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The New Massachusetts Pharmaceutical & Medical Device Marketing Regulations



*How Pharmaceutical Manufacturers Can
Identify, Address and Overcome
Likely Compliance Challenges*

Boston Bar Association

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Colin J. Zick

Foley Hoag LLP

czick@foleyhoag.com

(617) 832-1275

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Massachusetts: The Most Challenging Regulatory Environment in the U.S.

- Massachusetts has the broadest definition of “sales and marketing” of any state
- Only Massachusetts prohibits certain payments to providers by pharmaceutical and medical device manufacturers
- Massachusetts is one of two states to make disclosure of data part of the public record

What Questions Must Pharmaceutical Manufacturers Answer?

- Is your company covered by these regulations?
- What promotional activities does your company want to do and what can your company still do?
- What must you do to be compliant between:
 - now and July 1, 2009?
 - now and July 1, 2010?
- How do you make your Massachusetts efforts mesh with your compliance efforts in other states?
- Is federal regulation likely and will it supersede the new Massachusetts regulations?

Who are the Covered “Health Care Practitioners” under Massachusetts law?

- Health Care Practitioners (HCPs) covered by the regulations include those who:
 - Prescribe prescription drugs for any person; and
 - are licensed to provide health care in Massachusetts (also partnerships or corporations comprised of such persons or their agents).
- Does not include full-time company employees or board members who are not HCPs.
- Does not include hospitals.

Code of Conduct – Meals and Gifts

- Prohibits payments to HCPs for meals that are:
 - Part of an entertainment event
 - Offered without an informational presentation made by a marketing agent, or without the agent being present
 - Outside of the HCP’s office or “hospital setting”
 - Hospital, academic medical center, or “specialized training facility”
 - Provided to the HCP’s spouse or other guest
- Prohibits gifts to HCPs including:
 - Providing or paying for entertainment or recreation items of any value to any nonemployee HCP
 - Payments in cash or cash equivalents except as compensation for services
 - Expressly prohibits “complimentary items” such as pens, coffee mugs, gift cards, etc.
 - Grants, scholarships, contracts or practice items in exchange for prescribing drugs or using medical devices

Code of Conduct – What does Massachusetts Require?

- Massachusetts Code of Conduct Requirements
- How does the Massachusetts Code of Conduct compare to the PhRMA Code?
- How do these Code of Conduct requirements mesh with private codes, like that of Partners Healthcare or the Institute of Medicine guidance?

Code of Conduct – Prohibited CME Payments

- Sponsorship of CME seminars not accredited by ACCME or meeting ACCME standards
- Cost of travel, lodging or other personal expenses of non-faculty at conferences and meetings
- Funding for time spent by HCPs for participation in conferences
 - Exception for reasonable compensation or reimbursement to an HCP serving as a speaker or providing actual substantive services
- Direct payment for meals at conferences
 - Allows general financial support to conference provider or organizer

Code of Conduct - Allows

- Provision of peer reviewed academic, scientific or clinical information
- Advertising in peer reviewed academic, scientific or clinical journals
- Drug samples for use by and education of patients
- Compensation for professional consulting services in connection with research and clinical trials
- Expenses for technical training, including travel and lodging, if part of a purchase contract
- Price concessions, including rebates and discounts

Disclosure Requirement

- Requires covered companies employing marketers to disclose annually the:
 - Value, Nature, Purpose, 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”
 - Broader than just HCPs: person authorized to prescribe, dispense or purchase prescription drugs or medical devices in the Commonwealth, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner
 - Employees are excluded
 - in connection with the company’s “sales and marketing activities”

Questions Left Unanswered By the Regulations

- How much time and money should my company spend on compliance with these rules?
- What about discounts on drug sales by physicians (e.g., chemotherapy drugs that are administered in the physician's office, after being purchased by physicians), must they be disclosed?
- “Meals” are prohibited, but what about drinks at a bar?

Questions Left Unanswered By the Regulations (cont'd)

- Can the president of my company have lunch with a primary investigator to talk about the study the PI is conducting on our product?
- How do we determine who is a HCP?
 - Do we have to research every doctor we come into contact with?
- Should HCPs who are licensed in multiple states let their Massachusetts licenses lapse?

What Must You Do By July 1, 2009?

Per the requirements of 105 CMR 970.005:

- Adopt and comply with the Marketing Code
- Adopt and submit to DPH a description of your training program
- Certify compliance with the regulations
- Adopt and submit to DPH policies and procedures for:
 - investigating non-compliance,
 - taking corrective action in response to non-compliance, and
 - reporting instances of non-compliance to the Commonwealth
- Submit to DPH the contact information for the Compliance Officer responsible for certifying compliance with the Marketing Code and for implementing, monitoring, and enforcing your Marketing Code.
- Start tracking payments
- Pay your \$2,000 “disclosure fee”

What Must You Do By July 1, 2010?

On or before July 1, 2010 and each year thereafter, you must:

- Certify that you have completed an annual audit of compliance with the regulations
- File your disclosure report
- Pay your \$2,000 “disclosure fee”

Making Massachusetts Efforts Coincide with Compliance in Other States

- Three approaches:
 - Individualized state-by-state compliance
 - Consider Massachusetts the baseline and apply its standards to every state; or
 - Consider Massachusetts an outlier and pick another state (or the future federal standard) as your baseline.

Will Federal Regulation (and Pre-emption) Come to Your Rescue?

- It is far from certain that federal legislation will be enacted.
- Even if federal legislation is passed, there will be a major battle over the pre-emption of state laws.
- Outcome could resemble the federal health privacy regulations in HIPAA – the federal law will serve as a floor but will not supersede more stringent state laws.

Five Not-So-Easy Steps to Compliance

- Decide if you want to continue to interact with Massachusetts HCPs? If not, then you have completely eliminated your obligations in Massachusetts.
- If you continue your relationship with Massachusetts physicians, determine:
 - Who you want to interact with;
 - Why you need them;
 - Whether you are willing to have the relationship public;
 - How much you want to pay them.
- Appoint a Compliance Officer and establish an implementation team.
- Set a budget of time and money to come into compliance.
- Involve your Board of Directors.

Resources

- Massachusetts Department of Public Health:
http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_pharmacy_medical_devices&csid=Eeohhs2
- Massachusetts physician licensure information:
<http://profiles.massmedboard.org/MA-Physician-Profile-Find-Doctor.asp>
- PhRMA Code:
http://www.phrma.org/code_on_interactions_with_healthcare_professionals/
- AdvaMed Code: <http://www.advamed.org/MemberPortal/About/code/>
- Report of the Partners Commission on Interactions with Industry, April 2009,
http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf
- Institute of Medicine Report,
<http://www.iom.edu/Object.File/Master/65/993/COI%20report%20brief%20for%20web.pdf>