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LEGAL ALERT

PHARMACEUTICAL AND MEDICAL DEVICE UPDATE

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Pharmaceutical and Medical Device Manufacturer Conduct Law

By Kelly W. MacHenry

The most comprehensive and stringent state law regulating interactions between health care practitioners and pharmaceutical, medical device, and biotechnology companies goes into effect on July 1, 2009. Massachusetts recently passed into law and issued regulations for its Pharmaceutical and Medical Device Manufacturer Conduct Law. However, the law will impact all pharmaceutical or medical device manufacturers that market in that state or to practitioners of that state.

Activities occurring outside of Massachusetts are subject to this new law if they involve a Massachusetts-licensed healthcare practitioner. These include sales and marketing activities directed at or benefiting a Massachusetts recipient. The law also covers sales and marketing activity that takes place in the state, such as with a regional or local sales representative. As such, companies based elsewhere are still subject to the law when they are dealing with a Massachusetts health care practitioner or having covered interactions.

The law imposes new conduct and reporting requirements on pharmaceutical, biotechnology, and medical device manufacturers. It provides enforcement powers and fines. It is the first state law that requires pharmaceutical, biotechnology,

Kelly W. MacHenry
602.382.6370
kmachenry@swlaw.com

and medical device manufacturers to do all of the following:

- adopt and comply with a marketing **code of conduct**;
- implement **compliance** and training programs;
- **disclose** payments to health care practitioners of $50 or more; and
- file annual disclosures that will be publicly available and searchable on a website database.

A. Mandatory Marketing Code of Conduct

A state marketing code of conduct has been established. It expressly prohibits certain activities and places other restrictions on manufacturer interactions with a "health care practitioner." Health care practitioners are defined as persons who prescribe prescription drugs and are licensed in Massachusetts, or their partnerships, corporations, agents, or employees. This includes physicians, physician's assistants, nurse practitioners, hospitals, nursing homes, pharmacists, dentists, optometrists, and health benefit plan administrators.

Meals and Entertainment Are Restricted. Companies may only provide or pay for modest meals to health care practitioners as part of an informational presentation by a manufacturer representative. All such meals and entertainment paid for by companies or their agents must be in an office or hospital setting such as a physician's office, hospital, academic medical center, or specialized training facility. Meals may not be provided to spouses or guests. Purely entertainment or recreational events, items, or meals of any value are prohibited.

Gifts are Banned. Companies cannot make any payments in cash or cash equivalents to health care practitioners either directly or indirectly, except for bona fide services. Complimentary items such as pens, mugs, gift cards, and flowers are prohibited. Companies may not provide grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a health care practitioner in exchange for prescribing or continuing to prescribe prescription drugs or using or continuing to use medical devices.

Continuing Medical Education Sponsorship is Limited. Companies may not sponsor or pay for continuing medical education ("CME") that does not meet the Accreditation Council for Continuing Medical Education Standards for Commercial Support. Additionally, companies cannot make payments directly to a health care practitioner in connection with CME. Companies are barred from providing financial support for travel, lodging, or other personal expenses of non-faculty health care practitioners. Companies may not make such payments directly to health care practitioners or indirectly to practitioners through the event's sponsors.

Companies may not provide or pay for meals directly at any CME meetings, conferences, or professional meetings.

Other Activities Remain Permitted. Many common activities are still permitted. These include, for example, providing samples for the practitioner's patients; providing demonstration units; providing expenses necessary for technical training on the use of a medical device; advertising in peer-reviewed journals; and distributing scientific or clinical information.

B. Compliance

The first required compliance report is due to be filed by July 1, 2009. To demonstrate compliance, companies must perform the following by July 1, 2009:

- Adopt and comply with the marketing code of conduct;
- Adopt and provide regular training to all appropriate employees, including sales and marketing staff;
- Conduct annual audits to monitor compliance;
- Adopt policies and procedures for investigating noncompliance, take corrective action in the event of noncompliance, and report instances of noncompliance to the appropriate state authorities;
- Identify an officer charged with ensuring compliance; and
- File an annual report that includes a description of its training program and investigative policies; the name, title, and contact information of its compliance officer; and certification that it has conducted its annual audit and that it is in compliance.

C. Disclosure

The regulations require strict compliance with the disclosure requirements. Companies must pay an annual fee of $2,000 beginning July 1, 2009.

Companies must file a disclosure report by July 1, 2010 (covering activity from July 1, 2009 through December 31, 2009) and by July 1 of each following year. Companies must report "any fee, payment, subsidy, or other economic benefit with a value of at least $50" given to a "covered recipient in connection with the company's sales and marketing activities." Covered recipient is defined as any person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts, excluding employees of a manufacturer or consumers. The broadest of any state definition is given to "sales and marketing activities."

Each annual disclosure will be made publicly available on an easily searchable state agency website. The information provided will include the company's FDA identifier

number, the provider identifier number, dollar amount given, category of economic benefit, and number of events. This is a new development because other states that require disclosure do not make it publicly available or accessible.

This law has strong enforcement powers and penalties. Violations are punishable by fines of up to $5,000 per transaction, occurrence, or event. The Attorney General is granted enforcement powers. All persons subject to the law are under a duty of good faith compliance. Companies may not knowingly structure economic benefits to health care practitioners to circumvent the reporting requirements.

Pharmaceutical, biotechnology, and medical device manufacturers should act quickly to comply with these broad conduct and reporting rules, which begin in July 2009. Employees and salespeople must be trained to comply, especially those who will have direct contact with health care practitioners.

Kelly W. MacHenry
602.382.6370
kmachenry@swlaw.com

Kelly Wilkins MacHenry is Of Counsel with Snell & Wilmer L.L.P. She represents people and companies in disputes over products, financial services, and insurance. She is a member of Snell & Wilmer's Pharmaceutical and Medical Devices group, which advises U.S. and international businesses on compliance, marketing, and government communications. She defended product liability cases in Massachusetts for ten years before moving to the sunny state of Arizona, and she holds an active license in Massachusetts.