Physician's Guide to Stark Law – Part II

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Our initial article concerning the Stark law titled "Physician's Guide to Stark Law – Part I" addressed the Stark law self-referral prohibition in detail. As further explained therein, the Stark law, as amended, prohibits a physician from referring his or her Medicare or Medicaid patients for the furnishing of certain designated health services ("**DHS**") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. 42 U.S.C. § 1395nn(a)(1)(A). In addition, an entity may not present, or cause to be presented, a claim to the Medicare program or bill to any individual, third party payor or other entity for DHS furnished pursuant to a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B). Because the Stark law is a strict liability statute, meaning that proof of specific intent is not required to violate the statute, any prohibited referral *automatically* violates the statute unless the financial relationship between the referring physician and the entity to which the physician refers a patient for DHS ("**DHS Entity**") fully satisfies an applicable exception or exceptions. These exceptions are the focus of this article. Consistent with our previous Stark law prohibition article, this article is not intended to provide an exhaustive treatment of available Stark law exceptions, but rather, to serve as a general reference and educational guide. Accordingly, physicians and medical practices are encouraged to seek advice from their own counsel to address specific legal issues that arise in their individual practices.

The Stark Law Exceptions.

Over thirty-five separate Stark law exceptions exist. An exception is applicable to either or both of the two types of financial relationships that may exist between a referring physician and a DHS Entity, specifically, ownership or investment interests and compensation arrangements. We will first identify all Stark law exceptions that are available and then discuss the often-used exceptions concerning office space and equipment rental as well as in-office ancillary services. As also discussed herein, these exceptions each contain one or more of the following requirements that are contained in many Stark law exceptions, namely, that compensation be set in advance, be consistent with fair market value, and/or not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Under any circumstance, it is important to recognize that the exceptions are frequently re-defined, and typically contain subjective standards dependent on the facts and circumstances of the particular financial relationship. Indeed, whether a particular financial relationship fully satisfies an applicable exception or exceptions is rarely black and white, and many physicians and medical practices ultimately have to determine whether they are comfortable operating in some shade of grey.

i. Available Exceptions.

Exceptions applicable to ownership or investment interests. The exceptions applicable to ownership or investment interests include those that concern:

- hospitals in Puerto Rico;
- rural providers;
- hospital ownership; and
- ownership of or investment in publicly traded securities and mutual funds.

Exceptions applicable to compensation arrangements. The exceptions applicable to compensation arrangements include those that concern:

- office space rentals;
- equipment rentals;
- bona fide employment relationships;
- personal service arrangements;
- remuneration unrelated to the provision of DHS;
- physician recruitment;
- isolated transactions;
- certain group practice arrangements with a hospital;
- payments by physicians;
- charitable donations by physicians;
- nonmonetary compensation;
- fair market value compensation;
- medical staff incidental benefits;
- risk-sharing arrangements;
- compliance training;
- indirect compensation arrangements;
- referral services;
- obstetrical malpractice insurance subsidies;
- professional courtesies;
- retention payments in underserved areas;
- community wide information systems;
- electronic prescribing items and services;
- electronic health records items and services;
- assistance to compensate non-physician practitioners; and
- timeshare arrangements.

Exceptions applicable to ownership or investment interests and compensation arrangements. The exceptions applicable to both ownership or investment interests and compensation arrangements include those that concern:

- physicians' services;
- in-office ancillary services;
- prepaid plans;
- academic medical centers;
- implants furnished by an ambulatory surgery center (ASC);
- erythropoietin and other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal disease (ESRD) facility;
- preventive screening tests, immunizations, and vaccines;
- eyeglasses and contact lenses following cataract surgery; and
- intra-family referrals in rural areas.

ii. Key Exceptions.

Office Space and Equipment Rental Exceptions.

Physicians sometimes rent office space from hospitals to which they refer their Medicare or Medicaid patients for the furnishing of DHS. Likewise, physicians sometimes rent equipment to

hospitals to which they refer their Medicare or Medicaid patients for the furnishing of DHS that is performed with such equipment. In these (or similar) referral arrangements, remuneration passes, and therefore a financial relationship exists, between the referring physician and the DHS Entity. As such, these referrals *automatically* violate the Stark law unless the arrangement fits wholly within an applicable exception. As indicated by their titles, the most common exceptions relied on to insulate such arrangements are the exceptions for rental of office space and rental of equipment. Each of these exceptions includes identical requirements, specifically, that any payments made by the lessee to the lessor implicating the Stark law are permissible only if:

- **a.** the lease arrangement is set out in writing, signed by the parties, and specifies the premises or equipment covered;
- **b.** the space or equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor—although rental of shared common areas is permitted in certain circumstances);
- **c.** the duration of the lease arrangement is at least one year (and if terminated with or without cause, the parties may not enter into a new lease for the same space or equipment during the first year of the original lease);
- **d.** the rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and
- **e.** the lease arrangement would be commercially reasonable even if no referrals were made between the parties.

42 U.S.C. § 1395nn(e)(1)(A) and (B) and 42 C.F.R § 411.357(a) and (b). If the lease arrangement expires after a term of at least one year, an indefinite holdover lease arrangement immediately following the expiration of the original lease arrangement satisfies the requirements of the office space or equipment rental exceptions if the original and holdover leases contain the same terms and conditions and fully comply with the above requirements (i.e., requirements a – e). The most difficult of these requirements to understand and satisfy are typically the requirements that the compensation (in this case, rental charges) be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. As one or more of these requirements are also contained in numerous other Stark law exceptions, including the exceptions for bona fide employment relationships, personal service arrangements, fair market value compensation, academic medical centers and in-office ancillary services (which exception is further discussed below), let's briefly examine each of these requirements.

> ***"Compensation must be set in advance"*** – Stark law regulations provide that compensation is considered "set in advance" if it is set out in writing before the furnishing of the items or services for which the compensation is to be paid. 42 C.F.R. § 411.354(d)(1). While this mandate seems simple enough, the regulations also (1) recognize that compensation may include "aggregate compensation," "a time-based or per-unit of service-based (whether per-use or per-service) amount," or "[any other] specific formula for calculating compensation," (2) require that any formula for determining compensation be set forth in sufficient detail such that it can be objectively verified and not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician, and (3) provide that, although they may fluctuate or be indeterminate, certain percentage-based compensation formulae may satisfy the "set in

advance" requirement "depending on the facts," yet also provide that the exceptions for rental of office space and rental of equipment (as well as for fair market value compensation and indirect compensation arrangements) wholly preclude the use of such formulae. *Id.*, 72 Fed. Reg. 51,012, 51,031-31 (Sept. 5, 2007) and 73 Fed. Reg. 48,434, 48,709 (Aug. 19, 2008).

"Compensation must be consistent with fair market value" – Stark law regulations define "fair market value" as the value in an arm's-length transaction that is consistent with the price or compensation that would result from bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for each other. In connection with the exceptions for rental of office space and equipment (as well as for fair market value compensation), the Stark law regulations further define "fair market value" as 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, prohibit adjusting this value 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. 42 C.F.R. § 411.351. To establish the fair market value of any arrangement that involves compensation paid for with assets or services, the Centers for Medicare & Medicaid Services ("**CMS**") will accept any "commercially reasonable" valuation method, including obtaining a list of comparables and/or an appraisal from a qualified independent expert. 66 Fed. Reg. 944 (Jan. 4, 2001). It is recommended that both of these methods be employed, if possible, when developing a compensation arrangement that implicates the Stark law as the burden of establishing that any such arrangement is consistent with fair market value rests wholly with the contracting parties. *Id.*

"Compensation must not take into account the volume or value of any referrals or other business generated between the parties" – Stark law regulations provide that a referring physician may not be compensated based on the historical or anticipated volume or value of referrals or other business generated by the physician. For example, a physician cannot be paid a fixed amount for each Medicare or Medicaid patient he or she refers to another healthcare provider for the furnishing of DHS. Although seemingly straight-forward, the Stark law regulations also (1) provide that unit-based compensation (including time-based or per-unit of service-based, i.e., per-click, compensation) is deemed not to take into account "the volume or value of referrals" (or "other business generated between the parties") provided that the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS (or other business generated by the referring physician), and (2) yet further provide that the exceptions for rental of office space and rental of equipment (as well as for fair market value compensation and indirect compensation arrangements) wholly preclude the use of per-unit of service-based compensation arrangements, while permitting the use of certain time-based compensation arrangements. 42 C.F.R. § 411.354(d)(2) and (3).

A New Alternative: The Timeshare Exception.

Recognizing that there are situations where a traditional office space or equipment lease is not necessary or practical, CMS recently finalized a new Stark exception permitting physicians and hospitals or other physician groups to share "premises (space), equipment, personnel, items, supplies or services" through a non-exclusive, as-needed timeshare arrangement provided certain conditions are met, including that the arrangement is predominantly for the provision of evaluation and management services to patients (rather than predominantly for the furnishing of

DHS to patients) and does not convey a possessory leasehold interest in the office space that is the subject of the arrangement. 42 C.F.R. § 411.357(y). Other conditions that must be met (not surprisingly) include, but are not limited to, that the compensation paid over the term of the arrangement be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. *Id.* Before entering into a formal, exclusive lease for space or equipment when the Stark law is implicated, physicians should first determine whether a timeshare arrangement is a better fit for their needs and, if so, should structure such an arrangement to wholly satisfy this new exception.

In-Office Ancillary Services Exception.

The Stark law prohibition of a physician's referrals of Medicare or Medicaid patients for the furnishing of DHS to any entity with which the physician has a financial relationship, *includes referrals within the physician's own practice*. Accordingly, any such "in-office" physician referrals automatically violate the Stark law unless the arrangement fully satisfies an applicable exception. The most common Stark law exception relied upon by physicians to allow referrals for certain specified DHS in-office is the aptly-named "In-Office Ancillary Services Exception" (the "**IOASE**"). The IOASE permits all DHS (other than certain items of DME and parenteral and enteral nutrients, equipment, and supplies) to be provided within-practice provided that they are:

a. personally furnished by certain individuals

Specifically: (1) The referring physician, (2) a physician who is a member of the same group practice as the referring physician, or (3) an individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice.

b. in a certain location

Specifically: Three very detailed, regulatory options exist for satisfying this requirement, including that the DHS be offered in the same building in which the referring physician or group practice has an office normally open to patients for medical services at least 35 hours per week and the referring physician (or one or more members of the group practice) regularly practice medicine or furnish services at least 30 hours per week (which must include services unrelated to DHS payable by a government or private payor).

c. and billed by certain persons or entities

Specifically: (1) The physician performing or supervising the service, (2) the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice, (3) the group practice if the supervising physician is a "physician in the group practice" (as defined elsewhere in the regulations) under a billing number assigned to the group practice, (4) an entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice, or (5) an independent third party billing company in certain defined instances.

42 U.S.C. § 1395nn(b)(2) and 42 C.F.R. § 411.355(b). The IOASE now also includes certain disclosure requirements in connection with in-office referrals for MRI, CT and PET scans,

including that, at the time of the referral, the referring physician provide written notice to the patient of at least five other physicians, other practitioners or entities within a 25-mile radius of the referring physician's office that provide the imaging service for which the referral is being made. *Id.* Finally, for a medical practice, other than a true solo practice, to utilize the IOASE (and the much less frequently used Stark law exception for physician services), the medical practice must meet the Stark law definition of a "group practice." While volumes have been written on the nuances of this definition, at a high level, the Stark law defines a "group practice" as "a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association":

- **a.** in which each physician who is a member of the group provides substantially the full range of services that the physician routinely provides utilizing group resources;
- **b.** for which substantially all of the services of such physicians are provided through the group and are billed under a billing number assigned to the group and amounts received are treated as receipts of the group;
- **c.** in which the overhead expenses of and income from the practice are distributed in accordance with predetermined methods;
- **d.** in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician—*except through a permitted profit-sharing or productivity bonus arrangement*;
- **e.** in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice; and
- **f.** which meets other regulatory standards.

42 U.S.C. § 1395nn(h)(4). Significantly, medical practices that satisfy the Stark law definition of a "group practice" are not only able to take advantage of the IOASE, they are also able to take advantage of special compensation rules permitting its member physicians to share profits and pay certain productivity bonuses under certain circumstances. *Id.*

State Stark Law.

Every state, including Louisiana, has its own Stark law statutes, often referred to as "mini-Stark statutes." Louisiana's mini-Stark statute can be found at La. R.S. 37:1744. Once we address the federal anti-kickback statute in our next article, we will next address Louisiana's state Stark law and anti-kickback provisions.

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