ReedSmith

lshi

Life Sciences Health Industry

If you have questions or would like additional information on the material covered in this *Alert*, please contact the author:

Matthew E. Wetzel
Associate, Washington, D.C.
+1 202 414 9250
mwetzel@reedsmith.com

…or the Reed Smith lawyer with whom you regularly work.

Massachusetts Releases Proposed Restrictions on Drug and Device Marketing Activities, Annual Financial Disclosure Requirement

On Dec. 10, 2008, the Massachusetts Department of Public Health (the "Department") released proposed regulations that would impose aggressive restrictions on pharmaceutical and medical device manufacturers' sales and marketing activities that exceed similar restrictions in other jurisdictions.[1] The proposed regulations—intended to implement section 14 of the Massachusetts Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the "Act")[2]—would also require companies to file annual disclosures of all fees, payments and economic benefits paid to health care professionals that total $50 or more.

If the Department finalizes these regulations as proposed, Massachusetts will join the ranks of seven other jurisdictions that have issued similar requirements. Currently, California and Nevada both require manufacturers to adhere to restrictions on marketing activities, and the District of Columbia, Maine, Minnesota, Vermont and West Virginia all mandate periodic disclosures of payments and other economic benefits to health care professionals. Massachusetts, however, will be the most aggressive of all jurisdictions in several regards. First, Massachusetts will be the only state to include both a marketing code of conduct that is specifically enumerated in detail in the regulations, and annual financial disclosure obligations. Other jurisdictions require adherence to a marketing code or disclosure, but not both. Second, Massachusetts will be the first state to require financial disclosure from medical device companies. Financial disclosure requirements in other states currently only apply to pharmaceutical companies. Third, Massachusetts will become the first state to require disclosure of free drug samples and the provision of medical equipment to health care providers for demonstration and evaluation purposes.

Stakeholders interested in submitting comments to the proposed regulations can provide in-person testimony during one of two public hearings to be held Jan. 9, 2009 and Jan. 12, 2009 in Boston and Worcester, Mass., respectively. In addition, electronic testimony can be submitted to the Department's Office of the General Counsel by 5 p.m. Jan. 19, 2009. Comments presented at the Department's public hearings or electronically will be considered in developing final regulations as part of the state's formal notice and comment process. Final regulations are expected to be released in February or March 2009.

I. MARKETING CODE OF CONDUCT

A. Overview

As noted above, the proposed regulations contain a marketing code of conduct ("Marketing Code")[3] that would restrict the nature and extent of pharmaceutical and medical device companies' interactions with health care practitioners in Massachusetts. Pursuant to the Act, the Department was charged with creating a Marketing Code that would be "no less restrictive than the most recent version[s]" of the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code") and the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the "AdvaMed Code"). In a memorandum summarizing the proposed regulations, the Department notes that despite this statutory mandate, it developed the Marketing Code with an eye toward accounting for differences between the drug and device industries. The Department has stated that its intent was to recognize the difference between the two industries and not to subject medical device manufacturers to standards absent from both the Act and the AdvaMed Code; however, it does not appear that the Department has harmonized the distinctions between the PhRMA and AdvaMed Codes in all instances.

Several sections of the proposed Marketing Code do account for differences in the PhRMA and AdvaMed Codes. For example, the proposed Marketing Code would obligate pharmaceutical companies—not medical device companies—to separate continuing medical education ("CME") grant-making functions from sales and marketing functions. This is a requirement of the revised PhRMA Code but not a requirement of the current AdvaMed Code. Further with respect to CME,

pharmaceutical companies—not medical device companies—would be prohibited from providing advice or guidance to the CME provider on content or faculty selection, even if asked by the CME provider. Again, this is a requirement of the revised PhRMA Code but not the current AdvaMed Code.

In other areas, the proposed Massachusetts Marketing Code attempts to account for differences in how the pharmaceutical and medical device industries do business. For example, the Act indicates that meals provided to health care practitioners would have to be furnished in either the office or hospital setting, and must be accompanied by informational presentations. This requirement aligns with recent revisions to the PhRMA Code, but it does not account for the fact that demonstrations or informational presentations by medical device companies may involve large, immobile equipment and may not be practical in the office or hospital setting. Accordingly, the Department would expand the definition of "hospital setting" to include both hospitals and academic medical centers, as well as pharmaceutical or medical device specialized training facilities designed to approximate the conditions of a surgical suite or clinical laboratory. This expansion of "hospital setting," if proposed as finalized, would provide medical device companies additional flexibility to provide meals to health care professionals in conjunction with informational presentations not in the office or in an actual hospital setting.

Other provisions of the proposed Marketing Code include the following:

- **No Kickbacks.** Grants, scholarships, subsidies, consulting arrangements, or other items of value could not be furnished to health care practitioners in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices, or for a commitment to continue doing so in the future.
- **Meals.** Meals would have to be modest and occasional, provided in connection with an informational presentation and provided in the health care professional's office or in the hospital setting. (As noted above, the term "hospital setting" would be expanded to include a company's specialized training facility.)
- **Entertainment.** Entertainment or recreational items of any value (e.g., theater tickets, sports equipment, trips, etc.) would be strictly prohibited.
- **Reminder Items.** "Complimentary" items such as pens, coffee mugs, gift cards or calendars would be generally prohibited.
- **CME.** Funding for CME could only be provided for events that meet the Standards for Commercial Support of the Accreditation Council for CME ("ACCME") or equivalent standards. Further, a company could not pay for the cost of travel, lodging, attendance or other personal expenses of non-faculty health care professionals, nor could a company make direct payments for meals at a CME event.
- **Consulting Arrangements.** Companies could continue to pay reasonable compensation for bona fide consulting services. Consulting arrangements would have to be specified in written agreements, and there would have to be an identified, legitimate need for the consulting services, among other requirements.
- **Training Expenses.** Medical device manufacturers could reimburse health care professionals for reasonable expenses necessary for technical training on a medical device, so long as the terms of the reimbursement were subject to a written purchase agreement for the device.
- **Price Concessions.** Price concessions, such as discounts and rebates, would be permissible.
- **Reimbursement Assistance.** Companies could provide technical assistance concerning reimbursement information (e.g., identifying appropriate coverage, coding, or billing information).

A chart attached to the end of this *Client Alert* provides an expanded and detailed summary of the proposed Marketing Code.

B. Application

The Marketing Code as proposed would apply to any "pharmaceutical or medical device manufacturing company" that "employs a person to sell or market prescription drugs, biologics or medical devices" in Massachusetts. A "pharmaceutical or medical device manufacturing company" is defined as any entity that:

- Participates in a "commonwealth health care program"[4] and is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics or medical devices; or

- Is engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices.[5]

Accordingly, to the extent that a company fits within this definition and also engaged a person to sell or market a product in Massachusetts (e.g., sales representatives or other agents who promoted or otherwise attempted to market or sell the product), the company would be required to comply with the Marketing Code.

Companies subject to the Marketing Code would also be required to implement a training program on the Marketing Code. Specifically, the proposed regulations would require each company to which the Marketing Code applied to ensure that all representatives who "visit" health care professionals had "sufficient knowledge" of the Marketing Code, "general science" and product-specific information. In other words, a sales representative should be able to provide health care professionals with the most accurate, up-to-date information on the product he or she was selling. Further, any such training program would be required to include regular assessments of employees or agents to ensure that they complied with the Marketing Code and with internal company policies.[6]

C. Key Dates for Adopting the Marketing Code

By July 1, 2009, the proposed Massachusetts regulations would require pharmaceutical and medical device manufacturers to:

- Adopt and comply with the Marketing Code;
- Adopt and submit to the Department a description of its training program;
- Certify compliance with the Marketing Code;
- Adopt and submit to the Department policies and procedures for investigating non-compliance, taking corrective action in response to non-compliance, and reporting instances of non-compliance to appropriate state authorities; and
- Submit to the Department the name, title, address, telephone number and e-mail address of the compliance officer responsible for operating, monitoring, and enforcing the Marketing Code of Conduct.[7]

On or before July 1, 2010—and on or before July 1 of each year thereafter—a company would also be required under the proposed regulations to certify that it had completed an annual audit of compliance with the Marketing Code.

II. FINANCIAL DISCLOSURE REQUIREMENTS

A. Overview

In addition to the marketing restrictions described above, the proposed regulations would require pharmaceutical and medical device companies to file annual reports disclosing all payments or items of value worth $50 or more provided to health care practitioners. More specifically, any pharmaceutical or medical device manufacturing company that employed a person to sell or market a drug or device in Massachusetts would be required to submit an annual report (on a standardized form developed by the Department) detailing:

- The value, nature, purpose and particular recipient of
- Any fee, payment, subsidy or other economic benefit with a value of at least $50
- Paid directly or through its agents
- To any "covered recipient" (any person in Massachusetts authorized to prescribe, dispense, or purchase prescription drugs or medical devices, including physicians, hospitals, nursing homes, pharmacists, health benefit plan administrators, wholesalers or "health care practitioners")[9]
- In connection with the company's "sales and marketing activities."[10]

Whether a payment would be disclosable, therefore, would turn in part on whether it had been made in connection with "sales and marketing activities." This term, however, would be defined very broadly to include:

- Advertising, promotion or other activities intended to influence sales or market share; to influence or evaluate the prescribing behavior of an individual health care professional; or to evaluate the effectiveness of a company's detailing sales force
- Product education and training

- The provision of any fee, payment, subsidy or other economic benefit with a value of at least $50 for any purpose (other than compensation for professional or consulting services in connection with a genuine research project or clinical trial)[11]

In guidance documents posted to its website, the Department further states that the term would include advertisements, sales pitches, customer satisfaction studies and promotional messages for communication to both consumers and health care professionals. The Department also specifies that the term would be intended to include product samples, demonstration units, rebates, discounts, royalties, and licensing fees.[12]

In short, therefore, the Department's financial disclosure requirements would be the most sweeping state disclosure requirements in the country. The proposed financial disclosure requirements, in essence, mandate reporting of all payments of $50 or more in any form to any Massachusetts health care provider with only one exception—payments for consulting services in connection with research or clinical trials. This would include reporting free samples and product evaluation units. In addition, although not explicit in the regulations, the Department's public website states that discounts and rebates offered on products would also need to be disclosed.[13] Other jurisdictions' disclosure obligations contain at least a handful of exceptions (e.g., scholarships to attend medical conferences, free samples, drug rebates and discounts, etc.). None of these exceptions is listed in either the Act or the proposed regulations.

Further as to the sweeping nature of the Department's financial disclosure requirements, the Act indicates that the Department will post on its website all data disclosed by pharmaceutical and medical device companies. According to guidance documents posted to the Department's website, this would include identifying the particular recipient of any economic benefit or payment from a company.[14]

B. Filings

Under the proposed regulations, companies would be required to start tracking payments to health care practitioners July 1, 2009. The proposed regulations would require companies to file the first annual disclosure reports on or before July 1, 2010. The 2010 disclosure report would cover the period of July 1, 2009 through Dec. 31, 2009. Starting July 1, 2011, annual disclosures would cover the previous calendar year (Jan. 1-Dec. 31, 2010). Reports would be filed on a form to be developed by the state, by a $2,000 filing fee, and a certification as to the truth and accuracy of the report.[15]

III. PENALTIES

Under the proposed regulations, any violation of the Marketing Code or the financial disclosure requirements would be punishable by a fine of $5,000 for each transaction, occurrence or event. The penalties section of the proposed regulations is also clear that pharmaceutical and medical device companies would be subject to a duty of good faith compliance and, further, that companies could not retaliate in any way against an employee, agent or HCP who has "taken any action in furtherance of enforcement" of the regulations.[16]

IV. CONCLUSION

The proposed Massachusetts regulations signify a new trend in state compliance obligations. As noted above, once it finalizes its regulations, Massachusetts will become the eighth jurisdiction in the United States to mandate some type of restrictions on pharmaceutical and medical device companies' sales and marketing activities and/or some form of financial disclosure. With several other states also considering similar legislation, it is unclear whether the unique nature of the Massachusetts regulatory scheme—i.e., dual marketing and reporting requirements—will become the model for future state laws in this area. The future of federal legislation proposed by Sen. Charles Grassley (R-Iowa) that would require drug and device companies to disclose financial relationships with health care professionals is also unclear, including whether or to what extent such legislation would preempt the various state reporting requirements. If so, this could serve to create a uniform, national approach to both tracking and reporting these payments. Finally, with the impending release of a revised AdvaMed Code, it is also unclear whether Massachusetts will continue to refine its Marketing Code and its financial disclosure requirements.

Regardless, restrictions on sales and marketing activity have become a reality for the pharmaceutical and medical device industries, and tracking payments to health care professionals is becoming the norm. Companies should consider taking steps now to ensure that they will be able to comply with any final regulations, specifically requirements to track payments to health care professionals in both Massachusetts and elsewhere.

Summary of the Proposed Massachusetts Marketing Code

Subject	Proposed Marketing Code Guidelines
Meals	Must be modest and occasional. No meals that are part of an entertainment or recreational event. No meals without an informational presentation by a company agent or without an agent present. No meals outside the health care practitioner's ("HCP's") office or the hospital setting.* No meals provided to an HCP's spouse or other guest. ** "Hospital setting" is expanded to include hospitals and academic medical centers, as well as drug and device companies' specialized training facilities. These are facilities designed to approximate surgical suites or working clinical laboratories and that are used to provide training using human tissue and cadavers on large devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.*
Continuing Medical Education Third-Party Scientific or Educational Conferences Professional Meetings	**Prohibited Payments** Support for costs of travel, lodging, or other personal expenses of non-faculty HCP attendees, either directly to the individuals or indirectly to the event's sponsor. Funding to compensate for HCP time spent participating in any CME event, third-party scientific or educational conferences, or professional meetings. Direct payment for meals at any CME event, third-party scientific or educational conferences, or professional meetings. (A CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a drug or device company toward meals for all participants.) Sponsorship or payment for CME that does not meet ACCME guidelines or equivalent accrediting standards. Sponsorship or payment for CME that provides payment directly to an HCP. **Permitted Payments** Payment for a third-party scientific or educational conference, charitable conference or meeting or professional meeting paid directly to the conference or meeting organizer. Scholarships to permit medical students, residents, fellows, and other HCPs in training to attend major educational, scientific or policy-making meetings of national, regional, or specialty medical associations. (Selection of recipients must be made by academic or training institution.) Compensation or reimbursement to an HCP serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting. (Payment must be reasonable, based on fair market value, and comply with accreditation standards.) **Control of Content** Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference or meeting in accordance with their guidelines. A "pharmaceutical manufacturing company" cannot provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.[17] **Venue** Must be held in a venue that is appropriate and conducive to informational communication and training about medical information. **Separation of Sales and Grant-Making** A "pharmaceutical manufacturing company" must separate CME grant-making from sales & marketing.[18]
Entertainment and Recreation	No entertainment or recreational items of any value to HCPs who are not salaried employees (e.g., tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips).
Complimentary Items to HCPs	No "complimentary" items such as pens, coffee mugs, or gift cards to any HCP, except as compensation for "bona fide services."

Subject	Proposed Marketing Code Guidelines
Consulting Services Payments to HCPs for Bona Fide Services	In general, no payments of any kind, including cash or cash equivalents, equity, in kind or tangible items, except as compensation for "bona fide services."* Must have written agreement specifying services. Compensation must be based on fair market value. Must have a legitimate need for the consulting services clearly identified in advance. Competence and expertise of the consultant must be connected to the purpose of the arrangement. Number of HCPs retained to provide services cannot be greater than number reasonably necessary to achieve the purpose of the services. The venue and circumstances of any meeting with consultants must be conducive to the consulting services, and activities related to the services must be the primary focus of the meeting. ** "Bona fide services" includes any arrangement for consulting services (research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to promoting health and preventing disease, presentations at company-sponsored training) and the licensing of intellectual property when such arrangements are formalized in a written agreement based on fair market value.*
Payment for Research, Clinical Trials	Reasonable compensation for substantial professional or consulting services in connection with a genuine research project or clinical trial is permitted.[19] Reimbursement of other reasonable out-of-pocket costs incurred directly as a result of the performance of such services is permitted. All such compensation and reimbursement must be specified and paid pursuant to a written research agreement.
Expenses Necessary for Device Training	Device companies can pay or reimburse for the reasonable expenses—including travel and lodging—necessary for technical training on the use of a medical device. Such payment must be paid pursuant to and described under a written agreement between and the HCP and the "device vendor for the purchase of the device."
Distribution of Academic, Scientific and Clinical Information	Permissible to distribute peer-reviewed journals or academic, scientific, or clinical information. Permissible to purchase advertising in peer-reviewed academic, scientific or clinical journals.
Samples, Evaluation Units	Permissible to provide prescription drugs or medical device demonstration and evaluation units solely and exclusively for use by, and education of, the health care practitioner's patients.
Price Concessions	Permissible to provide customers with price concessions, including rebates and discounts, in the normal course of business.
Reimbursement Information	Permissible to provide reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products, or of procedures using those products and information.
Patient Assistance Programs	Permissible to provide payments or the provision of free outpatient prescription drugs to HCPs for the benefit of low income individuals through established Patient Assistance Programs ("PAPs"). Eligible PAPs would have to meet the criterion described in the U.S. Health and Human Services Office of Inspector General ("OIG") *Advisory Opinion* 06-03 (April 18, 2006).
Use of Prescriber Data	"Pharmaceutical manufacturing companies" that use non-patient-identified prescriber data must; • Maintain the confidential nature of the data. • Develop policies regarding the use of the data. • Educate employees and agents about these policies. • Maintain an internal contact person responsible for inquiries regarding the data. • Identify disciplinary action for misuse of the data. • Comply with any HCP's request not to make data available to sales representatives.[20]
Formulary Committee Members	"Pharmaceutical manufacturing companies" must require HCPs who serve as members of a formulary or clinical-guidelines committee, and who also serve as speakers or consultants, to disclose the relationship to the committee.[21] Disclosure would be required for at least two years beyond the termination of any speaker or consulting arrangement.

Endnotes

1 *See* 105 Mass. Code Regs. 970.000 (proposed), available at http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_reg105cmr970.doc.

2 *See* Mass. S.B. 2863 (July 31, 2008), available at http://www.mass.gov/legis/bills/senate/185/st02pdf/st02863.pdf.

3 *See* 105 Mass. Code Regs. 970.004-970.008 (proposed).

4 According to the regulations, the term "Participates in a Commonwealth Health Care Program" means that the company does business, directly or indirectly, with a program for which Massachusetts purchases or provides reimbursement for pharmaceuticals, biologics, or medical devices. This includes, for example, MassHealth, the Group Insurance Commission, the Massachusetts State Employees Retirement Board, and UMASS Correctional Health, or the contract medical provider for the Department of Corrections. 105 Mass. Code Regs. 970.004 (proposed).

5 *Id.*

6 *Id.* 970.005(1) (proposed).

7 *Id.*

8 *Id.*

9 "Covered Recipient" would not include bona fide employees of a pharmaceutical or medical device company, nor would it include consumers who purchase pharmaceuticals or medical devices. "Health care practitioner" appears to be a catch-all term describing any person who prescribes prescription drugs for any person and is licensed to provide health care in the state. It would include partnerships or corporations comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course of his/her employment, agency or contract. *Id.* 970.004 (proposed).

10 *Id.* 970.009 (proposed).

11 *Id.* 970.004 (proposed).

12 Massachusetts Department of Public Health, Pharmaceutical and Medical Device Conduct Questions/Answers, 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_081210_new_regs_qa&csid=Eeohhs2.

13 See *id.*

14 M. Lopes, Deputy General Counsel, Massachusetts Department of Public Health, Presentation on Pharmaceutical and Medical Device Manufacturer Conduct, available at http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_presentation.ppt.

15 105 Mass. Code Regs. 970.009 (proposed).

16 *Id.* 970.010 (proposed).

17 Note that the proposed guideline only applies to pharmaceutical companies.

18 Note that the proposed guideline only applies to pharmaceutical companies.

19 A "Clinical trial" is defined as a genuine research project involving a drug or medical device that uses volunteer human research subjects to evaluate the safety or effectiveness of the particular drug or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or to evaluate the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and/or has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.

A "Genuine Research Project" is defined as a project that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published freely by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry. 970.004.

20 Note that the proposed guideline only applies to pharmaceutical companies.

21 Note that the proposed guideline only applies to pharmaceutical companies.