Chapter 1

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

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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. 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, the Physician Self-Referral Law (Stark Law), the civil False Claims Act (FCA), the Civil Monetary Penalties Law, and the federal statutory authorities under which a physician may be subject to mandatory or permissive exclusion from participation in the 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-7b(b).
5. 42 U.S.C. §1320a-7a.
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A. The Federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b)

The federal Anti-Kickback Statute (the Anti-Kickback Statute) potentially applies to several different types of physician business relationships that involve the provision of items or services to patients covered by a federal healthcare program. The Anti-Kickback Statute is a criminal law that provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit, 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 statute. A violation of the statute constitutes a felony and is punishable by fines of up to $25,000, and imprisonment of up to five years. The OIG may also initiate administrative proceedings to exclude a provider from the federal healthcare programs. Violations of the 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

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 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 statute. Each type of remuneration in a business arrangement will need to meet an applicable safe harbor.

Physicians and other healthcare providers are generally advised to structure business arrangements to fit within a safe harbor to the statute. Physicians should keep in mind that an arrangement must meet each condition of a safe harbor in order to be protected by that safe harbor. However, an arrangement is not illegal or in violation of the 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 statute or is considered to have a low risk of fraud or abuse.
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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;
- certain risk-sharing and other arrangements with managed care organizations.6

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.
- 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.7

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7. 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 ASC. 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).