

Pharmaceutical and Medical Device Manufacturer Conduct

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Why is this an issue?

- According to the Prescription Project, an advocacy group dedicated to advancing medical practice and policy:
 - 94% of physicians nationally have received food, drug samples or other reimbursements and payments from the drug industry.
 - Pharmaceutical industry marketing expenditures directed at physicians in the U.S. doubled from \$3.5 billion in 1996 to \$7.2 billion in 2005.
 - Possible negative effects include reduced generic prescribing and increased overall prescription rates, among others.
 - Studies show that even small gifts may create an unconscious “demand for reciprocity.”

Evolving Policy Solutions

- **Non-binding guidelines developed** - The American Medical Association, the Pharmaceutical Researchers and Manufacturers of America (“PhRMA”), the Advanced Medical Technology Association (“AdvaMed”) and the Office of the Inspector General have developed guidelines. All lack measures to monitor and ensure compliance.
- **Federal action possible** - Senator Charles Grassley (R-IA), introduced the Physician Payments Sunshine Act of 2007, requiring disclosure of industry payments in excess of \$25.00. If passed, the Physician Payments Sunshine Act would preempt state law.
- **Varied State Initiatives** – Six states other than Massachusetts and the the District of Columbia have laws or regulations

State Comparison

Table that compares Massachusetts to several other states with regard to having a state code of conduct, compliance requirement, disclosure requirement, public disclosure and medical devices. Massachusetts would be the only state to have all of those elements.

Massachusetts: A Robust Approach

- **Massachusetts law is the most stringent of the existing state laws.**
- A **Marketing Code of Conduct** that restricts certain marketing activities.
 - Sets PhRMA and AdvaMed Codes as the floor.
- A **Compliance Program** that goes beyond California and Nevada law.
- A **Disclosure Requirement** that mandates public disclosure above and beyond the disclosure requirements of Vermont, Maine, Minnesota, Vermont, West Virginia and the District of Columbia.

What is in the PhRMA and AdvaMed Codes of Conduct

- **PhRMA Code of Conduct**
 - Pharmaceutical industry guidelines established by the Pharmaceutical Research and Manufacturers of America.
- **AdvaMed Code of Conduct**
 - Medical Device industry guidelines established by the Advanced Medical Technology Association
- **Both outline ethical approaches** - to interactions with health care practitioners, including informational presentations and conferences, consulting agreements, the provision of educational items and the training of company representatives.

Proposed Regulations: Most Comprehensive in the Country

- **Only state to require adoption of and compliance with a state-authored Marketing Code of Conduct.**
- **Only state to prohibit certain payments to HCPs by both pharmaceutical and medical device manufacturers.**
- **Only state to require financial disclosures by medical device manufacturers.**
- **Only state regulation to require disclosure of free drug samples and the provision of demonstration or evaluation units.**
- **One of only two states to make disclosure data part of the public record.**

Proposed Regulations: Background

- Drafted pursuant to Chapter 111N, part of Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Healthcare.
 - Signed into law August 10, 2008
 - Overview of the law presented to the Council in September.

Proposed Regulations: Purpose

- **Seeks to identify and minimize potential financial conflicts of interest.**
- **Seeks to balance transparency interests with the legitimate proprietary concerns of HCPs and pharmaceutical and medical device manufacturers in conjunction with genuine research and clinical trials.**
- **Seeks to place pharmaceutical and medical device manufacturers on equal footing with respect to the specific requirements of Chapter 111N**

- Clarifies permissible activities beyond those specifically allowed in Chapter 111N.
- Specifically incorporates provisions from the PhRMA and AdvaMed Codes not included in Chapter 111N.

Marketing Code Of Conduct

Who is Subject to the Marketing Code of Conduct?

- Pharmaceutical or Medical Device Manufacturing Companies (“PMDMC”) that employ a person to sell or market prescription drugs or medical devices in the Commonwealth

Who is Affected by the Marketing Code of Conduct?

- Persons who:
 - Prescribe prescription drugs for any person, and
 - Are licensed to provide health care in the Commonwealth
 - Partnerships or corporations comprised of such persons, or their agents.
- Does not include bona fide employees of PMDMC

Marketing Code of Conduct Prohibited Activities

General Marketing Prohibitions

- Grants, scholarships, subsidies, consulting contracts, or educational items in exchange for prescribing or disbursing prescription drugs or medical devices.
- Entertainment or recreational items of any value;
- Payments in cash or cash equivalents either directly or indirectly except as compensation for bona fide services;
- The provision of complimentary items such as pens, coffee mugs, gift cards, flowers, etc.

Prohibited Meals

- Meals that are part of an entertainment or recreational event.
- Meals that are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such agent being present.
- Meals outside of a HCP’s office, hospital, academic medical center or specialized training facility;
- Meals provided to a HCP’s spouse or other guest.

Prohibited Payments: CMEs, Conferences and Meetings

- Financial support for the cost of travel, lodging, attendance or other personal

- expenses of *non-faculty* HCPs
- Direct payment of meals
- Sponsorship of CME that is not compliant with the appropriate standards set by ACCME or other equivalent accrediting body.

Marketing Code of Conduct

Permissible Activities

Permissible Meals

- Modest and occasional meals in conjunction with informational sessions in specified clinical training settings.
- Sponsorship of meals at third-party scientific, educational or charitable conferences or professional meetings.
- Meals pursuant to a written consulting agreement for bona fide services, sponsored genuine research or clinical trials.

Permissible Payments to Health Care Practitioners

- Reasonable compensation for substantial professional and consulting services of an HCP for a genuine research project or clinical trial.
- Reimbursement of reasonable costs necessary for technical training on a medical device if subject to a written agreement for purchase of the device.
- The provision of price concessions, such as rebates or discounts in the normal course of business.
- Payments for bona fide services.

Payments Permitted for “Bona Fide Services”

- **Consulting services, including, but not limited to:**
 - **Research,**
 - **Participation on Advisory Boards, and/or**
 - **Presentations at company-sponsored trainings**

- **Royalties or licensing fees.**

Permissible Payments: CME, Conferences and Meetings

- Permissible payments:
 - Scholarships for residents and interns
 - Compensation and reasonable expenses of conference faculty.
 - Sponsorship - where the payment is made directly to the conference or meeting organizers

Other Permissible Activities

- The provision of peer reviewed journals or other academic, scientific or clinical information;

- Advertising in peer reviewed journals;
- The provision of prescription drug or medical device demonstration and evaluation units;
- The provision of free outpatient prescription drugs through established “patient assistance programs” for the benefit of low income individuals; and
- Technical assistance concerning reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products.

Compliance Requirements

Compliance Program Requirements

- **Pharmaceutical/Medical Device Manufacturers must:**
 - Adopt and comply with the DPH Marketing Code of Conduct.
 - Adopt a training program in conjunction with the Code.
 - Adopt policies and procedures for investigating instances of noncompliance.
 - Identify an officer charged with ensuring compliance.
 - File an annual report with DPH that includes a description of its training program and investigative policies, the name, title and address of its compliance officer and certifies compliance.

Disclosure Requirements

Disclosure of Industry Payments to Physicians

- PMDMCs must report any “fee, payment, subsidy or other economic benefit with a value of at least \$50, directly or through its agents, to any covered recipient in connection with the company’s sales and marketing activities.”

“Covered Recipient”

- Any person in the Commonwealth authorized to:
 - Prescribe,
 - Dispense, or
 - Purchase prescription drugs or medical devices
- Does not include:
 - Bona fide employees of pharmaceutical or medical device manufacturers
 - Consumers who purchase prescription drugs or medical devices

Mass. Regs Offer the Broadest State Definition of “Sales and Marketing Activities”

- Advertising, promotion, or other activity used to:
 - Influence sales/market share of a prescription drug,, biologic or medical device;
 - Influence the prescribing behavior of an individual HCP to promote a drug, biologic, or medical device;
 - Evaluate the effectiveness of a professional pharmaceutical or medical device

- detailing sales force;
- Product education, training; and
- The provision of any economic benefit with a value of at least \$50 for any purpose other than the reasonable compensation for substantial professional/consulting services in connection with a genuine research project or clinical trial.

Mass. Regs Have the Most Comprehensive, Publicly Searchable Website on Disclosures

- Each annual disclosure report filed by PMDMCs will be made publicly available on an easily searchable website established by the Department. The information provided will include:
 - fees, payments, subsidies and other economic benefits related to sales and marketing including the provision of product samples and demonstration units.
 - the value, nature, purpose and **particular recipient**.

Mass Regs Require Strict Compliance with Disclosure Requirements

- Pharmaceutical and medical device manufacturers shall not knowingly structure fees, payments, subsidies or other economic benefits to HCPs to circumvent the reporting requirements of Chapter 111N and 105 CMR 970.000.

Mass. Regs Have Strong Enforcement and Penalties

- A person who violates 105 CMR 970.000 shall be punished by a fine of up to \$5,000.00 per transaction, occurrence, or event.
- All persons subject to 105 CMR 970.000 are under a duty of good faith compliance.
- Non-retaliation provision: No PMDMC or other person or employer shall retaliate or take any adverse personnel action against any employee, applicant, hcp, or covered recipient who takes action in furtherance of the enforcement of 105 CMR 970.000.

Summary

Proposed Regulations Break New Ground in Industry Oversight

Implementation Dates

July 1, 2009

- Compliance with Code of Conduct
- Submission of information in Section 970.005 (name of compliance officer, investigation policies, etc.)
- Initial payment of fee (proposed \$2,000)

July 1, 2010

- Submission of reportable activities for period July 1, 2009 to December 31, 2009

Department Process

- Hold public hearings.

- Hearings (dates / locations):
 - January 9, 2009: Boston
 - January 12, 2009: Worcester
- Attending a hearing is not required; written testimony accepted until 5:00PM on January 19, 2009.
- Weigh the comments received during the notice and comment period.
- Present regulations to the Public Health Council for final promulgation.

Conclusion

- Most comprehensive state regulation of pharmaceutical and medical device marketing to health care practitioners.
 - Only state to require adoption of and compliance with a state-authored Marketing Code of Conduct.
 - Only state to prohibit certain payments to HCPs by both pharmaceutical and medical device manufacturers.
 - Only state to require financial disclosures by medical device manufacturers.
 - Only state regulation to require disclosure of free drug samples and the provision of demonstration or evaluation units.
 - One of only two states to make disclosure data part of the public record.
 - Broadest definition of "Sales and Marketing" of any state.