

CMS Extends Publication of Final Stark Rule Amendments until August 31, 2021

Sep 03 2020

Practice Area: Health Law

CMS announced on August 27 that it is delaying publication of its final rule on amendments to the Stark physician self-referral rule until August 31, 2021. CMS had previously announced its intent to publish the final rule in August 2020.

CMS issued its proposed rule on October 17, 2019 in conjunction with its "Patients over Paperwork Initiative." The proposed rule is part of HHS's "Regulatory Sprint to Coordinated Care," which looks at federal regulations that may be impeding provider efforts to better coordinate patient care. CMS intended to address what it characterized as Stark's "undue regulatory impact and burden." It proposed new exceptions for certain value-based compensation arrangements in recognition of the ongoing transition to value-based rather than fee-for-service arrangements, and for donations of cybersecurity technology and related services. The proposed rule would also amend an existing exception for electronic health records (EHR) items and services. Further details on the October 2019 proposed rule are set forth in a summary prepared by von Briesen's Health Law Section, found [here](#).

CMS received a significant volume of comments and stated in its August 27 announcement that "we are still working through the complexity of the issues raised by comments received on the proposed rule and therefore we are not able to meet the announced publication target date" of August 2020. The American Hospital Association quickly panned the delay, issuing a statement that "This is an extremely disappointing setback for hospital and health system efforts to continue to innovate coordinated care arrangements, which have great potential to benefit patients, lower costs and make care more accessible for everyone." AHA urged CMS "to move more quickly to finalize these improvements." Read the AHA article [here](#).

At the time that CMS issued its proposed rule in October 2019, the HHS Office of Inspector General published a companion proposal for changes to the Federal anti-kickback statute and civil monetary penalties law (CMP) for certain coordinated care and associated value-based arrangements; patient engagement and support arrangements to improve quality and efficiency of care and care outcomes; donations of cybersecurity technology; EHR arrangements; and other new and existing safe harbors. As of the date of this *Legal Update*, it remains uncertain how the delay in publication of the CMS Stark final rule will impact finalization of the OIG proposed rule.

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