The Stark Law

Be careful not to violate these self-referral situations.

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Most podiatrists have heard of the Stark Law, but other than having to do with self-referral, know little else. This article will act as a primer for this law. As the law and its revision are hundreds of pages, this short review can only cover so much. It is not designed to make you into experts in this area of the law.

The Stark Law was originally passed in 1992 and substantially amended in 1995. It was also changed in 2009 involving professional recruitment and again in 2016 to deal with office timeshare arrangements and to ease some of the compliance burden. Along with the False Claims Act (FCA) and the Anti-Kickback Statute (AKS), they constitute much of the backbone concerning fraud and abuse laws.

The AKS covers the payment of anything of value, such as, but not limited to, money, bribes, rebates, trips, that can act as an "incentive" to use a product or service that is payable under a federal program. This would include Medicare and Medicaid. Examples include: giving cash payments to people to "refer" patients billed under Medicare or Medicaid; deals to rent space at rates above fair market value; to induce use of a laboratory or product for patients that are billed under federal health programs. "Favorable" rates for equipment rental, management services, discounts, and patient transportation also would come under this law. It is important to note that referrals for legitimate regular reasons may still violate this law, as long as there is an illegal financial component as part of the referral.

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The Stark Law deals with self-referrals, which include immediate family members. It includes both Medicare and Medicaid claims. In 1995, self-referral law expanded the designated health services (DHS) from clinical laboratories, to also include physical therapy, occupational therapy, radiology, durable medical equipment and supplies, parenteral equipment and supplies, prosthetics, orthotics, and hospital services, including, outpatient outpatient prescription drugs and home health services.

An immediate family member is specified to include parents, brother or sister, grandparents, grandchildren and spouse. The prohibited "financial arrangement" (the kickback) can involve any type of ownership or investment. It also can involve any type of "compensation arrangement".

Before we proceed, let's show how the AKS and Stark Law differ. The Stark Law can only assess civil or administrative penalties, not crim-

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inal penalties. The AKS Law violation may result in prison time. The AKS law requires an intent to violate that law's prohibitions. The Stark Law only needs the healthcare provider or others to violate the law's requirements—whether or not they meant to! That is a big difference, with a very different legal burden on the prosecutors.

Violations of Stark can result in exclusion from Medicare and Medicaid. They can also result in fines and penalties involving a lot of money, especially when part of a False Claims Act lawsuit. These lawsuits often result from the findings of a Stark Law violation. A Stark Law violation can result in civil penalties up to $15,000 for *each* service violation! It can result in penalties up to $100,000 for each scheme involving self-referral violations, as well as up to $10,000 for each day for which reporting of a potential violation is required under the law. This can get life-changing in a hurry.

The key to compliance in not referring to medical services or supplies to yourself (or an excluded relative) is the list of exceptions. Some of the important exceptions involve referral to or from a legitimate employee (not an independent contractor). Other exceptions to Stark concerning compensation are professional courtesy situations and fair market value compensation. Referral of a patient within the same practice is allowed, even if it is with a Medicare or Medicaid patient. In-office ancillary testing is allowed. This includes x-rays and lab tests, *if performed in the same location*. Many other exceptions apply. Another term for these exceptions is "safe harbor."

To be considered a violation of the Stark Law the following must be present:

A physician must make a referral for the provision of a designated health service payable by Medicare or Medicaid to an entity with which he or she, or one of the immediate family members, has a financial relationship. Remember, a safe harbor such as a family member being a legitimate employee of the referring person renders it an exception to the violation of the law.

Examples of Violation of the Stark Law

All of this can be very confusing. Let's see some real-life examples of Stark Law violation that will seem more relevant to your everyday practice. Some of these might also be considered, at least in part, violation of the Anti-Kickback Act too, not to mention state versions of these laws.

1) Recently, it has been in the news that podiatrists were prescribing and dispensing medical care to Medicare or Medicaid patients, such as medically unnecessary foot bath medications.

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2) A practice prepared contracts with physicians that required them to make referrals to its own new outpatient surgical center. In return, they received compensation that included money received from Medicare.

3) Physicians received money from a management service organization (MSO) in exchange for ordering laboratory tests on Medicare patients from specific facilities.

4) You refer a patient to a facility owned by your brother without telling the patient of the connection.

5) You own a durable medical equipment company and refer a patient to that company.

6) Paying a healthcare provider for referring Medicare or Medicaid patients. A blood lab started referring Medicare and Medicaid patients to a podiatrist, in return for the referrals they received from the podiatrist. If it is a quid pro quo, it is not allowed. If it is a recommendation, due to the fine quality of the lab's work, that is allowed. Of course, it must be made known to the patient that they can go to any blood lab they want.

7) Different scenario: A podiatrist is using, exclusively, a pathology laboratory for all their biopsies. They use the lab because they do excellent work with a timely follow-up with the practitioner. The lab sends the podiatrist to the Bahamas, all expenses paid. This is not allowed, even if in the Bahamas there is a pathology lecture waiting to be attended.

8) A pharmacologic company recruits you to lecture about anti-fungal medication. They train you and give you a script to use as the lecture. They schedule several lectures in the local steakhouse. They state that you can invite local friends and relatives to fill up the seats, even if they are not healthcare providers. Very few healthcare providers show up during several of these "events". There is an open bar. You are paid $5,000 per event, much more than the local going rate for such "education". Your practice is the state's biggest prescriber of this very expensive medication. Many of the patients treated with these prescriptions have Medicare and/or Medicaid. This is clearly not allowed.

9) Investing in a healthcare practice offering financial incentives, such as low rent, for referrals.

10) Paying physicians more than the fair market value for their services to obtain their referrals for a service or hospitalization.

11) Failing to prepare or retain proper documentation related to financial relationships and referrals. Yes, the law requires you to report a possible Stark violation. Why self-disclose? It might result in lower punishment.

12) A podiatrist was performing surgery on behalf of non-surgical practices. The podiatrist had independent contractor agreements with several podiatrists. She would split the fee on Medicare patients. She would perform surgery, and the referring podiatrist did all the pre-op and post-op aftercare. Federal agents were fine with the podiatrist performing the surgery if she had used part-time employment contracts, instead of inde-

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pendent contractor agreements. The employee exception is a "safe harbor". Once part-time employee contracts were prepared and shown to the agents, they lost interest.

Again, it must be emphasized that there are several exceptions that, if met, will insulate you from Stark Law violations. As proper documentation and structure are crucial, it is virtually mandatory to use experienced attorneys to set this up so that there is no Stark Law or AKA violation.

In 2010, the Affordable Care Act, in effect, amended the Stark Law concerning self-referral of ancillary exceptions—the physician must inform the patient in writing, if being referred in-house for a CT or MRI, that they can obtain these tests elsewhere, and they must provide the patient with a list of other suppliers of these services in that area.

Does an attorney or a plumber or carpenter have to worry about self-referral type situations? The short answer is NO. Physicians seem to receive special attention. Kickbacks and referral fees abound in our society, just not legally in the healthcare arena.

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Finally, please make sure not to confuse various state Stark Laws with the federal Stark Law. Depending on the state, there can be real differences. It can all be very confusing. It is strongly advised that upon being notified that you are being investigated for possible Stark or False Claim Act violations, you consult with an experienced health law attorney as soon as possible. Better yet, have an experienced health law attorney review your current situation for possible problems prior to any investigation, and correct them! **PM**

Dr. Kobak is Senior Counsel in Frier Levitt's Healthcare De-partment in New York. Larry has extensive experience representing physicians in connection with licensure issues, as well as suc-cessfully defending physicians before Medical Boards, OPMC, OPD investigations, as well as Medicare Fraud, Fraud & Abuse, Hospital Actions, RAC Audits, Medicare Audits, OIG Fraud, Healthcare Fraud, Medical Audits, and Health Plan Billing Audits. As a licensed po-diatrist prior to becoming an attorney, he served as the interna-tional president of the Academy of Ambulatory Foot and Ankle Surgery.