



THE FRAUD AND ABUSE LAWS

WHAT DO YOU NEED
TO KNOW ABOUT
THESE LAWS?

WHY ARE YOU AT
RISK?

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THE FRAUD AND ABUSE LAWS: WHAT DO YOU NEED TO KNOW ABOUT THEM?

Plenty, not only because of the unprecedented number of health care fraud enforcement actions, but because it impacts the manner in which health care manufacturers, distributors, providers, physicians and patients can interact with each other.

Please take a moment to read this leaflet.

Understanding these laws could help you and/or your organization avoid the imposition of severe criminal and civil penalties.

THE FEDERAL ANTI-KICKBACK STATUTE: A STRICT LAW WITH STRICT PENALTIES

The Federal Anti-Kickback Statute is a broad statute that provides civil, criminal, and administrative penalties to any person or entity who knowingly offers, pays, solicits, or receives remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business for which payment may be made in whole or in part, under a federal health care program. For purposes of the Federal Anti-Kickback Statute, "remuneration" includes the transfer of anything of value, directly or indirectly, covertly or overtly, in cash or in-kind.¹

Given the breadth of the term "remuneration," the Federal Anti-Kickback Statute can be implicated by a wide variety of relatively commonplace activities, including, but not limited to, payment of compensation to a medical advisor, lease agreements, management agreements, the provision of free goods, and the routine waivers of coinsurance for individuals without a good faith determination that each individual is in financial need.

A person or entity that violates the Federal Anti-Kickback Statute is subject to the following penalties for each offense:

- a criminal fine of up to \$25,000
- imprisonment for up to five years
- exclusion from all federal health care programs
- civil monetary penalties of up to \$50,000 plus three times the remuneration amount paid or received.

THE ANTI-INDUCEMENT STATUTES: A NEW LAW WITH ENHANCED PENALTIES

The Health Insurance Portability and Accountability Act of 1996² established new civil monetary penalties³ for any individual or entity that provides remuneration to any federal health care program beneficiary as an inducement to order items or services from that individual or entity for which payment may be made by a federal health care program. Under this so-called "Anti-Inducement Statute," the term "remuneration" is defined broadly to include the "waivers of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value."⁴

A person or entity that violates this Anti-Inducement Statute is subject to civil monetary penalties of up to \$10,000 for each item or service claimed in violation of this provision. Again, in light of these new federal provisions, arrangements involving the provision of "free goods" or services to Medicare and Medicaid beneficiaries should be closely examined.

FREE GOODS

In general, free goods are no good. Why? Both the Federal Anti-Kickback Statute and the Anti-Inducement Statute are implicated whenever a person who offers or provides free goods or services to a provider in order to induce the referral of a patient covered by government health programs or to induce the ordering of a good or service covered by Federal health care programs.

The Office of the Inspector General ("OIG") of the CMS Centers for Medicare & Medicaid Services (formerly HCFA) in various special Fraud Alerts and Advisory Opinions has voiced a longstanding concern that free goods provided to parties in a position to refer or recommend business may violate the Federal Anti-Kickback Statute. In fact, in the preamble to the "safe harbor" regulations, the OIG stated that it *"did not propose to protect many kinds of marketing incentive programs such as case rebates, free goods or services, redeemable coupons, or credits."*⁵ More recently, the OIG stated in 1998: *"This Office's concern with the provision of goods and services for free or at below-market rates to potential referral sources is longstanding and clear: such arrangements are suspect under the anti-kickback statute."*⁶

In addition, on numerous occasions the OIG has voiced its suspicion of arrangements in which a provider provides free goods or services to a health care provider in a position to refer business. For example, in a Special Fraud Alert regarding clinical lab services, the OIG stated:

[i]n cases where the provision of free services results in a benefit to the provider, the anti-kickback statute is implicated. If offered or accepted in return for the referral of Medicare or State health care plan business, both the laboratory and the physician may be violating the anti-kickback statute.⁷

The bottom line: Offering or accepting any free goods or services from a DME supplier, implicates and may give rise to significant sanctions under the Federal Anti-Kickback Statute.

WAIVER OF COPAYMENT AND DEDUCTIBLES

The routine waiver of coinsurance and deductible amounts due from Medicare beneficiaries also implicates both the Federal Anti-Kickback Statute and the Anti-Inducement Statute. Specifically, the Anti-Inducement Statute provides that the term "remuneration" includes waivers of coinsurance and deductible amounts unless.

- the waiver is not offered as part of any advertisement or solicitation;
- the supplier does not routinely waive coinsurance and deductible amounts; and
- the supplier waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need or the person waives the coinsurance and deductible amounts only after making reasonable collection efforts.⁸

Additionally, the OIG has voiced its suspicion of arrangements in which a DME supplier routinely waives Medicare deductible and copayment charges to beneficiaries for items and services covered by Medicare. In a Special Fraud Alert regarding routine waiver of copayment or deductibles under Medicare Part B, the OIG stated:

[w]hen . . . [DME] suppliers forgive financial obligations [e.g., copayments or deductibles] for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.⁹

The bottom line: As a result of the newly enacted Anti-Inducement Statute as well as the OIG's longstanding concerns under the Federal Anti-Kickback Statute, providers and suppliers must take certain steps to ensure the collection of coinsurance and deductible amounts due from beneficiaries of federal health care programs or face significant civil and criminal repercussions.

WHAT DOES THIS ALL MEAN FOR YOU?

The federal government has focused its investigatory efforts in many directions to include all types of providers. Recent initiatives suggest that **the OIG intends to focus its fraud and abuse enforcement activities on physicians who accept or solicit remuneration from parties with whom the physician maintains a referral or ordering relationship.**

- On January 7, 1999, the OIG issued a Special Fraud Alert in which the OIG stated that physicians may cause a false claim to be submitted to a Federal health care program when a physician signs a Certificate of Medical Necessity ("CMN") if the physician receives any financial benefit from a DME supplier for signing such CMN (including free or reduced rent, free supplies, free equipment, or free labor).¹⁰
- In 1996, Doctors Harvey Harris, D.O., Kenneth Wiseman, D.O. and Michael Helzner, D.O., settled for \$98,000 a federal government lawsuit that the three doctors falsely certified to Medicare the medical necessity for items of DME in exchange for kickbacks from the supplier.
- In 1997, Physicians First Choice, Inc., a DME supplier, settled for \$2 million a federal government action alleging the submission of false Medicare claims for patient referrals received through an allegedly illegal kickback arrangement that was characterized by the parties as rent payment for office space located within the physicians' offices.

By learning about the Federal Anti-Kickback Statute and the Anti-Inducement Statute, providers and suppliers ensure that a patient's freedom of choice is preserved and that the selection of medical equipment is made on the basis of quality, price, convenience, and service.

REFERENCES:

- 1) *Social Security Act § 1128B(6)(i).*
- 2) *Social Security Act § 1128A(a)(5).*
- 3) *Social Security Act § 1128A(a).*
- 4) *Social Security Act § 1128A(i)(6). (emphasis added).*
- 5) *56 Fed. Reg. 35,952, 35,953 (July 29, 1991).*
- 6) *OIG Advisory Opinion 98-13 (September 23, 1998).*
- 7) *OIG Special Fraud Alert, Arrangements for the Provision of Clinical Lab Services, p. 2 (October 1994) (emphasis added).*
- 8) *Social Security Act § 1128A(i)(6). (emphasis added).*
- 9) *OIG Special Fraud Alert, Routine Waiver of Copayments or Deductibles Under Medicare Part B, p. 2 (May 1991).*
- 10) *OIG Special Fraud Alert, Physician Diligence Urged in Ordering Home Care, Durable Medical Equipment (January 7, 1999). Under the Federal Civil False Claims Act, individuals or entities that submit or cause to be submitted a false claim may be liable for civil penalties of up to \$10,000 for each claim submitted to the federal government plus three times the amount of actual damages sustained by the federal government. 31 U.S.C. § 3729.*

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