Physician's Guide to Stark Law – Part I

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Physicians are under increasing scrutiny by federal and state enforcement agencies with respect to their financial relationships both within their medical practices and outside their medical practices. This article provides a cursory summary of the federal statutes and regulations that govern the so-called "Stark law" that prohibits certain physician self-referrals. The Stark law and its implementing regulations are extremely complex. Indeed, some of the invective that has been used to describe the Stark law include: "ambiguous," "arcane," "very vague," and "heaps of words in barely decipherable bureaucratese." The complexity of the Stark law is exacerbated by potentially devastating civil sanctions, and further heightened by the fact that the Stark law is a strict liability statute. The remarks of Judge Wynn, of the United States Court of Appeals for the Fourth Circuit, are particularly telling: "It seems as if, even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act." *See U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 675 F.3d 394 (4th Cir. 2012). This article is not intended to provide an exhaustive treatment of the Stark law, but rather, to serve as a general reference and educational guide. Physicians and medical practices are encouraged to seek advice from their own counsel to address specific legal issues that arise in their individual practices.

This initial article will address the Stark law prohibition in detail and then briefly list the categories of exceptions thereto. In a follow up article, we will address in greater detail those exceptions most often relied on by physicians in an effort to avoid violating the Stark law.

The Stark Law Prohibition.

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). Again, the Stark law is a strict liability statute meaning proof of specific intent is not required to violate the statute. Thus, by way of example, if a physician invests in an imaging center, the Stark law requires the resulting financial relationship between the physician and the imaging center to fit fully within a Stark law exception or, regardless of whether there was an intent to violate the statute, the physician may not refer a patient to the imaging center and the imaging center may not bill for the referred imaging services without violating the statute. Sanctions for violating the Stark law can be severe and include non-payment, or refund of payment made, for services provided pursuant to prohibited referrals, substantial civil monetary penalties, and exclusion from participation in federal health care programs. 42 U.S.C. § 1395nn(g). In an effort to avoid these dangers, let's take a closer look at each element of the Stark law prohibition.

The Stark law prohibits:

i. a physician

Comment: A "physician" means a doctor of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry as well as a chiropractor. Note that a physician and a

professional corporation of which the physician is the sole owner are treated the same for purposes of this definition.

ii. from referring

Comment: A "referral" does not include any DHS that is personally performed by the referring physician or referrals to a referring physician's wholly owned professional corporation. Otherwise, however, the term "referral" is broadly defined to encompass a physician's request for, order of, or certification or recertification of the need for any DHS performed by (1) a referring physician's employees, independent contractors, or group practice members, including any "incident to" services performed by an employee or independent contractor of the referring physician and billed as part of the referring physician's fee, (2) any other entity, including the technical component and/or facility fee that is billed by a hospital in connection with any DHS that is personally performed by a referring physician as either an inpatient or outpatient procedure at a hospital, or (3) a consulting physician, including any DHS supervised by the consulting physician. A "referral" also includes a physician's request for, or establishment of, a plan of care.

iii. his or her Medicare or Medicaid patients

Comment: The Stark law, and specifically the definition of "referral" set forth therein, explicitly provides that it applies to referrals for DHS reimbursable by Medicare. In contrast, neither the Stark law nor its corresponding regulations mentions Medicaid referrals. Even so, several federal district courts have held, and the United States Department of Justice contends, that the Stark law also encompasses Medicaid referrals. *See, e.g., U.S. ex rel. Schubert v. All Children's Health System*, 2013 WL 6054803 (M.D. Fla. Nov. 15, 2013) and *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, Civil Action No. 6:10-CV-64 (S.D. Tex. Sept. 20, 2013). In support of these holdings, courts typically note that the federal government is prohibited from making federal financial participation ("**FFP**") payments to state Medicaid programs for DHS furnished as a result of a referral that would violate the Stark law under the Medicare program and, thus, causing a state Medicaid program to submit claims for FFP payments based on referrals that would otherwise be prohibited by the Stark law is actionable as a Stark law violation under the False Claims Act. Unless and until this issue is clarified, physicians should proceed as if the Stark law applies to both Medicare and Medicaid referrals.

iv. for the furnishing of certain DHS

Comment: The original version of the Stark law only identified clinical laboratory services as DHS because Congress believed these services were particularly prone to over-utilization by referring physicians who had a financial relationship with the entity receiving payment for such services. However, the statute has been subsequently amended to include various other categories of DHS. The complete list now includes: (1) clinical laboratory services, (2) physical therapy services, (3) occupational therapy services, (4) radiology services, including MRI, CT and PET scans as well as ultrasounds, (5) radiation therapy services and supplies, (6) durable medical equipment and supplies, (7) parenteral and enteral nutrients, equipment, and supplies, (8) prosthetics, orthotics, and prosthetic devices and supplies, (9) home health services, (10) outpatient prescription drugs, (11) inpatient and outpatient hospital services, and (12) outpatient speech-language pathology services. To further eliminate confusion about which services qualify as DHS, the Centers for Medicare & Medicaid Services ("**CMS**") has issued a list of CPT/HCPCS codes to specifically identify those services that are subject to the Stark law in the following DHS categories: clinical laboratory services, physical therapy services, occupational therapy services, radiology services, radiation therapy services and supplies and outpatient

speech-language pathology services. The remaining DHS categories are not susceptible of definition through codes.

v. to an entity

Comment: An "entity" includes a physician's sole practice, a practice of multiple physicians, or any other person or entity that furnishes DHS, excluding the referring physician himself or herself. While the Stark law originally provided that an "entity" was only the person or entity that billed, or presented a claim to, Medicare for DHS, the Stark law currently provides that an "entity" also includes the person or entity that "performed" the services billed as DHS – regardless of whether another person or entity actually billed for these services.

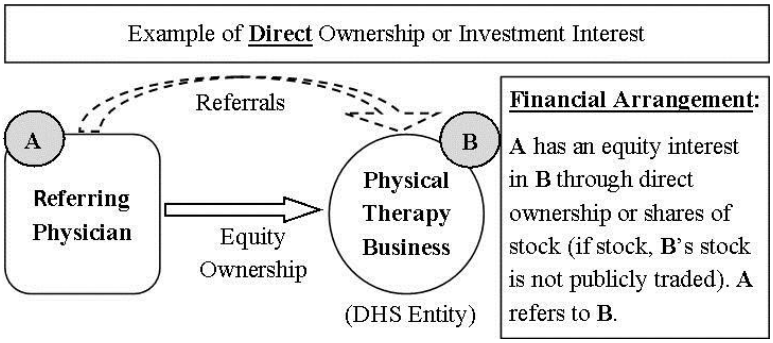
vi. with which the physician (or an immediate family member of the physician)

Comment: The definition of "physician" was discussed *supra*. An "immediate family member of the physician" means the physician's husband or wife, natural or adoptive parent, child, sibling, stepparent, stepchild, stepsibling, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent or grandchild, and spouse of a grandparent or grandchild.

vii. has a financial relationship

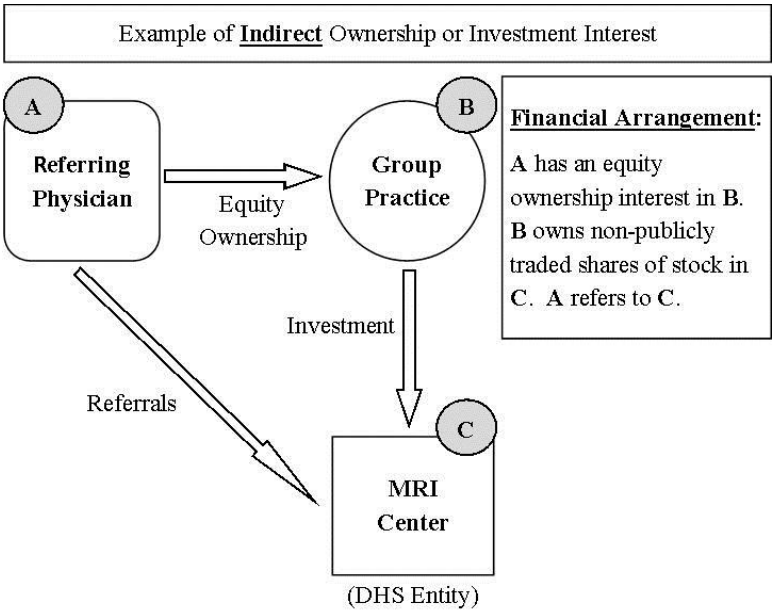
Comment: A "financial relationship" is either a direct or indirect ownership or investment interest in, or a direct or indirect compensation arrangement with, an entity. An ***"ownership or investment interest"*** may exist through "equity, debt, or other means" and includes an interest in an entity that holds an ownership or investment interest in an entity that furnishes DHS.

A ***"direct ownership or investment interest"*** exists between a referring physician (or an immediate family member of the referring physician) and an entity furnishing DHS if there are no intervening persons or entities between them having ownership or investment interests:



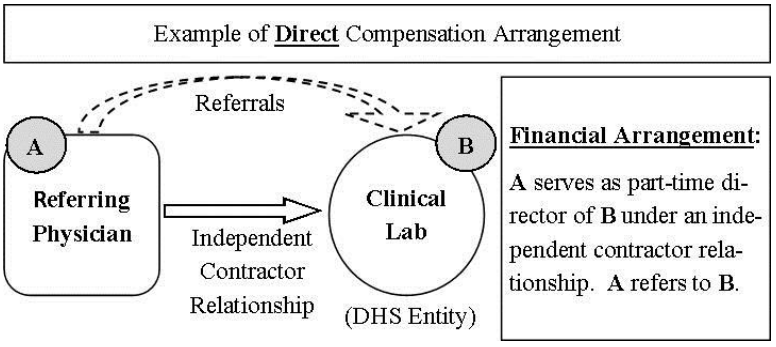
An ***"indirect ownership or investment interest"*** exists between a referring physician (or an immediate family member of the referring physician) and an entity furnishing DHS if (1) between them there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests and (2) the entity furnishing DHS "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership

or investment interests) in the entity furnishing the DHS" (note that the entity furnishing the DHS need not know the precise composition of the chain):



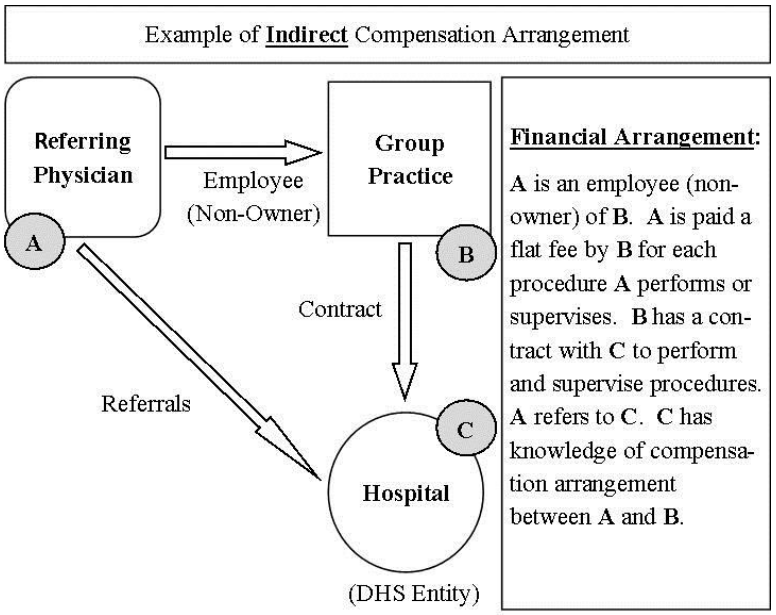
A **"*compensation arrangement*"** is any arrangement involving remuneration between a physician (or an immediate family member of the physician) and an entity. "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, with certain limited exceptions, e.g., a hospital's provision of a computer or other technology wholly dedicated to use in connection with hospital services is deemed to be for the hospital's benefit and is not deemed remuneration to a physician.

A **"*direct compensation arrangement*"** exists if remuneration passes between the referring physician (or an immediate family member of the physician) and the entity furnishing DHS without any intervening persons or entities:



An **"*indirect compensation arrangement*"** exists between a referring physician (or an immediate family member of the referring physician) and an entity furnishing DHS if (1) between them there exists an unbroken chain of any number (but no fewer than one) of persons or entities having financial relationships, i.e., each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link; (2) the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or

immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS; and (3) the entity furnishing DHS "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician to the entity furnishing the DHS":



viii. unless an exception applies

Comment: As the Stark law is a strict liability statute, a referral that implicates the statute is illegal *per se* unless it fully qualifies for an exception.

The Stark Law Exceptions.

Over thirty-five separate Stark law exceptions exist. An exception is applicable to either ownership arrangements, compensation arrangements or both. Each exception has very specific requirements that must be satisfied, often including that compensation 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. In our next article, we will focus on each of these requirements in the context of explaining several exceptions that contain one or more of these requirements, including exceptions for in-office ancillary services and office space and equipment rental.
