Regulatory Changes to Stark Law

By Richard Kusserow | November 25, 2020

The Centers for Medicare and Medicaid Services (CMS) announced regulatory changes to the Physician Self-Referral Law ("Stark Law"), which prohibits a physician from referring a patient for many types of services (or "designated health services") to a provider with which the physician has a financial relationship. CMS stated that the old rules were designed for a health care system that reimburses providers on a fee-for-service basis, which provides financial incentives to deliver more services. It recognized the increasing movement toward financial arrangements that reward providers who are successful at keeping patients healthy and out of the hospital and thereby tie payment to value rather than volume. The prior system has resulted in health care providers spending millions of dollars to comply with obscure regulations instead of putting those funds toward patient care. It has also impeded the move toward value, not just in Medicare, but across all payers, including Medicaid and private health plans. With providers taking on the accountability for the total cost of care for their patients, the risks related to self-referral have changed and needed to be recognized in the regulations. The final rule changes include the following:

- **Finalizing new permanent exceptions for value-based arrangements** that will permit physicians and other health care providers to design and enter into value-based arrangements without fear that legitimate efforts to increase care coordination, increase quality of care, and lower costs will violate the Stark Law. This supports CMS' broader push to advance coordinated care and innovative payment models across Medicare, Medicaid, and private plans.

- **Finalizing additional guidance on key requirements of the exceptions to the physician self-referral law** to make it easier for physicians and other health care providers to make sure they comply with the law.

- **Finalizing protection for non-abusive, beneficial arrangements** that apply regardless of whether the parties operate in a fee-for-service or value-based payment system.

- **Reducing administrative burdens that drive up costs** by taking funds previously spent on administrative compliance and redirecting them to patient care.

Unless otherwise specified, all provisions in this rule will go into effect 60 days from the rule's display date in the Federal Register.

CMS indicated that this rule will result in better access and outcomes for patients by creating clearer paths for providers to engage in enhanced coordinated care arrangements. CMS further

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stated that the new exceptions are narrowly tailored to allow for value-based care coordination. CMS has also retained the strong patient protections from the original law that prohibit referrals based solely on financial incentives to the provider. Patients can therefore be assured that referrals are based on the best interest of their health rather than maximum financial gain for the provider.

More information on the final rule may be found at the following links:

https://www.federalregister.gov/public-inspection/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations

https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f

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