Introduction

Most physicians strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Society places enormous trust in physicians, and rightly so. Trust is at the core of the physician-patient relationship. When our health is at its most vulnerable, we rely on physicians to use their expert medical training to put us on the road to a healthy recovery.

The Federal Government also places enormous trust in physicians. Medicare, Medicaid, and other Federal health care programs rely on physicians’ medical judgment to treat beneficiaries with appropriate services. When reimbursing physicians and hospitals for services provided to program beneficiaries, the Federal Government relies on physicians to submit accurate and truthful claims information.

The presence of some dishonest health care providers who exploit the health care system for illegal personal gain has created the need for laws that combat fraud and abuse and ensure appropriate quality medical care. This brochure assists physicians in understanding how to comply with these Federal laws by identifying “red flags” that could lead to potential liability in law enforcement and administrative actions. The information is organized around three types of relationships that physicians frequently encounter in their careers:

I. Relationships with payers,

II. Relationships with fellow physicians and other providers, and

III. Relationships with vendors.

The key issues addressed in this brochure are relevant to all physicians, regardless of specialty or practice setting.
Relationships With the Pharmaceutical and Medical Device Industries

Physician-industry collaboration can produce important medical advances. However, some pharmaceutical and device companies have used sham consulting agreements and other arrangements to buy physician loyalty to their products. Such illegal arrangements induce physicians to prescribe or use products on the basis of that loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient.

As a practicing physician, you may have opportunities to work as a consultant or promotional speaker for the drug or device industry. For every financial relationship offered to you, evaluate the link between the services you can provide and the compensation you will receive. Test the propriety of any proposed relationship by asking yourself the following questions:

- Does the company really need my particular expertise or input?
- Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
- Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?

A good discussion that assists in distinguishing between legitimate and questionable industry relationships is located in the OIG’s “Compliance Program Guidance for Pharmaceutical Manufacturers” available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.
If your contribution is your time and effort or your ability to generate useful ideas and the payment you receive is fair market value compensation for your services without regard to referrals, then, depending on the circumstances, you may legitimately serve as a *bona fide* consultant. **If your contribution is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.**

For example, if a drug company offers to pay you and a hundred other “thought leaders” to attend a conference in the Bahamas without requiring preparatory work on your part or information about your expertise in the field (other than the fact that you are a licensed physician), you should be suspicious that the company is attempting to influence you to prescribe its drug.

### Case Example of Kickbacks in the Device Industry

- Four orthopedic device manufacturers paid $311 million to settle kickback and false claims allegations that the companies bribed surgeons to recommend their hip and knee surgical implant products. The companies allegedly would award physicians with vacations, gifts, and annual “consulting fees” as high as $200,000 in return for the physicians’ endorsements of their implants or use of them in operations. Many of the individual orthopedic surgeons at the receiving end of the kickbacks are the subject of ongoing investigations by the Government. One orthopedic surgeon recently paid $650,000 to resolve allegations that the surgeon accepted payments from device manufacturers to use their hip and knee implants.
Transparency in Physician-Industry Relationships

Although some physicians believe that free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows that these types of perquisites can influence prescribing practices. Recent pharmaceutical company settlements with the Department of Justice and OIG require “transparency” in physician-industry relationships, whether by requiring the pharmaceutical company to provide the Government with a list of physicians whom the company paid and/or by requiring ongoing public disclosure by the company of physician payments. The public will soon know what gifts and payments a physician receives from industry. The Patient Protection and Affordable Care Act of 2010 requires drug, device, and biologic companies to publicly report nearly all gifts or payments they make to physicians beginning in 2013.

Academic institutions also may impose various restrictions on the interactions their faculty members or affiliated physicians have with industry. These and other considerations may factor into your decision about whether you want to conduct industry-sponsored research; serve as a consultant or director for a drug, biologic, or device company; apply for industry-sponsored educational or research grants; or engage in other relationships with industry.

Both the pharmaceutical industry (through PhRMA) and the medical device industry (through AdvaMed) have adopted codes of ethics for their respective industries regarding relationships with health care professionals. Both codes are available online.

Conflict-of-Interest Disclosures

Many of the relationships discussed in this brochure are subject to conflict-of-interest disclosure policies. Even if the relationships are legal, you may have an obligation to disclose their existence. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders, such as States, universities, and the National Institutes of Health, and from the Food and Drug Administration (FDA) when data are submitted to support marketing approval for new drugs, devices, or biologics. To “manage” your conflicts of interest, consider the conflicts policies that affect your professional activities, candidly disclose any industry money subject to these policies, and adhere to restrictions on your activities. If you are uncertain whether a conflict exists, ask someone. You always can apply the “newspaper test” and ask yourself whether you would want the arrangement to appear on the front page of your local newspaper.
Continuing Medical Education

After finishing your formal graduate medical training, you will assume greater responsibility for your continuing medical education (CME) to maintain State licensure, hospital privileges, and board certification. Drug and device manufacturers sponsor many educational opportunities for physicians. It is important to distinguish between CME sessions that are educational in nature and sessions that constitute marketing by a drug or device manufacturer. Industry satellite programs that occur concurrently with a society meeting are generally promotional, even if the primary speaker is a physician who is well known in the field. You should be circumspect about a discussion that focuses on a particular brand drug or device, as opposed to all the treatment alternatives for a specific condition.

For example, if speakers recommend use of a drug to treat conditions for which there is no FDA approval or use of a drug by children when FDA has approved only adult use, you should independently seek out the empirical data that support these recommendations. Note that although physicians may prescribe drugs for off-label uses, it is illegal under the Federal Food, Drug, and Cosmetic Act for drug manufacturers to promote off-label uses of drugs.

Advertisements and other promotional materials for drugs, biologics, and medical devices must be truthful, not misleading, and limited to approved uses. FDA is requesting physicians’ assistance in identifying misleading advertisements through its Bad Ad Program. If you spot advertising violations, you should report them to FDA by calling 877-RX-DDMAC (877-793-3622) or by emailing badad@fda.gov.

If you are invited to serve as faculty for industry-sponsored CME, ask yourself the following questions:

- Does the sponsor really need my particular expertise or input?
- Does the amount of money the sponsor is offering seem fair and appropriate for the educational value I will add to the presentation?
- Is it possible the sponsor is paying me for my loyalty so that I will prescribe its drugs or use its devices?
- Does the sponsor prepare a slide deck and speaker notes, or am I free to set the content of the lecture?