September 1, 2020

- **As nursing facilities across the country struggle to cope with the ongoing challenges presented by COVID-19, the Centers for Medicare & Medicaid Services ("CMS") highlight certain state actions that could enhance payments for such facilities during the public health emergency.**

    - On August 24, 2020, CMS released a Medicaid Informational Bulletin, "Nursing Home Strategies for COVID-19 Only Isolation of COVID-19 Residents," (the "Bulletin"), identifying flexibilities available to state Medicaid agencies to enhance payments for nursing facilities during the COVID-19 crisis. Enhanced payments to such facilities would "account for potentially increased resident acuity levels and to support any necessary actions that facilities are implementing to mitigate the further spread of COVID-19, such as isolation or quarantine of residents and adherence to Federal infection control guidelines."

    - In the Bulletin, CMS states that it has prioritized, and will continue to prioritize, the review and approval of Medicaid Disaster Relief State Plan Amendments ("SPAs") that address enhanced payments to nursing facilities, and provides examples of nursing facility payment enhancements available to states, including but not limited to, the following:

        - Instituting per diem dollar increases or percentage increases to existing base rates for all nursing facilities, or only for facilities with residents diagnosed with COVID-19;

        - Establishing new payment methodologies for nursing facilities serving as isolation centers;

        - Modifying current rate setting methodologies to allow for additional costs and factors to be considered;

        - Removing state plan-established payment penalties, such as penalties for late filing of cost reports or for not satisfying certain metrics; and

        - Creating new targeted supplemental payments.

    - CMS also discusses flexibilities available to states with managed care delivery systems, including implementing state-directed payments, and highlights specific actions taken by Ohio, Michigan and Iowa to support nursing facilities during the pandemic.

    - **Key Takeaway**: In addition to funds available to nursing facilities through the Coronavirus Aid, Relief, and Economic Security Act and the Paycheck Protection Program and Health Care Enhancement Act, enhanced payments to nursing facilities could serve as an additional tool to help nursing facilities provide their residents with the quality care they deserve.

- **In a move heavily criticized by the American Hospital Association ("AHA") as "heavy-handed," the Center for Medicare & Medicaid ("CMS") bypassed the normal process and revised regulations to strengthen COVID-19 testing and reporting requirements, threatening to expel from participation hospitals that fail to comply with now mandatory reporting requirements.**

    - On August 25, 2020, CMS announced an interim final rule with comment period ("IFC") updating regulatory requirements for COVID-19 reporting, among other things.

    - Although the vast majority of hospitals and critical access hospitals ("CAHs") already were reporting COVID-19 data on a voluntary basis, the IFC will require universal COVID-19 reporting, and CMS is threatening to expel from Medicare and Medicaid participation those hospitals and CAHs that fail to comply.

    - The reporting obligation is implemented through amendments to Medicare conditions of participation ("CoPs") and will require data to be reported in a standardized format, at a frequency, and in a manner all as to be specified by the Secretary of the U.S. Department of Health and Human Services ("Secretary"). The IFC refers to July 29 FAQs (available here) for the current list of reportable items; an associated CMS press release states that hospitals will be required to report daily on elements that include but are not limited to the number of confirmed or suspected COVID-19 positive patients, ICU beds occupied, and the availability of essential supplies and equipment (e.g., ventilators and PPE). The IFC also mentions numbers of staffed and occupied beds as potential reporting elements.

    - According to the IFC, CMS "will enforce violations of reporting requirements to the extent authorized by the Secretary." Moreover, hospitals or CAHs that consistently fail to report results throughout the COVID-19 public health emergency will be out of compliance with CoPs and subject to termination from program participation. Although CMS notes that it currently lacks statutory authority to impose civil money penalties against hospitals and CAHs, CMS states, "we will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation."

    - The AHA issued a press release in response to the IFC almost immediately, requesting immediate reversal and characterizing CMS's threat to expel hospitals from Medicare participation as a "disturbing move." "America's hospitals remain fully committed to ensuring that the federal government gets the data it needs. It's beyond perplexing why CMS would use a regulatory sledgehammer—threatening Medicare participation—to the very organizations that are on the frontlines in the fight against COVID-19."

    - **Key Takeaway:** Although the IFC is accompanied by a 60-day comment period, hospitals may need to scramble to ensure compliance, particularly if the required reporting elements differ from those hospitals that have been voluntarily reporting. The IFC is scheduled to be published in the *Federal Register* on September 2; because CMS found good cause to waive the normal 30-day delay in the effective date, the IFC will become effective immediately upon publication.

- **The delay in finalizing proposed clarifications to the Stark Law means uncertainty and risk will linger for at least another year.**

    - In June, we addressed the upward trend in Stark Law related False Claims Act ("FCA") settlements and the continuing lack of clarity around interpretation of certain Stark Law provisions, and noted that the October 17, 2019 Proposed Rule published by CMS to update and clarify the Stark Law regulations included proposals to clarify key provisions of the Stark Law, not the least of which was the oft-misinterpreted "taking into account the volume or value of referrals" provision.

    - Although a final rule was originally slated to be finalized last month, on August 27, CMS published a notice continuing the effectiveness of the proposed rule and extending the timeline for publication of a final rule to August 31, 2021, due to "the complexity of the issues raised by comments received on the proposed rule."

    - This is not welcome news for providers. The proposed rule included important clarifications on several key regulatory provisions aimed to reduce misinterpretations and misapplications of the law, including much needed clarifications on the volume or value standard and the removal of such standard from the regulatory definition of fair market value. Unfortunately, the current ambiguities around such terms—and the associated risk of misinterpretations thereof—will linger for at least another year.

    - **Key takeaway:** By delaying finalization of the proposed rule to August 2021, providers are left with something less than half a loaf – the concepts of fair market value and the volume or value standard will remain intertwined in the regulations, and providers will have to rely solely on the proposed rule's preamble discussion should enforcement officials, qui tam relators or courts misapply these concepts.

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