

Massachusetts Enacts Pharmaceutical and Medical Device Disclosure Law

August 19, 2008

Following the lead of several other states, on August 10, 2008, the Commonwealth of Massachusetts enacted a state marketing disclosure law that requires pharmaceutical and medical device manufacturers to report information related to marketing activities with physicians and other health care providers.¹ An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care² (the Act) is part of a broad effort to contain health care costs and increase patient safety in the Commonwealth. The Act becomes effective January 1, 2009.

Section 14 of the Act requires pharmaceutical and medical device manufacturers³ that employ a person to sell or market prescription drugs or medical devices in the Commonwealth to “adopt and comply” with the Department of Public Health’s (the Department’s) “marketing code of conduct” and to report annually gifts and other economic benefits with a “value of at least \$50” given to providers and entities authorized to prescribe, dispense or purchase prescription drugs or medical devices in the Commonwealth.

The Act’s monetary reporting and marketing code of conduct requirements are similar to existing laws in other states, with certain key distinctions.⁴ Importantly, there are aspects of the Department’s marketing code of conduct that are more restrictive than the current Pharmaceutical Research and Manufactures of America Code on Interactions with Healthcare Professionals⁵ (PhRMA Code) and the Advanced Medical Technology Association’s Code on Interactions with Healthcare Professionals⁶ (AdvaMed Code). In addition, while pharmaceutical manufacturers have been reporting marketing costs to the states for some time,⁷ Massachusetts is the first state to require medical device manufacturers to report information regarding gifts and other economic benefits given to prescribers and purchasers of medical devices in the state.⁸

A summary and analysis of the Act, as well as the distinctions from industry guidance and other state marketing disclosure laws, is discussed below.

Marketing Code of Conduct

The Act requires the Department to promulgate regulations to develop a comprehensive pharmaceutical and medical device marketing code of conduct which is “no less restrictive” than the most recent version of the PhRMA Code and the AdvaMed

¹ Massachusetts is the eighth state to enact a marketing disclosure law. The other states with marketing disclosure laws are: California, the District of Columbia, Maine, Minnesota, Nevada, Vermont and West Virginia. *See generally*, Cal. Health & Safety Code §§ 119400 – 119402; D.C. Code Ann. §§ 48-833.01 – 48-833.09; Maine Rev. Stat. Ann. tit. 22, § 2698-A; Minn. Stat. §§ 151.461, 151.47; Nev. Rev. Stat. § 639.570; Vt. Stat. Ann. tit. 22, § 4632; W. Va. Code § 5A-3C-13.

² To be codified as Chapter 111N of the Massachusetts General Acts, Pharmaceutical and Medical Device Manufacturer Conduct (hereinafter Massachusetts Disclosure Law).

³ The Act defines a pharmaceutical or medical device manufacturing company as “any entity that participates in a Commonwealth health care program and which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs or medical devices, either directly or indirectly . . . or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that ‘pharmaceutical or medical device manufacturing company’ shall not include a wholesale drug distributor licensed under section 36A of chapter 112 or a retail pharmacist registered under section 37 of said chapter 112.”

⁴ *See, e.g.*, Vt. Stat. Ann. tit. 18 § 4632(a)(1) (requiring annual reporting of the value, nature and purpose of any gift, payment or other economic benefit given to prescribers or purchasers of prescription drugs in the state); Nev. Rev. Stat. § 639.570(1)-(2) (requiring all wholesalers and manufacturers to adopt a written marketing code of conduct and to annually submit information related to the company’s code of conduct, training and investigation policies).

⁵ Available at http://www.phrma.org/code_on_interactions_with_healthcare_professionals/. The recent revisions to the PhRMA Code become effective January 1, 2009.

⁶ Available at <http://www.advamed.org/MemberPortal/About/code/>.

⁷ For example, Minnesota’s marketing disclosure law has been in effect since the early 1990s. *See* Minn. Stat. § 151.47; The Vermont disclosure law was enacted in 2002 and the first disclosure report was due in early 2004. *See* Vt. Stat. tit. 18, § 4632.

⁸ Two states, California and Nevada, have marketing disclosure requirements that apply to device manufacturers; however, neither requires reporting of marketing gifts or other economic benefits. *See* Cal. Health & Safety Code § 19402(a), (b) (requiring development and publication of a Comprehensive Compliance Plan); Nev. Rev. Stat. § 639.570(2) (requiring annual submission of a company’s marketing code of conduct and other information regarding training, and investigation policies).

Code. The Commonwealth's marketing code of conduct requires the inclusion of specific prohibitions and permissible activities as set forth in the Act, including the following:

PROHIBITED ACTIVITIES

- Meals that are (i) provided outside of a practitioner's office or hospital setting, (ii) offered without an accompanying information presentation or without the company's marketing agent being present, (iii) part of an entertainment event or (iv) provided to a practitioner's spouse or other guest
- Providing entertainment or recreational items of any value to a health care practitioner who is not a salaried employee of company (this includes, for example, the provision of sports or theatre tickets or vacations)
- Sponsoring continuing medical education (CME) that does not meet the Accreditation Council for Continuing Medical Education Standards For Commercial Support (ACCME), or that provides payment directly to a health care practitioner
- Meals provided directly at any CME event, third-party scientific or educational conference or professional meeting
- Paying for travel, lodging or other personal expenses associated with a non-faculty health care practitioner's attendance at a (i) CME event, (ii) third-party scientific or education conference, or (iii) professional meeting, except in circumstances as determined by the Department
- Compensating a health care practitioner for (i) time spent at a CME event, (ii) third-party scientific or education conference, or (iii) professional meetings
- Compensating a health care practitioner for anything other than the provision of *bona fide* services
- Providing grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items to a health care practitioner in exchange for prescribing, or a commitment to continue prescribing, prescription drugs or using medical devices⁹

PERMISSIBLE ACTIVITIES

- Distribution of peer-reviewed academic, scientific or clinical publications and the purchase of advertising in such journals or publications
- Compensation for "substantial" professional or consulting services in connection with a "genuine research project" or clinical trial (the Act does not define what "substantial" and "genuine" mean in this context)
- Prescription drugs provided solely and exclusively for a practitioner's patients
- Payment of reasonable expenses necessary for technical training on the use of a medical device, so long as the expense is part of the vendor's purchase contract for the device¹⁰

Marketing Code Adoption and Reporting

Much like the current Nevada disclosure law, pharmaceutical and medical device manufacturers must "adopt and comply" with the Department's marketing code of conduct. Also like the Nevada law, manufacturers are required to (i) adopt an employee training program, (ii) adopt policies and procedures to investigate noncompliance with the marketing code of conduct, (iii)

⁹ Massachusetts Disclosure Law § 2.

¹⁰ *Id.*

conduct annual compliance audits and (iv) identify a compliance officer responsible for operating and monitoring the Code.¹¹ Information regarding these requirements must be submitted to the Department on an annual basis, and there must be a certification that the company has conducted an annual audit and is in compliance with the marketing code of conduct.¹²

Of note is the fact that the Act does not inform or instruct how a manufacturer is to “adopt” the Department’s marketing code of conduct, nor does it provide specific requirements for conducting the annual audit. These issues may be addressed when the Department develops its implementing regulations.

Disclosure of Gifts and Payments to Providers and Purchasers of Prescription Drugs and Devices

The Act requires annual reporting, by July 1, of the value, nature, purpose and recipient of “any fee, payment, subsidy or other economic benefit with a value of at least \$50” provided directly or through an agent to any “physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner, or other person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs in the commonwealth.”¹³ The disclosure must be accompanied by a fee, which will be determined by the Department.

While these disclosure provisions are similar to what is currently required in other states, the Act is written very broadly and potentially encompasses reporting of any gift, fee, payment or other economic benefit provided to health care professionals or entities, not just those connected with marketing or promotional activities. By contrast, Vermont’s marketing disclosure law requires manufacturers to report the value, nature, purpose and recipient of any gift, fee or other economic benefit “*provided in connection with detailing, promotional or other marketing activities . . .*”¹⁴

Equally important, unlike most other state marketing disclosure laws, the Act provides that all disclosed data will be made publicly available on the Department’s web site and provides no protection for trade secrets or other confidential information. Thus the name of every health care provider or entity that receives a reportable gift or economic benefit from a pharmaceutical or medical device manufacturer will be publicly available.¹⁵ To date, only one other state, Minnesota, makes this type of detailed information publicly available.¹⁶

Development of Regulations

Many of the Act’s requirements have raised a high level of concern within the industry. The Department could take measures to alleviate or clarify some of the Act’s more draconian provisions when the implementing regulations are developed. In this regard, Governor Patrick recently stated that he is “confident the Department of Public Health, pursuant to its regulatory authority, will safeguard the confidentiality of companies’ trade secrets and proprietary information and protect against roadblocks to medical research or the education of health care providers.”¹⁷

Enforcement

The Act prohibits manufacturers from “knowingly and willfully” violating the Department’s marketing code of conduct.¹⁸ Violations are punishable by a fine of up to \$5,000 per offense.¹⁹ The Act will be enforced by the Attorney General, the district

¹¹ Massachusetts Disclosure Law § 4.

¹² *Id.* § 5.

¹³ *Id.* § 6(1).

¹⁴ Vt. Stat. Ann. tit. 18, § 4632(a)(1) (emphasis added).

¹⁵ Massachusetts Disclosure Law § 6(2).

¹⁶ *See* Minn. Stat. § 151.47(f). Manufacturer marketing disclosure reports are publicly available on the Minnesota Board of Pharmacy’s web page.

¹⁷ BNA Health Care Daily Report, Vol. 13, No. 155 (Aug. 12, 2008).

¹⁸ Massachusetts Disclosure Law § 3.

¹⁹ *Id.* § 7.

attorneys with jurisdiction over a violation or the Department.²⁰ The Act also requires the Department to report to the Attorney General any payment, entertainment, meal or other activity provided in violation of the marketing code of conduct.²¹

The Massachusetts marketing disclosure law is the first such law to include a “scienter” requirement.²² Equally significant is that the terms “knowingly and willfully” are not defined. As such, it remains an open question as to the level of scienter that might be applied to alleged violations. The terms “knowingly and willfully” are commonly found in criminal statutes, such as the federal anti-kickback statute,²³ although notably, violations of the Massachusetts marketing disclosure law are civil offenses, punishable only by a monetary fine. Several sections of the Massachusetts Medicaid laws prohibit “knowing and willful” conduct; however there is little published case law interpreting these provisions.²⁴ It is conceivable, however, that the Massachusetts Attorney General may look to the state’s Medicaid laws for guidance in enforcing the marketing disclosure law.

Massachusetts also has a state false claims act, which, like the federal False Claims Act, prohibits “knowingly” presenting or causing to be presented of false or fraudulent claims for payment from the Commonwealth.²⁵ The Massachusetts false claims statute defines “knowing and knowingly” as “possessing actual knowledge of relevant information, acting with deliberate ignorance of the truth or falsity of the information or acting in reckless disregard of the truth or falsity of the information and no proof of specific intent to defraud is required.”²⁶ The “knowing and knowingly” standards in the Massachusetts false claims act could also be taken into consideration in enforcing the marketing disclosure law.

To date, there has been little, if any, enforcement action among the various states with regard to marketing disclosure laws.²⁷ The undefined scienter standard in the Act will present additional compliance challenges because, absent further guidance, it will be difficult for pharmaceutical and medical device manufacturers to envisage the standards of intent that may apply to their conduct. In this respect, every pharmaceutical or medical device company that employs sales representatives in the Commonwealth should consider actively participating in the forthcoming regulatory proceedings to encourage clarification and guidance to this otherwise remarkably broad statute.

Comparison to the PhRMA and AdvaMed Code Requirements

Certain provisions of the PhRMA and AdvaMed Codes are less restrictive than the required prohibitions in the Department’s Code of Conduct. Specifically, both the PhRMA Code and the AdvaMed code have more liberal provisions regarding industry

²⁰ *Id.* § 7.

²¹ *Id.* § 6(3).

²² *See, e.g.*, Vt. Stat. Ann. tit. 18, § 4632(b) (manufacturers that fail to disclose marketing costs may be sued for injunctive relief, costs and attorneys’ fees and assessed a civil penalty of not more than \$10,000 per violation.); D.C. Code Ann. § 48-833.06; D.C. Mun. Regs. Tit. 22, § 1804 (manufacturers that fail to report marketing costs may be fined \$1,000 plus costs and attorneys’ fees. Violations of the marketing disclosure rules may be enforced by a civil action brought by the D.C. Attorney General).

²³ The federal anti-kickback statute prohibits “knowingly and willfully” soliciting and receiving in exchange for, or to induce, the referral of patients for, or the purchase, lease, order or recommendation of, any facility, item or service for which payment may be made by Medicare, Medicaid or other Federal Health Care Programs. 42 U.S.C. § 1320a-7b(b).

²⁴ *See* Mass. Gen. Laws ch. 118E, § 43 (prohibiting knowing or willful solicitation or receipt of any gift or other consideration to guarantee or expedite admission of a Medicaid recipient to a long term care facility or nursing home); Mass. Gen. Laws, ch. 118 § 4 (prohibiting, among other things, persons who furnish Medicaid items or services from knowingly or willfully making or causing to be made any false statement or representation of material fact in an application for payment under the Medicaid program).

²⁵ Mass. Gen. Laws ch. 12, § 5B. The federal false claims act prohibits knowingly presenting or causing to be presented to the United States Government false or fraudulent claims for payment. *See* 31 U.S.C. § 3729(a).

²⁶ *Id.* § 5A(a).

²⁷ To date, Vermont is the only state that has taken specific steps towards enforcing violations of its marketing disclosure statute. In the past several years, the state has initiated actions against five pharmaceutical manufacturing companies for failing to file timely marketing disclosure reports. The Vermont Attorney General has required each of these companies to enter into an “Assurance of Discontinuance,” which obligates the company to establish procedures to ensure that future marketing disclosures are filed in a timely manner and provides for a \$10,000 penalty in the event of a future failure to file by the statutory deadline. *See* 2007 and 2008 Pharmaceutical Marketing Disclosures, Report of Vermont Attorney General, William Sorrell, *available at* <http://www.atg.state.vt.us/display.php?smod=151>.

support for CME. For example, the Act includes a flat prohibition against sponsoring CME that does not meet the ACCME standards, whereas both the PhRMA Code and the AdvaMed Code encourage compliance with industry standards for commercial support.²⁸ Similarly, meals provided outside of the practitioner's office without an accompanying informational presentation are prohibited under the Code of Conduct while the PhRMA Code permits manufacturers to provide meals outside of a practitioner's office, so long as they are not provided by the field sales representative or his or her immediate manager,²⁹ and the AdvaMed Code places no restrictions on the location of meals.³⁰

Given important distinctions such as these, it will be crucial for pharmaceutical and medical device manufacturers to ensure their sales representatives and field managers are aware of the unique requirements for marketing and promotional activities in Massachusetts.

What Now? State-by-State Disclosure Requirements or a Uniform Federal Standard?

In addition to the current state marketing disclosure requirements, U.S. Congress is also now considering legislation that would impose disclosure requirements for pharmaceutical and medical device manufacturers on a national basis.³¹ If enacted, the federal disclosure laws would preempt current state reporting requirements.³² Perhaps the possible silver lining of a federal requirement would be the elimination of different and potentially conflicting requirements adopted by the various states. But, until such federal legislation is enacted, pharmaceutical and device manufacturers must be alert to and cognizant of the increasing number of state marketing disclosure laws. Unfortunately, as each new state adopts a disclosure law, compliance becomes ever more complicated.

²⁸ See PhRMA Code § 4 (providing that manufacturers "should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit the CME"); AdvaMed Code § 3 (stating that members may provide a grant directly to a conference sponsor or to a training institution and that such grants "should be consistent with relevant guidelines established by professional societies or organizations").

²⁹ See PhRMA Code, FAQ #12.

³⁰ See AdvaMed Code § 4.

³¹ See Physician Payments Sunshine Act of 2008, H.R. 5605; Physician Payments Sunshine Act of 2007, S. 2029; Drug and Medical Device Company Gift Disclosure Act, H.R. 3023.

³² See Press Release, *Senators Praise Growing Support for Transparency in Drug Industry Payments to Physicians*, United States Senate, Special Committee on Aging, (May 13, 2008), available at <http://aging.senate.gov/record.cfm?id=297721>.

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