

CMS SOLICITS COMMENTS TO PROPOSED MODIFICATIONS TO STARK REGULATIONS, INCLUDING ADDITION OF VALUE-BASED ARRANGEMENTS AND CYBERSECURITY EXCEPTIONS

Hodgson Russ Healthcare Alert
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On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule to clarify the regulations that interpret the physician self-referral law, often called the “Stark Law.” The proposed changes advance the health care industry’s transition from traditional fee-for-service payment models to a “value-based healthcare delivery and payment system.”

The proposed rule would create new exceptions to the Stark Law for value-based arrangements that range from full risk bearing arrangements to arrangements with minimal risk that still include value. Under the proposed rule, value based arrangements must achieve at least one value-based purpose, including care coordination, improving quality of care, reducing healthcare costs, or transitioning from payment mechanisms based on volume to quality-based payment models.

These exceptions are significant because they protect remuneration provided to physicians to incentivize care coordination and improve health care outcomes related to innovative treatment strategies and financial arrangements.

Other new exceptions include flexibility for financial arrangements involving donations of certain cybersecurity technologies.

If adopted as final, the following types of arrangements could be permissible:

- A shared savings payment distributed by a group of providers organized as a Medicare Accountable Care Organization to a physician to achieve savings by utilizing a new treatment regimen for patients undergoing knee replacement surgery.
- An incentive payment by a hospital to physicians for each instance they order dual-modality screening for lung cancer to incorporate newly issued national guidelines to avoid unnecessary overtreatment of false positive results associated with single-modality screenings.

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- A hospital provides a referring physician's practice with cybersecurity software to improve security and mitigate risks of cyberattacks.

The proposed rule also includes additional clarifications of key statutory terms and other compliance requirements. For example, CMS is proposing to revise the definition of fair market value "to eliminate the connection to the volume of value standard." CMS is also proposing to define commercially reasonable to mean "that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." Further "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

CMS is soliciting comments on a variety of issues including:

- the need to define key terms, including "coordinating and managing care"
- methodologies to determine whether quality of care has improved
- methodologies to determine whether costs are reduced via a value-based arrangement
- which persons or entities should qualify as "value-based enterprise" participants
- whether to exclude pharmaceutical manufacturers, manufacturers and distributors of DMEPOS (durable medical equipment, prosthetics, orthotics & supplies), and pharmacy benefit managers from the definition of "value-based participant"

The proposed rule can be accessed at <https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>. Comments must be submitted by December 31, 2019.

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