS Releases Its FY 2021 IPPS and LTCH-PPS Proposed Rule

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CMS recently released its annual inpatient prospective payment system (IPPS) and long term care hospital prospective payment system (LTCH PPS) proposed rule for FY 2021. CMS' "singular objective" for the rule is to "transform[] the healthcare delivery system through competition and innovation to provide patients with better value and results." Comments on the proposed rule are due by Friday, July 10, 2020. Noting the significant resources currently being devoted to the nation's response to the COVID-19 public health emergency (PHE), CMS is waiving the 60-day delay in the effective date of the final rule, and replacing it with a 30-day delay in the effective date of the final rule. By shortening the period between publication and implementation of the final rule, CMS is giving itself more time to work on the rule (90 rather than 60 days) and giving those to whom the rule applies less time to implement the final rule (30 rather than 60 days).

In the proposed rule, CMS proposes several different payment rules and policies designed to achieve different ends. CMS introduces proposals to impact new technology add-on payments, create a new MS-DRG, and change payment rates for hospitals and for long term care hospitals. The agency seeks to redefine and automatically adopt applicable periods for certain programs, to publicly report electronic clinical quality measures and some hospital-acquired infection measures, to propose new performance standards for the future of the Hospital Value-Based Purchasing Program, and to rely on new data sources to distribute Medicare uncompensated care payments. Additional proposals are meant to assist residents transitioning to alternative hospitals, to postpone certain rulemakings (also in recognition of the significant impact of the PHE), and to encourage eligible professionals and hospitals to achieve meaningful use of certified electronic health record (EHR) technology.

A summary of the proposed rule's highlights is provided below.

New Technology Add-On Payment (NTAP) for Certain Products

- CMS presents 24 new applications for new technology add-on payments for FY 2021. Of the 24 technologies:
  - Three technologies were submitted by applicants as a new medical device through the FDA Breakthrough Devices Program.
  - Six of the technologies had received the FDA Qualified Infectious Disease Product (QIDP) designation.
  - The remaining 15 technologies were submitted by applicants through the traditional new technology add-on payment pathway criteria.
- CMS proposes continuing the new technology add-on payment for ten of the 18 technologies currently receiving the add-on payment, as the other eight technologies will no longer be within their newness period in FY2021.
- CMS also proposes two new processes to increase the availability of products approved under the FDA's Limited Population Pathway for Antimicrobial and Antifungal Drugs (LPAD).

- As is currently the case for QDIPs, an antimicrobial drug approved under the FDA's LPAD pathway would be considered new and not substantially similar to an existing technology and would not need to demonstrate that it meets the substantial clinical improvement criterion. The technology would still need to meet the cost criterion for new technology add-on payments.
- The agency would provide conditional approval for antimicrobial products that otherwise meet the NTAP alternative pathway criteria but have not yet received FDA approval in time to be included in the final rule. CMS will allow these products to begin receiving the NTAP effective for discharges the quarter after the date of the FDA marketing authorization, provided the authorization is received by July 1 of the year for which the applicant applied for a NTAP. This will allow the applicant to receive the NTAP payments sooner than they would otherwise.

New MS-DRG for Chimeric Antigen Receptor (CAR) T-cell Therapy

- CMS proposes to create a new MS-DRG specifically for cases involving CAR T-cell therapies.

Proposed Changes to Payment Rates under IPPS

- CMS estimates a total increase in overall IPPS payments of approximately 1.6 percent, which will lead to a projected increase in Medicare spending on inpatient hospital services, including capital, of about $2.07 billion in FY 2021. For hospitals, this includes:

  - An increase in operating payment rates of approximately 3.1 percent for general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful EHR users. This reflects:
    - A projected hospital market basket update of 3.0 percent;
    - A 0.4 percentage point downward reduction for a productivity adjustment; and
    - A proposed 0.5 percent adjustment/increase required by legislation.
  - Hospitals may also be subject to other payment adjustments under the IPPS, including:
    - Penalties for excessive readmissions;
    - Penalties for the worst performing quartile under the Hospital-Acquired Condition Reduction Program; and/or
    - Upward and downward adjustments under the Hospital Value-Based Purchasing Program.

Medicare Uncompensated Care Payments

- CMS proposes distributing approximately $7.8 billion in uncompensated care payments in FY 2021, a decrease of approximately $0.5 billion from FY 2020.
- To distribute the funds in FY 2021, CMS proposes to use a single year of previously-audited data on uncompensated care costs from Worksheet S-10 of the FY 2017 cost report. For all fiscal years going forward, CMS further proposes using the most recent available single year of audited Worksheet S-10 data to distribute uncompensated care payments.

  - To allow for the "unique challenges" facing Indian Health Service and Puerto Rico hospitals, CMS proposes to use a methodology similar to that of FY 2020 where data regarding low-income insured days (Medicaid days for FY 2013 and FY 2018 SSI days) would be used to determine the amounts of their uncompensated care payments.

Graduate Medical Education Policy

- CMS proposes expanding the current definition of a "displaced resident" to address the needs of residents at closing teaching hospitals and residency programs in their attempts to find alternative hospitals in which to complete their training, and to foster "seamless" Medicare indirect medical education and direct graduate medical education funding.

Hospital-Acquired Condition (HAC) Reduction Program

- CMS proposes to:

  - Update the definition of "applicable period" at 42 C.F.R. § 412.170;
  - Automatically adopt applicable periods beginning with the FY 2023 program year and going forward; and
  - Refine the program's validation procedures so that they align with the concurrent Hospital IQR Program's validation procedures.

Hospital Readmissions Reduction Program (HRRP)

- CMS proposes to:

  - Update the definition of "applicable period" at 42 C.F.R. § 412.152 and
  - Automatically adopt applicable periods beginning with the FY 2023 program year and going forward.

Hospital IQR Program

- CMS proposes changes to the reporting and public reporting of electronic clinical quality measures (eCQMs) and the existing validation process including:

  - Changing hospital reporting of eCQMs by:
    - Increasing over a three-year period the number of quarters of eCQM data that hospitals must report by requiring them to report two quarters of data for the CY 2021 reporting period/FY 2023 payment determination. From this, the number of quarters that hospitals must report would increase by one each year so that four quarters of data are reported for the CY 2023 reporting period/FY 2025 payment determination and for all years going forward.
    - Publicly displaying the hospital eCQM data on Hospital Compare and/or data.medicare.gov for the first time, beginning with the CY 2021 reporting period/FY 2023 payment determination and for all years going forward.
  - Changing the Hospital IQR Program validation process by:
    - Requiring the use of electronic file submissions via a CMS-approved secure file transmission process for chart-abstracted measure validation.
    - Reducing from up to 800 to up to 400 the number of hospitals selected for validation.
    - Aligning data submission quarter, hospital selection, and scoring processes to combine the validation processes for chart-abstracted measures and eCQMs. Hospitals would receive one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the score weighted at zero.
    - Aligning the process for conducting educational reviews for eCQM validation with the more formalized current processes for providing feedback for chart-abstracted validation results.

Hospital Value-Based Purchasing (VBP) Program

- CMS is not proposing to add or remove measures from the Hospital VBP Program in this proposed rule but is providing estimated and new established performance standards for certain measures for the FY 2023, FY 2024, FY 2025, and FY 2026 program years.

PPS-Exempt Cancer Quality Reporting (PCHQR) Program

- CMS proposes to:

- Incorporate an updated methodology developed by the Centers for Disease Control and Prevention to refine the existing National Healthcare Safety Network measures for catheter-associated urinary tract infection (CAUTI) and central line-associated bloodstream infection (CLABSI) in a manner that uses updated and risk-adjusted HAI baseline data to stratify results by patient location.
- Begin publicly reporting the updated CAUTI and CLABSI measures in the fall of CY 2022.

Hospital Star Ratings

- CMS proposes to postpone rulemaking to update the Overall Hospital Quality Star Rating methodology in recognition of the significant impact of the PHE on the capacity of health care providers to review and provide comment on the proposals.

Medicare and Medicaid Promoting Interoperability Programs

- CMS seeks public comment on several CY 2021 proposals to encourage eligible professionals, hospitals, and critical access hospitals "to adopt, implement, upgrade, and demonstrate meaningful use of certified EHR technology" including:

  - A minimum EHR reporting period for new and returning eligible hospitals and critical access hospitals of 90 continuous days in the Medicare Promoting Interoperability Program.
  - Continuing the Query of Prescription Drug Monitoring Program measure as an optional measure worth five bonus points in CY 2021.
  - Renaming the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.
  - Changing hospital reporting of eCQMs by:
    - Increasing over a three-year period the number of quarters of eCQM data that hospitals must report by requiring hospitals to report two quarters of data for the CY 2021 reporting period/FY 2023 payment determination. From this, the number of quarters that hospitals must report would increase by one each year so that four quarters of data are reported for the CY 2023 reporting period/FY 2025 payment determination and for all years going forward.
    - Publicly displaying the hospital eCQM data for the first time on Hospital Compare and/or data.medicare.gov beginning with the CY 2021 reporting period/FY 2023 payment determination and for all years going forward.
  - Correcting technical errors in the regulation text regarding the transition factors for the incentive payments to Puerto Rico eligible hospitals.

Payment Rates Under LTCH PPS

- CMS estimates a total decrease in overall LTCH PPS payments of approximately 0.9 percent or about $36 million in FY 2021. LTCH PPS payments are expected to decrease by approximately 20 percent for cases that will complete the statutory transition to the lower payment rates under the dual rate system.
- Payments for discharges paid using the standard LTCH payment rate are expected to increase by 2.1 percent, including the proposed annual standard federal rate update for FY 2021 of 2.5 percent, an estimated decrease in outlier payments, and other factors.

Provider Reimbursement Review Board Electronic Filing

- The Provider Reimbursement Review Board (PRRB) is responsible for resolving provider payment disputes typically arising from certain Medicare Part A final determinations (usually cost report

appeals). On August 18, 2018, the Board began accepting filings electronically. The agency proposes technical changes to its rules to support the use of electronic filing, e.g., updates to definitions such as "date of receipt."
- The agency is also proposing to update the regulations to allow the Board to adopt mandatory electronic filing no earlier than FY 2021, and require at least 60 calendar days' notice by the PRRB.

Medicare Bad Debt Policies

- CMS proposes to adopt a number of rules consistent with its bad debt litigating positions in past years. Most of these rules would be adopted retrospectively as clarifications, but not all. A discussion of the provisions of the proposed rule related to Medicare bad debts can be found in Tom Coons' accompanying article in *Payment Matters*, which can be found here.

Implications of the Proposed Rule

The FY 2021 IPPS and LTCH PPS proposed rule focuses on revising payment rates for IPPS and long term care hospitals, increasing the role of data collection and reporting, standardizing and modernizing data-related definitions and validation processes, setting a framework for the future of some programs, and making allowances for the effects that the PHE has had on all health care providers.

Although the agency is giving itself additional time to finalize the rule, it is giving providers less time to prepare to implement the final rule once it is published. Specifically, the agency now has until September 1, 2020, to publish the final rule; since the final rule becomes effective October 1, 2020, providers may have as little as 30 days to adapt to the changes required by this rule. Providers should start preparing now.

Those interested in providing comments to the agency for consideration in formulating the final rule must do so be 5 p.m. on July 10, 2020. Baker Donelson is assisting interested parties in analyzing the impact the proposed payment rates and policies will have on their operations and in preparing responses to CMS to influence the final rule. For specific guidance or more information on this topic, please contact Stefanie Doyle or any member of Baker Donelson's Reimbursement Team.