

# CMS Issues Proposed Rule to “Modernize and Clarify” the Stark Law

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10.30.2019

On October 9, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a Proposed Rule to “modernize and clarify” the federal physician self-referral law (the “Stark Law”). The Proposed Rule was issued in conjunction with CMS’ Patients over Paperwork initiative to reduce unnecessary regulatory burden on physicians and other health care providers. CMS has acknowledged that the broad reach of the Stark Law potentially inhibits beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors. The consequences of non compliance with the Stark Law are so dire that physicians and other health care providers may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs. The Proposed Rule represents a major attempt by the government to “address these concerns, and to help accelerate the transformation of the health care system into one that better pays for value and promotes care coordination.”

The Proposed Rule includes several substantive changes to existing Stark regulations that would remove barriers to value-based arrangements and facilitate the transition to value-based payment models. The Proposed Rule adds three new Stark Law exceptions for value-based care arrangements and provides for definitions related to such arrangements. These changes promoting value-based care have now been widely discussed since CMS issued the Proposed Rule. However, the Proposed Rule also provides more broadly applicable guidance on several of the Stark Law’s existing fundamental requirements. This updated guidance from CMS on fundamental Stark Law requirements and terminology deserves close attention as well.

The Proposed Rule includes detailed guidance on certain terminology and requirements fundamental to the Stark Law in response to stakeholder comments submitted to CMS upon public request. Among other important

Stark Law requirements, the Proposed Rule provides updated guidance on the requirements that a) a compensation arrangement itself is commercially reasonable; b) the amount of the compensation is fair market value; and c) a compensation arrangement not take into the account the volume or value of referrals by a physician or other business generated between the parties. As noted in the Proposed Rule, many of the Stark Law exceptions include at least one and often more than one of these requirements. Below is an overview of the updated guidance CMS provided on these requirements.

As a threshold matter, CMS clarified that these are separate and distinct requirements, so they must be satisfied individually and one can technically be satisfied without the others being satisfied.

## Commercial Reasonableness

The term “commercially reasonable,” or some equivalent language, appears in several Stark Law exceptions, including the bona fide employment exception and the personal service arrangements exceptions. Despite the prevalence of this requirement, CMS had formally addressed the concept of commercial reasonableness only once previously. In a 1998 Proposed Rule, CMS stated that it was interpreting “commercially reasonable” to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals. The Stark Law does not currently have a codified definition for the term commercially reasonable.

According to CMS, as restated in the Proposed Rule, “[t]he key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. . . . The determination of commercial reasonableness is not one of valuation. Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable.” To formalize its interpretation of the term, CMS is proposing in the Proposed Rule the following two alternative definitions for the term “commercially reasonable:”

- 1) The arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.
- 2) The arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

CMS is seeking comment on each of these proposed definitions as well as input from stakeholders regarding other possible definitions that would provide clearer guidance on how to ensure that a particular arrangement is commercially reasonable. CMS is also proposing to clarify in the text of the Stark Law regulations that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

## Fair Market Value

The term “fair market value” appears in several Stark Law exceptions, including the exceptions for space and equipment rentals, bona fide employment relationships, isolated transactions, and personal services arrangements. Possibly because of the term’s prominence in and importance to the Stark Law, the Proposed Rule provided a detailed history of the codified definition of fair market value and CMS’s prior guidance related to the term before introducing its most recent proposals. CMS also made clear in the Proposed Rule that the fair market value standard is separate and apart from the volume and value of referral standard. Accordingly, CMS proposed a new definition of “fair market value” intended to more clearly distinguish those two standards and to conform the definition more closely to general, prevailing valuation principles.

The new definition under the Proposed Rule for fair market value generally is “the value in an arm’s-length transaction with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.” The Proposed Rule uses similar language to specifically define fair market value with respect to rentals of equipment and office space. “General market value” is defined as “the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement” with corresponding specific definitions for equipment or office space rentals.

As context for these new definitions, CMS explained, “[i]t is our view that the concept of fair market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction . . . , while general market value (or market value) relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe.” Thus, according to CMS, the fair market value standard requires that “the hypothetical value of a transaction must be consistent with the value of the actual transaction transpiring between the particular buyer and seller.”

Importantly, CMS did note that it is cognizant that the hypothetical value of a transaction may not always be identical to the market value of the actual transaction being considered. Thus, the fair market value standard could be satisfied where “extenuating circumstances may dictate that parties to an arm’s length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject the transaction.”

## Volume or Value of Referrals

Many of the Stark Law exceptions require that compensation paid under a compliant arrangement not be determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement. To date, CMS has not codified any regulations defining or otherwise interpreting the volume or value standard. CMS proposes to do so in the Proposed Rule by providing bright-line, objective tests for determining whether compensation takes into account the volume or value of referrals.

Under CMS' proposed approach, compensation would not be considered to take into account the volume or value of referrals so long as it was outside of the circumstances expressly set forth in the new regulations. For a compensation arrangement between an entity that provides Stark Law "designated health services" (a "DHS Entity") and a physician, the arrangement would take into account the volume or value of referrals only if:

A) The formula used to calculate the compensation includes the physician's referrals to the DHS entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlated with the number or value of the physician's referrals to the DHS entity; or

B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

The Proposed Rule also provides similar rules for compensation from a physician to a DHS entity and for whether an arrangement takes into account the volume or value of business generated between the parties. It also defines certain key terms used in the new rules (e.g., "positive correlation"). The Proposed Rule also removes the modifier "directly or indirectly" from the Stark Law regulations where it appears in connection with the volume or value standards. CMS chose to make this change because it believes the modifier is implicit in the requirements that compensation is not determined in any manner that takes into account the volume or value of referrals.

The provisions of the Proposed Rule, if finalized, would supersede CMS' previous guidance on the volume or value of referrals standard, including guidance with which the new provisions may be (or appear to be) inconsistent. However, CMS stated in the Proposed Rule commentary that it believes its approach in the Proposed Rule is consistent with its long-standing position from Stark Law Phase I commentary that a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's referral of designated health services. Further, CMS reaffirmed its position, as originally stated in its guidance to Stark Law Phase II regulations (at 69 FR 16088 through 16089), that a physician's productivity bonus does not take into account the volume or value of an employed physician's referrals solely because corresponding hospital services (e.g., a facility fee) are billed each time the employed physician personally performs a service. CMS makes clear in the Proposed Rule that it still endorses this policy notwithstanding commenters' concerns that a 2015 United States Court of Appeals opinion may have interpreted the Stark Law in a manner arguably inconsistent with this policy.

The Proposed Rule reflects only CMS' proposed changes at this point. Comments on the Proposed Rule, which CMS has requested from all stakeholders, are due by December 31, 2019.

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