

False Claims in Healthcare

Chapter 3. The Stark Law and Anti-Kickback Statute as FCA Risks

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Many False Claims Act (FCA) cases are premised on alleged violations of the federal Physician Self-Referral Law, 42 U.S.C. § 1395nn (Stark Law) and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and often on both. The theory is that claims submitted to federal healthcare programs are tainted, and hence false, if the services for which payment is claimed are performed as a result of a violation of the Stark Law or Anti-Kickback Statute. The Stark Law and Anti-Kickback Statute are both designed to prevent financial relationships from corrupting healthcare decision-making, but they take very different approaches in achieving those aims.

The Stark Law is a civil law and takes a “strict liability” approach, meaning a party is legally responsible for an impermissible activity, regardless of whether intent to harm or actual negligence were involved. The law aims to prevent conflicts of interest in financial relationships that might interfere with a physician’s exercise of unfettered medical judgment, regardless of the intentions of the parties to the arrangement. By contrast, the Anti-Kickback Statute is a criminal law that seeks to prevent financial arrangements that are entered into with the corrupt intent of trying to influence the other party’s judgment. Despite these important differences, it is common for FCA cases to involve allegations of both Stark Law and Anti-Kickback Statute violations, and a common set of alleged facts (and related issues arising from those alleged facts) often form the basis for these FCA allegations. Likewise, there are many similarities in the strategies used to prevent and mitigate these issues and address them in response to an internal or external investigation.

Stark Law Overview

The Stark Law is focused on patient referrals for designated health services (DHS) reimbursable under Medicare. It prohibits a physician from referring a patient to an entity that furnishes DHS if the physician, or a member of the physician’s family, has a financial relationship with that entity, unless the requirements of a permissible exception are satisfied. Likewise, an entity is prohibited from billing Medicare for any services provided pursuant to a prohibited referral. DHS include clinical laboratory services; physical and occupational therapy services; radiology or other diagnostic imaging services; radiation therapy services and supplies; durable medical equipment; parenteral and enteral nutrients; equipment and supplies; home health services; prosthetics, orthotics, and prosthetic devices; outpatient prescription drugs; and inpatient and outpatient hospital services.

The Stark Law defines prohibited financial relationships to include both ownership interests and compensation arrangements. The law further divides compensation arrangements into two categories, which are subject to two different analytical frameworks: “direct” compensation arrangements and “indirect” compensation arrangements. Direct compensation arrangements are those that are directly between the individual referring physician and the entity receiving the physician’s referrals, without any intervening entity interposed between them. One important caveat: a “physician organization” (i.e., a medical practice) is not considered an intervening entity for a physician owner. Physician owners are considered to stand in the shoes of their physician organization (i.e., the physician organization’s direct compensation arrangements are viewed as the direct compensation arrangements of each physician owner of the organization).

As defined in the Stark regulations, an indirect compensation arrangement exists if all three of the following

conditions are satisfied:

1. Between the referring physician (or immediate family member) and the entity furnishing DHS, there is an unbroken chain of two or more persons or entities that have financial relationships between them (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 the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the individual unit of compensation received by the physician (or immediate family member):
 - a. Is not fair market value for items or services actually provided; or
 - b. Includes the physician's referrals to the DHS entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the physician's referrals to the DHS entity, or
 - c. Includes other business generated by the physician for the DHS entity as a variable, similarly linked to the DHS entity; 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 otherwise reflects, the value or volume of the physician's referrals or other business generated for the DHS entity.^[2]

Because of the strict liability nature of the Stark Law, if there is a financial relationship between a physician and an entity to which the physician refers Medicare patients for DHS, then ***the parties must satisfy a Stark Law exception***. Otherwise, the referrals are prohibited, and the entity is prohibited from billing for services provided pursuant to such referrals. If the entity discovers it has previously received Medicare payments in violation of the Stark Law, then it must refund them within 60 days.^[3] An entity that bills for services it knows or should know cannot permissibly be billed under the Stark Law is subject to civil money penalties of up to \$15,000 per service billed.^[4]

Because the Stark Law is essentially a payment law, if the parties have actual knowledge, or act in deliberate ignorance or reckless disregard of the circumstances causing a Stark Law violation, then they run the risk of being found to have submitted or caused the submission of false claims in violation of the FCA.

The exceptions that must be satisfied in order for the physician to permissibly refer Medicare patients for DHS come in three categories. One category of exceptions protects both ownership and compensation arrangements (e.g., there is a broad exception for referrals of Medicare Advantage patients, and a broad but highly technical exception called the "in-office ancillary services" exception that allows physicians to refer to their own medical practice, if certain requirements are satisfied).^[5] Another category protects ownership interests if certain requirements are satisfied (e.g., for certain rural providers, or for hospitals that had physician ownership as of March 23, 2010).^[6]

The third category of exceptions, which generates the most attention and causes the greatest frustration, protects a range of different types of compensation arrangements, if they satisfy certain documentation and valuation requirements.^[7] Among the more common requirements that must be satisfied for most compensation

arrangement exceptions is that the arrangement be documented in writing and signed by the parties and that the compensation be consistent with fair market value, not take account of referrals or other business generated between the parties, and be commercially reasonable without regard to referrals or other business generated between the parties.

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