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MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH PUBLISHES FINAL REGULATIONS ON PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT

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On March 11, 2009, the Massachusetts Department of Public Health ("DPH") published final regulations to implement Chapter 111N of the General Laws of Massachusetts, which was signed into law on August 10, 2008. The final regulations are intended to "ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners."[1] According to the DPH, these final regulations are ***more comprehensive*** than comparable health care manufacturer conduct laws and regulations adopted in several other states.[2]

The final regulations impose two requirements on pharmaceutical, biologic, and medical device manufacturers. First, by **July 1, 2009**, each manufacturer must have adopted and implemented a code of conduct that applies to its marketing activities. Second, beginning on **July 1, 2010**, each manufacturer must submit reports to the DPH detailing certain payments or other economic benefits to health care practitioners licensed in Massachusetts on a transaction-by-transaction basis, which would be included in a searchable database on the DPH public Website.

This Alert provides an overview of the final regulations. A description of the underlying act is available at http://www.ebglaw.com/showclientalert.aspx?Show=8935http://www.ebglaw.com/showclientalert.aspx?Show=8935, and a summary of the draft regulations is available at: http://www.ebglaw.com/showclientalert.aspx?Show=9522http://www.ebglaw.com/showclientalert.aspx?Show=9522.

Manufacturer Obligations

Under the final regulations, all pharmaceutical, biological, and medical device manufacturers doing business in Massachusetts that employ or contract with any marketing or detailing agent must "adopt" a marketing code of conduct by July 1, 2009 that meets DPH specifications.[3] These specifications are described in more detail below.

The final regulations abandoned the requirement contained in the draft regulations that

manufacturers adopt a DPH prescribed code of conduct, but retained the requirement that manufacturers certify that the company has adopted a marketing code of conduct, and that manufacturers submit (1) descriptions of their compliance training programs for appropriate employees, (2) contact information for their compliance officers responsible for implementing and monitoring the code of conduct, and (3) actual policies and procedures for investigating and responding to alleged non-compliance, including appropriate reports of violations to state agencies.[4] In addition, all manufacturers must conduct annual audits to monitor compliance with the final regulations; however, the final regulations do not include further guidance as to the scope or standards to be used for the annual audit.

The obligations that are addressed in the final regulations regarding other types of payments to health care practitioners, including *bona fide* consulting services, meals, support of continuing medical education and professional meetings, distribution of peer-reviewed scientific or clinical information, and certain coverage, coding, and reimbursement information did not change significantly from the language in the draft regulations.[5]

The final regulations also retain the proposed language governing agreements between health care practitioners and pharmaceutical manufacturers for consulting or speaking services. Specifically, manufacturers may compensate health care practitioners for speaking at a professional or scientific meeting or continuing medical education event sponsored by a third party, as long as the compensation is reasonable, based on the fair market value of the services, and complies with the policies of the third-party sponsor.[6] Further, as in the draft regulations, the final regulations state that if the practitioner also is a member of a committee that either sets clinical guidelines or makes formulary decisions, the regulations require that the agreement stipulate that the practitioner must disclose the existence of the agreement to the respective committee.[7]

Reporting Obligations

Beginning on July 1, 2010, all manufacturers must submit an annual report to the DPH disclosing the nature, purpose, and value of any "fee, payment, subsidy, or other economic benefit with a value of at least $50" to a health care practitioner in connection with sales and marketing, along with a certification that the data is accurate to the best of the company's knowledge.[8] The term "sales and marketing" includes all advertising or promotion intended to influence the sale or market share of a drug, biologic, or device, including any comparisons with other products and training and educational activities sponsored by a manufacturer's marketing department unless expressly exempted as discussed below.

The final regulations clarify that the data must be disclosed on an individual transaction basis, and may not be aggregated. Each manufacturer will be charged a $2000 filing fee. The DPH declined to allow for a sliding scale for the fees.

Exemptions From Reporting

As set forth above, the definition of reportable sales and marketing activities is broad. In response to comments received from industry and consumer advocacy groups, the DPH clarified and revised several important definitions that define the scope of a manufacturer's reporting obligations. Specifically, the final regulations include several revisions to the definitions that were included in the proposed regulations and provide exceptions from certain reporting requirements.

Clinical Trials: In the final regulations, the DPH distinguished clinical trials that evaluate the safety or effectiveness of a drug, biologic, or device for FDA filing purposes or examines the comparative effectiveness of an item from trials that are sponsored by the marketing department of a manufacturer and are intended to promote a product, commonly known as "seeding trials". Only the latter category would be subject to the reporting requirements. The final regulations also expressly exempt from reporting all trials that must be posted on http://www.clinicaltrials.gov/ pursuant to the Food and Drug Administration Amendments Act of 2007. [9]

Discounts and Price Concessions: The DPH acknowledged that the definition of "sales and marketing activities" could not include information on individual discounts, rebates, or price concessions without creating concerns about potential restraints of trade in violation of Federal Trade Commission laws, or that might lead to increased costs to consumers and providers if manufacturers were reluctant to offer such concessions due to disclosure and reporting requirements. In the final regulations, the DPH will not require the reporting of this data.

Drugs Furnished for Use By Patients and Charity Care Donations: The reporting obligations under the final regulations also will exclude two new categories of items. First, manufacturers will not be required to report the furnishing of prescription drugs to a health care provider or practitioner for the exclusive use by patients.

Similarly, no reporting will be required for any direct financial support of a non-profit 501(c)(3) entity or the in-kind donation of drugs, biologics, or devices for charity care purposes.[10] However, under the final regulations this exception does not apply to donations made in exchange for prescribing, disbursing, or using a particular drug, biologic, or device, or for making a similar commitment in the future. Disclosure also is required if, in lieu of a direct payment to a health care practitioner, the manufacturer made a charitable donation to an institution where the practitioner is employed or affiliated, or if the manufacturer sponsored a continuing medical education program or conference at the practitioner's institution.[11]

Training and Demonstration Devices: The final regulations add a new provision permitting a manufacturer to supply a health care practitioner with a "reasonable quantity" of a device to allow the practitioner to "assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future."[12] This language was added in response to comments from the medical device industry that practitioners and patients can benefit when the practitioner is trained appropriately in the use of a new device, or can use a new device on a sample basis.

The final regulations contain a separate provision that allows manufacturers to incur "reasonable expenses" for the training of health care practitioners in the use of medical devices if there is a written agreement between the manufacturer or vendor and the practitioner that sets out these expenses.[13]

Enforcement and Penalties for Non-Compliance

Any person who "knowingly and willfully" violates the final regulations is subject to a penalty of up to $5000 per transaction or event. The final regulations removed the language from the draft regulations that would have made any violation of the law a strict liability offense. Further, the final regulations include an opportunity for manufacturers to contest proposed fines and to seek judicial review of any final agency actions.[14] The final regulations also include a non-retaliation provision prohibiting a manufacturer from taking any adverse action against an

employee, applicant, or health practitioner who takes any action related to enforcement.[15]

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ENDNOTES:

[1] 105 CMR 970.001.
[2] To date, California, the District of Columbia, Maine, Minnesota, Nevada, Vermont, and West Virginia have adopted some form of compliance or manufacturer disclosure laws.
[3] 105 CMR 970.005(1)(a).
[4] 105 CMR 970.005(1).
[5] The details for each type of payment or compensation are described in EBG's December 19, 2008 Client Alert, which is available at: http://www.ebglaw.com/showclientalert.aspx?Show=9522. Generally, the regulations require a written agreement for consulting services. Further, meals may be furnished to health care practitioners if they are modest, infrequent, and furnished in an office or hospital setting. Additionally, support of medical education or professional meetings may be made through a third-party sponsor. No direct financial support may be offered to a health care practitioner in connection with such events except that a manufacturer may pay for the travel and other reasonable compensation to program faculty in accordance with the third-party sponsor's standards.
[6] 105 CMR 970.007(4)(a).
[7] 105 CMR 970.005(3). This subsection refers to "pharmaceutical manufacturing companies." It is unclear from the plain language of the final regulations whether it also applies to medical device manufacturers.
[8] 105 CMR 970.009.
[9] 105 CMR 970.004. The reporting requirements for www.clinicaltrials.gov are set out in 42 U.S.C. § 282(i).
[10] 105 CMR 970.008(2)(j).
[11] *See* March 11, 2009 Memorandum from Melissa J. Lopes, Deputy General Counsel, Massachusetts Department of Public Health, to Massachusetts Public Health Council at 10; *available at:* http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2C+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_pharmacy_medical_devices&csid=Eeohhs2
[12] 105 CMR 970.008(2)(f).
[13] 105 CMR 970.008(2)(b).
[14] The final regulations state that the affected party shall receive notice and an "informal opportunity to dispute the issuance of the fine in person or by counsel" but they do not refer to any established procedure or incorporate any other hearing procedures by reference.
[15] 105 CMR 970.010 and 970.011.