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Shining the light on physician–pharmaceutical and medical device industry financial relationships

Lawrence Conn, JD, and **Lawrence Vernaglia, JD, MPH,** *Boston, Mass*

Long subject to legal scrutiny under the federal Anti-Kickback Statute, financial ties between physicians and drug manufacturers have recently come under additional pressure as a result of recently enacted state and federal disclosure laws and state gift restrictions, the latest coming in connection with the Federal Health Reform Law. These "sunshine" laws have been motivated by the concern that gifts and payments by manufacturers to physicians may lead to conflicts of interest and improperly influence physicians in their drug- or device-prescribing decisions. As a backdrop to these new laws, it is helpful to review prior guidance regarding manufacturer–physician financial relationships, both from the federal government and the industry itself. These laws do not prohibit physician involvement with industry in research and education, but they impose various new compliance requirements on these relationships, and also in many cases, require public disclosure of arrangements that previously were treated as confidential. It is still too early to tell if these laws will stifle innovation, but they do require a heightened degree of diligence to avoid, at a minimum, adverse publicity and embarrassment and, at worst, criminal and civil liability. (J Vasc Surg 2011;54:22S-5S.)

VOLUNTARY GUIDANCE

Office of the Inspector General recommendations for voluntary compliance. The federal government has, for some time, indicated its potential concern with physician–industry financial relationships under the Anti-Kickback Statute. The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services stated in its 2003 *Compliance Program Guidance for Pharmaceutical Manufacturers*:

> Suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions . . . Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.[1]

In particular, the OIG focuses on potentially problematic items, including entertainment, recreation, travel, meals, or other benefits in connection with informational or marketing presentations, as well as gifts, gratuities, and other business courtesies. The OIG also indicated the need for caution with educational or research grants provided to physicians, advising drug manufacturers to ensure that funding is for bona fide educational or research purposes and in no way based on the physician's ordering the manufacturer's product(s).[2]

The OIG also took note of the Pharmaceutical Research and Manufacturers of America's (PhRMA) 2002 *Code on Interactions with Healthcare Professionals*, stating that although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the Anti-Kickback Statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good-faith effort to comply with the applicable federal health care program requirements.[3]

The PhRMA and Advanced Medical Technology Association codes. The PhRMA first issued the PhRMA Code in 2002 and later updated it in 2008 to be effective on January 2009.[4] The PhRmA Code is a voluntary set of standards and principles for the industry covering topics such as the provision of meals to health care professionals at informational presentations, financial support for continuing medical education (CME) provided by the manufacturer or a third party, consulting arrangements, and a suggested prohibition on entertainment and recreational items, among other areas. The medical device industry has published similar requirements, and effective as of July 1, 2009, the Advanced Medical Technology Association (AdvaMed) Board of Directors approved a matching update to its *Code of Ethics on Interactions with Health Care Professionals*.

Sources of enforcement authority

In addition to voluntary guidance, financial relationships between physicians and manufacturers are subject to three primary sources of legal restrictions and enforcement.

Federal Anti-Kickback Statute. The Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) is a criminal law that prohibits any person from "knowingly and willfully" paying

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Reprint requests: Lawrence William Vernaglia, Foley & Lardner, LLP, Health Care Practice Group, 111 Huntington Ave, Boston, MA 02199 (e-mail: lvernaglia@foley.com).

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or offering any remuneration in exchange for or to induce the referral or recommendation of any item or service covered by a federal health care program. Federal courts have broadly interpreted the statute to prohibit any payment if one purpose of the payment is to induce the referral of covered goods or services, irrespective of whether there are other legitimate business purposes for the payment. Convictions under the Anti-Kickback Statute constitute a felony and may result in a fine not to exceed $25,000, imprisonment up to 5 years, or both. In addition, there is the possibility of civil exclusion from the federal health care programs for 5 years or more and civil money penalties.

In the pharmaceutical and medical device arena, there is a concern that physicians' financial relationships with pharmaceutical and medical device companies may improperly cause them to order or prescribe those products for their patients. If payments from such companies were made with the intent to induce the physician to prescribe their products, then the Anti-Kickback Statute may be violated. It is important to note that the recent health reform legislation made Anti-Kickback Statute violations easier for the government to prove. In particular, Congress amended the intent standard under the Anti-Kickback Statute to provide that a person need not have actual knowledge of the statute or specific intent for an Anti-Kickback Statute violation to occur.[5]

In recognition that many common, nonabusive arrangements could constitute technical violations of the law, the OIG has promulgated regulations under the Anti-Kickback Statute, commonly known as "safe harbors" (42 C.F.R. §1001.952). Among the activities that safe harbors potentially cover are certain investment interests, personal services and management contracts, discounts (also a statutory exception), and warranties. Only if an arrangement satisfies all the elements of each applicable safe harbor, then payments under those arrangements will be protected from criminal prosecution and civil penalties under the Anti-Kickback Statute. Arrangements that create more than one financial relationship may need to meet more than one safe harbor to immunize the entire arrangement. Failure to satisfy the applicable safe harbor(s) does not mean that an arrangement is *necessarily* illegal, but rather that it *may* be subject to scrutiny and prosecution.

Physicians who receive (or solicit) improper payments and manufacturers that make (or offer) such payments are both at risk under the Anti-Kickback Statute. Hospitals and other participants in improper financial relationships are similarly at risk. The federal government has increasingly focused on investigation and prosecution in this arena, resulting in a number of high-profile settlements. For example, on April 27, 2010, AstraZeneca paid $520 million to settle allegations of kickbacks to physicians in connection with illegally marketing drugs for unapproved uses. Prior settlements involving improper off-label marketing have been even larger, including Pfizer paying $2.3 billion in September 2009 and Eli Lilly settling for $1.4 billion in January 2009.

Although the most attention-getting fines have been imposed on manufacturers, physicians are also clearly in the government's prosecution cross-hairs. In the wake of the Eli Lilly settlement, Lew Morris, chief counsel to the OIG, was quoted as saying:

> What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it. . . . A common problem in illegal drug and device marketing cases is doctors' willingness to delude themselves into thinking that cash, lucrative trips, and other kickbacks do not affect them.[6]

State anti-kickback laws. State anti-kickback laws, although varying by individual state, tend to impose prohibitions similar to the federal statute. However, state laws typically cover referrals of business covered by any payor (or, in some cases, even if self-pay), whereas the federal statute applies only to items or services covered by a federal health care program. In addition, state statutes may or may not incorporate exceptions analogous to the federal safe harbors. For example, the Massachusetts anti-kickback statute is an "all payor" statute that does not incorporate the federal safe harbors and has no explicit intent standard.[7] Many state attorneys general (including in Massachusetts) have signaled a willingness to interpret their laws in a way that is harmonious with the federal Anti-Kickback Statute, but there is often no guarantee of such treatment.

State and federal sunshine laws

State laws. A number of states have adopted statutes imposing restrictions and requirements on manufacturers with respect to marketing and other activities. These requirements include (varying by state) items such as mandatory codes of conduct, "gift bans" or limitations, compliance requirements, and public disclosure. For example, Minnesota law prohibits giving anything of value to practitioners (subject to certain exceptions),[8] and California requires manufacturers to declare annual spending limits on gifts and promotional materials given to health care professionals.[9] Numerous states require disclosure of marketing expenditures.[10] Many also require manufacturers to adopt codes of conduct or compliance plan requirements, or both.[11] A state-by-state comparison of applicable requirements is presented in the Table.

An example of the scope of these statutes can be found in California's sunshine law. These provisions require pharmaceutical companies to adopt a comprehensive compliance program that is in accordance with both the OIG's compliance guidance and the PhRMA Code (each discussed above) and must reflect any updates to that guidance. The compliance program must explicitly establish a specific annual dollar limit on gifts, promotional materials, or items or activities to a physician or other health care professional in accordance with the PhRMA Code. Certain items (eg, drug samples, CME support, financial support for health educational scholarships and payments for legitimate consulting and other professional services arrange-

Table. State-by-state comparison[a]

State	*State code of conduct*	*Compliance requirement*	*Disclosure requirement*	*Public disclosure*	*Medical devices*
California		X			X
Maine			X		
Massachusetts	X	X	X	X	X
Minnesota			X	X	
Nevada		×			X
Vermont	X	X	X	X	X
West Virginia			X		

[a]As adapted from the Massachusetts Department of Public Health.

ments) are exempt if they conform to OIG guidance and the PhRMA Code. The pharmaceutical company must make its compliance program and an annual written declaration of compliance available to the public on the pharmaceutical company's Web site.

Notably, the medical societies in certain states (eg, Massachusetts and Vermont) supported enactment of these statutes. Still other states are considering or have recently considered creating similar statutes, including New York, Mississippi, New Mexico, Colorado, Illinois, Maryland, and Texas.

State sunshine statutes implicate a number of political "hot buttons." The mandatory disclosure that many of these laws entail may require manufacturers to divulge information regarding their marketing, research, and development initiatives that they consider to be proprietary information or confidential trade secrets. In addition, the mandated public disclosure of payments to physicians could have a chilling effect on physician participation in manufacturer-funded research because many physicians might fear negative reactions to their being listed as recipients of industry dollars.

Moreover, state limitations on manufacturer expenditures for items such as physician education and marketing seminars, as well as manufacturer spending cutbacks that may occur as a result of public disclosure requirements, could have an adverse impact on certain sectors of a state's economy, such as the convention and catering industries. Studies have shown that manufacturer payments with respect to Vermont physicians, hospitals, and universities significantly decreased in fiscal year 2008-2009 from the previous year. This trend has been reported on the national level as well.[12]

As an increasing number of states adopt such laws, other states may be likely to follow suit and perhaps even "compete" with respect to implementing the most stringent requirements and limitations. This is particularly true as state legislatures struggle with demonstrating a commitment to contain the growth of health care expenditures. The perception that physician prescribing practices result in increased health care costs may well result in added pressure to restrict payments and other expenditures that are believed to impact such practices. Given the recent federal provisions enacted as part of health reform, questions may also arise about how state and federal requirements will mesh.

Federal physician-payment sunshine law. The Patient Protection and Affordable Care Act (PPACA) of 2010 created the new §1128G of the Social Security Act at §6002. This provision does not ban or limit gifts or expenditures, but is focused instead on transparent reporting of transfers of value by manufacturers of drugs, devices, biologicals, and medical supplies to a physician or teaching hospital.

The PPACA requires annual "transparency reports" (beginning March 31, 2013) to the U.S. Department of Health and Human Services of such payments or other transfers of value, subject to certain limited exceptions. Reports will be publicly available on a searchable Internet Web site. Among the information these reports must include are the following items:

- recipient's name;
- date of payment;
- business address, specialty, and National Provider Identifier number;
- amount and form of the payment;
- description of the nature of the payment, including consulting, honoraria, gift, entertainment, food, travel, education, and research; and
- if the payment relates to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered item.

Delayed reporting is permitted for payments pursuant to product research or development agreements or clinical investigations. These payments must be reported on the *earlier* of (1) the date of U.S. Food and Drug Administration approval or clearance, or (2) 4 years after the date of the payment. Although these items must be reported, they will not be subject to public disclosure, pursuant to PPACA or the Freedom of Information Act.

Certain payments are exempt from reporting, including the following:

- De minimus payments (<$10 for any item, <$100 calendar year aggregate, both subject to a Consumer Price Index escalator)
- Educational materials that directly benefit patients

- Loans of devices for trial period evaluations (90 days)
- Items under contractual warranty
- Discounts and rebates
- In-kind items used for charity care
- Expert witness fees
- Samples (not for sale)[13]

PPACA §6002 also requires disclosure of physician ownership of manufacturers and group purchasing organizations other than in publicly traded companies. Such disclosures must include the dollar amount invested, the value of that investment, and any payments or transfers of value to the physician. The same disclosure requirements apply to ownership held by "immediate family members" of physicians.[14]

PPACA provides for preemption, effective January 1, 2012, of state laws that require manufacturers to report the same "type of information" regarding transfers of value as PPACA does. No preemption exists for other types of disclosures or entities other than the manufacturers covered by PPACA. In addition, it also seems that state "gift bans" (such as in Massachusetts and Vermont) enacted with the local sunshine laws will not be preempted. Because state laws that require disclosures beyond PPACA requirements will remain in full force, a patchwork quilt of disclosure requirements will remain in effect.

PPACA also provides for civil money penalties for noncompliance with reporting requirements. If the violation is not "knowing," penalties range from $1,000 to $10,000 *for each payment* not reported (up to a maximum of $150,000 for any one annual report). For "knowing" failures to report, penalties range from $10,000 to $100,000 *for each unreported payment* (up to a maximum of $1 million for any one annual report).

Most of the laws addressed in this article target manufacturers. However, physicians still need to understand certain key issues, including (1) whether their state prohibits certain types of financial relationships, (2) what information about their business relationships will be made public, and (3) the limits of what is permissible under the enforcement authorities, including the federal and state anti-kickback laws.

Although public disclosure may sound innocuous, the lobbying regarding sunshine laws on the federal and state levels often focused on the concern that physicians' fears of being listed on public Web sites would be a "Scarlet Letter," causing patients to doubt that their physicians' loyalties were pure. An overreaction to this fear may result in physicians refusing to participate in research, education, and consulting. Such a reaction would result in an overall loss to the expansion of knowledge, innovation, and education in the pharmaceutical field. It may be too early to know if such negative effects will occur because little persuasive evidence exists at this point. However, anecdotal and experiential evidence supports the conclusion that these laws are causing delays in the development of new arrangements and relationships between physicians and manufacturers of drugs and devices.

Transparency is the word of the day. There is a perception that more transparency will both reduce cost and improve quality. The impact on innovation and the advancement of research and development is far from certain. For the foreseeable future, however, physicians and their colleagues in industry will need to adapt to these new requirements on both state and federal levels.

REFERENCES AND FOOTNOTES

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4. Pharmaceutical Research and Manufacturers of America. Code on interactions with health care professionals. http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf.
5. 42 U.S.C. §1320a-7b(h).
6. Harris G. Prosecutors plan crackdown on doctors who accept kickbacks. NY Times March 4, 2009. Section A. p. 14.
7. See M.G.L. c. 175H § 3.
8. Minnesota Statutes §151.461 and 151.47(f).
9. California Health & Safety Code §119402.
10. Mass General Laws ch. 111N; Vermont tit. 18 §4632; West Virginia Code §16-29h-8; Maine Revised Statutes tit. 22 §§2698-A; District of Columbia Code Ann. §§48-833.01, et seq.
11. Nevada Statutes §639.570.
12. American Medical Association's on-line Amednews, Nov. 29, 2010. http://www.ama-assn.org/amednews/2010/11/29/prl11129.htm.
13. Section 6004 of PPACA requires disclosure of drug samples.
14. "Immediate family member" is defined in the same manner as that term is defined under the Stark law. See 42 C.F.R. §411.351.

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