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Health Law Client Alert: Massachusetts DPH Releases Final Rules for Pharmaceutical and Medical Device Manufacturers' Conduct

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On March 11, 2009, the Massachusetts Department of Public Health ("DPH") adopted final regulations ("Final Rules")[1] that include a Massachusetts Marketing Code of Conduct.[2] Effective as of July 1, 2009, the Final Rules apply to "pharmaceutical or medical device manufacturing companies" ("Manufacturers"). Manufacturers are defined to exclude health care practitioners, physician practices, home health agencies, hospitals, wholesale drug distributors, or retail pharmacists.

The Final Rules include a number of provisions that will directly affect Manufacturers and the entities with which they do business. These include the following:

- Manufacturers must adopt a code of conduct and designate a compliance officer.
- Manufacturers must disclose fees, payments and other compensation given to health care providers and other covered recipients.
- Certain payments including, among others, entertainment or recreational items, and complimentary items such as pens, coffee mugs, or gift cards, are prohibited.
- Manufacturers must protect the confidentiality of non-patient identified prescriber data and implement certain steps to do so.

The Final Rules require Manufacturers that employ or contract with pharmaceutical or medical device manufacturer agents ("Agents") to perform the following activities:

- adopt a marketing code of conduct ("Code of Conduct") in compliance with the Final Rules;
- train the appropriate employees on the Code of Conduct;
- submit a training description to DPH;
- certify annually to DPH that, to the best of the Manufacturer's knowledge, information and belief, it is in compliance with the Final Rules;
- adopt and submit annually to DPH policies and procedures for investigating non-compliance with the Final Rules, taking corrective action in response to noncompliance, and reporting instances of noncompliance to the appropriate state authorities;
- certify to DPH that the Manufacturer performed annual audits to monitor compliance with the Final Rules; and
- designate a compliance officer and submit to DPH certain information about the compliance officer.

The Final Rules contain groundbreaking disclosure requirements, including the requirement that Manufacturers must make annual disclosures to DPH of any payment, subsidy, or economic benefit of at least $50 made to covered recipients, including certain prescribers and purchasers. The $50 threshold should be calculated on an individual transactional basis and should not be aggregated. Manufacturers must also include disclosure provisions in their speaker and commercial consultant contracts. Of note, the definition of "sales and marketing activities" excludes clinical trials and genuine research. The Final Rules also provide that clinical trials posted on clinicaltrials.gov are specifically exempt from disclosure.

The Final Rules place strict limits on a Manufacturer's ability to give any type of gift or payment to health care providers. With certain limited exceptions, Manufacturers that employ or contract with Agents are prohibited from, among other things, providing to health care practitioners certain meals, funding for attendance at speaking or conference events, or more generally, payments or items of value. "Agents" include those individuals engaged in "detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in the commonwealth." Agents do not include health care practitioners (including pharmacists or physicians) with authority to prescribe prescription drugs, biologics or medical devices who are acting within the ordinary scope of the practice for which they are licensed, or certain wholesale drug distributors or their marketing representatives.

The Final Rules do permit compensation for bona-fide services, payment or reimbursement for expenses necessary for certain technical device training, charitable donations, and other enumerated purposes.

The Final Rules also contain provisions governing the use of non-patient identified prescriber data. Each "pharmaceutical manufacturing company" is required to maintain the confidential nature of prescriber data, develop policies for use of the data, designate an internal contact person, and comply with health care providers' requests that their prescriber data be withheld from sales representatives and not be used for marketing purposes.

DPH, the Attorney General, or a district attorney may enforce the Final Rules through fines, although the Final Rules do provide certain rights to notice and hearing. A person who "knowingly or willfully violates" the Final Rules may be punished by a fine up to $5,000 for each transaction, occurrence or event.

Mintz Levin is preparing a more detailed analysis of the Final Rules and relevant industry codes, which will be forthcoming in the near future.

Endnotes

[1]The Final Rules are expected to be codified as 105 CMR 970.000.

[2]The Final Rules implement M.G.L. c. 111N, the law enacted in August 2008 that governs marketing activities by pharmaceutical and medical device manufacturers operating in Massachusetts.

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