

HEALTH CARE PRACTICE GROUP ADVISORY

Massachusetts Approves Regulations Governing Pharmaceutical and Medical Device Industries

Introduction

On March 11, 2009, the Massachusetts Public Health Council approved final regulations¹ drafted by the Massachusetts Department of Public Health (“DPH”), implementing a recently enacted law governing gift-giving and other sales and marketing practices of pharmaceutical and medical device manufacturers. The final regulations place Massachusetts at the forefront nationally in monitoring the relationship between pharmaceutical and medical device manufacturers and health care practitioners, and will be the strictest in the nation in mandating reporting and public disclosure of certain fees, payments and other compensation provided by pharmaceutical and medical device manufacturers to health care practitioners. The final regulations also contain gift prohibitions and restrictions on meals provided by pharmaceutical and medical device manufacturers to health care practitioners.

Background

On August 10, 2008, Governor Patrick signed into law Chapter 305 of the Acts of 2008, “An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare”. Section 14 of this Act added a new chapter to the General Laws, Chapter 111N, entitled “Pharmaceutical and Medical Device Manufacturer Conduct”. With a focus on preventing undue influence in the relationship between health care practitioners and pharmaceutical and medical device manufacturers, Chapter 111N requires that manufacturers adopt and comply with a Marketing Code of Conduct, establish compliance and training programs pursuant to the Marketing Code of Conduct, and disclose marketing payments made by pharmaceutical or medical device manufacturers to health care practitioners. Chapter 111N calls for DPH to promulgate and implement regulations adopting a standard Marketing Code of Conduct for all pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs and medical devices in Massachusetts, and to establish a public database of payments to health care practitioners by pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs in Massachusetts, as well as to set fees in conjunction with the disclosure requirements of the Act.

¹ 105 CMR 970.000, *et seq.*, available online at:
http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_manufacturer_conduct_regs.doc.

Final Regulations

The final regulations set out what is and is not permissible with respect to marketing prescription drugs or medical devices in Massachusetts, outline the statutory compliance directives, and interpret the contours of the disclosure requirements for pharmaceutical and medical device manufacturers. With the promulgation of the final regulations, Massachusetts is:

- the only state to require that companies adopt and comply with a state-authored Marketing Code of Conduct;
- the only state to require disclosure of payments to health care practitioners by both pharmaceutical and medical device companies;
- the state with the broadest definition of “sales and marketing”²; and
- one of only two states to make disclosure data part of the public record.

The final regulations impose an ongoing duty of good faith compliance on every person subject to the regulations. Specifically, the final regulations require pharmaceutical or medical device manufacturers to:

- adopt and comply with the most recent Marketing Code of Conduct as adopted by DPH;
- adopt and submit to DPH a description of a training program designed to ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of the Marketing Code of Conduct, general science, and product-specific information;
- certify to DPH that they are in compliance with the Marketing Code of Conduct;
- adopt and submit to DPH policies and procedures for investigating and taking corrective action in response to instances of non-compliance with the Marketing Code of Conduct; and

² Sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose.

Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a covered recipient except as follows: sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or “new use” or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan’s formulary. 105 CMR 970.004.

- submit to DPH the name, title, address, telephone number, and electronic mail address of the compliance officer it has identified as responsible for operating, monitoring, and enforcing the Marketing Code of Conduct.

Pharmaceutical and medical device manufacturers must also certify to DPH that they have performed annual audits to ensure compliance with the Marketing Code of Conduct.

What is Prohibited?

The final regulations prohibit, among other things, a pharmaceutical or medical device manufacturer, or its agent, from providing the following to a Massachusetts health care practitioner:

- payment for entertainment or recreation, such as tickets to a sporting event, passes to a museum, etc.;
- complimentary items such as pens, mugs, and calendars;
- payment in cash or cash equivalents, either directly or indirectly, except as compensation for *bona fide* services;
- meals that are part of an entertainment or recreational event, offered without an informational presentation, offered outside of a health care practitioner's office, or provided to a health care practitioner's spouse or other guest;³ and
- financial support for the cost of travel, lodging, attendance, or other personal expenses of a non-faculty health care practitioner in connection with continuing medical education events, conferences, or meetings.

What is Allowed?

The final regulations do not, however, prevent pharmaceutical and medical device manufacturers from providing, among other things, the following:

- modest and occasional meals in conjunction with informational sessions in specified clinical training settings;
- reasonable compensation for substantial professional and consulting services of health care practitioners for a genuine research project or clinical trial;
- prescription drugs to a health care practitioner solely and exclusively for use by patients;
- reasonable quantities of medical device demonstration and evaluation units to assess the appropriate use of a product;
- payments for *bona fide* services, which are defined to include consulting services such as research and participation on advisory boards; and
- charitable donations, provided that the donation is not meant to influence prescribing patterns or other medical decisions.

³ While pharmaceutical or medical device manufacturers may not directly pay for meals outside of a "hospital setting", third-party organizers of CME or other meetings may use general funds from such manufacturers to provide meals.

The final regulations also allow for the use of hotels and convention centers for CME conferences and professional meetings, as well as the provision, distribution, dissemination or receipt of, or purchase of advertising in, peer reviewed academic, scientific or clinical journals.

Annual Disclosure

The final regulations require pharmaceutical and medical device manufacturers to make an annual disclosure to DPH by July 1 of each year setting forth the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to any health care practitioner in connection with the company's sales and marketing activities. For the purpose of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions are calculated on an individual basis and not in the aggregate. The definition of sales and marketing activities included in the final regulations excludes payments made as reasonable compensation in connection with a genuine research project or clinical trial, as well as the provision of prescription drugs to a health care practitioner solely and exclusively for use by patients and in-kind items used for the provision of charity care. Each annual disclosure must be accompanied by a fee of \$2,000 and a certification of accuracy by the disclosing company.

The final regulations also prohibit a pharmaceutical or medical device manufacturer from knowingly structuring fees or payments to health care practitioners to circumvent the reporting requirements. A knowing and willful violation of the final regulations will be punishable by a fine of up to \$5,000 for each transaction, occurrence or event. Fines will be issued and enforced by DPH in conjunction with the Office of the Massachusetts Attorney General.

Conclusion

The final regulations take effect on July 1, 2009, and submission of the first required disclosure report by pharmaceutical and medical device manufacturers will be due by July 1, 2010. The information reported by pharmaceutical and medical device manufacturers to DPH will be posted on the DPH web site (www.mass.gov/dph), and will be searchable by pharmaceutical and medical device manufacturers and by health care practitioners.

If you have any questions regarding the final regulations, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

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