

Promotion Programs

Legal ISSUES

Under the Anti-kickback Statute, it is illegal to knowingly or willfully:

- offer, pay, solicit, or receive remuneration;
- directly or indirectly;
- in cash or in kind;
- in exchange for;
referring an individual; or
furnishing or arranging for a good or service; and
- for which payment may be made under a Federal Health Care Program

Kickback Statute Penalties

Fine of not more than \$50,000

and/or

Imprisoned for not more than 5 years

False Claims Act *being used more frequently -
imposes huge Penalties and Fines*

Necessary Elements

- Direct or Indirect Payment of Remuneration intended to *Induce* the Referral or purchase of goods or services.
- Actual knowledge of statute or Specific Intent to violate statute not required.

Safe Harbor Provisions -

There are 22 types of payments that have been designated as “Safe Harbors” that are not be treated as criminal offenses under the Antikickback Statute ”

The Regulations at Section (h) except certain payments that are made in the form of “**discounts** ”**from** criminal prosecution. The discount regulations are very very complex. Companies who wish to seek any safe harbor protection should seek legal advice to insure that their program is properly tailored to meet the legal requirements.

42 CFR § 1001.952

State Antikickback Statutes

A majority of the states (36) have enacted antikickback provisions that function independently of the federal anti-kickback statute. Many of these statutes are similar to the Federal statute providing for prosecution and fines for kickbacks or rebates in cases where state funds are used to pay for the services or items provided.

Examples of Federal Prosecutions

- Pharmaceutical company offered 1,000 frequent flier miles every time physician starts patient on certain drug and completes a marketing questionnaire; after 50 patients, physician given free plane ticket for anywhere in U.S violated Antikickback Statute

- Company provides free surgical packs (sutures, gloves, etc.) with purchase of company's intraocular lens did not fall within Safe Harbor provisions.

- Struggling hospital paid physicians \$70 for each patient they admitted—payments were designated as “consulting fees.” Payments Not covered by Safe Harbor. Violated the Antikickback statute.

(OIG Special Fraud Alert, May 1992)

- Ten defendants from hospital in Chicago conspired to pay kickbacks and bribes to physicians to induce them to refer patients for services where hospital knew, or should have known, that services would be reimbursed by Medicare and Medicaid.

- Novartis fined under the False Claims Act for paying kickbacks to doctors to induce them to prescribe Novartis pharmaceutical products that were reimbursed by federal health care programs.

➤ Pacemaker Manufacturer offered doctor \$250 for each of its pacemakers doctor implants; a competitor offers \$400--in the end, doctor receives \$238,000 from two firms and implants scores of unnecessary pacemakers. Antikickback violation

- Pharmaceutical company offers 1,000 frequent flier miles every time physician starts patient on certain drug and completes a marketing questionnaire; after 50 patients, physician has free plane ticket anywhere in U.S. Anti-kickback False Claims act fraud
- Laboratory offers 15% rebate to physicians for using their services. Antikickback violation.

Recommendations

1. Review Programs.

To avoid federal or state criminal liability, payors must take precautions to be certain that payments are not made in cases where the completed eyewear will be paid for through a federal healthcare program or a state program that receives federal funds or state paid programs.

2. Notices to Customers with Disclaimers.

Companies that are concerned that eyecare products for which spiffs are given could ultimately be paid for by a federal or state health care programs should consider providing notices to customers which should state:

- A.** Advise customers that participation in a payment or rebate program is prohibited by federal and state laws when payment for the finished eyewear will be made in full or in part by any federal or state funded health care programs, such as Medicare or Medicaid.

- B.** Be mindful of the fact that such advise may not be sufficient absent some kind of compliance program.

B. Tell the customer that sales involving eye care products, which are part of a prescription that is paid for by federal or state funded health care programs, are not eligible for participation in the programs, and that requests for ineligible payments could subject the customer to criminal prosecution under federal and state antikickback laws.

C. Have a disclaimer.

*Seek legal advice
before starting promotional programs.*