Chapter 1

ENTREPRENEURIAL MEDICINE: FRAUD AND ABUSE RISK AREAS FOR PHYSICIAN BUSINESS RELATIONSHIPS

BY: CLAY J. COUNTRYMAN, J.D.

I. Introduction

Physicians are potentially subject to significant liability under federal fraud and abuse laws that apply to common business relationships. In recent years, there continues to be aggressive enforcement of federal fraud and abuse laws 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.

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 physician business arrangements.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) for the U.S. Department of Health and Services 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 federal healthcare programs.

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

The federal Anti-Kickback Statute (Anti-Kickback Statute) potentially applies to several different types of physician business relationships that involve items or services provided to patients reimbursable under federal healthcare programs. The Anti-Kickback Statute provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward an individual 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 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 up 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 FCA.  

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 payment and business practices that will not be subject to criminal prosecution under the Anti-Kickback Statute, the imposition of civil monetary penalties (CMPs), federal healthcare program exclusion, or liability under the FCA (31 U.S.C. §§ 3729-33). 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 should structure their business arrangements to fit within a safe harbor to the Anti-Kickback Statute. An arrangement

Chapter 1

must meet each condition of a safe harbor in order to be protected by that safe harbor. However, the OIG has emphasized in various guidance documents that 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 regulatory “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

\(^7\) 42 U.S.C. § 1320a-7b(b)(3).
Entrepreneurial Medicine

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.
- 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.\(^8\)
- 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, Bulletins, and Other Guidance 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.\(^9\) 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 $20,000 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.

---

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 Corp., et al.,569 F.3d 736 (7th Cir., 2009).

Chapter 1

In this policy statement, the OIG adjusted the figures to interpret “nominal value” as having a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis. If a gift has a value at or below these thresholds, then a gift need not fit into a statutory exception to the remuneration prohibition.

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 emphasized in the Fraud Alert that physicians will be held liable under the Anti-Kickback Statute for compensation payments that are not fair market value for bona fide services physicians actually provided.10

The OIG commented that compensation paid under “questionable medical directorships” in recent settlements 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 in some cases the physicians did not actually provide the services described in the medical director agreements.

c. 2014 OIG Special Fraud Alert Regarding Laboratory Payments to Referring Physicians

3. 2014 OIG Special Fraud Alert Regarding Laboratory Payments to Referring Physicians

In June, 2014, the OIG issued a Special Fraud Alert focused on compensation paid by clinical laboratories to referring physicians for: (1) blood specimen collection, processing, and packaging and (2) submitting patient data to a registry or database.11 In this Fraud Alert, the OIG emphasized its belief that these arrangements are suspect under the Anti-Kickback Statute.12

The 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

---

12. 42 U.S.C. § 1320a-7b(b).
Entrepreneurial Medicine

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 fair market value of the services provided by the physician or physician group.

The OIG listed the following as some of the characteristics in a specimen processing arrangement that may indicate an unlawful purpose under the Anti-Kickback Statute:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment.
- 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 during 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.
- 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.
- Payment is for services for which payment is also made by a third party, such as Medicare.

The OIG also described arrangements where laboratories are establishing, coordinating, and maintaining databases purportedly to collect data on patients who have undergone tests performed by the laboratory (Registry Arrangements). The OIG described the following characteristics of Registry Arrangements that may be evidence of an unlawful purpose:

- the laboratory requires or recommends that physicians who enter into Registry Arrangements perform the test with a stated frequency to be eligible to receive, or not to receive, a reduction in compensation;
- compensation is paid on a per-patient basis or other basis that takes into account the volume or value of referrals;
- compensation paid to physicians is not fair market value for the physician’s efforts in collecting and reporting data;
- no documentation is maintained or submitted of the physician’s efforts in performing the services; and