5 Key Stark and Anti-Kickback Legal Rules You'll Want to Know

December 1, 2018
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While federal Stark and anti-kickback laws, and state law equivalents (often known as "mini-Stark" and "fee-splitting prohibitions") are very complex, there 5 key legal rules you'll want to know.

Think of these as The Five People You Meet in Heaven—only you meet them on Earth, and they don't teach you about love or forgiveness or sacrifice or purpose. They teach you about compliance.

Here, briefly are the 5.

1. What's a "Referral"?

Stark, anti-kickback, and fee-splitting laws often refer to illegal "referrals," but what exactly is a "referral?"

Under federal law, "referral" means the request by a physician for an item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician).

Taking California state law as one example, California attorney general opinions likewise interpret the term "referral" expansively.

Sending the patient to a particular provider or facility for healthcare services is a "referral."

2. How does Stark affect transactions involving family members of a physician?

The federal self-referral statute ("Stark") provides that if a physician (or immediate family member) has a financial relationship with an entity, then, unless the arrangement qualifies for a specific exception:

- The physician may not refer patients to the entity for "designated health services" ("DHS") payable by federal health care programs (including Medicare, Medicaid or CHAMPUS, and in California, Medi-Cal), and
- Where DHS are involved and the referral is prohibited, the physician may not present a claim to any third-payer for the same.

3. How are state laws like Stark and the federal anti-kickback statute?

In general, state laws often have a self-referral prohibition that mirrors Stark, only is less dense and comprehensive. Sometimes these are known as "mini-Stark" statutes.

For example, California law contains prohibitions against self-referral in the Physician Ownership and Referral Act of 1993 ("PORA"), as well as California Labor Code Section 139.3 (workers' compensation), and some other statutes.

See some of our prior posts:

How substance abuse treatment centers navigate anti-kickback rules
Substance abuse treatment centers must steer carefully when sending patients for labs. Self-referral, anti-kickback, and fee-

splitting rules can create legal enforcement issues and must be […]

Quick Summary of Federal “Stark” Self-Referral & Anti-Kickback Law and California Self-Referral and Fee-Splitting Prohibitions
Here is a quick summary of federal self-referral (“Stark law”) and anti-kickback law, and California self-referral and anti-kickback / fee-splitting rules.

Fee-splitting 101 for medical doctors, chiropractors, acupuncturists, and others
Is it fee-splitting to hire another medical doctor, chiropractor, acupuncturist, or other health care practitioner in your office and give them a “cut” of patient revenues?

PORA applies to healthcare licensees. Even if none of the designated health services in the statute are being provided, then the prohibition is inapplicable; however, a disclosure of the financial interest must be provided to patients at the time of the referral.

California Law Code Section 139.3 provides that:

(a) …. it is unlawful for a physician to refer a person for clinical laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, outpatient surgery, diagnostic imaging goods or services, or pharmacy goods, whether for treatment or medical-legal purposes, if the physician or his or her immediate family has a financial interest with the person or in the entity that receives the referral.

However, Section 139.3.1 provides:

(c) (1) A physician may refer a person to a health facility as defined in Section 1250 of the Health and Safety Code, to any facility owned or leased by a health facility, or to an outpatient surgical center, if the recipient of the referral does not compensate the physician for the patient referral, and any equipment lease arrangement between the physician and the referral recipient complies with the requirements of paragraph (2) of subdivision (b).

(2) Nothing shall preclude this subdivision from applying to a physician solely because the physician has an ownership or leasehold interest in an entire health facility or an entity that owns or leases an entire health facility.

There is always a “however,” or a “nothing shall preclude….” That’s what makes the whole area so rich and nested.

4. What’s the big deal about the Federal Anti-Kickback Statute (“AKS”)?

The federal anti-kickback statute prohibits the knowing and willful offer or receipt of remuneration to induce the referral of business or services covered by a federal health care program, including Medicare.

Even in the presence of other legitimate purposes, the courts have interpreted the statute to cover any arrangement where one purpose of the payment or offer of payment (albeit not the only purpose) was to obtain money for the referral of services or to induce further referrals.

You don’t want to get on the wrong side of this one.

Note, however, that if you violate Stark, there’s strict liability unless you find an exception that you can completely fit. With AKS, there are “safe harbors.” Meeting the elements of the safe harbor doesn’t guarantee immunity from enforcement; then

again, failing to meet the elements of the safe harbor doesn't guarantee enforcement. (We know, you can read that sentence again.)

There are plenty of Stark exceptions and AKS safe harbors. For example, under 42 CFR 1001.952(r), a safe harbor exists for ambulatory surgery centers (ASCs). Specifically:

"remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories –

(1) Surgeon-owned ASCs….

(2) Single-Specialty ASCs….

(3) Multi-Specialty ASCs….

(4) Hospital/Physician ASCs….

The multi-specialty ASC safe harbor adds to the criteria from the single-specialty ASC safe harbor, the requirement that:

At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

5. State Anti-Kickback Prohibitions Can be Just as Onerous and Tricky

To take an example, with respect to potential kickbacks, California Business & Professions 650 provides:

(a) …. the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

Section 650(a) is the "thou shalt not" and Section 650(b) is the "thou mayest." So which one controls?

Much depends on enforcement discretion and the specific circumstances. This is why it's important to get legal counsel and specifically analyze the venture.

Section 650(b) is often used to justify payment of the management fee based on a percentage of gross revenues at fair market value. This provision allows payment to management companies, billing persons, and other personnel for "services other than the referral of patients," provided:

1. The compensation is at fair market value ("FMV") for the services rendered; and

2. The compensation does not vary by volume or value of patients referred.

As we note elsewhere, even though 650(b) allows compensation under these circumstances, based on a percentage of gross revenues, we typically recommend a flat fee for marketing services, because marketing activities tend to be heavily scrutinized by regulatory authorities for kickbacks and fee-splitting. We discourage any percentage-based or patient-based remuneration for marketing, which would take into account the volume or value of referrals.

As well, out of abundance of precaution, and because of the influence federal standards can have on enforcement of state anti-kickback issues, it is prudent to comply with the federal safe harbor for remuneration from an entity under a personal service arrangement or management contract. But again, every venture deserves its own analysis.

Now, for the back story.

Stark

Penalties for violation of Stark can be significant. In a recent case, a large health system agreed to pay more than $25 million to resolve self-disclosed allegations that it illegally paid bonuses to doctors based on how much the system earned from their patient referrals. According to an article in Modernhealthcare.com entitled, Intermountain to pay $25.5 million to settle Stark case, the health system reportedly "characterized the violations as 'technical in nature' and said they arose partly because of the 300 pages of federal regulations and commentary that govern financial relationships between hospitals and physicians. "

Note the following definitions under Stark:

- The financial relationship can be an ownership or investment interest in the entity, or a compensation arrangement between the physician (or immediate family member) and the entity.
- A compensation arrangement is any arrangement involving remuneration between a physician (or an immediate family member) and an entity.
- The Stark regulations define a physician as a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.

In general, "remuneration" means "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."

A first step is to determine whether DHS is involved. DHS within Stark include:

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- outpatient speech-language pathology services;
- radiology services, including nuclear medicine, MRI, CAT scans, and ultrasound services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;

- outpatient prescription drugs; and
- inpatient and outpatient hospitalization services

With regard to the first six categories of DHS, the Stark regulations identify the specific insurance billing codes in each category, which are considered to constitute DHS. These are updated annually by CMS. The remaining six categories of DHS are defined in the Stark regulatory text.

If DHS is involved, then proposed arrangements must be structured to fit an exception.

PORA

Under PORA:

- A “financial interest” includes “any … compensation,” whether direct or indirect. In other words, a physician need not have a stock ownership in the entity to which the physician is referring, in order for PORA to apply. Spouses are considered an immediate family member under PORA.
- Unlike the Stark law, PORA applies to designated health care services regardless of the source of payment, i.e. for private insurers and cash patients.

California’s definition of “physician” is broader than that under federal law, and includes, for example, acupuncturists (Christine). For purposes of PORA, under section 650(b)(4), the term “licensee” means “a physician as defined in Section 3209.3 of the Labor Code.” Under section 3209.3(2) of the Labor Code, the term “physician” “includes physicians and surgeons holding an M.D. or D.O. degree, psychologists, acupuncturists, optometrists, dentists, podiatrists, and chiropractic practitioners licensed by California state law and within the scope of their practice as defined by California state law.”

The PORA prohibition on referrals only applies if the services provided are those designated as health services triggering the prohibition by PORA, Section 650.01(a) (laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services).

In connection with PORA, a physician must report to the California Medical Board of any “financial interest” in a “health-related facility.” The term “financial interest” is broadly defined to include, among other things:

Any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, to a licensee or the licensee’s immediate family from a health-related facility.

The term “health-related facility:”

shall include a facility for clinical laboratory services, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, diagnostic imaging, and outpatient surgery centers. “Diagnostic imaging” shall include, but is not limited to, all X-ray, computed axial tomography, magnetic resonance imaging, nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services. (emphasis added)

If any of designated health services in PORA apply, then we must look to a PORA exception.

Things You Wanted to Know about AKS But were Afraid to Ask

Federal anti-kickback law can apply to all practitioners, not just physicians, where federal reimbursement monies are involved. Here, practitioners may benefit from cross-referrals and be induced by the financial benefit to cross-refer to Medicare-reimbursed practitioners, irrespective of medical benefit.

Among other dangers, enforcement authorities can potentially view an arrangement as a disguised kickback scheme. One of the ways this could be expressed is an unlawful joint venture between the two entities. The Office of the Inspector General ("OIG") has expressed concern about joint ventures violating federal anti-kickback law.

In order to protect beneficial arrangements, the federal Centers for Medicare and Medicaid Services ("CMS") has published certain statutory safe harbor regulations that define practices that are not subject to the anti-kickback statute. If the conditions in the safe harbors are met, neither party will be prosecuted or sanctioned for the arrangement. Fitting into an exception under Stark is mandatory, whereas under anti-kickback law, if an arrangement does not meet every element of a safe harbor, it is not necessarily unlawful, but rather, is at risk of scrutiny by the OIG.

In the preamble to the 1991 final safe harbor rules, the OIG explained that the anti-kickback statute "on its face prohibits offering or acceptance of remuneration, inter alia, for the purposes of 'arranging for or recommending purchasing, leasing, or ordering any . . . service or item' payable under Medicare or Medicaid." The OIG has also observed that "many marketing and advertising activities may involve at least technical violations of the statute." As a result, it is critical to scrutinize payments for marketing activity involving physicians for the risk of falling within the anti-kickback prohibition.

If a proposed arrangement fully complies with all the detailed requirements of the safe harbor, the arrangement is not subject to enforcement under the anti-kickback statute; but practices that do not fit within a safe harbor are not necessarily illegal. The arrangement must be carefully scrutinized. The OIG will "evaluate both the form and substance of arrangements," and take enforcement action against arrangements that are merely disguised kickbacks.

The Safe Harbor for Personal Services and Management Contracts

We mentioned California Business & Professions Code 650(b). A similar concept is embodied in this important safe harbor to AKS, which is the basis for the MSO model.

This safe harbor applies only if all of the following standards are met:

- The agency agreement is set out in writing and signed by the parties.
- The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
- If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
- The term of the agreement is for not less than one year.
- The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Note that unlike in the Stark exception, there is a reference to "aggregate compensation," and a requirement that if be "set in advance." This can cause problems, but we'll defer these for another day.

Conclusion

When you've got health care practitioner referring to one another within a proposed business arrangement, you could have potential yellow lights in the form of federal Stark, federal anti-kickback, state mini-Stark (self-referral) and state anti-kickback, fee-splitting, and patient brokering rules. This is not an area for DIY.