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Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule

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Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule (CMS-1720-P)

On October 9, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to modernize and clarify the regulations that interpret the Medicare physician self-referral law (often called the “Stark Law”), which has not been significantly updated since it was enacted in 1989. The proposed rule supports the CMS “Patients over Paperwork” initiative by reducing unnecessary regulatory burden on physicians and other healthcare providers while reinforcing the Stark Law’s goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician’s financial self-interest. Through the Patients over Paperwork initiative, the proposed rule opens additional avenues for physicians and other healthcare providers to coordinate the care of the patients they serve – allowing providers across different healthcare settings to work together to ensure patients receive the highest quality of care. In addition, as part of the Regulatory Sprint to Coordinated Care, CMS worked closely with the Department of Health and Human Services Office of Inspector General in developing proposals to advance the transition to a value-based healthcare delivery and payment system that improves the coordination of care among physicians and other healthcare providers in both the Federal and commercial sectors.

This fact sheet discusses the major provisions of the proposed rule (CMS-1720-P), which can be downloaded from the *Federal Register* at: <https://www.federalregister.gov/public-inspection/current>. In order to be considered, comments must be submitted by December 31, 2019.

Background

When the Stark Law was enacted in 1989, healthcare was paid for primarily on a fee-for-service basis. The law rightly recognized that a profit motive could influence some physicians to order services based on their financial self-interest rather than the good of the patient. For this reason, the Stark Law prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship. The Stark Law also prohibits the entity from filing claims with Medicare for services resulting from a prohibited referral, and Medicare cannot pay if the claims are submitted.

Since then, Medicare and the private market have implemented many value-based healthcare delivery and payment systems to address unsustainable cost growth in the current volume-based system. A value-based system pays based on the quality of patient care rather than the volume of services provided. The Stark Law has not evolved to keep pace with this transition. In its current form, the Stark Law may prohibit some arrangements that are designed to enhance care coordination, improve quality, and reduce waste. Although the regulations that interpret the Stark Law have been updated several times, all previous changes left in place a framework that is tailored to a fee-for-service environment.

CMS published a Request for Information (RFI) on June 25, 2018 seeking input from stakeholders about how to address regulatory barriers to a value-based healthcare payment and delivery system under the Stark Law. Commenters told us that the regulations have not kept up with the evolution of a healthcare landscape that is focused more on value than volume. They also asked for additional guidance on fundamental requirements and other changes to help ease burden and make compliance more straightforward.

The proposed rule includes a comprehensive package of proposed reforms to modernize the regulations that interpret the Stark Law

while continuing to protect the Medicare program and patients from bad actors. Under this proposed rule, for the first time, the regulations would support the necessary evolution of the American healthcare delivery and payment system.

Exceptions for Value-based Arrangements

The proposed rule would create new, permanent exceptions to the Stark Law for value-based arrangements. Industry stakeholders have informed us that, because the consequences of noncompliance with the Stark Law are so dire, physicians and other healthcare providers may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). The proposed rule would unleash innovation by permitting physicians and other healthcare providers to design and enter into value-based arrangements without fear that legitimate activities to coordinate and improve the quality of care for patients and lower costs would violate the Stark Law. The exceptions would apply regardless of whether the arrangement relates to care furnished to people with Medicare or other patients.

The new value-based exceptions include a carefully woven fabric of safeguards to ensure that the Stark Law continues to provide meaningful protection against overutilization and other harms. These proposals recognize that incentives are different in a healthcare system that pays for the value, rather than the volume, of services provided.

In addition, we are soliciting comments about the role of price transparency in the context of the Stark Law and whether to require cost-of-care information at the point of a referral for an item or service. As an agency priority, [price transparency](#) is important to transforming America's healthcare system to pay for value as it empowers healthcare customers by providing them with the best information available to make informed decisions about their care and lowers the rate of growth in healthcare costs. We believe that such information could empower patients to have conversations about costs with their physicians at the point of care and serve as an additional safeguard at the point of referral.

New Guidance and Clarifications

Commenters on the June 2018 RFI told us that they currently invest sizeable resources to understand and comply with the Stark Law, and requested additional guidance in this regard. The proposed rule would

provide additional guidance on several key requirements that must often be met in order for physicians and healthcare providers to comply with the Stark Law. For example, compensation provided to a physician by another healthcare provider generally must be at fair market value. The proposed rule would provide guidance on how to determine if compensation meets this requirement. The proposed rule also provides clarity and guidance on a wide range of other technical compliance requirements intended to reduce administrative burden that drives up costs.

Other New Exceptions

Commenters on the June 2018 RFI also requested new exceptions to provide protection for non-abusive, beneficial arrangements between physicians and other healthcare providers. The proposed exceptions would provide new flexibility for certain arrangements, such as donations of certain cybersecurity technology that safeguard the integrity of the healthcare ecosystem, regardless of whether the parties operate in a fee-for-service or value-based payment system.

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