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A Roadmap for New Physicians Fraud & Abuse Laws

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The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.

False Claims Act [31 U.S.C. § § 3729-3733]

The civil FCA protects the Government from being overcharged or sold shoddy goods or services. It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent. Filing false claims may result in fines of up to three times the programs' loss plus \$11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law.

Under the civil FCA, no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Further, the civil FCA contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any recoveries. Whistleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors.

There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines. Physicians have gone to prison for submitting false health care claims. OIG also may impose administrative civil monetary penalties for false or fraudulent claims, as discussed below.

Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for

referrals is a crime. The statute covers the payers of kickbacks-those who offer or pay remuneration- as well as the recipients of kickbacks-those who solicit or receive remuneration. Each party's intent is a key element of their liability under the AKS.

Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to bona fide employees.

For additional information on safe harbors, see "[OIG's Safe Harbor Regulations](#)."

As a physician, you are an attractive target for kickback schemes because you can be a source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.

Many people and companies want your patients' business and would pay you to send that business their way. Just as it is illegal for you to take money from providers and suppliers in return for the referral of your Medicare and Medicaid patients, it is illegal for you to pay others to refer their Medicare and Medicaid patients to you.



Kickbacks in health care can lead to:

- Overutilization
- Increased program costs
- Corruption of medical decisionmaking
- Patient steering
- Unfair competition

The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients. Routinely waiving these copays could implicate the AKS and you may not advertise that you will forgive copayments. However, you are free to waive a copayment if you make an individual determination that the patient cannot afford to pay or if your reasonable collection efforts fail. It is also legal to provide free or discounted services to uninsured people.

Besides the AKS, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the AKS. A physician can be guilty of violating the AKS even if the physician actually rendered the service and the service was medically necessary. Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug or ordered that wheelchair even without a kickback.

Physician Self-Referral Law [42 U.S.C. § 1395nn]

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.



"Designated health services" are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME 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 hospital services.

For more information, see [CMS's Stark law Web site](#) ^o.

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in the Federal health care programs.

Exclusion Statute [42 U.S.C. § 1320a-7]



OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations.

If you are excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that you furnish, order, or prescribe. Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice. In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program.

For more information, see OIG's Special Advisory Bulletin entitled "[The Effect of Exclusion From Participation in Federal Health Care Programs](#)".

You are responsible for ensuring that you do not employ or contract with excluded individuals or entities, whether in a physician practice, a clinic, or in any capacity or setting in which Federal health care programs may reimburse for the items or services furnished by those employees or contractors. This responsibility requires screening all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities. This online database can be accessed from OIG's Exclusion Web site. If you employ or contract with an excluded individual or entity

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