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Advertising and Marketing

Medical Device Manufacturers and Distributors in State Regulators' Crosshairs

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Recent activity in various states has put medical device manufacturers' and distributors' marketing activities squarely in the crosshairs of state regulators. The most recent activity has been in Massachusetts, where passage of Senate Bill 2863 imposes a variety of compliance requirements and reporting obligations on medical device manufacturers and distributors (2 MELR 527, 8/13/08).

Over the past 10 years, state regulations have increasingly targeted the pharmaceutical industry, with a number of states, including Minnesota, Vermont, West Virginia and Maine, passing compliance and reporting obligations that apply to the sales of prescription drugs. However, new laws in three of the states—Massachusetts, California, and Nevada—also apply to medical device manufacturers and distributors. These companies are encouraged to closely monitor compliance with these new laws.

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I. Massachusetts

The Commonwealth of Massachusetts recently passed Senate Bill 2863¹, which was signed into law in August 2008 and takes effect on Jan. 1, 2009. SB 2863 applies to any entity that engages in the marketing or sale of drugs or devices in the Commonwealth of Massachusetts. The bill requires the Department of Public Health (the "Department") to develop a comprehensive marketing Code of Conduct that is "no less restrictive" than the AdvaMed Code of Ethics (the "AdvaMed Code") from the Advanced Medical Technology Association.² Once the Department adopts the Code of Conduct, all manufacturers and distributors that are subject to the law must comply with it, properly train employees on the Code of Conduct, adopt policies and procedures to encourage compliance with the Code of Conduct, investigate noncompliance with the Code of Conduct, conduct annual compliance audits, and appoint a compliance officer responsible for overseeing compliance with the Code of Conduct. Each manufacturer and distributor is required to submit an annual certification of compliance with the Code of Conduct that will be promulgated by the Department. Since the law was recently passed, there has not yet been promulgation of

¹ S.B. 2863, 2007-2008 Leg., 185th Sess. (Mass. 2008).

² The AdvaMed Code is available at <http://www.advamed.org/NR/rdonlyres/D96644D9-7FA9-4DCC-B944-F00A8351FE57/0/AdvaMedCodeofEthicswithFAQ.pdf>.

the Code of Conduct or the form of required annual certification by the Department. It is important to note that SB 2863 would require compliance with the Department's promulgated Code of Conduct even if it contains a standard that is different from a manufacturer's existing compliance plan or code of conduct.

In addition to requiring compliance with the Code of Conduct, the medical device manufacturers subject to the law must annually report "any fee, payment, subsidy or other economic value with a value of at least \$50.00" that is paid to any physician, hospital, nursing home, pharmacist, benefit plan administrator, practitioner, or other person in the Commonwealth authorized to prescribe, dispense or purchase a prescription device.

It is important to note that this fee reporting obligation is not limited to marketing expenses alone, but could potentially include consulting, advisory board and other fees that are paid by a medical device manufacturer to one of the covered parties. This information will be reported to the Department on an annual basis, and the Department is required to publish the data on its Web site. This raises concerns whether certain trade secrets or other confidential information will be protected by this public disclosure. The bill instructs the Department to promulgate rules and structure the disclosures in order to protect such confidential information.

II. California

California has had a compliance program requirement for the past several years that was initially promulgated pursuant to California Health & Safety Code Section 119402.³ The California compliance program requirement applies to any manufacturer of "drugs," and the definition of drugs includes a manufacturer of a prescription device. Each manufacturer that is subject to the law must adopt a Comprehensive Compliance Program ("CCP") that is in accordance with the Office of the Inspector General ("OIG") compliance guidelines for pharmaceutical manufacturers. Additionally, the California compliance program requires compliance with the PhRMA Code from the industry group Pharmaceutical Research and Manufacturers of America.

This raises an interesting issue for medical device manufacturers, to which much of the OIG's compliance guidelines may not be directly applicable and which generally follow the medical device-specific AdvaMed Code instead of the PhRMA Code.

The California CCP law requires that each company establish a specific dollar limit on gifts, promotional materials, items and services provided to health care professionals. The law does not specify an upper limit, but each manufacturer must self-regulate and designate its own limit for these types of payments.

³ Cal. Health & Safety Code § 119402 (2005).

The California law does not require reporting to the state of California but does require each manufacturer to post their CCP to their Web site along with a declaration of compliance and a toll-free telephone number for inquiries. Notably, the California law does not apply to medical device distributors and does not designate any enforcement authority or penalties for non-compliance.

III. Nevada

A recently promulgated Nevada statute also applies to medical device manufacturers and wholesale distributors of devices. Nevada Revised Statute Section 639.570 requires a medical device manufacturer or wholesale distributor to adopt the AdvaMed Code or a modified form of the AdvaMed Code as its compliance plan.⁴ Additionally, the statute requires appointment of a compliance officer, performance of annual compliance audits, the implementation of a training program, and the adoption of policies and procedures intended to facilitate compliance with the AdvaMed Code or applicable compliance plan.

Manufacturers and wholesale distributors that are subject to the law must submit an annual statement to the Nevada Board of Pharmacy that includes a statement that they comply with its compliance plan, a description of any differences between their compliance plan and the AdvaMed Code, a description of any training done on the compliance plan, and a description of auditing that the manufacturer or wholesale distributor has conducted. This annual submission must be provided on a Nevada Board of Pharmacy form and is due by June 1 of each year. The form can be found at the Nevada Board of Pharmacy's Web site at <http://bop.nv.gov/wholesalers-EPP.htm>.

The first reporting period ended June 30, 2008 and manufacturers or wholesale distributors that have not yet submitted should contact the Board of Pharmacy to arrange for a late submission. At this point the Board of Pharmacy has indicated that late submissions may be submitted without penalty.

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These state laws are part of a trend of increasing state regulation of device manufacturers and distributors. In addition, a number of proposed laws have been introduced into Congress that would potentially preempt these state laws.⁵ However, at this point, none of these federal initiatives have succeeded, and manufacturers and distributors will be forced to carefully monitor their compliance with this patchwork of state regulation.

⁴ Nev. Rev. Stat. § 639.570 (2007).

⁵ See, e.g., Physician Payments Sunshine Act, S. 2029, 110th Cong. (2007).