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

On March 11, 2009, the Massachusetts Department of Public Health (DPH) issued final regulations implementing the pharmaceutical and medical device manufacturer conduct law at Mass. Gen. L. c. 111N (Manufacturer Conduct Law). Pharmaceutical and medical device manufacturers must comply with these requirements beginning July 1, 2009. The final regulations and DPH guidance can be accessed here.

Overview

The Manufacturer Conduct Law imposes far-reaching requirements on pharmaceutical and medical device manufacturers. The law is the first state law that requires pharmaceutical and medical device manufacturers to do all of the following:

- adopt and comply with a state-developed marketing code of conduct;
- implement compliance and training programs; and
- disclose payments to health care providers of $50 or more.

The Manufacturer Conduct Law reaches interactions between manufacturers and health care providers licensed in Massachusetts regardless of where the interactions occur.

Marketing Code of Conduct

The final regulations establish a state marketing code of conduct that reflects the provisions in the Manufacturer Conduct Law expressly prohibiting and permitting certain manufacturer interactions with health care practitioners. The new code also responds to the statutory mandate that the code be no less restrictive than the codes on interactions with health care professionals developed by the Pharmaceutical Research and Manufacturers of America (PhRMA Code) and the Advanced Medical Technology Association (AdvaMed Code). Key code provisions include:

- **Meals**. Manufacturers may only provide modest meals to health care practitioners as part of an informational presentation by a manufacturer representative in a physician office, hospital, academic medical center, or specialized training facility (which includes a simulated surgical suite, clinical laboratory, or large medical device training facility). These on-site limitations are more restrictive than those in the PhRMA Code (which apply only to sales representatives and their immediate managers) and the AdvaMed Code (which allow meals in any setting conducive to *bona fide* scientific, educational or business discussions).
- **Continuing Medical Education, Conferences, and Professional Meetings**. Manufacturers are prohibited from sponsoring or paying for continuing medical education (CME) that is not accredited by the Accreditation Council for Continuing Medical Education or an equivalent accreditation organization. Additional provisions prohibit payments for non-faculty CME attendees and manufacturer guidance to a CME provider regarding the content or faculty of a program. The CME funding provisions are stricter than the corresponding provisions of

the PhRMA Code and AdvaMed Code. For example, the final regulations eliminate a provision in the proposed regulations that would have permitted financial support for medical residents and other health care professionals in training to attend educational conferences; such support is permitted under the PhRMA Code and AdvaMed Code. Manufacturers are still permitted to sponsor non-CME scientific, educational or charitable conferences or professional meetings if payment is made directly to the organizers.

- **Other Payments to Health Care Practitioners**. The code specifies categories of payments and non-cash items of value (all referred to here as "payments") that are expressly prohibited or permitted to be made to health care practitioners by manufacturers.
  - Prohibited payments include:
    - payments of any kind, including cash and cash equivalents, equity, and tangible items such as pens and mugs, except as compensation for *bona fide* services;
    - financial support provided in exchange for prescribing, disbursing, or using prescription drugs, biologics, or devices; and
    - payments prohibited under the federal anti-kickback statute or state analogues.
  - Permitted payments include:
    - reasonable compensation for *bona fide* services;
    - reimbursement of expenses associated with product training, if included in a product purchase agreement with a health care practitioner;
    - prescription drugs for use solely by the health care practitioner's patients;
    - reasonable quantities of medical device demonstration and evaluation units to allow the health care practitioner to assess a product;
    - price concessions offered in the normal course of business;
    - provision of academic, scientific, or clinical information;
    - purchase of advertising in peer-reviewed academic, scientific, or clinical journals;
    - provision of product reimbursement information if the information is not provided with an intent to induce the health care practitioner to use or recommend the product;
    - support for the benefit of low-income individuals through patient assistance programs that comply with the federal anti-kickback statute; and
    - charitable donations not given in exchange for business.

The code again differs from the PhRMA Code and AdvaMed Code. For example, those codes expressly allow the provision of educational items, while the state marketing code of conduct is silent regarding educational items.

Compliance Activities

Manufacturers must comply with the marketing code of conduct and implement policies and procedures related to other compliance activities by July 1, 2009. Specifically, manufacturers must conduct training to ensure that all manufacturer representatives who visit health care practitioners have sufficient knowledge of the marketing code of conduct, general science, and product-specific information in order to "provide accurate, up-to-date information, consistent with state law and FDA

requirements." Manufacturers must also undertake "regular assessments" of representatives to ensure they are complying with compliance policies. The regulations include provisions generally consistent with provisions of the PhRMA Code on the use of non-patient identified prescriber data and on the disclosure of manufacturer consulting arrangements with health care practitioners who serve on committees that establish formularies or clinical guidelines. The regulations also require manufacturers to comply with annual filing and certification requirements concerning compliance initiatives beginning July 1, 2009.

Disclosure Requirements

Manufacturers must file a disclosure report with DPH by July 1, 2010 (covering activity from July 1, 2009 through December 31, 2009), and by July 1 each year thereafter (covering activity during the prior calendar year). Manufacturers must pay an annual fee of $2,000 beginning July 1, 2009. The disclosure report must include the value, nature, purpose, and recipient of any economic benefit with a value of $50 or more provided to a "covered recipient" in connection with "sales and marketing activities." "Covered recipient" is defined to include any person authorized to prescribe, dispense, or purchase prescription drugs in Massachusetts, excluding employees of a manufacturer or consumers. "Sales and marketing activities" is specifically and broadly defined in the regulations. Exemptions to the disclosure requirement exist for:

- clinical trials and genuine research (which exclude research projects involving the marketing department of a manufacturer or having a marketing or promotional purpose);
- provision of prescription drugs to a covered recipient solely and exclusively for use by patients (e.g., samples);
- demonstration or evaluation units;
- in-kind items used for the provision of charity care; and
- confidential price concessions "established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan's formulary."

The final regulations clarify that the $50 threshold applies per transaction (rather than in the aggregate). These disclosure requirements differ from the current version of the proposed federal Physician Payment Sunshine Act in a number of ways (e.g., the state law has a broader class of recipients covered by reporting obligations and does not include the same exemptions from disclosure as the federal legislation). All data reported to DPH will be made publicly available and easily searchable on the DPH website.

Contact Information & Related Event

If you have questions about the Manufacturer Conduct Law or the final regulations and their effect on your business activities, please do not hesitate to contact your regular Ropes & Gray attorney. In addition, we invite you to join us at a March 25 teleconference at which we will provide an overview and detailed analysis of the Manufacturer Conduct Law and final regulations.