Update on Massachusetts Pharmaceutical and Device Manufacturer Conduct Law: Massachusetts Department of Public Health Issues Proposed Regulations

On December 10, 2008, the Massachusetts Department of Public Health (DPH) publicly released proposed regulations implementing the new pharmaceutical and medical device manufacturer conduct law at Mass. Gen. L. c. 111N. The new law requires pharmaceutical and medical device manufacturers to: (1) comply with a marketing code of conduct developed by DPH; (2) undertake specific compliance activities (training, auditing and corrective action); and (3) disclose payments to providers with a value of $50 or more in connection with sales and marketing activities. DPH has announced that the proposed regulations will "put Massachusetts at the forefront of regulating sales and marketing practices of the pharmaceutical and medical device industry." This alert, which updates a previous alert on the law, reviews key clarifications and changes proposed by the regulations.

Scope

The proposed regulations provide some clarification on the types of manufacturers and interactions with healthcare practitioners subject to the new law.

- Manufacturers include manufacturers of biologics as well as drugs and devices that do business directly or indirectly with a program for which the Commonwealth purchases or provides reimbursement for drugs, biologics or medical devices.
- Healthcare practitioners do not include *bona fide* employees of manufacturers. DPH has indicated that the law would apply to healthcare practitioners licensed in Massachusetts regardless of where the interaction occurs.
- Sales and marketing activities are defined broadly to include essentially any activity used to influence the use of drugs, biologics or medical devices or to evaluate sales representatives as well as product education and training and the provision of any benefit with value of at least $50 to healthcare practitioner other than as payment for services in connection with a clinical trial or genuine research project.

Marketing Code of Conduct

The proposed regulations do not expressly reference compliance with the codes on interactions with healthcare professionals developed by the Pharmaceutical Research and Manufacturers of America (PhRMA Code) and the Advanced Medical Technology Association (AdvaMed Code). DPH has indicated that the agency chose instead to incorporate provisions from the codes. The proposed regulations separately address conduct standards for three categories of activities:

- **Meals**. Proposed regulations would allow meals to be provided only as part of an informational presentation by a manufacturer representative. The regulations would permit such meals to be provided at academic medical centers and specialized training facilities (which are defined as simulated surgical suites or clinical laboratories providing training on human tissue or cadavers using medical devices), as well as in physician offices and hospitals.

- **Continuing Medical Education and Third Party Events**. Proposed regulations would allow sponsorship of continuing medical education (CME) programs accredited by organizations other than the Accreditation Council for Continuing Medical Education, but still would not allow sponsorship for unaccredited independent medical education. Proposed regulations would additionally allow scholarship or other financial assistance for medical students and residents, as well as sponsorship for third party events when payment is made directly to the organizers. The proposed regulations incorporate the substance of provisions from the PhRMA Code requiring separation of CME grants and sales and marketing functions and prohibiting manufacturer input regarding CME content or faculty.
- **Other Payments to Healthcare Practitioners**. Proposed regulations would expand the prohibition on payments of cash or cash equivalents to payments of any kind, including equity and tangible items other than compensation for *bona fide* services. The regulations would also define prohibited activity to include any payment that would be prohibited under the federal anti-kickback statute or state analogues. Permitted activities would include the following activities not addressed in the statute: (1) the provision of price concessions in the normal course of business; (2) the provision of reimbursement information unless provided to induce healthcare practitioners to use products (incorporating the substance of AdvaMed Code provisions); (3) the provision of medical device demonstration/evaluation units to healthcare practitioners solely for use by and education of the healthcare practitioner's patients (providing consistency with the treatment of drugs); and (4) drugs or other support provided through established patient assistance programs that comply with the federal anti-kickback statute.

Compliance Activities

The proposed regulations would require pharmaceutical and medical device manufacturers to comply with the applicable marketing code of conduct and implement policies and procedures related to other compliance activities by July 1, 2009 and to certify compliance by July 1, 2010. DPH would apply the training requirements to employees other than sales and marketing staff and would require training not just on the marketing code of conduct but also general science and products to ensure representatives visiting providers can "provide accurate, up-to-date information, consistent with state law and FDA requirements." DPH would also require manufacturers to undertake "regular assessments" of representatives to ensure they are complying with compliance policies. The proposed regulations would incorporate the substance of provisions from the PhRMA Code on the use of non-patient identified prescriber data and on the disclosure of manufacturer consulting arrangements with healthcare practitioners who serve on committees that establish formularies or clinical guidelines.

Disclosure Requirements

The proposed regulations would require annual disclosure to begin July 1, 2010; payment of a $2000 fee annually (with the first fee due July 1, 2009); and use of a standardized reporting form for disclosures. Payments to employees or consumers are excluded as is reasonable compensation to a healthcare practitioner for substantial services provided in connection with a clinical trial or genuine research project. There is no specific guidance on the determination of the $50 or more benefit that must be disclosed (*e.g.*, when gifts must be aggregated). DPH has stated that the agency intends to provide that guidance through the reporting forms once developed. Pharmaceutical and medical device manufacturers are prohibited from structuring activities to circumvent the disclosure requirements.

Compliance

The proposed regulations would impose an ongoing duty of good faith compliance on every person subject to the regulations, which DPH has indicated could include the healthcare practitioners with which manufacturers and their agents interact. The proposed regulations also prohibit retaliation for whistleblowers.

Regulatory Process

Public hearings on the proposed regulations will be held in January 2009. Written comments on the proposed regulations may be submitted to DPH before 5 p.m. on January 19, 2009.

Contact Information

If you have questions about the Massachusetts law or the proposed regulations and their effect on your business activities, please do not hesitate to contact your regular Ropes & Gray contact.