



GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE

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Massachusetts Proposes Groundbreaking New Rules Governing Medical Device and Pharmaceutical Manufacturer Sales and Marketing Activities

The Massachusetts Public Health Council (the "Council") recently proposed rules that would implement the state's new compliance law applicable to medical device and pharmaceutical manufacturers that (i) participate in a Massachusetts healthcare program and (ii) employ a person to sell or market a drug or device in Massachusetts. The proposed rules require medical device and pharmaceutical manufacturers to comply with the Marketing Code of Conduct standards set forth in the proposed rules. The proposed rules also require manufacturers subject to the new law to report certain information about any fee, payment, subsidy or other economic benefit of \$50 or more provided to certain healthcare providers and organizations.

The Marketing Code of Conduct and disclosure requirements will be familiar to many pharmaceutical manufacturers as the proposed standards are similar to those that have been implemented in a handful of other states. Medical device manufacturers, however, will face new code of conduct and reporting requirements not previously applied to the medical device industry if the proposed rules are finalized. Therefore, medical device manufacturers may wish to consider which proposed Massachusetts standards, if any, might require the development and implementation of new compliance systems and / or changes to current sales and marketing practices. Implementation of the Marketing Code of Conduct and the first annual disclosure report are proposed to be due by July 1, 2009 and July 1, 2010, respectively.

Two public hearings will be held to discuss the proposed rules (one in Boston on January 9 and one in Worcester on January 12). Parties that cannot attend in person may submit written testimony by or before January 19, 2009. We would be happy to assist clients with preparations for the hearings and / or the submission of written comments. We also are available to advise on the development and implementation of appropriate compliance systems to ensure timely and accurate implementation and reporting.

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A. Scope of Law

The implementing Massachusetts statute applies to medical device and pharmaceutical companies that participate in at least one Massachusetts healthcare program and employ a person to sell or market a device or drug within the State of Massachusetts (“Covered Manufacturers”). Wholesale drug distributors, hospitals, and pharmacists are expressly excluded from the proposed regulatory definition of “pharmaceutical or medical device manufacturing company.” Medical device and pharmaceutical drug distributors appear to be included, although a non-binding memorandum (the “Council Memorandum”) from the Council’s Commissioner to the Massachusetts Department of Public Health (the “Department”) suggests otherwise.

Under the proposed rules, “Participates in a Commonwealth Health Care Program” means “does business, either directly or indirectly, with a program for which the commonwealth purchases or provides reimbursement for pharmaceuticals, biologics, or medical devices, including, but not limited to MassHealth [the Massachusetts Medicaid program], the Group Insurance Commission, the Massachusetts State Employees Retirement Board, and UMASS Correctional Health or the contractual medical provider for the Department of Corrections.”

B. Marketing Code of Conduct

1. Proposed Standards Applicable to Both Medical Device and Pharmaceutical Manufacturers

In accordance with the implementing Massachusetts statute, the Council believes it has adopted regulations that are “at least as restrictive as” the Code of Ethics on Interactions adopted by the Advanced Medical Technology Association (the “AdvaMed Code”)¹ and the Code on Interactions with Healthcare

¹ On December 18, 2008, AdvaMed announced the release of a newly revised version of the “Code of Ethics on Interactions with Healthcare Professionals.” Sidley Austin LLP is currently preparing an Update on the recent revisions to the AdvaMed Code.

Professionals issued by the Pharmaceutical Research and Manufacturers of America (the “PhRMA Code”).² The Council Memorandum states that although the medical device and pharmaceutical industries “differ in a number of ways,” the Council “where appropriate[,] sought to place the two industries on equal footing.” Even though some of the differences between the two industry codes were eliminated with the recent publication of an updated AdvaMed Code, there are still instances in the proposed rules where some of the updated PhRMA Code provisions (effective January 1, 2009) are more restrictive than the newly-published AdvaMed Code restrictions (effective July 1, 2009).³ In some of those cases, the more restrictive PhRMA Code provisions would be applicable to both pharmaceutical and medical device manufacturers, a groundbreaking development for many medical device manufacturers.⁴

For example, the proposed rules prohibit the provision of or payment for meals for healthcare practitioners when the meals are offered, consumed, or provided without an informational session or outside of the healthcare practitioner’s office or hospital setting. The updated PhRMA Code is generally consistent with this proposed standard.⁵ However, the updated

² Sidley Austin LLP released an Update on July 23, 2008, relating to recent revisions to the PhRMA Code, entitled “PhRMA Releases Updates to Marketing Code; Voluntary Code Tightens Requirements and Calls for Increased Transparency,” which is available at: <http://www.sidley.com/clientupdates/Detail.aspx?news=3672>.

³ Since the Massachusetts proposed regulations were published before the updated AdvaMed Code became available, the Council’s proposals do not take into account new AdvaMed restrictions. However, given the comment period, it is possible the Council will consider incorporating restrictions from the updated AdvaMed Code.

⁴ Some medical device manufacturers may already be in compliance with the PhRMA Code requirements if, for example, they interpret the California Compliance Program Law, California Health and Safety Code §§ 119400-119402, to apply to their practices. Other medical device manufacturers may find the Massachusetts code of conduct requirements to be novel in their clear application of certain PhRMA Code provisions to medical device companies.

⁵ This is stricter than even the PhRMA Code, which only imposes these location restrictions on the provision of meals by certain types of sales and marketing personnel.

AdvaMed Code continues to permit the provision of occasional meals and refreshments by medical device sales representatives in connection with a sales or promotional discussion, regardless of the location of the discussion so long as the site is conducive to the exchange of information.

As another example, the proposed rules, like the updated PhRMA Code, prohibit the provision of or payment for meals for healthcare practitioners when the meals are offered directly at CME events, third-party scientific or educational conferences, or professional meetings. In contrast, the updated AdvaMed Code permits medical device manufacturers to provide funding to a CME sponsor to support the provision of meals and refreshments to conference attendees if certain requirements are met. Covered Manufacturers, particularly medical device manufacturers that plan to follow the updated AdvaMed Code once it takes effect, will need to carefully consider whether they must adjust their practices in Massachusetts if the proposed standards are finalized.

The proposed rules also prohibit the provision of or payment for meals for healthcare practitioners in several other circumstances, including when the meals are:

- Provided in connection with an entertainment or recreational event;⁶ or
- Provided to a healthcare practitioner's spouse or other guest.

Both the updated PhRMA and AdvaMed Codes are generally consistent with these proposed standards.

The proposed Massachusetts Code of Conduct standards also reach many other common marketing activities. For example, under one proposed standard, "tangible items, including any 'complimentary' items such as pens, coffee mugs, gift cards, etc." would be prohibited unless the items are provided as compensation for bona fide services. This is similar to the

⁶ The proposed regulations also separately prohibit the provision of entertainment or recreational items of value.

restrictions on promotional items such as "reminder" or logo items set forth in both the updated PhRMA and AdvaMed Codes.

The proposed rules also prohibit the following:

- The sponsorship of CME that does not meet the Accreditation Council for Continuing Medical Education Standards for Commercial Support. The proposed standard is more restrictive than the updated AdvaMed Code, which permits medical device manufacturers to provide financial support to non-accredited CME programs sponsored by national, regional, or specialty associations.
- The provision of financial support for the travel or related expenses of non-faculty healthcare practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, whether it is furnished directly to the individuals participating in the event or indirectly to the event's sponsor, except in cases as determined by the Department.

Additional and important restrictions on funding paid to a Massachusetts healthcare practitioner are set forth in the proposed rules.

There are certain exceptions to the proposed Code of Conduct restrictions, including the following:

- The proposed rules expressly permit the provision, distribution, dissemination or receipt of peer-reviewed academic, scientific or clinical information and the purchase of advertising in peer-reviewed academic, scientific or clinical journals.
- Covered Manufacturers are also permitted to provide prescription drugs and medical device demonstration and evaluation units to healthcare practitioners solely and exclusively for use by the healthcare practitioner's patients.

- The proposed rules also permit Covered Manufacturers to compensate healthcare practitioners for bona fide services, which would include the provision of substantial professional or consulting services in connection with a genuine research project or a clinical trial.
- The proposed rules state that payment can be made for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

Other limited exceptions are set forth in the proposed rules.

2. Proposed Standards Applicable to Pharmaceutical Manufacturers Only

The proposed rules also contain certain limitations that apply only to pharmaceutical manufacturers. Those provisions are as follows:

- Consistent with the updated PhRMA Code, the proposed rules would require pharmaceutical manufacturers to separate CME grant-making functions from sales and marketing departments. Moreover, pharmaceutical manufacturers may not provide any advice or guidance to the content or faculty for any of its funded CME programs, as is recommended under the updated PhRMA Code.
- Also consistent with the updated PhRMA Code, pharmaceutical manufacturers that use "non-patient identified prescriber data" are required to maintain the confidential nature of the data; develop policies regarding the data's use; educate employees and agents about the policies; maintain an internal contact person to handle inquiries regarding the use of the data; identify appropriate disciplinary actions for misuse of the data; and comply with "opt-out" requests that would prevent the use of the requesting prescriber's data by the pharmaceutical manufacturer's sales and marketing personnel.

- Like the updated PhRMA Code, the proposed rules stipulate that pharmaceutical manufacturers must require any Massachusetts healthcare practitioner who sits on formulary or clinical guideline committee(s) and serves as a speaker or "commercial consultant" for the manufacturer, to disclose to the relevant committee(s) the nature and existence of his or her relationship with the manufacturer. This disclosure requirement extends for two years beyond the termination of any speaker or consultant arrangement.

It is unclear why the Council limited certain provisions in the proposed rules to pharmaceutical manufacturers.

3. Proposed Effective Date

Compliance with the Marketing Code of Conduct is required by July 1, 2009. The Department must update its Code at least every two years.

C. Other Compliance-Related Obligations

In addition to adherence to the Marketing Code of Conduct, the Massachusetts proposed rules impose other compliance program-type obligations on Covered Manufacturers, many of which will be familiar to manufacturers that are subject to the Nevada Marketing Code of Conduct Law.⁷ Like the Nevada Marketing Code of Conduct Law, the proposed rules specifically require Covered Manufacturers to provide regular code of conduct training to appropriate personnel. The Massachusetts proposed rules identify sales and marketing personnel as among the "appropriate employees" who must receive the training mandated under the law. The training program must ensure that all company representatives who call on Massachusetts-licensed healthcare practitioners have

⁷ The Nevada Marketing Code of Conduct Law, Nevada Rev. Stat. §639.570, requires pharmaceutical and medical device manufacturers and wholesalers to "adopt a written code of conduct which establishes the practices and standards that govern the marketing and sale of its products." Pharmaceutical manufacturers that adopt the most recent version of the PhRMA Code and medical device manufacturers that adopt the most recent version of the AdvaMed Code are deemed in compliance with the Nevada requirement.

“sufficient knowledge” of the Marketing Code of Conduct, “general science” (an undefined term under the proposed rules) and product-specific information. The proposed rules also require Covered Manufacturers to regularly assess employees to ensure compliance with the Marketing Code of Conduct and other relevant company policies.

Also similar to the Nevada Marketing Code of Conduct Law, the Massachusetts proposed rules specifically require Covered Manufacturers to:

- Conduct annual audits to assess compliance with the Marketing Code of Conduct;
- Adopt policies and procedures that describe how the company will investigate noncompliance reports and what corrective actions the company will take in response to noncompliance; and
- Adopt policies and procedures that require the company to report instances of noncompliance to “appropriate state authorities.”

Finally, the Massachusetts proposed rules require Covered Manufacturers to identify a compliance officer responsible for “operating, monitoring, and enforcing” the Marketing Code of Conduct.

D. Annual Compliance Reporting

Consistent with the Massachusetts statute, the proposed rules require Covered Manufacturers to annually file with the Department the following information by July 1:

- A description of the company’s code of conduct training program;
- A description of the investigation and noncompliance reporting policies and procedures;
- The Compliance Officer’s name, title, address, telephone number, and e-mail address; and

- A certification that the company has conducted its annual audit and is in compliance with the Marketing Code of Conduct.

Under the proposed rules, the first compliance certification is due by July 1, 2010.

E. Reporting of Payments

Under the implementing Massachusetts statute, Covered Manufacturers must report to the Department the value, nature, purpose, and recipient of any fee, payment, subsidy or other economic benefit of \$50 or more that they provide, directly or through their agents, to any “covered recipient.” The term “covered recipient” is defined in the proposed rules as persons, businesses, or other organizations authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the state. Examples of covered recipients enumerated in the proposed rules are physicians, hospitals, nursing homes, pharmacists, health benefit plan administrators, and wholesalers licensed to sell or distribute prescription drugs or medical devices to a healthcare practitioner.

According to a presentation by the Department’s Deputy General Counsel, the Department intends to interpret the disclosure requirement broadly and, unlike other states that have implemented similar rules, require Covered Manufacturers to report drug samples and demonstration or evaluation devices provided to covered recipients.⁸ The Department has, however, expressly provided for one exception from the disclosure requirement for reasonable compensation paid to a healthcare practitioner for the substantial professional or consulting services performed in connection with a genuine research project or clinical trial.

⁸ This proposed requirement is consistent with the recent recommendations of MedPAC, an independent committee that advises Congress on Medicare matters. Last month, MedPAC voted to recommend to Congress that manufacturers be required to report detailed information on payments to physicians and other healthcare professionals and organizations, including information regarding patient samples given to such recipients.

Under the proposed rules, the disclosures must be made by July 1 of each year, with the first such disclosure due on July 1, 2010 covering the period between July 1, 2009 and December 31, 2009. A fee of \$2,000 is due on July 1, 2009 and with every annual disclosure report.

Unlike pharmaceutical manufacturers that face similar reporting requirements in a handful of other states, the Massachusetts reporting requirement would be the first of its kind to be applicable to medical device companies. Medical device manufacturers may wish to consider options for compliance systems that will ensure timely and accurate reporting once implementing regulations are finalized.

Both medical device and pharmaceutical manufacturers might also consider closely monitoring the status of the federal

Physicians Payments Sunshine Act. This a federal bill that, if passed, could impose a periodic disclosure requirement on manufacturers making payments to physicians, and could potentially preempt state disclosure requirements such as this one in Massachusetts.

F. Penalties

Under the proposed rules, Covered Manufacturers who violate the Massachusetts requirements may be fined up to \$5,000 by the Council for each transaction, occurrence, or event that violates the new requirements. The Massachusetts statute further provides that the law may be enforced by the Massachusetts Attorney General or a district attorney with jurisdiction over the violation.

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The Council's proposed rules, if finalized, would implement Massachusetts's new compliance law for pharmaceutical and medical device manufacturers and impose significant changes to sales, marketing, and other activities in Massachusetts, particularly for medical device manufacturers. Massachusetts considers the proposed regulations to go further than those of any other state and is expected to actively monitor compliance. We would be happy to assist with preparation for one of the two upcoming January 2009 public hearings, submission of comments, and the development and implementation of internal systems to ensure compliance with the new Massachusetts requirements once they are finalized.

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