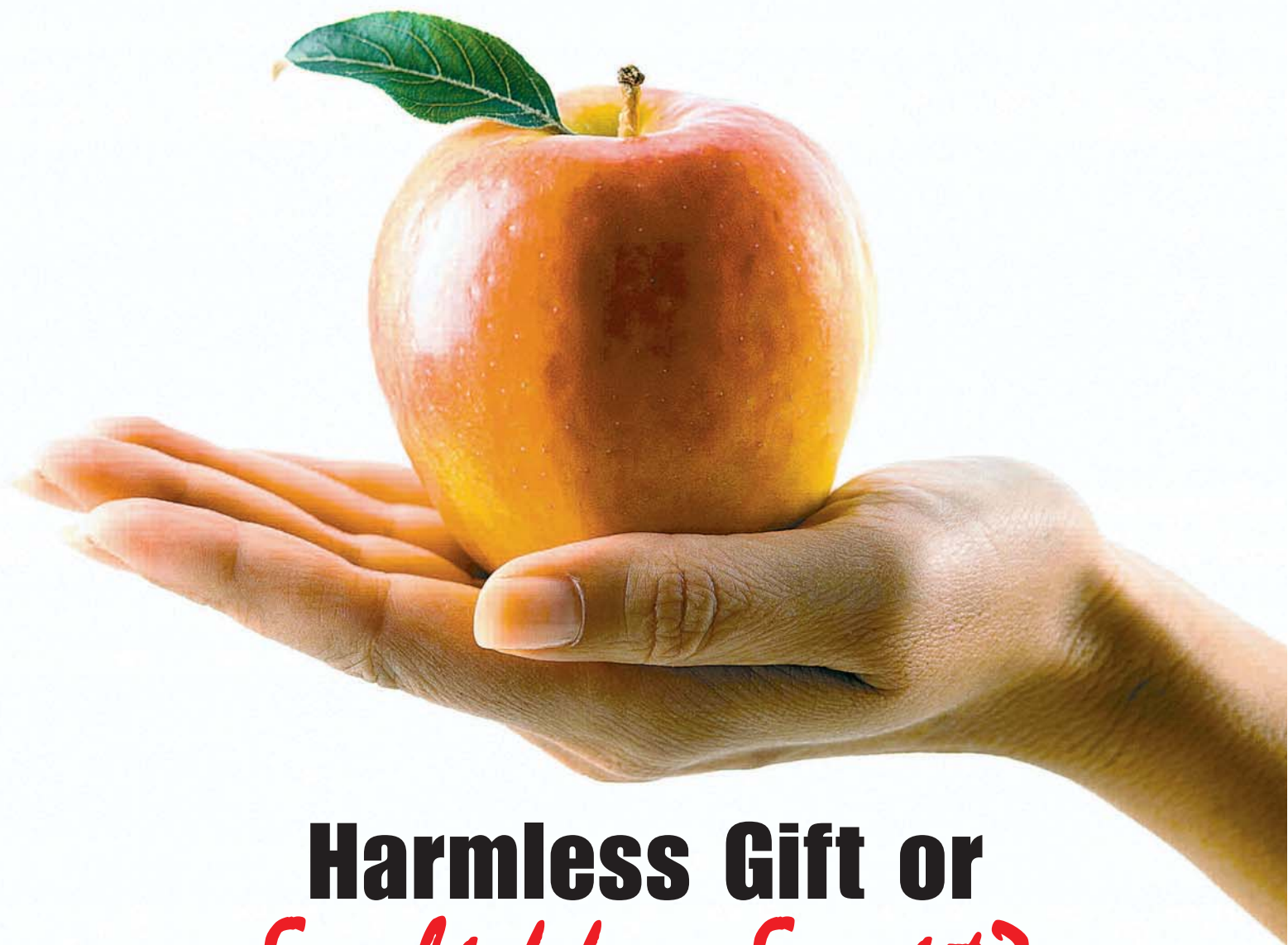


HEALTH CARE LAW



Harmless Gift or *Forbidden Fruit?*

Structuring compliant physician-vendor arrangements

Harmless Gift or Forbidden Fruit?

Structuring compliant physician-vendor arrangements

By Anjana D. Patel and
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In the increasingly competitive health care industry, hospitals, pharmaceutical manufacturers, medical device makers and other vendors often provide gifts or other benefits to secure physician loyalty to their products and services. Such arrangements can become the subject of intense scrutiny under federal and state health care laws and regulations, requiring vendors and physicians to be careful when dealing with each other.

Typically, these arrangements take a variety of forms — outright cash payments, freebies such as pads and pens, benefits such as free travel, entertainment and meals, research grants, continuing medical education (CME) subsidies, consulting and medical directorship agreements, provision of free or discounted services (e.g., billing and collections), office space and equipment. These arrangements are problematic because they are viewed as incentives which create a conflict of interest — physicians will arguably refer a patient, prescribe a drug or select a device based on receiving these incentives rather than using independent clinical judgment.

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One significant law impacting these arrangements is the federal Anti-Kickback Statute (AKS), which makes it a crime for any person to knowingly and willfully solicit, receive, offer or pay remuneration to induce or reward referrals for items or services reimbursable under any federally funded health care program. The AKS also makes it illegal to offer or pay remuneration in return for purchasing, leasing, ordering or arranging for any item or service, which is reimbursable by a federal health care program. Thus, the AKS' prohibitions apply to both the hospital/vendor providing (or offering) the incentive and the physician or entity receiving the incentive. In addition to criminal penalties, violations of the AKS can result in substantial civil monetary penalties, damages and exclusion from participation in federal health care programs, such as Medicare.

The Office of the Inspector General (OIG), which enforces the AKS, has issued guidance for hospitals and vendors in the form of industry-specific compliance program guidance, special fraud alerts and bulletins, and advisory opinions. For example, in its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, the OIG states that pharmaceutical compa-

nies seeking to structure compliant physician arrangements should consider whether the arrangement: (i) interferes with clinical decision-making; (ii) provides physicians with accurate, complete and truthful information; (iii) potentially increases the costs to federal health care programs or beneficiaries; (iv) poses a risk of overutilization or inappropriate utilization; or (v) raises patient safety or quality concerns. The OIG also provides further guidance for specific types of incentives:

Cash and Gifts. While the provision of cash, gifts, entertainment, recreation, travel expenses, meals and other benefits clearly implicates the AKS, under certain facts and circumstances, provision of these items may be acceptable. However, the OIG does not elaborate on acceptable facts and circumstances, but instead recommends that vendors, at a minimum, comply with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (see below). Thus, compliance with PhRMA's standards would most likely be viewed as a good-faith compliance effort under the AKS.

Research Funding. Pharmaceutical manufacturers, in particular, often engage physicians to provide research services. Research arrangements should: (i) not be initiated or directed by marketing personnel; (ii) include genuine scientific oversight; (iii) avoid unnecessary or duplicative research;

and (iv) not be a post-marketing pretense to promote a product. Research whose only purpose is to generate business or promote the product should be avoided. All contracts should meet the AKS personal services safe harbor to the extent possible, be in writing, and all payments should be fair-market value for the legitimate services actually provided.

CME Subsidies. Vendors should ensure that they are not using CME programs to pay improper remuneration to physicians in a position to generate business. Vendors should not influence or control the content of CME programs and should follow FDA guidelines with respect to their involvement in the programs.

Tying, Switching and Detailing Arrangements. Certain arrangements should be avoided altogether. For example, the following are almost never acceptable: “tying” arrangements (providing cash, gifts or other benefits contingent upon physician referrals of the vendor’s products), “switching” arrangements (offering cash or other benefits for changing a patient’s prescription to the manufacturer’s product from a competing one), and “detailing” (compensating for time spent listening to marketing information).

Consulting and Medical Director Arrangements: Consulting positions or medical directorships also raise concerns under the AKS. Wherever possible, these arrangements should satisfy the AKS safe harbor for personal service arrangements. At a minimum, the parties should ensure that (i) a signed written agreement is in place; (ii) there is a legitimate need for the physician’s services; (iii) the required services are actually provided; and (iv) the compensation is fair-market value. These facts should be documented prior to paying the physician, and the arrangement should be monitored on an on-going basis to ensure that the parties’ written agreement reflects their actual practice.

In an effort to police themselves and supplement regulatory guidance, several industry organizations have promulgated codes of ethics, which provide additional insight on structuring arrangements with physicians. Some of the more comprehensive examples

include the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals and PhRMA’s Code on Interactions with Healthcare Professionals. While an exhaustive review of these codes is outside the scope of this article, several of the more notable provisions are described below.

PhRMA’s Code prohibits the provision of cash or cash equivalents (i.e. gift certificates) altogether. PhRMA further takes the position that any gifts should be of less than \$100 value and should primarily benefit the patients or serve an educational function, for example, anatomical models and text books. Promotional products are acceptable if they relate to the physician’s practice — pens and notepads are acceptable; golf balls are not. PhRMA’s Code allows manufacturers to give informational presentations if they are “modest,” informational and provide scientific and educational value. Manufacturers may pay a direct subsidy to a CME conference organizer, provided that the subsidy is used to reduce conference fees for all attendees. Manufacturers may not directly pay for a physician’s travel, lodging, meals, or other personal expenses. By contrast, AdvaMed’s Code allows a manufacturer to compensate the physician for reasonable travel and modest lodging — thus, the conservative approach would be to avoid payments for these items altogether.

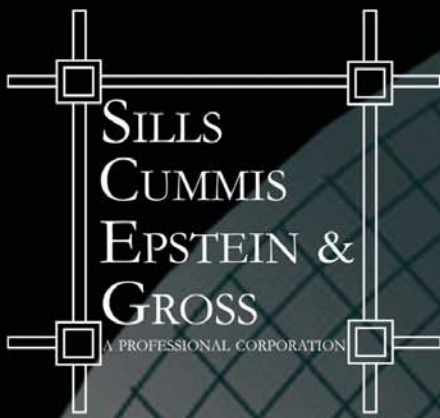
Arrangements between hospitals and physicians also raise concerns under the federal Stark Law, which prohibits a physician from referring certain types of services to a hospital if the physician has a financial relationship with the hospital and such services would be paid for by the Medicare/Medicaid programs. For physician service arrangements, such as medical directorships, the Stark Law, like the AKS, has an exception for personal services provided by the physician. However, unlike the AKS, which is an intent-based statute, the Stark Law is a strict liability statute — the arrangement must satisfy all of the requirements of an exception. The key requirements are that the agreement be in writing and that the payment equate to the fair-market value compensation for services

actually provided by the physician.

The Stark Law also contains exceptions for certain “de minimus” gifts and benefits to physicians. Noncash gifts with an aggregate annual value of up to \$329 (adjusted annually) are permitted so long as they are not solicited by the physician and do not take into account referrals generated by the physician. Further, a hospital may provide certain incidental benefits to all members of its medical staff if such benefits are of nominal value (less than \$28 dollars), do not take into account referrals generated, and are utilized at the hospital in connection with the provision of medical services. A hospital may also provide physicians with compliance training related to federal and state health care programs, as well as certain types of electronic medical record and e-prescription technology.

Other laws may also impact arrangements with physicians, such as the IRS’s rules prohibiting private benefit and private inurement, and state specific prohibitions on self-referrals and kickbacks. To avoid IRS scrutiny, hospitals should ensure that any compensation paid to physicians is reasonable, fair-market value and the result of arms’ length negotiations. Further, New Jersey’s Codey Law prohibits physicians from making referrals to entities in which they have a significant beneficial interest, and the Board of Medical Examiners’ regulations prohibit physicians from receiving gifts of more than negligible value or any other compensation which reasonably would be recognized as having been given to promote or reward certain conduct by the physician.

In summary, effective representation of any hospital, pharmaceutical manufacturer, medical device maker or other similar vendors that routinely enter into arrangements with physicians should not only include an in-depth review of these various state and federal laws, but also of the industry-specific codes of ethics. While these codes do not carry the impact of law, they can provide detailed and practical guidance that is useful in structuring compliant physician-vendor arrangements, and demonstrate the good faith of the parties to the arrangements. ■



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