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Stark Law Updates Delayed Until August 2021

Many in the healthcare industry have been anxiously awaiting the release of finalized updates to the physician self-referral laws, commonly known as the “Stark Laws.” However, on August 24, the Centers for Medicare and Medicaid Services (“CMS”) and the Department of Health and Human Services (“HHS”) released a [notice](#) that the deadline to finalize these regulations has been delayed until August 31, 2021. These regulations are significant because they contain provisions that govern financial arrangements between healthcare entities and those, namely physicians, in a position to make referrals to such entities. The proposed rule was released in October 2019, and was open to public comments until December 31, 2019. The changes were intended to provide a framework for healthcare providers to develop value-based arrangements to enhance care coordination for patients, while maintaining reasonable protections against fraud and abuse. The regulations are significant to valuers of hospital and physician services arrangements because they are intended to clarify guidance on the definition of “commercial reasonability” and update guidance on how regulators define “fair market value”.

Additionally, the proposal created new exceptions for donations of cybersecurity technology and amendments to existing exceptions relating to electronic medical records equipment and services. The proposed rule has been under review by the Office of Management and Budget since July 21, and it was expected to be issued in final form this month. The proposal received broad support from hospitals, physicians, and insurers. However, HHS indicated that they are still “working through the complexity of the issues raised by comments received on the proposed rule.”

It is not known at this point whether the release of finalized updates to anti-kickback regulations will also be delayed. Those proposed rules were released by the Office of the Inspector General (“OIG”) in October 2019, coinciding with the release of the proposed Stark Law updates given that both sets of regulations address financial arrangements between hospitals and physicians and therefore both must be updated in tandem to allow healthcare entities to develop compliant arrangements. Accordingly, the delayed release of the Stark Law updates almost certainly means we will see a similar delay in the updates to the anti-kickback regulations.