

Recent Stark Law and Anti-Kickback Statute Cases

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Stark Law and Anti-Kickback Statute Cases That Can Kill Your Healthcare Venture

Several recent announcements by the US Department of Justice confirm that medical practices will pay a heavy price for illegal-self referrals. The announcements confirm settlements for violations of the Stark Law, a federal anti-self-referral law and the Anti-Kickback Statute (AKS). The purpose of Stark Law is to ensure that patients will receive medical advice and will treat with physicians based on their medical needs and not on what profits the doctors or medical practices involved.

Experienced Stark Law attorneys explain to physicians and practices when Stark Law and a similar law, the Anti-Kickback Statute (AKS), apply to their medical relationships. Doctors and practices need to understand that many referrals may be legal – if the referral is covered by the Stark Law exceptions of AKS safe harbor. The healthcare lawyer can explain what documentation and what steps need to be taken to convince the government that their medical relationships comply with these exceptions or safe harbor rules.

Improper billing and Stark Law referrals harm anyone who uses Medicare or other federal healthcare services – in addition to hurting the patient by not providing the best medical care possible.

Firms that violate Stark Law and the AKS will be subject to criminal and civil prosecution which can result in substantial economic penalties, the cessation of the medical practice, and possible imprisonment.

DO YOU KNOW THE KEY DIFFERENCES BETWEEN THE 4 AMBULATORY SAFE-HARBORS TO THE FEDERAL ANTI-KICKBACK STATUTE (AKS)?

There are four types of ambulatory safe harbors in the federal Anti-Kickback Statute. We explain the key differences between the ambulatory safe harbors to the federal anti-kickback statute (AKS)

Orthopedic surgery and physical therapy practice agree to pay \$1.25 million to settle Stark Law claims

The US Attorney for the Southern District of Alabama announced in 2019 that Baldwin Bone & Joint, had agreed to settle claims it violated the False Claims Act, a law designed to help the government recover funds for illegal transactions involving the government.

The illegal transactions, in this case were violations of the Physician Self-Referral Law, also called Stark Law. The agencies that were the subject of the alleged fraud were Medicare, a healthcare program for seniors, and TRICARE, a healthcare

program for retired veterans and their families. The lawsuit was brought pursuant to the qui tam provisions of the False Claims Act which reward individual whistleblowers for disclosing fraud by paying the whistleblower a percentage of any recoveries.

In this case, the whistleblower was a former employee of the medical practice. The OIG office of the US Department of Health and Human Services and the Defense Criminal Investigative Service brought the legal actions on behalf Medicare and TRICARE.

The basis for the False Claim Act claim was that the orthopedic practice billed for services for **physical therapy** that were performed by unauthorized athletic trainers and an exercise psychologist. The basis for the Stark Law claim was that the practices' "direct compensation arrangements with its shareholder physicians, violated Stark Law because the medical providers:

payments "to its shareholder physicians directly or indirectly related to the volume of each shareholder physician's referrals for designated health services such as physical therapy, X-rays and MRI's."

Stark Law forbids doctors from referring patients to specific designated health facilities in which the doctors have a **financial relationship** – where the patients bill Medicare or other federal healthcare programs. The term "financial relationship" is interpreted fairly broadly. It generally includes referrals that are based on the volume of the referrals. The law applies if the physician or a doctor has the financial relationship. Stark Law is a civil law, unlike the AKS which allows for criminal prosecution. Physicians and medical practices that violate Stark Law can be required to pay fines up to \$15,000 for each billed service in addition to being required to return to Medicare any payments improperly received. In addition, the doctors and providers may be subject to triple damages on the overpayment.

There are specific **exceptions to Stark Law** which allow for certain types of referrals under certain conditions. An experienced healthcare lawyer can explain when exceptions apply (for example – for in-house ancillary services or services based on fair market value) and what document (usually a written document) is required.

The Anti-Kickback statute is similar to Stark Law but there are key differences. Specific intent is required for AKS violations but not for Stark Law violations. The AKS, as mentioned, includes criminal sanctions. The AKS applies to Medicare – and Medicaid and TRICARE. Stark Law involves referrals between a doctor and another entity. Stark Law lists specific exceptions. The AKS relies on the concept of a safe harbor. If an arrangement does not meet a Stark exception then the arrangement is non-compliant; on the other hand, the safe harbor elements need not necessarily be strictly met.

As of this blog post, the whistleblower employee above will receive \$200,000 for his work in obtaining the settlement. The claims were settled without a determination of liability.

WHAT MEDICAL PRACTICES SHOULD KNOW ABOUT THE STARK LAW

The Stark Law is named after California U.S. Congressman, Peter Stark. It seeks to regulate how physicians refer Medicare and Medicaid patients. The law is part of the Omnibus Budget [...]

Several Medical Facilities Agree to Pay \$35 million to settle False Claims Act Charges based on Stark Law – involving Kickbacks to a Maryland cardiology practice.

The US Department of Justice announced in 2019 the terms and basis of the settlement. DOJ stated that the kickbacks are alleged to be in return for patient referrals by the cardiology group – through a series of professional services contracts.

"Kickbacks give doctors an incentive to pursue unnecessary treatments that are costly and sometimes even dangerous to patients," said U.S. Attorney Robert K. Hur. "We will not tolerate medical care providers who put their patients at risk and

waste taxpayers' dollars in order to line their own pockets."

"Patients rightly expect their doctors will make recommendations based on sound medical practice – not payoffs that too often result in needless and sometimes even harmful procedures," said Maureen R. Dixon, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. "We will continue to protect patients and taxpayer-funded government health programs from these unnecessary services, as the government contended in this case."

The kickbacks were in "guise of professional services agreements" in return for "lucrative cardiovascular procedures, including cardiac surgery and interventional cardiology procedures, from Jan. 1, 2006, through July 31, 2011."

The litigation was brought by several cardiac surgeons who practice together asserting violations of the Anti-Kickback Statute and the False Claims Act. The False Claims Act was involved because some of the cardiac procedures were billed to Medicare.

A second whistleblower lawsuit was brought by patients of one medical doctor and several other medical facilities that some of the procedures weren't medically necessary.

KICKBACKS, FEE-SPLITTING, CORPORATE PRACTICE OF MEDICINE, STARK, MSOS: GUIDING HEALTHCARE VENTURES THROUGH THE MAZE

Fundamentally, you're worried about legal rules prohibiting kickbacks, fee-splitting, corporate practice of medicine, as well as Stark law; you don't know whether the MSO or management structure [...]

A Capital Management Company and Its Affiliate Agree to Pay \$3.6 Million to Settle Stark Law, AKS, and False Claim Act Allegations Doctors Referred Patients to Them Illegally

The Department of Justice announced in 2019, that Rialto Capital Management LLC (Rialto) and a former affiliate agreed to the \$3.6 million payment based on claims they and a hospital in Indiana entered into illegal financial arrangements with two doctors who referred patients to the Indiana hospital.

"When doctors refer patients for tests and medical procedures, they must do so based on their own professional judgment and the medical needs of their patients, not personal financial benefits," said Assistant Attorney General Jody Hunt for the Department of Justice's Civil Division. "Illegal financial arrangements between health care providers undermine the integrity of our health care system, and we will continue to pursue those who engage in such conduct."

The settlement was based on claims the hospital, under the direction of the capital management company, made personal loans to the two doctors who referred patients and then "repeatedly forbore from requiring repayment of those loans." The government claimed that the failure to make the effort to collect on the loans was "remuneration" in return for referrals – which is prohibited by both Stark Law and the AKS.

- *"The AKS prohibits the provision of remuneration to induce the referral of services or items that are paid for by a federal health care program."*
- *"Stark Law restricts financial relationships that hospitals may enter into with physicians who refer patients to them."*
- *"The False Claims Act prohibits the submission of claims to Medicare for items or services that are tainted by financial arrangements that violate the AKS or the Stark Law."*

"Rialto, through RL BB, acquired KMC as part of KMC's bankruptcy reorganization in 2013. As part of that reorganization, KMC and Rialto initially offered to award partial ownership in the hospital's real estate to certain physicians who had been

important referral sources for KMC, but those offers were challenged in the bankruptcy proceedings. Instead, Rialto approved personal loans from KMC to two of the hospital's key referral sources, and Rialto and KMC then allegedly repeatedly forbore from requiring repayment of those loans for more than two years after each loan matured and became due in full."

"Healthcare entities need to ensure that financial arrangements with physicians are clear and appropriate," said Lamont Pugh III, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services (OIG). "The practice of providing any kind of remuneration in exchange for the referral of Medicare patients is a violation of the Anti-Kickback Statute. OIG will continue to examine and investigate those relationships that violate federal statutes in an effort to protect vital taxpayer dollars."

The whistleblower in this case was a doctor who was awarded \$612,000 for disclosing the alleged fraud. The settlement is not an admission of liability.

As these cases, and many other DOJ cases indicate, the consequences for violations of Stark Law and the Anti-Kickback Statute are quite severe. Often medical practices can be named as defendant. In the last two cases, they may not have been named defendants because the whistleblowers were physicians in the practices or related somehow to the practices. There are often correct ways to establish referral arrangements that an experienced healthcare lawyer can explain.

Contact Cohen Healthcare Law Group, PC to learn what financial relationships between doctors or medical practices and any health provider, hospital, family, investment firm, or other entity might fit within a Stark exception or safe harbor and which ones might result in enforcement. Our Stark and Anti-kickback attorneys have a strong track record of helping physicians and medical practices structure arrangements, and craft documents, with an eye toward mitigating potential regulatory risk.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.