Massachusetts Imposes Compliance Requirements on Pharmaceutical and Medical Device Manufacturers

Pharmaceutical and medical device manufacturers who wish to sell or market their products in Massachusetts after January 1, 2009, must comply with a marketing code of conduct ("Code") promulgated by the Massachusetts Department of Public Health ("DPH") or face civil penalties. Under the law, DPH must adopt a mandatory Code that is "no less restrictive than" the most recent version of the voluntary codes of conduct developed by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Advanced Medical Technology Association. The Massachusetts law also requires manufacturers to submit annual reports describing anything given to a healthcare provider that is valued at $50 or more.

On August 10, Governor Deval Patrick signed into law Senate Bill No. 2863, entitled "An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care." The new law, which comes on the heels of simi¬lar measures in California and Nevada, applies to any pharmaceutical or medical device manufacturer that participates in a Massachusetts health care program.

The new law sets forth requirements that DPH must adopt in regulations establishing the Code. Many of these requirements track the recent revisions to the PhRMA Code on Interactions with Healthcare Professionals, which also will take effect in January 2009. These include:

- A ban on providing branded items or items of entertainment or recreation to a healthcare provider ("HCP");
- A prohibition against paying for any meal outside the context of an informational presentation; and
- A ban on providing meals directly at continuing medical education ("CME") events, although CME providers presum-ably may use manufacturer financial support to provide meals to all participants.

In other respects, however, the Massachusetts law differs from the new PhRMA code. For example, the Massachusetts law prohibits manufacturers from paying for a non-faculty HCP's travel, lodging, and personal expenses associated with attending a CME event or other professional meeting "except in cases as determined by [DPH]." The PhRMA code, by contrast, has no such exception. DPH will have to reconcile this apparently more lenient provision with the statutory requirement that the DPH Code be "no less restrictive than" the PhRMA code.

Other provisions of the Massachusetts law appear to be more restrictive than the PhRMA code. The Massachusetts law limits all meals associated with manufacturers' informational presentations to in-office or in-hospital settings, whereas the PhRMA code adopts this policy only for presentations "made by field representatives or their immediate managers." Likewise, the Massachusetts law bans sponsorship of CME programs that do not meet the ACCME Standards for Commercial Support, whereas the PhRMA code allows financial support for non-accredited third-party scientific and professional meetings, subject to certain safeguards.

The Massachusetts law also provides that the DPH Code must allow a manufacturer to:

- Disseminate peer-reviewed academic, scientific, or clinical information and advertise in peer-reviewed academic, scien¬tific, or clinical journals;

- Provide drug samples to a HCP for patients' use;
- Compensate a HCP for services rendered in connection with a genuine research project or clinical trial; and
- Pay the reasonable expenses necessary for technical training on the use of a medical device if the expense is included in the purchase contract for the device.

In addition to adoption of the new DPH Code, the law requires each manufacturer to:

- Implement a training program for sales and marketing staff;
- Conduct annual compliance audits;
- Adopt policies and procedures for investigations and follow through with corrective actions, including self-reporting of violations to state authorities;
- Identify a compliance officer; and
- Submit an annual report to DPH describing its training program and investigation policies and certifying that it has con¬ducted its audit and is in compliance with the DPH Code.

By July 1 of each year, every manufacturer must disclose to DPH the value, nature, purpose, and recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50. DPH will make this information publicly available on its website and report any violations of the Code to the Attorney General.

These new requirements will present difficult policy and operational challenges for pharmaceutical and medical device manufacturers and may heighten the risk of state-level enforcement actions. Manufacturers will have to reconcile their current compliance policies with the latest versions of the industry codes and the increasingly complex and inconsistent web of state regulations. Operationally, the new law will create another set of auditing and reporting requirements, which may or may not overlap with manufacturers' existing systems.

DPH has not released a proposed Code or implementing regulations. Ropes & Gray anticipates that DPH will promulgate the mandatory Code in advance of the January 1 deadline. This leaves little time for companies to make their views heard on the Code's provisions and other implementing regulations. After January 1, 2009, any manufacturer who knowingly or will¬fully violates the law may be liable for a civil penalty of up to $5,000 per violation.

Contact Information

If you have questions about the new Massachusetts marketing code of conduct and its affect on your business activities, please do not hesitate to contact one of our attorneys below or your regular Ropes & Gray contact.

Albert Cacozza
(202) 508-4611

Alan Bennett
(202) 508-4604

Howard Dorfman
(212) 596-9114

Greg Levine
(202) 508-4831

Steven Wilcox
(617) 951-7319

Michael Sexton
(617) 951-7807