

CHANGES TO STARK LAW WHICH IMPACT INNOVATIVE RELATIONSHIPS AND “COMMERCIALLY REASONABLE” CONSIDERATIONS

Overview. The Final Rule of the Stark Law revises the definitions of Fair Market Value and includes a definition of General Market Value to better align with actual practices without unduly restricting innovative relationships between physicians and entities providing designated health services.

Background. On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) published a final rule titled “Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations” (the Final Rule). The Final Rule modifies the regulations for the Physician Self-Referral Law (Stark Law) in the Social Security Act (the Act). The Stark Law is a strict liability statute, and strict adherence to the elements of the applicable exception is required to be in compliance. CMS included changes to the Final Rule that revise existing definitions, as well as added definitions to enable physicians and other providers to comply more easily with the applicable exception requirements. The revisions and additions to the definitions in the Final Rule are only applicable to the Stark Law.

The three requirements applicable to many of the Stark Law exceptions are: compensation for the applicable arrangement must be at fair market value, the arrangements must be commercially reasonable, and no arrangement may take into account the volume or value of referrals (or other business generated) between the parties. One or more of each of these requirements is included in many of the Stark Law exceptions, and each of these requirements is an independent factor that, if applicable to the relevant exception, must be analyzed when the Stark Law is implicated. The revisions to the definitions, and the addition of new definitions, help clarify these different required elements.

Fair Market Value. The relationships contemplated by Stark and those that are included in the Stark exceptions contain a requirement that the payments or compensation for space, equipment, or services be at “fair market value.” Fair market value is defined in the Act as “the value in arms-length transactions, consistent with the general market value.” There are additional requirements for rentals or leases that “the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.” The Final Rule modifies the definition of “fair market value” generally, and more specifically, modifies the definition of fair market value applicable to the rental of equipment and rental of office space.

The Final Rule defines fair market value as:

- Fair market value is generally defined as “the value in an arms-length transaction, consistent with the general market value of the subject transaction.”
- Fair market value for rental of equipment is defined as “the value in an arms-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.”

DISCLAIMER: The information presented is not meant to constitute legal advice. Please consult your attorney for advice on a specific situation. Of particular importance, many states have similar Stark and/or AKS laws that prohibit kickbacks and/or restrict physician self-referrals. The information presented is current as of the initial date of publication. Readers are encouraged to check government and other relevant websites for the most up to date information.

- Fair market value for rental of office space is defined as “the value in an arms-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.”

CMS additionally noted that a determination of fair market value is usually the fair market price for completed bona fide sales of “assets of like type, quality and quantity in a particular market at the time of the acquisition” or compensation in bona fide service agreements with comparable terms at the time of the agreement,” without taking into account any actual or anticipated volume or value of referrals.

PRACTICE NOTE: When evaluating a potential relationship in which the Stark Law is a factor, the dollar amount of the fair market value is one of two components that must be reviewed. The compensation to be paid must be at fair market value and must also not take into account the volume or value of referrals (or volume or value of other business generated by the physician, if applicable). If either of those two components cannot be met, then the relationship would not be permissible under the Stark Law.

General Market Value. Prior to the Final Rule, the term “general market value” was included in the definition of “fair market value” of the Stark Law and was not separately defined. Instead, the definition of “general market value” was equated to “market value,” a term utilized in valuation principles. However, based on industry concern, CMS acknowledged that the use of the term “market value” did not achieve the objective in defining “general market value.” Similar to the revised definitions of “fair market value,” the Final Rule provides a general definition of “general market value,” as well as general market value definitions applicable to specific types of arrangements.

PRACTICE NOTE: While the term “market value” is not included in the Final Rule, it is important to remember that parties are still obligated to consider the general market value of the transaction entered into by the parties without taking into account any other business arrangements between the parties.

The new definitions of general market value are:

- For Assets: With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
- For Compensation: With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

DISCLAIMER: The information presented is not meant to constitute legal advice. Please consult your attorney for advice on a specific situation. Of particular importance, many states have similar Stark and/or AKS laws that prohibit kickbacks and/or restrict physician self-referrals. The information presented is current as of the initial date of publication. Readers are encouraged to check government and other relevant websites for the most up to date information.

- For Rental of Equipment or Office Space: With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Commercially Reasonable. The Stark Law’s commercial reasonableness standard has never been defined by statute or regulation. The Final Rule now defines “commercially reasonable” to mean that “the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.” The definition also provides that an arrangement “may be commercially reasonable even if it does not result in profit for one or more of the parties.” Notably, all Stark compensation exceptions, except the value-based arrangement exceptions, that have a “commercially reasonable” element require that the compensation to the physician (or immediate family member) be paid pursuant to an arrangement that would be commercially reasonable (as defined above) *even if one or more parties does not benefit financially from the arrangement*. This standard represents a significant change from the government’s earlier position where it took the position that arrangements resulting in financial losses (i.e., arrangements where a party did not benefit financially) could not be commercially reasonable.

PRACTICE NOTE: As mentioned, for value-based arrangements, the new exceptions do not include a requirement that the value-based arrangement be commercially reasonable. For a comprehensive analysis of the new value-based arrangement requirements, please refer to the “New Stark Law and Anti-Kickback Reforms Aimed at Value-Based Care” resource on ACP Online under Regulatory Resources.

While CMS did not offer examples of arrangements that may be commercially reasonable, it did discuss the following three elements which can be instructive:

First, while an arrangement with a physician does not necessarily need to be profitable for the entity to satisfy the commercial reasonableness standard, the economics of the arrangement remain relevant to the analysis of whether the arrangement would be commercially reasonable even if the physician made no referrals to the employer. CMS has recognized there can be legitimate reasons why an employer would pay a physician-employee more in compensation than the employer’s collections from the physician’s services will support. However, CMS maintains that medical practice “losses” incurred and tolerated by a health system remain a relevant factor when analyzing an arrangement for commercial reasonableness. Therefore, it is still important to be able to articulate a legitimate business purpose, particularly where the arrangement results in a loss. CMS has identified the following examples of reasons parties might enter into an arrangement involving a loss on clinical services: “community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes.”

DISCLAIMER: The information presented is not meant to constitute legal advice. Please consult your attorney for advice on a specific situation. Of particular importance, many states have similar Stark and/or AKS laws that prohibit kickbacks and/or restrict physician self-referrals. The information presented is current as of the initial date of publication. Readers are encouraged to check government and other relevant websites for the most up to date information.

Second, CMS clarified that the reference to “even if no referrals were made to the employer or between parties” means designated health services (DHS) (Medicare-covered) referrals, not “other business generated.” This is helpful because, if “referrals” is not limited to DHS referrals, it would be difficult to justify arrangements where the very nature of the arrangement makes sense only if there is some level of business generated between the parties. Of important note, this guidance implies that “other business generated” could be the basis for concluding that an arrangement is commercially reasonable. However, it should be cautioned that CMS does not explicitly state this directly and any such justification of commercial reasonable could raise other material compliance concerns, including with respect to the “legitimate business purpose” requirement discussed below.

Third, CMS indicates that the requirement that an arrangement furthers a *legitimate business purpose* of the parties is not met if the arrangement violates federal or state law. Violation of federal or state anti-kickback laws likely would be the primary reason that an arrangement between a DHS entity and physician would violate federal or state law. Therefore, the commercial reasonableness definition appears to incorporate a requirement of complying with federal and state anti-kickback laws. This interpretation reflects that a commercial reasonableness determination is still subject to an intent-based facts and circumstances analysis.

PRACTICAL TAKEAWAYS. The intent of the revisions to the Final Rule is to ease the regulatory burden for parties entering into arrangements where the Stark Law is implicated.

- Parties should review existing arrangements for compliance with the new commercial reasonableness definition, and ensure that the compensation paid is consistent with fair market value and general market value.
- Parties should review their existing agreements to ensure compliance with the specified requirements with respect to compensation for space, equipment, or services, including that the compensation must not take into account other business arrangements between the parties or the generation of referrals between the parties. If the specific arrangement is for space or equipment, there are additional considerations and requirements that must be met.
- Any future relationships entered into where the Stark Law is implicated must be compliant with the newly defined requirements, and any existing arrangements that are determined not to be compliant with the relevant exception will need to be modified to meet all of the applicable elements for that particular exception.