Massachusetts Releases Proposed Pharmaceutical and Medical Device Manufacturer Code of Conduct

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On December 10, 2008, the Massachusetts Public Health Council released proposed regulations to implement M.G.L. c. 111N, the recently-enacted state statute governing marketing activities by pharmaceutical and medical device manufacturers operating in Massachusetts.

The proposed regulations establish a Marketing Code of Conduct (Code) that will, when effective, prohibit certain payments to health care practitioners in the Commonwealth of Massachusetts, require disclosure of the nature, amount, and recipient of payments over $50 made to health care practitioners, and impose auditing and reporting requirements on pharmaceutical ***and*** medical device manufacturers to ensure compliance with the Code. The regulations apply to pharmaceutical and medical device manufacturers that employ a person to sell or market prescription drugs or medical devices in the Commonwealth. In a press release and presentation accompanying the release of the proposed regulations, Massachusetts described the proposed Code as the most "stringent" and "comprehensive" regulation of pharmaceutical and medical device manufacturer conduct to date. The proposed regulations are "intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners." 105 CMR 970.001.

Prohibited Activities

The proposed regulations would, among other things, prohibit a pharmaceutical or medical device manufacturer, or its agent, from providing to a health care practitioner in the Commonwealth:

- grants, scholarships, subsidies, consulting contracts, or educational items in exchange for prescribing or disbursing prescription drugs or medical devices;
- entertainment or recreational items of any value;
- payments in cash or cash equivalents either directly or indirectly except as compensation for *bona fide* services;
- complimentary items such as pens, coffee mugs, gift cards, or flowers;
- meals that are part of an entertainment or recreational event, offered without an informational presentation, offered outside of a health care provider's office, or provided to

a health care provider's spouse or other guest; and

- financial support for the cost of travel, lodging, attendance, or other personal expenses of a non-faculty health care provider in connection with continuing medical education events, conferences, or meetings.

The proposed regulations do not prevent pharmaceutical and medical device manufacturers from providing 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, the provision of prescription drug or medical device demonstration and evaluation units, and payments for *bona fide* services, which are defined to include consulting services such as research and participation on advisory boards.

Disclosure Requirement

The proposed regulations require annual disclosure to the Department of Public Health (Department), by July 1 each year, of "the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50" provided by a pharmaceutical or medical device manufacturer to any health care practitioner in connection with the company's sales and marketing activities. 105 CMR 970.009. The definition of sales and marketing activities included in the proposed regulations excludes payments made as reasonable compensation in connection with a genuine research project or clinical trial. 105 CMR 970.004. Each annual disclosure must be accompanied by a fee of $2,000 and a certification of accuracy by the disclosing company. The proposed regulations also prohibit a pharmaceutical or medical device manufacturer from knowingly structuring fees or payments to health care practitioners to circumvent the reporting requirements.

Compliance Requirement

The proposed regulations require pharmaceutical or medical device manufacturers to:

- adopt and comply with the most recent Code as adopted by the Department;
- adopt and submit to the Department a description of a training program to provide regular training to appropriate employees on the Code, which must 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 Code, general science and product-specific information;
- certify to the Department that it is in compliance with the Code;
- adopt, and submit to the Department, policies and procedures for investigating and taking corrective action in response to instances of non-compliance with the Code; and
- submit to the Department 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 Code.

105 CMR 970.005. Pharmaceutical and medical device manufacturers must certify to the Department that annual audits to ensure compliance with the Code have been conducted.

The proposed regulations suggest July 1, 2009, as the deadline for initial compliance with the Code, and July 1, 2010, as the date for submission of the first required disclosure report by pharmaceutical and medical device manufacturers.

Although certain consumer and industry groups submitted written and oral comments in advance of the issuance of the proposed regulations, the release of these proposed regulations begins the formal notice and comment period. The Department has set two public hearings on the proposed regulations. The hearings are scheduled to occur on January 9, 2009, at the Public Health Council Room, 250 Washington Street, Boston, MA, at 9 a.m., and on January 12, 2009, at UMASS Medical School, Amphitheater I, 2nd Floor, 55 Lake Avenue North, Worcester, MA, at 1 p.m.

The proposed Code would impose stringent and comprehensive restrictions on the marketing activities of pharmaceutical and medical device companies. Companies that will be affected by these restrictions should consider submitting comments to the Department or participating in the public hearings scheduled for January 2009.

Department of Public Health Press Release

Department of Public Health Informational Briefing Memorandum

Department of Public Health Informational Presentation

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