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CMS Releases Long-Awaited Stark Proposed Rule

The Centers for Medicare and Medicaid Services (CMS) has released a long-awaited proposed rule that aims to reform and modernize the regulations ([42 C.F.R. §411.350](#) et seq.) pertaining to the physician self-referral law (42 U.S.C. §1395nn), often referred to as the “Stark” law.

The Stark law prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of any “designated health services” if the physician or his/her immediate family member has a financial relationship with the entity. The list of Stark’s designated health services includes clinical laboratories, diagnostic imaging, and inpatient and outpatient hospital services. The referrals are prohibited unless the particular arrangement meets all requirements contained in a regulatory exception. Twenty-five different exceptions exist under the current Stark regulations.

The Stark law, along with the [federal anti-kickback statute](#) (42 U.S.C. § 1320a-7b(b)), the federal civil monetary penalty rules ([42 U.S.C. § 1320a-7a\(a\)\(5\)](#)) and other anti-fraud laws, have come under criticism that they act as roadblocks to certain arrangements that support value-based and coordinated care. Critics have called on regulators to update these provisions to reflect the trend, in both the government and private sectors, toward paying for care based on outcomes rather than volumes.

Perhaps not for the faint of heart, CMS’s proposed rule and its preamble background discussion and commentary clock in at nearly 400 pages in length. The proposed rule is part of what the Department of Health and Human Services (HHS) has deemed as the “Regulatory Sprint to Coordinated Care.” That initiative reflects the agency’s efforts, in its words, to “promote value-based care by examining federal regulations that impede efforts among providers to better coordinate care for patients.”

The proposed rule would create new exceptions to the Stark law for value-based arrangements, which aim to reflect that incentives are

different in a healthcare system that pays for value rather than the volume of services provided, as with traditional fee-for-service Medicare. CMS indicated these new exceptions “ensure the Stark law will continue to provide meaningful protection against overutilization and other harms, while giving physicians and other healthcare providers added flexibility to improve the quality of care for their patients.”

The proposed rule also seeks to modernize itself with new exceptions reflecting the current healthcare landscape. For example, an existing exception covers donations of electronic health records by a hospital to a physician practice. In the same vein, a new proposed exception covers donations of cybersecurity software, which is practical in light of the recent proliferation of hacking episodes aimed at electronic health records.

In addition, the proposed rule seeks to [improve certain existing elements of the Stark law exceptions](#). As one example, several exceptions include a requirement that the particular arrangement must be “commercially reasonable”; however, the current regulations do not include a definition for that term. Under the proposed rule, “commercially reasonable” would be defined as meaning “the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.”

CMS will be accepting comments on the proposed rule for a 75-day period after its official publication in the Federal Register.

HHS’s press release on the proposed Stark rules can be read [here](#), while the proposed rule in its entirety can be read [here](#).

If you have questions, please contact [Jim Dietz](#) at 859-817-5928.

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