Physicians Under the Microscope: The Anti-Kickback Law

Practical Steps To Take in an Aggressive Enforcement Environment

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elationships between medical device manufacturers and physicians are common in the health care industry and have many benefits. Manufacturer-physician relationships have the potential to advance science and technology, improve patient care and facilitate compliance with FDA-mandated training. However, these relationships also present a risk for fraud and abuse—particularly under the federal Anti-Kickback Law (42 U.S.C. §1320a-7b). Government regulators have greatly increased their scrutiny of manufacturer-physician arrangements, especially concerning gifts, the exchange of gifts or gratuities and improper referral arrangements.

The government’s principal concern is that because physicians play a critical role in deciding which medical devices are used in patient care, any relationship with a manufacturer potentially creates a conflict of interest for the physician. Indeed, the Anti-Kickback Law is designed to prevent this type of conflict of interest through a broad prohibition against the payment or receipt of anything of value, where one’s purpose is to induce the recipient (the physician) to order, recommend or buy a product, such as a manufacturer’s medical device. Although government scrutiny has historically focused on the manufacturer side of these relationships (i.e., the entities providing or offering kickbacks), the government is now turning its attention to physicians (the persons asking for, or accepting, the kickbacks).

Consequently, physicians, nurses and other personnel who interact with medical device representatives should understand the Anti-Kickback Law and the constraints it places on interactions with device manufacturers. Ethical codes—such as the AdvaMed Code on Interactions with Health Care Professionals—provide valuable guidance in this regard as well. To this end, this article reviews recent government enforcement actions against physicians, sets forth examples of the types of arrangements that may present a risk to physicians under the Anti-Kickback Law, and provides information about additional resources and relevant authorities related to manufacturer-physician relationships.

Enforcement Actions Against Physicians

Recent statements from the Office of Inspector General (OIG; the federal agency that enforces the Anti-Kickback Law) and state regulators indicate increased enforcement activity against physicians. For example, Lewis Morris, OIG chief counsel, informed physicians and industry representatives at the March 2008 meeting of the American Academy of Orthopedic Surgeons that the OIG was going to be looking at parties who solicit kickbacks, including physicians.1 Likewise, in early 2009, Mr. Morris further elaborated that “what we [OIG] need to do is make examples of a couple of doctors so that their colleagues see that this isn’t worth it.” He noted that “money works on [physicians] just like everybody else” and “that [OIG] want[s] to send the message to the physician community—particularly surgeons—that you can’t do this.”2 Echoing that sentiment was Christopher Christie Jr., U.S. attorney of New Jersey, who, after targeting hip and knee manufacturers in a federal investigation, recently stated that after dealing with the supply of kickbacks, it was time for him to deal with the demand for them.3

In fact, members of the physician community have expressed their concern regarding improper manufacturer-physician arrangements. Charles D. Rosen, MD, a spine surgeon with the University of California in Irvine and founder of the Association for Ethics in Spine Surgery, said, “I think we’ll see more doctors facing charges going forward … it’s been coming to a head for the past 10 to 15 years. The consulting agreements are so woven into the culture of being a spine surgeon that some people think it is normal.”4

Given this context, it is not surprising that the government has pursued a number of cases against physicians. Several recent enforcement actions are summarized below.

Arkansas Neurosurgeon Loses License

In October 2006, an Arkansas neurosurgeon was indicted on four counts of violating the Anti-Kickback Law for soliciting and receiving kickbacks. The neurosurgeon pleaded guilty to one count of soliciting and accepting kickbacks from a sales representative selling products on behalf of multiple medical device companies. Criminal investigators found that the neurosurgeon agreed with sales representatives to split the commission on any products that he used during and after his surgeries. The neurosurgeon was sentenced to three years probation and a $25,000 fine, and also was ordered to immediately pay $23,000 to the FBI for the cost of the investigation. Included in his sentence was the requirement that he pay the cost of his supervision at a rate of $3,535.18 per year. Along with the monetary fines, the neurosurgeon relinquished his medical license in 2006 and is no longer able to practice medicine in Arkansas.

Bill Temple, special agent in charge of the FBI’s Little Rock Field Office, said that the neurosurgeon investigation “will serve as a deterrent to other health care providers and cause them to think twice before soliciting or receiving kickbacks from medical suppliers,” and noted that “health care fraud is one of the FBI’s greatest national priorities and [his] office will continue to devote significant investigative resources to combat this insidious crime.”4

Physicians Involved in TAP Pharmaceutical Case

In 2001, TAP Pharmaceutical Products, Inc. pleaded guilty to participating in a criminal conspiracy by providing doctors with free samples of their oncology drug Lupron (leuprolide), for which doctors then billed Medicare. As part of this case—in which the government collected almost $1 billion from TAP—six physicians were indicted for various criminal and civil violations. In September 2004, two of these physicians, one from California and another from Texas, agreed to pay $57,500 and $38,941, respectively, and entered into integrity agreements (a contract that includes various compliance obligations) to resolve their liability under the Anti-Kickback Law and other federal fraud statutes.

Heavy Fines for Accepting Gifts, Meals, Football Tickets

In February 2006, two Florida pulmonologists paid significant fines ($65,066 and $57,030) and entered into a three-year integrity agreement to resolve their liability under the Anti-Kickback Law. The government alleged that the doctors violated the law by accepting gifts, including tickets to Miami Dolphin football games and meals, from a durable medical equipment supplier in exchange for patient referrals.

Investigated for Accepting Bribes for Referrals

In March 2007, a New York physician agreed to pay $75,000 and to enter into a five-year integrity agreement to resolve his liability for allegedly violating the Anti-Kickback Law. The OIG alleged that the physician solicited and received remuneration in exchange for referring patients to a particular imaging center for magnetic resonance imaging.

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imaging and/or computed tomography scans.

In August 2003, a Pennsylvania physician agreed to pay $140,000 and enter into a three-year integrity agreement to resolve his liability under the Anti-Kickback Law and other federal statutes. The OIG alleged that the physician received $30,000 in kickbacks disguised as loans for improvements to his medical office. In exchange, the physician allegedly referred Medicare patients to the company to receive treatment with its equipment.

Risks for Physicians Under The Anti-Kickback Law

Because the Anti-Kickback Law is so broad, it encompasses essentially all relationships between manufacturers and physicians. The Anti-Kickback Law applies equally to both the giver of the kickback (such as a device manufacturer) and the recipient (such as a physician). Below are examples of common arrangements that potentially present a risk to physicians. Each example is followed by practical guidelines for minimizing or avoiding such risk.

Gifts, Gratuities and Other Business Courtesies

Under certain circumstances, the solicitation or acceptance of gifts, gratuities, free items or business courtesies could result in a violation of the Anti-Kickback Law. Physician activities the government may scrutinize as potential violations of the law include:

• Requesting or accepting payment from manufacturers for a meal, reception or entertainment event (such as a holiday or office party) for the physician, the physician’s spouse or his or her practice group.

• Requesting or accepting payment from manufacturers for fundraisers or other charitable contributions to be made in the physician’s name.

• Requesting or accepting gifts such as food, wine, gift baskets or tickets to sporting or entertainment events.

To avoid exposure under the Anti-Kickback Law, physicians should not solicit any type of gift or gratuity from a manufacturer. Similarly, physicians should not request or accept payment from a device manufacturer for items or services that lessen the cost of doing business (e.g., office supplies and fixtures, staff lunches) or company events (e.g., company picnics) or that support a physician’s personal hobbies or interests (e.g., rounds of golf, tickets to a sporting event or tickets to a society gala).

Arranging for, or Facilitating, Patient Referrals

The Anti-Kickback Law also prohibits manufacturers from directing patient referrals to customers. Examples of activities that may implicate or violate the law include:

• Requesting or permitting a manufacturer’s sales representatives to pay for dinners, newspaper advertisements or other marketing initiatives with the intent of recruiting patients or obtaining patient referrals for the physician’s practice.

• Requesting that a device manufacturer host an event, such as a dinner, whereby the manufacturer invites area physicians (such as primary care physicians) with the intent of influencing the physician to refer patients to a specialist who is a customer of the manufacturer.

Physicians should understand that manufacturers are not permitted to relieve physicians of their marketing costs by marketing a physician’s practice. Therefore, a physician should not request—or suggest—that a medical device company deliver patients or physician referral sources to his or her practice in exchange for promises to use the company’s products for those referrals. Similarly, a physician should not ask manufacturers to shoulder the cost to market his or her practice.

Educational Conferences

Another form of remuneration specifically identified by the OIG as vulnerable to abuse is financial support offered by a device manufacturer to a health care professional for the cost of attending an industry conference. Examples of arrangements that may implicate or violate the Anti-Kickback Law include:

• Physicians receiving payment from, or expenses paid by, a device manufacturer to attend a professional association’s annual conference without providing any service to the manufacturer.

• Physicians or nurses asking for and/or accepting payment for registration, accommodation, or travel costs to attend a third-party educational conference.

Physicians should pay their own way when attending a third-party educational conference or a professional association event, and should refrain from seeking financial support or sponsorship from a medical device company.

Consulting Arrangements and Clinical Study Agreements

The Anti-Kickback Law also prohibits manufacturers from entering into financial arrangements with physicians in which the payments do not reflect a fair market value for bona fide services, but are instead an attempt to improperly influence—and curry favor with—the physician. Examples of practices that may implicate or violate the Anti-Kickback Law include:

• Receiving payment from medical device manufacturers to provide consulting services if the compensation exceeds fair market value for the services provided.

• Receiving payment where the agreement does not serve a legitimate need and purpose.

• Receiving payment without performing necessary services.

• Requesting to be an investigator in a clinical study in exchange for future product purchases.

Physicians should not provide consulting services for a company if the arrangement seems like a sham designed to encourage the physician to purchase that company’s products. In other words, physicians should only undertake consulting services where the physician performs bona fide services in exchange for fair market value compensation, and where other legal requirements are met. Similarly, studies must be undertaken only for bona fide research purposes.

Resources To Comply With the Law

Recent enforcement actions and statements from government representatives demonstrate increased interest in enforcing the Anti-Kickback Law against physicians and others who solicit or receive kickbacks. It is incumbent on physicians to familiarize themselves with the restrictions of the Anti-Kickback Law and to carefully assess all relationships to ensure proper compliance. Many resources are available to educate physicians about compliance with the Anti-Kickback Law:

• The Advanced Medical Technology Association (AdvaMed) has issued an ethics code—known as the AdvaMed Code on Interactions with Health Care Professionals—that provides additional guidance on interactions between medical device manufacturers, physicians and other health care professionals. AdvaMed recently issued a revised code that will take effect July 1, 2009. To access the code and other AdvaMed resources, go to www.advamed.org.

• The American Medical Association has issued guidance in the form of formal statements, opinions and a Code of Medical Ethics designed to ensure ethical conduct of physicians. To access these documents, go to www.ama-assn.org.

• The OIG issues regulations, fraud alerts, advisory opinions and examples of enforcement actions. To access this information, go to www.oig.hhs.gov.

References


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