HEALTH LAW360

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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Business Conduct Guidelines For Health Care

Wednesday, Mar 05, 2008 --- As the attention of the press, the public and government enforcement agencies has shifted to potential physician conflicts of interest with suppliers and vendors (such as pharmaceutical and device manufacturers), health professional and medical industry groups have responded by developing or updating voluntary Guidelines for Business Conduct, Codes of Conduct, and Ethical Guidelines (collectively, “Codes and Guidelines”) relating to contacts with healthcare professionals.

The trade associations leading the way in adopting such Codes and Guidelines are among the biggest players in the industry, including the Pharmaceutical Research and Manufacturers of America (PhRMA), the Advanced Medical Technology Association (AdvaMed), the American Medical Association (AMA), the National Electrical Manufacturer’s Association (NEMA), and the Healthcare Information and Management Systems Society (HIMSS).

Even the Institute of Medicine (IOM) is in the process of drawing up gift-giving guidelines for the medical community, which should be ready by the end of the year, according to IOM president Harvey V. Fineberg, MD, PhD.

As pertinent here, Codes and Guidelines generally summarize an entity’s commitment to compliance with the law, provide broad constructs to manage conflicts of interest and protect patient interests, and usually also provide general tenets to reduce enforcement risks.

The Office of Inspector General of the Department of Health and Human Services (OIG), which has oversight for federal healthcare programs including Medicare and Medicaid, has consistently recommended that organizations adopt Codes of Conduct as one element of their compliance programs.

Corporate Integrity Agreements (CIAs), in which the OIG waives its option to exclude (debar) an entity as part of a False Claims Act settlement, usually require that the entity adopt such a Code or an equivalent document, if one is not already in place.

In its 2003 monograph addressing Corporate Responsibility and Corporate Compliance, which was directed to Health Care Boards of Directors, the OIG observed that a Code of Conduct is fundamental to a successful compliance program because it articulates the organization’s commitment to ethical behavior.

OIG further advised that a Code should function in the same way as a constitution, i.e., as a document that details the fundamental principles, values, and framework for action within the organization.

Traditionally, most Codes and Guidelines have not specifically addressed contacts with healthcare professionals or potential physician/industry conflicts of interest, but rather have included more broadly applicable principles, such as the entity's pledge to assuring full compliance with all laws.

Many Codes and Guidelines specifically reference the need to avoid violations of the federal Anti-Kickback statute, a criminal prohibition against knowingly and willfully offering to pay or to solicit or to receive remuneration in order to induce business which is paid for by the federal health care programs.

It is this provision, which if violated may also give rise to civil liability under the False Claims Act, which can serve as the basis for legal liability if improper remunerations are offered to or received by physicians.

Claims submitted to the federal healthcare programs may be alleged to be false if they are shown to be "tainted" by the improper remuneration. There is also a civil monetary penalty provision which allows the OIG to pursue conduct which it determines involves kickbacks.

In recent years, contacts with healthcare professionals and potential physician/industry conflicts of interest have become a significant concern because of perceptions as to their potential for compromising physicians' medical judgment and causing over-utilization of services and misallocation of health care resources.

Financial conflicts of interest occur when a medical provider's single-minded commitment to patient care is at least potentially susceptible to influence by economic or other personal gain, often unintentionally and sometimes unconsciously.

Conflicts of interest have the potential for compromising the best interests of patient care and the scientific integrity of research.

Problems associated with conflicts of interest may be exacerbated by lack of oversight. For example, a recent report by the OIG concluded that financial conflicts of interests are inadequately monitored at universities and other institutions receiving billions of dollars in research grants from the National Institute of Health.

Recent settlements by the Department of Justice with device companies have required website postings of all payments to physicians in an apparent effort to encourage transparency and public oversight.

Codes and Guidelines issued by sector trade associations play an important

role in governing relationships between vendors and healthcare professionals.

Whether these industry sector Codes and Guidelines will be able to prevent improper relationships between physicians and vendors is as yet unproven. However, these Codes and Guidelines offer the most definitive and generally well-accepted guidance for structuring and monitoring such relationships. Who could be better positioned to set the rules for business conduct than the industry sector itself?

Adoption of the sector Codes and Guidelines for individual entity use, or compliance with the principles expressed within these Codes and Guidelines, is voluntary.

To a large degree, however, the industry Codes and Guidelines must be considered to represent the “industry standard,” such that deviations might be viewed by a government enforcement entity as reckless disregard for the consequences.

The steady growth of the medical device and pharmaceutical industries is paralleled by greater opportunities for perceived conflicts of interest to arise in patient care.

Although in many situations physicians may not be the actual purchasers of devices or pharmaceuticals (hospitals or other institutional providers may be the ones with the checkbooks or credit lines), a substantial amount of marketing is directed at physicians because of their influence on product selection by institutional purchasers.

Financial benefits that may influence a physician’s clinical decision are potentially implicated in a host of industry transactions that are directed towards physicians, particularly:

(1)Vendor-sponsored product training and education

(2)Industry support of third-party educational conferences

(3)Sales and promotional meetings with physician participation

(4)Gifts, paid entertainment, recreation and meals

(5)Charitable donations

(6)Research grants, and

(7)Consulting arrangements

Codes and Guidelines are intended to minimize the potential conflicts of interest by establishing recommended parameters for contacts with healthcare professionals.

Although some organizations, such as the AMA, had established ethical guidelines as early as the early 1990s, there was a proliferation of industry Codes and Guidelines addressing interactions between vendors and health care professionals beginning in 2003 which continues through the present time.

Industry sector Codes and Guidelines vary somewhat in the level of detail provided and the issues addressed, but are generally tailored toward providing detailed guidance on issues that are most prevalent for that sector.

For example, the PhRMA Code on Interactions with Healthcare Professionals provides the pharmaceutical industry with voluntary guidelines that establish internal processes to counter the potential conflicts of interest present in the pharmaceutical and biotechnology companies.

OIG expressed its support for the PhRMA Code in its Compliance Program Guidance for Pharmaceutical Manufacturers, and has verbally indicated that it considers the PhRMA Code applicable to device manufacturers as well.

AdvaMed's Code of Ethics for Interaction with Healthcare Professionals and NEMA's Code of Ethics for Interaction with Healthcare Professionals focus on business issues facing the medical technology industry.

For example, the NEMA Code makes it clear that research funding must be totally separate from sales. It implements this rule by requiring that research proposals be evaluated, negotiated, and managed by persons who have no role in sales. In addition, the NEMA Code expressly prohibits any conditions linking past, present or future product purchases to research.

The AMA has also updated its Code of Medical Ethics. The AMA developed a body of ethical statements primarily for the benefit of patients and intends for the Code to operate as "standards of conduct which define the essentials of honorable behavior for the physician." It includes very specific provisions relating to the acceptance of gifts, travel funds for conferences, honorariums, etc.

The AMA Code also establishes standards related to a variety of physician issues besides conflicts of interest, including practice matters, social policy, confidentiality, advertising and media related communications.

In spite of the propagation of these multiple and highly visible Codes and Guidelines for contacts with health care professionals, common practices still evidence a need for vigilant monitoring to avoid conflicts of interest.

According to a 2007 national survey of physician-industry relations, which was reported in the April 26, 2007 New England Journal of Medicine, the vast majority of physicians (94%) report some type of relationship with the pharmaceutical industry, such as receiving food and drinks in the workplace (83%), receiving free drug samples (78%), receiving reimbursement for

meeting costs or continuing medical education (35%), receiving payments for consulting or speaking, or receiving payments for enrolling patients in clinical trials (28%).

Institutional academic-industry relationships are also highly prevalent. A national survey reported in the Oct. 17, 2007 Journal of the American Medical Association disclosed that almost two-thirds of medical school department chairs identified personal relationships with industry, such as serving as a consultant, speaker, member of a scientific advisory board, officer, founder, or member of the Board of Directors.

In addition to the industry Codes and Guidelines, many healthcare systems have established stringent internal policies that prohibit common practices involving potential conflicts of interest resulting from contacts with healthcare professionals by drug and medical device companies.

Many of these policies ban or limit the amount of gifts. For example, the Hospital of the University of Pennsylvania has banned its staff from accepting gifts of any size during office hours – including free lunches. Federal Veterans Affairs hospitals have also banned gifts.

One Minnesota-based hospital system has not only banned future gifts but purged itself of all remnants of promotional gifts from pharmaceutical companies – pens, notepads, coffee cups, and other trinkets – and shipped them off to Cameroon, a developing country in Western Africa.

Academic medical centers and health maintenance organizations are taking similar steps. Kaiser Permanente and HealthPartners of Minnesota adopted strict conflict of interest policies for physicians and employees, including limits on gift and disclosure requirements.

Stanford University adopted Guidelines for Interactions with Pharmaceutical, Biotech and Medical Device Supplier Industries, which bans meals and gifts and sets rules for industry funding for education. Other major universities, such as Yale University School of Medicine, Boston University School of Medicine, and the University of California at San Francisco, have followed suit.

In addition to the Federal laws referenced above, State laws are also becoming increasingly important as enforcement tools. While some states have anti-kickback laws which are similar to the Federal Anti-kickback statute, some states also regulate conflicts of interest as “unprofessional conduct” pursuant to the health professional practice acts.

Many states have enacted their own False Claims Acts that extend to payments from state and/or local government and have adopted federal enforcement priorities, which can be readily applied to scrutinize physician arrangements.

Other jurisdictions have considered alternative approaches to regulate

contacts with healthcare professionals, such as licensing pharmaceutical sales representatives or requiring public reporting of gifts received by physicians.

The OIG has also declared – and demonstrated - increased interest in examining physician/industry financial relationships. In 2007, the OIG announced plans to issue additional voluntary compliance guidance addressed to pharmaceutical companies and device manufacturers.

Recent enforcement activity has also focused on industry contacts with physicians. Through a series of cases that resulted in significant settlements (Lincare, Medtronic, Advanced Neuromodulation Systems, and the Orthopedic Device Settlements), the OIG demonstrated its commitment to using CIAs as prospective administrative enforcement tools to regulate and monitor medical device manufacturers in their payments (e.g. gifts, grants, medical equipment, consulting arrangements) to physicians.

The 2008 OIG Workplan emphasizes that the agency will continue to investigate business arrangements that allegedly violate the federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians for designated health services (Stark law).

Conclusion

With the increasing enforcement emphasis on physician/industry conflicts of interest, it is imperative that compliance programs be implemented effectively.

OIG's compliance guidance continues to emphasize the importance of implementing written policies and procedures; designating a compliance officer and compliance committee; conducting effective training and education; developing effective lines of communication; conducting internal monitoring and auditing; enforcing standards through well-publicized disciplinary guidelines; and responding promptly to detected problems and undertaking corrective action.

These components are generally applicable to health care systems, manufacturers, suppliers, and physician organizations alike.

In order to reduce enforcement risk, entities must identify and focus on the high risk areas for their organizations. As applicable, this risk assessment should include a review of policies on physician contacts and relationships, including gifts, marketing activities, continuing medical education, distribution and use of pharmaceutical samples, systems purchases of medical devices, payments for educational activities, speaking engagements funded by industry, and consulting or research support.

Overall, a Code of Conduct should generally identify what relationships will be subject to scrutiny, ban inappropriate activities, develop mechanisms to guard against improper influence or conflicts on decision-making, and

emphasize transparency in relationships between physicians and industry.

As the OIG has noted, a Code of Conduct can function like a constitution. Industry sector Codes and Guidelines provide guidance and models applicable to the risks of a specific sector which should be studied and adapted for individual entity use.

--By Judith A. Waltz, Leeann Habte and Jeannine Y. McGregor, Foley & Lardner LLP

Judith Waltz is a partner and co-chair of Foley & Lardner's life sciences industry team and former vice chair of the firm's health care industry team. Leeann Habte and Jeannine Y. McGregor are members of the firm's health care industry team.