Entrepreneurial Medicine: Fraud and Abuse Risk Areas for Physician Business Relationships

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Chapter 1

I. Introduction

Physicians are potentially subject to significant liability under federal and state fraud and abuse laws that apply to common business relationships. In recent years, federal and state fraud and abuse laws have been aggressively enforced in relation to healthcare services paid for by both government and private payors. The focus of this chapter is to provide an overview of federal fraud and abuse laws that apply to common physician business relationships and a summary of recent enforcement and guidance by the government on compliance with federal fraud and abuse laws.

Physicians should keep in mind that in addition to the federal fraud and abuse laws discussed in this chapter, the potential application of a state’s fraud and abuse laws should also be considered in attempting to minimize potential liability from applicable fraud and abuse laws.1 Based on recent guidance and policy initiatives announced by the government, physicians should expect to see more scrutiny of their financial relationships with other providers and their business partners.

II. Federal Fraud and Abuse Laws

Physician business relationships potentially raise several issues under different federal fraud and abuse laws. These issues may arise from business relationships such as physicians investing in other healthcare providers in which a physician investor is a source of patient referrals, or physician compensation arrangements with their own practice or with other healthcare providers. The Office of Inspector General (OIG) has described the following statutory authorities as the five most important federal fraud and abuse laws that apply to physicians: the federal Anti-Kickback Statute,2 the Physician Self-Referral Law (Stark Law),3 the False Claims Act (FCA),4 the Civil Monetary Penalties Law,5 and the federal statutory authorities under which a physician may be subject to mandatory or permissive exclusion from participation in the federal healthcare programs.

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1. Physicians should also consider whether a business arrangement would be affected by a particular state statute prohibiting the “corporate practice of medicine” in their particular state.

2. 42 U.S.C. §1320a-7b(b).


5. 42 U.S.C. §1320a-7a.
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A. The Federal Anti-Kickback Statute

The federal Anti-Kickback Statute (the Anti-Kickback Statute) potentially applies to several different types of physician business relationships that involve items or services provided to patients covered under a federal healthcare program. The Anti-Kickback Statute authorizes penalties against anyone who knowingly and willfully offers, pays, solicits or receive remuneration, in cash or in kind, in order to induce or in return for:

- referring an individual to a person or an entity for the furnishing, or arranging for the furnishing, of any item or service payable under the federal healthcare programs; or
- purchasing, leasing or ordering, or arranging for, or recommending the purchasing, leasing, or ordering, of any item or service payable under the federal healthcare programs.

The Anti-Kickback Statute subjects both parties in a particular business arrangement (i.e., hospital and a physician group) to potential criminal or civil penalties and fines for a violation of the Anti-Kickback Statute. A violation of the Anti-Kickback Statute constitutes a felony and is punishable by fines of up to $100,000, and imprisonment of from five to ten years. The OIG may also initiate administrative proceedings to exclude a provider from the federal healthcare programs. Violations of the Anti-Kickback Statute may also result in the imposition of civil money penalties, and liability under the False Claims Act.6

1. Exceptions and Safe Harbors to the Anti-Kickback Statute

a. Exceptions to the Anti-Kickback Statute

The Anti-Kickback Statute contains several statutory exceptions and regulatory “safe harbors” that describe certain payment and business practices that would not be subject to civil or criminal offenses under the Anti-Kickback Statute. If an individual or entity satisfies all of the conditions of an applicable exception or safe harbor for a particular business arrangement, then that particular business arrangement will not be subject to an enforcement action under the Anti-Kickback Statute. Each type of remuneration in a business arrangement will need to meet an applicable safe harbor.

Physicians and other healthcare providers are generally recommended to structure business arrangements to fit within a safe harbor to the Anti-Kickback Statute. Physicians should keep in mind that an arrangement must meet each condition of a safe harbor.

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harbor in order to be protected by that a safe harbor. However, an arrangement is not illegal or in violation of the Anti-Kickback Statute if it does not meet a safe harbor, but will be evaluated on the totality of its facts and circumstances to determine if the arrangement potentially violates the Anti-Kickback Statute or is considered to have a low risk of fraud or abuse.

The following are examples of statutory exceptions to the Anti-Kickback Statute that apply to common physician business relationships:

- payments to bona fide physician employees;
- properly disclosed discounts or other reductions in price;
- certain payments to group purchasing organizations;
- waivers of coinsurance for Medicare services for individuals who qualify for certain Public Health Service programs; and
- certain risk-sharing and other arrangements with managed care organizations. 7

b. Safe Harbors to the Anti-Kickback Statute

The OIG has also adopted several safe harbor regulations for particular business arrangements. The following safe harbor regulations apply to common physician business relationships:

- Investment interests safe harbor, 42 C.F.R. §1001.952(a)—this safe harbor protects remuneration in the form of returns on investments (i.e., profit distributions) paid to referral-source investors.
- Space rentals safe harbor, 42 C.F.R. §1001.952(b)(c)—this safe harbor applies to rental amounts paid between healthcare providers and other individuals or entities.
- Employee safe harbor, 42 C.F.R. §1001.952(i)—this safe harbor applies to compensation paid to individuals who are bona fide employees.
- Personal services and management contracts safe harbor, 42 C.F.R. §1001.952(d)—this safe harbor applies to compensation arrangements created by arrangements such as medical director agreements, independent contractor agreements, and management service agreements.
- Practitioner recruitment safe harbor, 42 C.F.R. §1001.952(n)—this safe harbor applies to physician recruitment agreements.

7. 42 U.S.C. §1320a-7b(b)(3).
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- Group purchasing safe harbor, 42 C.F.R. §1001.952(j)—this safe harbor applies to group purchasing arrangements.
- Ambulatory surgical centers (ASC) safe harbor, 42 C.F.R. §1001.952(r)—this safe harbor applies to profit distributions from an ownership or investment interest in an ASC.  
- Free or discounted transportation or shuttle services, 42 C.F.R. §1001.952(bb)—this safe harbor protects free or discounted transportation services provided to federal healthcare program beneficiaries.

2. **OIG Special Fraud Alerts Involving Physicians**

   **a. OIG General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries**

   In December 2016, the OIG issued a general policy statement revising the monetary value of gifts considered “inexpensive” or of “nominal value” that are not considered remuneration likely to influence a beneficiary’s selection of a particular provider. Under Section 1128A(a)(5) of the Social Security Act, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary selection of a particular provider, practitioner, or supplier of Medicare and Medicaid payable items or services may be liable for civil monetary penalties up to $15,270 for each wrongful act. For purposes of Section 1128A(a)(5), the statute defines “remuneration” to include waivers of co-payments and deductible amounts in transfers of items or services for free or for other than fair market value.

   In this policy statement, the OIG adjusts these figures to interpret “nominal value” as having a retail value of no more than $15.00 per item or $75.00 in the aggregate per patient on an annual basis. If a gift has a value at or below these thresholds, then the gift need not fit into a statutory exception to the remuneration prohibition.

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8. Advisory opinions issued by the OIG involving the ASC safe harbors and recent enforcement actions related to physician ownership interests in ASCs should be considered in structuring physician business relationships with ASCs. See OIG Advisory Op. 03-02 (Jan 21, 2003) and OIG Advisory Op. 03-05 (Feb. 13, 2003). See also DeBartolo v. HealthSouth Corporation, et al., 569 F.3d 736 (7th Cir., 2009).
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b. 2015 OIG Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

In June 2015, the OIG released a Fraud Alert focused on compensation arrangements with physicians such as medical directorships. The OIG reminded physicians that they will be held liable under the AKS for compensation payments that do not ensure fair market value for bona fide services physicians actually provided.9

In this Fraud Alert, the OIG gave an example of recent settlements with physicians who entered into “questionable” medical directorships. The OIG commented that compensation paid under these medical directorships to physicians constituted illegal remuneration under the Anti-Kickback Statute for several reasons, including that the payments took into account the physicians’ volume or value of referrals and did not reflect the fair market value for the services to be performed, and because the physicians did not actually provide the services described in the arrangement.

c. Special Fraud Alert Regarding Laboratory Payments to Referring Physicians

1. Special Fraud Alert Regarding Laboratory Payments to Referring Physicians

In June 2014, the OIG issued a Special Fraud Alert that concerned compensation paid by clinical laboratories to referring physicians and physician group practices for: (1) blood specimen collection, processing, and packaging and (2) submitting patient data to a registry or database.10 In this Fraud Alert, the OIG emphasized its belief that these arrangements are suspect under the Anti-Kickback Statute.11

OIG noted that the Anti-Kickback Statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation has occurred depends on the intent of the parties (if one purpose of the payment is to induce or reward for referrals, OIG believes that the Anti-Kickback Statute has been violated). The probability that the payment is for an illegitimate purpose is increased if the payment exceeds the

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11. 42 U.S.C. Section 1320a-7b(b).
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fair market value of the services provided by the physician or physician group.

The OIG listed the following factors that may indicate an improper intent under the Anti-Kickback Statute in an arrangement between a clinical laboratory and a physician practice:

- payment is made directly to the ordering physician, rather than the practice bearing the overhead;
- payment is made on a per-specimen basis for more than one specimen collected in a single patient encounter or any other basis that would indicate that the payment takes into account the volume or value of referrals;
- payment is offered on the condition of a specified volume or type of test ordered; and
- payment is made to the physician or the group practice despite the fact that the work is being performed by a phlebotomist placed in the office by the laboratory or a third party.

OIG also identified arrangements where laboratories are establishing, coordinating, and maintaining databases purportedly to collect data on patients who have undergone tests performed by the laboratory (Registry Payments). The OIG commented that Registry Payments from a laboratory to a physician to compensate the physician for data collection and reporting may be reasonable under certain circumstances; however, the OIG also described the following suspect payment characteristics:

- the laboratory requires or recommends the test to be performed with a stated frequency to receive compensation;
- compensation is paid on a per-patient basis or other basis that takes into account the volume or value of referrals;
- compensation paid exceeds the fair market value of the services provided;
- no documentation is maintained or submitted of the physician’s efforts in performing the services; and
- when a test is performed by multiple laboratories, the laboratory collects data only from the test it performs.
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B. The False Claims Act

There are several federal statutes that impose criminal or civil penalties for the submission of false claims to the government or other payers. The civil False Claims Act (FCA) is the primary federal law used by the government to bring a case against a healthcare provider for submitting false claims to federal healthcare programs. Under the FCA, a person or entity is liable for civil penalties plus three times up to treble damages and a penalty between $11,181 and $22,363 for each false or fraudulent claim it knowingly submits or causes to be submitted, to a federal program. The FCA also prohibits knowingly making or using (or causing to be made) a false record or statement to get a false or fraudulent claim paid by a federal healthcare program.

The FCA defines “knowingly” to include when a person has actual knowledge that the claim is false or instances in which the person acted in deliberate ignorance, or reckless disregard of the truth or falsity of the information. Under the FCA, no specific intent to defraud is required.

1. Whistleblower Actions under the False Claims Act

In recent years, lawsuits by private plaintiffs, known as “relators” or “whistleblowers,” under the qui tam provisions of the FCA have significantly grown at a steady pace. For example, of the $4.7 billion the government recovered in Fiscal Year 2016, more than $2.9 billion was related to lawsuits filed under the whistleblower provisions of the FCA.

2. Examples of Potential False Claims for Items and Services

The OIG and other government agencies have generally described the following as examples of false claims for services or supplies that were not provided as specifically as described in a claim:

- a claim for a service or supply that was never provided;
- a claim indicating the service was provided for some diagnosis code other than the true diagnosis code in order to obtain reimbursement;
- a claim indicating a higher level of service than was actually provided; and
- a claim for services provided by an unlicensed individual.

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3. Penalties for Violation of the FCA

There are significant damages and penalties for violations of the False Claims Act, which include up to three times the amount of the false claims submitted to the federal government and civil penalties of $11,181 and $22,363 for each false claim it knowingly submits or causes to be submitted to a federal program. The ACA expanded the potential liability under the FCA by specifically providing that:

- a claim submitted for items or services that were provided as a result of a violation of the Anti-Kickback Statute are false claims under the FCA; and
- a person or entity that does not report and return an overpayment within 60 days of discovery or by the date a cost report is due, if that date is later, may be liable under the FCA.

4. The 60-Day Overpayment Obligation

As described above, the ACA expanded potential liability under the FCA by making it a reverse false claims violation of the FCA if a person or entity fails to report and return an overpayment to the Medicare or Medicaid program by the later of 60 days after the overpayment is identified or the date a corresponding cost report is due (generally referred to as the 60-Day Overpayment Rule).\(^\text{14}\)

CMS released final regulations interpreting the 60-Day Overpayment Rule for Medicare Parts A and B on February 12, 2016\(^\text{15}\). These regulations provide that identification of an overpayment occurs when the provider has or should have, through the exercise of reasonable diligence, determined that it has received an overpayment and quantified the amount of the overpayment to be returned. CMS acknowledged that the investigation and quantification of a potential overpayment may take up to six (6) months. After a provider has credible evidence of receipt of a potential overpayment, the provider may have up to eight (8) months to return an overpayment, i.e., six months to investigate plus an additional sixty (60) days to report. CMS also finalized a six-year look back period.

In a recent notable settlement, a Jacksonville cardiovascular practice agreed to pay more than $440,000 to resolve FCA allegations for failing to reimburse government healthcare programs of more than $175,000 in overpayments owed to Medicare, Medicaid, TRICARE, and the Department of Veterans Affairs. The cardiovascular group had accrued credit balances or overpayments owed to federal healthcare

\(^{14}\) ACA, §6402.

\(^{15}\) 81 Fed. Reg. 7654 (Feb. 12, 2016).
programs, and despite several warnings from the government, had failed to pay the money back. 16

C. The Stark Law

The Stark Law17 affects a wide range of physician business arrangements, including ownership interests in other providers and compensation arrangements for a physician’s professional services. The Stark Law is similar to a strict liability statute because an arrangement subject to the Stark Law must meet an exception or it will be in violation of the Stark Law self-referral prohibition. Accordingly, the Stark Law should be considered by physicians in structuring almost any business relationships with other healthcare providers, including their own group practice.

1. Scope of the Stark Law Physician Self-Referral Prohibition

The Stark Law prohibits physicians from making referrals for the furnishing of certain designated health services payable by Medicare or Medicaid to an entity with which a physician (or an immediate family member) has a financial relationship, unless an exception applies. The Stark Law also prohibits the entity (i.e., provider receiving the referral) from presenting or causing to be presented a claim for payment to Medicare or Medicaid (or billing another individual, entity, or third-party payer) for any designated health services furnished pursuant to a prohibited referral.

The Stark Law applies indirectly to referrals for Medicaid covered services. Specifically, the Stark Law authorizes the federal government to deny state programs the federal matching funds for any Medicaid services provided pursuant to a prohibited referral if the patient had been a Medicaid beneficiary.18 Although the Centers for Medicare and Medicaid Services (CMS) has not finalized proposed regulations with respect to the application of the referral prohibition to the Medicaid program, courts have recently recognized the application of the Stark Law to Medicaid services in FCA litigation.19

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18. Most states have false claims acts that would also apply to the state portion of funds from a state’s Medicaid program.
19. See, e.g., United States ex rel. Schubert v. All Children’s Health System, Inc. No. 8:11-cv-01687-T-27EAJ2013 WL 6054803 (M.D. Fla. Nov. 15, 2013), in which a Florida Federal District Court denied a motion to dismiss and rejected the defendant hospital’s argument that the Stark Law did not apply to Medicaid.