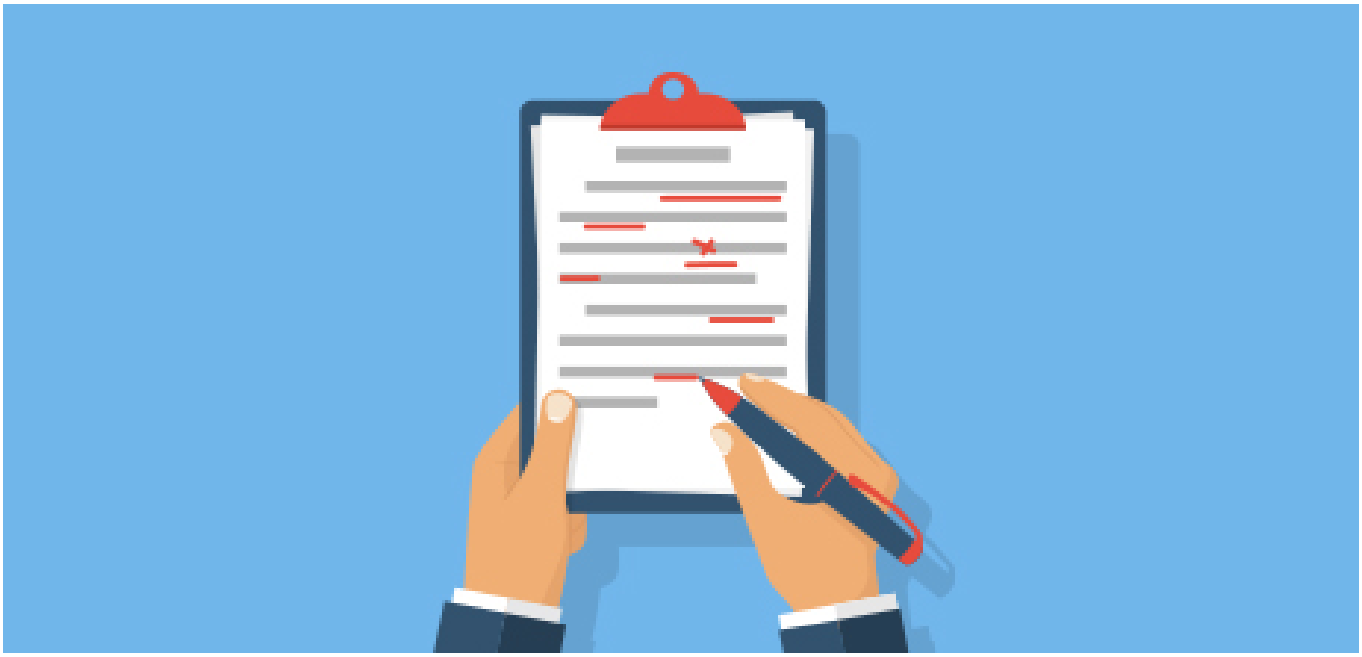

# CMS proposes changes to and clarifications of key Stark Law terms

October 18, 2019

Part of the Centers for Medicare and Medicaid Services' (CMS) proposed changes "to modernize and clarify" regulations interpreting the Physician Self-Referral Law (the "Stark Law"), released on October 9, 2019, contain "bright-line rules" to clarify several key terms used in the Stark Law exceptions. Specifically, CMS proposes changes to the terms "commercial reasonableness," "takes into account the volume or value of referrals or other business generated," and "fair market value."

**"Commercially reasonable" – A new definition**

For the first time, CMS is proposing to define the term "commercially reasonable" with two alternative definitions:

- the arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements; *or*
- 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.

In a notable departure from the government's position in prior enforcement actions, CMS clarified that the commercial reasonableness requirement is *not* based on valuation and, in particular, *does not depend on whether an arrangement is profitable*. Arrangements must satisfy the "even if no referrals were made" requirement when it is included in the applicable Stark Law exception, in addition to meeting the new "commercially reasonable" definition.

**"Takes into account the volume or value of referrals or other business generated" – A bright-line rule**

To provide objective benchmarks for determining when compensation takes into account the volume or value of referrals or other business generated between the parties (*i.e.*, by the physician for the entity paying the compensation), CMS is proposing that compensation takes into account the volume or value of referrals or other business generated *only* if:

- For arrangements without fixed compensation – The mathematical formula used to calculate the amount of the compensation *includes as a variable* referrals or other business generated *and* the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity*; or*
- For arrangements with fixed compensation – There is a predetermined direct correlation between the physician's referrals to the entity or the business generated by the physician for the entity and the prospective fixed rate of compensation to be paid over the entire duration of the arrangement.

For a fixed amount of compensation, if the amount the physician is to be paid or charged is either higher or lower, depending on whether the physician's prior referrals or other prior business generated for the entity are above or below a threshold amount, the compensation takes into account the volume or value of the physician's referrals or business generated for the entity.

To address concerns raised following *United States ex rel. Drakeford v. Tuomey Healthcare System*, CMS reaffirmed its position that "[w]ith respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service."

It is unclear whether CMS intended to address the issues raised by the recent Third Circuit decision in *United States ex rel Bookwalter v. UPMC*. In the proposed revisions, without any discussion, CMS deleted two of three references to the "varies with" concept in the definition of "indirect compensation arrangement" in the regulations. However, CMS left intact one reference to "varies with" in the designated health services entity knowledge section of that definition. Given the lack of comment from CMS, we will be closely watching to see if CMS finalizes changes to the "varies with" concept in the final rule.

**"Fair market value" vs. "general market value"**

In an effort to be consistent with the Stark Law statute, CMS is proposing to revise the regulatory definition of the term "fair market value" as:

> *The value in an arms' length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction.*

CMS is also proposing to define the term "general market value" to be consistent with the terms used in the valuation industry as:

> *The price that assets or services [or rental property] would bring as the result of* bona fide *bargaining between the buyer and seller [or lessee and lessor] in the subject transaction [on the effective date of the transaction].*

CMS clarified that the concept of *fair* market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction, whereas the concept of *general* 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. CMS noted that the hypothetical value must be consistent with (but not necessarily identical to) the value of the actual transaction. However, extenuating circumstances may require a departure (upward or downward) from salary surveys or other benchmark data, such as for a uniquely qualified physician, or due to actual market conditions. CMS also clarified that the volume or value standard and the fair market value standard are two separate and distinct requirements that must be met when they appear in exceptions.

Overall, CMS has proposed meaningful changes to the Stark Law in an effort to respond to the industry's desire for clear guidance on these key terms. The proposed changes will likely generate many public comments regarding how these proposals will impact real-life arrangements. Public comments are due by December 31, 2019. As a result, CMS will not finalize the proposed Stark Law changes until 2020.

*This publication is part of a series of updates regarding CMS and OIG's proposed fraud and abuse law changes. Bricker & Eckler's health care attorneys will continue to publish analyses of the proposed rule.*

# Authors