Regulatory Summary of 105 CMR 970.000 - Final Pharmaceutical & Medical Device Manufacturer Conduct Regulations

March 5, 2009

On March 11, 2009, the Massachusetts Public Health Council promulgated final regulations (105 CMR 970.000) for the administration of Chapter 111N of the Massachusetts General Laws, which governs the marketing activities of pharmaceutical and medical device manufacturing companies. When the Legislature passed Chapter 111N in August 2008 (as Section 14 of Chapter 305 of the Acts of 2008) (the "Law"), Massachusetts joined the District of Columbia and six other states in regulating the relationships between the pharmaceutical and medical device industries and physicians.

Understanding these final regulations is of significant importance to anyone involved in the Massachusetts biotechnology, health care, and drug and device sectors. The regulations apply broadly to pharmaceutical or medical device manufacturing companies ("PMDMCs"), including companies that are "directly" engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices. In accordance with the requirements of the law, the regulations establish a fine of $5,000 for each knowing and willful violation.

As summarized in greater detail below, the final regulations generally track the substance and organization of the Law, in three key areas:

- First, the regulations establish a marketing code of conduct that applies to both pharmaceutical and medical device companies, with certain limited exceptions.
- Second, the regulations mandate that PMDMCs implement certain training and compliance programs, and require that PMDMCs provide related certifications to the Department of Public Health ("DPH").
- Third, the regulations require PMDMCs to disclose certain payments and other benefits provided to certain covered recipients, and clarify that these disclosures are limited to sales and marketing activities. The disclosures will be made publicly available for review on a dedicated website.

Summary of the Final Regulations

SECTION 970.005 - GENERAL REQUIREMENTS

ADOPTION OF MARKETING CODE OF CONDUCT AND TRAINING PROGRAMS

Requires that by July 1, 2009, each PMDMC that "employs or contracts with a pharmaceutical or medical device manufacturer agent" must (a) adopt a code of conduct consistent with the regulations, (b) adopt and submit to DPH a description of a training program for the code, (c) certify compliance with the code "to the best of the company's knowledge", (d) adopt and submit to DPH a program for addressing non-compliance, and (e) identify a compliance officer.

NON-PATIENT PRESCRIBER DATA

- Requires pharmaceutical manufacturers using non-patient identified prescriber data to (a) maintain confidentiality, (b) develop policies regarding use of the data and educate employees about such policies, (c) designate an internal contact person for data inquiries, (d) establish appropriate disciplinary actions for data misuse, (e) withhold the data from sales representatives at the request of health care practitioners ("HCPs"), and (f) give HCPs the opportunity to request that their prescriber data be withheld from company representatives and not be used for marketing purposes.

- Allows PMDMCs to use prescriber data to impart important safety and risk information to prescribers, conduct research, comply with FDA-mandated risk management plans, or track adverse effects of drugs or devices.

DISCLOSURES TO FORMULARY AND CLINICAL GUIDELINES COMMITTEES

- Requires PMDMCs to require any HCP who both a) serves as a member of a committee that sets formularies or develops clinical guidelines, and b) serves as a speaker or commercial consultant for the PMDMC, to disclose to the committee the nature and existence of his or her PMDMC relationship.

ANNUAL AUDITS

- Requires each PMDMC to certify annually to DPH that it has conducted an internal annual audit in compliance with the code. The first certification is required on July 1, 2010.

SECTION 970.006 - PROVISION OF MEALS

PROHIBITIONS ON CERTAIN MEALS

- Prohibits PMDMCs that employ or contract with pharmaceutical or medical device agents from providing or paying for meals that are (a) part of an entertainment or recreational event, (b) offered without an informational presentation, (c) provided to a spouse or other guest, or (d) offered outside the "office or hospital setting," where that term is defined as a hospital, an academic medical center, or a facility that the PMDMC has certified to DPH as being a "specialized training facility."

SECTION 970.007 - CME, THIRD-PARTY SCIENTIFIC OR EDUCATIONAL CONFERENCES, OR PROFESSIONAL MEETINGS ("EVENTS")

PROHIBITIONS ON FUNDING FOR CERTAIN EVENTS

Prohibits PMDMCs that employ pharmaceutical or medical device manufacturer agents from:

- directly or indirectly reimbursing the expenses of "non-faculty" physicians attending Events,
- compensating physicians for time spent attending Events,
- paying for meals directly to HCPs at Events (although a CME provider or conference organizer may use PMDMC funding to provide meals for all participants), or
- sponsoring CME Events not meeting ACCME or equivalent standards.

REASONABLE FACULTY COMPENSATION

- Permits "reasonable" and "fair market value" compensation or expense reimbursement to HCPs serving as speakers, faculty organizers, or academic program consultants for an Event.

SEPARATION OF CME FUNDING

- Requires pharmaceutical manufacturers to separate their CME grant making functions from their sales and marketing departments, and prohibits pharmaceutical manufacturers from providing advice or guidance to a CME provider regarding the content or faculty for a CME program funded by the company.

FACILITIES

- Permits the use of hotel or convention center facilities or other venues for Events.

SECTION 970.008 - OTHER MISCELLANEOUS PAYMENTS

ALLOWABLE PAYMENTS

Allows certain PMDMC payment activities, including:

- reasonable compensation or expense reimbursements for "bona fide services," (defined as including research, participation on advisory boards, collaboration with nonprofits dedicated to the promotion of health and the prevention of disease, and

presentations at company-sponsored medical education and training as formalized in a written agreement),

- distribution of peer reviewed academic, scientific or clinical information, and the purchase of advertising in academic, scientific, or clinical journals, free samples of prescription drugs for use by patients,
- payment for device training expenses pursuant to a written agreement,
- free medical device demonstration and evaluation units for evaluation purposes,
- price concessions, rebates or discounts in the normal course of business,
- reimbursement information concerning products that support accurate billing to Medicare and other payors, so long as the information is not offered to induce physicians to purchase, lease, or use products,
- payments, or free outpatient prescription drugs, provided through certain established patient assistance programs, and
- certain charitable donations.

PROHIBITED PAYMENTS

Prohibits certain PMDMC payment activity, including:

- the provision of entertainment or recreational items to HCPs who are not salaried employees of the PMDMC,
- payments of any kind, including cash, equity, "in kind" payments, and "complimentary items" such as pens and mugs, except as compensation for bona fide services,
- grants or scholarships, consulting contracts, or educational or practice items provided in exchange for prescribing or using drugs or devices, and
- any other payment or remuneration, including any rebate or "kickback" that is prohibited under federal or state fraud and abuse laws.

SECTION 970.009 - DISCLOSURE OF PAYMENTS

DE MINIMIS EXCEPTION

- Requires PMDMCs that employ marketers to disclose "the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities."
- Clarifies that for the purposes of computing the $50 threshold, "fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated."

DEFINITION OF "SALES AND MARKETING ACTIVITIES"

For the purposes of the disclosure requirement, "sales and marketing activities" *include*:

- advertising, promotion or other activity that is intended to be used or is used to (a) influence the sale or the market share of a prescription drug, biologic or medical device, or the prescribing behavior of a covered recipient, (b) market a drug or device, or (c) evaluate the effectiveness of a pharmaceutical or medical device detailing sales force.
- any product education, training, or research project that is designed or sponsored by the marketing division of a PMDMC, or has marketing, product promotion, or advertising as its purpose.

ACTIVITIES EXEMPT FROM DISCLOSURE

The following are not "sales and marketing activities" for purposes of the disclosure requirement, and are thus *exempt* from disclosure:

- clinical trials and genuine research, "particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or 'new use' or similar marketing or labeling claim requiring FDA approval",
- clinical trials posted on www.clinicaltrials.gov

- the provision of prescription drugs for use by patients,
- the provision of 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."

REQUIRED CERTIFICATION AND FEES

- Requires PMDMCs to certify their disclosure reports as true and accurate, and to submit with each annual report a $2,000 fee. The first fee is due on July 1, 2009, even though the first report is not due until July 1, 2010.

REPORTING DEADLINES

- Requires that disclosure reports be filed by July 1, 2010 for payments occurring from July 1, 2009 through December 31, 2009, and annually thereafter (by July 1) for payments occurring during the previous calendar year.

SECTION 970.010 - PENALTIES

MONETARY FINES

- Establishes a fine of not more than $5,000 for each knowing and willful violation of the regulations.

WHISTLEBLOWER PROTECTIONS

- Establishes whistleblower protections for individuals who take actions in furtherance of the regulations.

Comprehensiveness

DPH has stated that these regulations are the most comprehensive of their kind in the nation. Particularly, DPH has noted that, with the adoption of the regulations, Massachusetts is the only state to (a) require adoption of and compliance with a state-authored marketing code of conduct, (b) prohibit certain payments to physicians by both pharmaceutical and medical device manufacturers, and (c) require disclosures by medical device manufacturers. The regulations also make Massachusetts one of two states that make disclosure data part of the public record.

Conclusion

Foley Hoag has extensive experience advising PMDMCs in adopting and implementing codes of conduct as part of a comprehensive compliance program, and defending against government investigations regarding compliance program violations.

RELATED INDUSTRIES

- Life Sciences
