Legal Issues

Beware of Those Bearing Gifts: Are They Legal?

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As the health care marketplace remains ever competitive, the pressure to push the legal envelope intensifies. ACR members frequently have questions about whether to undertake similar business arrangements that other radiology or radiation oncology practices or hospital departments have started or are considering. If our competitors are doing XYZ with other physicians or companies, can we—should we—also do that for patient care and our bottom line?

One controversial legal and ethical area that the government, industry, and the media all have addressed involves whether to accept compensation or other items of value from medical vendors, such as pharmaceutical and medical equipment companies. These include educational grants or research funding linked to a specific product, or business “gifts,” such as travel, meals, or entertainment offered to physicians. If a manufacturer or vendor offers such remuneration to individual physicians or practices based on their position to generate federal health care business for the company directly or indirectly, that can represent an illegal inducement under the federal antikickback law. The American Medical Association (AMA), the US Health and Human Services Office of Inspector General (OIG), and the private sector have all published guidance on the limits of appropriate relationships between physicians and manufacturers. This column will review the legal danger zones for ACR members in dealing with manufacturers, outline key government and industry compliance initiatives, and explain how members can avoid the risks of fraud and abuse.

ANTIKICKBACK LAW AND ACR MEMBERS

What does the federal antikickback law cover? It is a criminal prohibition against payments by individuals or entities (in any form, whether direct or indirect) made purposefully to induce or reward the referral or generation of business reimbursable by Medicare, Medicaid, or any other federal health care program. Thus, the law applies to ACR members although most of them do not refer patients. The statute also bans offering or paying anything of value in return for purchasing, leasing or ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service for which a federal program would reimburse.

Some courts have interpreted the law broadly to cover any arrangement in which one purpose of the remuneration is to induce or compensate for program referrals or recommendations of federally payable business. Even if a radiologist or radiation oncologist has a legitimate clinical or educational reason for doing business with a manufacturer, but also accepts compensation in return for ordering a federally payable item like a contrast or other agent, that arrangement can violate the antikickback statute. Thus, any illegal intent by one party can taint the entire benefit.

Why does the antikickback law matter? Any person or entity found to have violated the law is guilty of a felony and can be jailed or pay major civil penalties of up to $50,000 per violation. Worse yet, the government can exclude a physician or even an entire practice from eligibility to participate in Medicare and all other federal health programs. The OIG, which investigates antikickback and other fraud and abuse violations, recently announced it will pursue more antikickback cases against individuals. Consequently, ACR members and other physicians need to evaluate current and potential business arrangements very carefully.

So, how would the antikickback law apply to receiving something from a manufacturer? An ACR member might receive an invitation to a reception or dinner from a pharmaceutical company or device manufacturer. The member, and typically other physicians, likely would have the opportunity to enjoy food and beverage with company representatives. The physicians would hear about how the company’s latest products could treat patients’ conditions and thus enhance their care. What is the legal harm if the member accepts the invitation?

Assume that the member subsequently orders a company product that is billed to Medicare or another federal health program. The federal government might well question the influence that the reception or dinner had on the member’s decision to use the manufacturer’s product rather than a competing brand. Would the “preferred” product help a patient more than the other brand? Is the physician now inclined to use the company’s product in situations where he normally would not use such a product? Does one company’s product potentially cost more to the government or to patients, or lead to overutilization or inappropriate utilization than others?

These are the factors that the antikickback regulators weigh. A pattern or practice of engaging in this type of arrangement could lead to a government investigation and prosecution. Certainly, the vast majority of physicians make sound clinical decisions on their patients’ behalf. However, the health care overseers are holding physicians and manufacturers more accountable for their business judgments.
BEST PRACTICES FOR HEALTH CARE

Since the late 1990s, the OIG has published model compliance guidelines that are voluntary but offer “best practices” that the health care industry should observe. The OIG’s 2000 compliance guidance for physicians spotlighted interactions with pharmaceutical manufacturers as one risk area where improper inducements could lead to antikickback violations. The OIG cautioned that any business arrangements between physicians and manufacturers should be based on fair market value.

The OIG took an even closer look at relationships between pharmaceutical manufacturers and physicians in its 2003 compliance guidance for the manufacturers (HTML version at http://www.oig.hhs.gov/fraud/complianceguidance.html). The OIG served notice to the industry that “these activities have a high potential for fraud and abuse and, historically, have generated a substantial number of antikickback convictions.” For example, if a manufacturer provided goods or services that eliminated an expense that the physician would have otherwise paid (eg, have independent value to the physician), that practice could run afoul of the law. Alternatively, a manufacturer could sell a medical item or service to a physician at below fair-market value. Manufacturers and physicians both need to structure their relationships to fit within an antikickback safe harbor, such as those for personal services and management contracts or employees.

The OIG recommends that physicians ask the following before saying yes:

• What degree of influence would I have, directly or indirectly, on generating business for the manufacturer?
• Does company ABC have other relationships with me or members of my group or department?
• Is the remuneration contingent wholly or partly on referrals or other business generated?
• Does the remuneration have more than trivial value (pens, notepads), including all gifts to me, my partners, or my practice?
• If I accepted the remuneration, would that reduce, or appear to reduce, the objectivity of my professional judgment?

CONSULTING AND ADVISORY PAYMENTS

Another antikickback danger zone with manufacturers deals with consulting and advisory payments. Manufacturers have extended these to physicians, seeking to obtain their clinical expertise about—and endorsement of—health care products. The OIG indicates that fair market value payments to “small numbers” of physicians for bona fide consulting or advisory engagements likely will not cause legal problems. But the OIG frowns on paying physicians as “consultants” when they are supposed to attend meetings or conferences primarily in a passive role. Why is a manufacturer paying money in that case, if the physician is not a program faculty member or a planning chair?

The OIG also targets compensating physicians for providing services linked directly or indirectly to a manufacturer’s marketing and sales activities. For instance, a physician might receive an offer of remuneration to speak, conduct research, or do preceptor or “shadowing” services. Although these services could have clinical benefit, the OIG thinks they carry a risk of fraud and abuse. The OIG especially disfavors a manufacturer paying physicians to listen to sales pitches and complete basic paperwork, known as “detailing,” or to view web-based marketing information or perform “research.”

MANUFACTURER/PHYSICIAN GUIDELINES

Entertainment, travel, or other benefits connected with information or marketing presentations could fall within the antikickback law. Whether a specific arrangement violates the law depends on the facts. The OIG urges manufacturers to review the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, available at http://www.phrma.org. PhRMA’s voluntary code allows industry representatives and others speaking on behalf of a company to make informational presentations and discussions if they have educational and scientific value.

The AMA has guidelines governing physician interactions with any proprietary health care industry member that could raise a conflict of interest. AMA advises physicians only to accept gifts from manufacturers that benefit patients and have insubstantial value.

Gifts of diagnostic equipment benefit patients and are permissible if they have low value, but accepting major equipment like CT, MR, and other scanners free or below market value would not qualify. ACR members can access the AMA’s guidance at: http://www.ama-assn.org/ama/pub/category/4001.html.

The Advanced Medical Technology Association (AdvaMed) and the National Electronic Manufacturers Association (NEMA) have published detailed guidelines for their industry members. ACR members can review these at www.acr.org under “Ethics.”

As sound risk management, ACR members should review the OIG, AMA, and industry guidance before agreeing to accept any gifts or other items of value from manufacturers. Assess the economic and clinical interests at issue and confer with legal counsel about potential fraud and abuse liability.