The Stark Law and Federal Anti-Kickback Laws: What You Need to Know

What is “Stark”?

The Stark Act is an amendment to the Social Security Act prohibiting physicians from engaging in a “self referral” when referring patients elsewhere for certain services. Stark prohibits physicians from referring their patients to other entities for designated health services (“DHS”) payable by Medicare when the physician or an immediate family member of the physician has a direct or indirect financial relationship with the entity. These referrals are commonly known as “self-referrals.”

In addition to the prohibition on the referral itself, the Stark Act prohibits the entity from billing Medicare or any individual, third party, or other entity for the services provided as a result of the self referral. The Centers for Medicare and Medicaid Services, (“CMS”), has enacted lengthy regulations designed to illuminate the boundaries of the Stark act. There several exceptions to the general rule disallowing self-referrals, providing physicians and DHS entities with some flexibility. As in other areas of health care law, however, the regulatory scheme governing self-referrals is complex and lengthy, with costly consequences for non-compliance. For that reason, physicians and DHS-providing entities should carefully plan their relationships with one another and not hesitate to contact our offices for assistance in determining compliance with the Stark act.

Definitions.

Before addressing some of the exceptions, it is important to define the key terms of the general rule. The fundamental way to avoid the application of the general rule is to distinguish oneself from the definition of critical terms. First and foremost, it should be noted that the Stark Act only prohibits referrals to entities for a DHS. Designated health services include:

1) clinical laboratory services;

2) physical therapy services;

3) occupation therapy services;

4) radiology services (including MRIs, Ultrasounds, and CAT scans);

5) radiation therapy 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; and

11) inpatient and outpatient hospital services.

If that seems like pretty much everything, it is.

Who is part of my <u>immediate family</u>?

Physicians must take note that the direct or indirect financial relationships of an "immediate family member" will be imputed to them for the purpose of determining whether a referral was a prohibited one. "Immediate family member" is defined as a "husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild." Once again, the regulations use a broad definition that should give physicians and health care providers pause.

What counts as a <u>financial relationship</u>?

The most critical definition for physicians wishing to comply with Stark entails understanding what constitutes a "direct or indirect financial relationship." In general, a "financial relationship" is a direct or indirect **ownership interest, investment interest, or compensation arrangement** with any entity that furnishes DHS. What constitutes a direct financial relationship is fairly straightforward, with one twist: A direct relationship exists if the investment interest or the compensation passes between either the referring physician *or a member of his or her immediate family* and the entity furnishing the designated health service without any intervening persons or entities. Thus, even if a physician has no contact with a DHS-providing entity, he or she may still have a *direct* financial relationship with the entity through an immediate family member. In contrast to a direct relationship, what constitutes an indirect relationship is more complex, and requires analysis in the context of the three different types of "financial relationships."

What is an <u>Ownership or Investment Interest</u>? What counts as an Indirect Ownership or Investment Interest?

An ownership or investment interest in a DHS entity can take the form of equity, debt, stock, certain stock options, partnership interests, memberships interests in an LLC, etc. An ownership or investment interest "includes an interest in an entity that holds an ownership or investment interest" in the DHS entity. Thus, an ownership interest in a subsidiary company is not an ownership interest in the parent or another subsidiary of the parent *unless* the subsidiary has an interest in the parent or another subsidiary of the parent. An interest in a retirement plan is specifically excluded from the definition of ownership or investment interest. The following, while specifically excluded from the definition of ownership or investment interest, are nonetheless considered a form of "compensation arrangement":

1) stock options or convertible securities until executed;

2) an "under arrangement" contract between a hospital and a physician-owned entity;

3) a security interest held by a physician in equipment sold to a hospital and financed through a loan from the physician; and

4) an unsecured loan subordinated to a credit facility.

An indirect ownership or investment interest exists if there is "an unbroken chain" of persons having an ownership or investment interest and the entity providing DHS has actual knowledge or acts in "reckless disregard or deliberate ignorance" that the referring physician has an indirect ownership interest in the entity, no matter how many "intermediary" interests exist. In fact, an indirect ownership or investment interest exists even though the entity providing DHS does not know the "precise composition of the unbroken chain." Referring physicians and DHS entities must therefore be careful to check that no "unbroken chain" establishes an indirect ownership or investment interest. As noted above, the DHS entity will be denied payment despite its lack of knowledge if, depending on the circumstances, CMS determines that the entity has acted with reckless disregard or ignorance of the referring physician's investment and ownership interests along the chain. A DHS entity therefore should make certain it knows exactly whom they are dealing with before accepting a referral.

What is a Compensation Arrangement? What counts as an Indirect Compensation Arrangement?

If you thought the definition of an ownership or investment interest was complex, it gets worse. Of the types of financial relationships prohibited by the Stark law, compensation arrangements are the most onerous to grasp. A compensation arrangement is "any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity," including "under arrangement" contracts.

In addition to the twist involving members of the physician's immediate family noted above, a physician is deemed to have a direct compensation arrangement with a DHS entity if "the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization."

The regulations entail a long definition of an indirect compensation arrangement. First, an indirect compensation, like an indirect investment or ownership interest, requires an "unbroken chain" of persons or entities having a financial interest between the referring physician and the DHS entity. However, unlike the indirect investment or ownership interest, an indirect compensation arrangement can exist if the intervening interest is *either* an investment or ownership interest *or* a compensation arrangement. Second, the referring physician must receive compensation from a person or entity in the chain with which the physician has a *direct* financial relationship that varies with the volume or value of referrals generated by the physician for the DHS entity. Finally, just as in the context of an indirect ownership or investment interest, the DHS entity must have "actual knowledge of, or act in reckless disregard or deliberate ignorance of" the referring physician's compensation varying with the volume or value of referrals. For the purposes of determining whether an unbroken chain exists, the physician will "stand in the shoes" of his or her physician organization.

Concerned your Financial Relationships Might Implicate the Stark Act?

You should be. Violation of the Act will result in a denial of payment by Medicare to the DHS and could result in a civil penalty of up to $100,000 for the DHS entity, referring physician, or both. A physician or other entity wishing to determine compliance with the Stark act has several options. The physician or entity can contact our offices with their questions and receive guidance based on their situation. Further, a physician or entity can request an "advisory opinion" from CMS regarding whether their referral arrangement violates the Act and regulations promulgated under it. It should be noted that advisory opinions are *binding* on both the requesting party *and* CMS. This can be a useful tool because it will give assurance to the

physician or DHS-providing entity. Although both options entail costs, those costs are dwarfed by the potential costs associated with the CMS determining a referral to be "prohibited."

What is the Anti-Kickback Law and How is it Different from Stark?

Although similar in purpose, the statute colloquially known as the "Anti-Kickback" law imposes even more severe penalties on entities violating its provisions. The Anti-Kickback law makes it a felony for anyone who receives a form of payment in return for referring a patient to another for Medicare or Medicaid-covered services. The law also forbids payment in return for purchasing, leasing, or ordering any good, facility, service or item which would be paid for under either Medicare or Medicaid. Violating the act comes with a heavy penalty – a felony conviction punishable by a fine up to $25,000 and/or five years in jail. Both sides of the transaction are forbidden – the law forbids both the receipt of and the offering to pay or payment of the kick-back.

Recently, Physician-Vendor relationships have come under heightened scrutiny by federal and state regulators. It is important for physicians and their vendors to carefully structure their relationships to avoid potentially violating the Anti-Kickback law.

"Safe Harbor" Transactions

Congress and the Department of Health and Human Services ("HHS") have provided several "safe harbors" allowing entities to avoid violations of the Anti-Kickback law. Many of the excepts are made to exclude certain arrangements or transfers from the definition of payment, thus shielding the parties from potential criminal liability under the Anti-Kickback law. The safe harbors include:

1. Investment Interests:

Three types of payments are exempted under the safe harbor for "investment interests." To fit in the first exemption, the entity must have less than $50 million in assets related to the furnishing of health care items and services. With active and passive investors, there are restrictions on the respective ownership interests that may be held by those capable of making referrals or furnishing Medicare or Medicaid covered health services. These restrictions are relaxed somewhat if the entity is located in an "underserved area." The exemption for investment interests allows that, in certain circumstances, dividends or interest are deemed not to be payments as far as the Anti-Kickback law is concerned. However, the regulations impose very precise and lengthy conditions on compliance with the exemption. Entities wishing to use this exemption should consult with their attorney to ensure full compliance with the investment interest safe harbor.

2. Space Rental:

Remember that the Anti-Kickback law forbids certain leasing arrangements. Recognizing that this could put a strain on health care providers attempting to find a place to set up shop, HHS provided a safe harbor for space rental. This safe harbor requires the lease to be in writing, cover all the premises leased between the parties and specify those premises, be for at least one year, be for fair market value rent, which is set in advance, and not lease more space than is "reasonably necessary" to provide the desired service. The rent can in no way reflect the volume or value of referrals between the parties for Medicare or Medicaid covered services.

3. Equipment Rental:

What good is an empty office? Modern health care requires some very complicated and very expense equipment. Many health care providers find it more economical to rent rather than own their equipment. In a corollary to the safe harbor for space rental, HHS has provided a safe harbor for equipment rental. The same conditions as applied to the space rental lease apply to the equipment lease.

4. Personal Services / Management Contracts:

A safe harbor exists for payment made to agents (persons authorized to act for another) as compensation, so long as the agency agreement is set out in writing and covers all the services the agent will provide, be for not less than one year, be for an amount equal to the fair market value for such services, be for an amount set out in advance, and in no way take into account the volume or value of any referrals or business generated payable by Medicare or Medicaid.

5. Referral Services:

Payment can even be made to a referral service under a safe harbor promulgated by HHS. The payment, as you've probably guessed, cannot be based on the volume or value of referrals, but only on the costs of operating the referral service. There can be no restrictions on the manner in which the services referred are provided. Further, the referral service must make certain disclosures to the person seeking the referral and maintain a written record certifying those disclosures.

6. Payments made to *Bona Fide* Employees:

Payments to an employee will be safe so long as there is a "bona fide" (real) employment relationship and the payments do not take into account the value or volume of referrals for Medicare or Medicaid covered services.

7. Recruitment:

Just as there were relaxations under STARK for physician recruitment, there exists a safe harbor under the Anti-Kickback regulations for payments made to induce a practitioner to join with an entity. There is a litany of conditions that must be met for this safe harbor to be met. For example, if the recruit is leaving an established practice, the revenues at the recruiting entity must generate 75% of its revenue from new patients; that is, the recruit can only bring 25% worth of patients with him from his old practice. Further, there can be no condition that the recruit make referrals, influence referrals, or otherwise generate business for the new entity as a condition of receiving the benefits of his or her new employ.

This article is designed only as an introduction to the STARK and Anti-Kickback laws. The exceptions outlined above are presented in a simplified manner and it should be stressed that health care providers should consult with their attorneys to ensure full compliance with any and all regulations under STARK or the Anti-Kickback laws.

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