

# Pharmaceutical and Medical Device Manufacturer Conduct

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1



## Overview

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- Background
- Summary of Public Comments
- Department's Response to Comments
  - Response to Consumer Concerns
  - Response to Industry and Other Affected Parties
- Publicly Accessible Website
- Summary and Implementation of the Regulations

2

## Proposed Regulations: Background

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- 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 originally presented to the Council in September.

3

## Proposed Regulations: Purpose

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- **Seeks to identify and minimize potential financial conflicts of interest.**
- **Seeks to ensure transparency around industry payments to health care practitioners without compromising legitimate and beneficial industry-health care practitioner interactions.**
- **Seeks to place pharmaceutical and medical device manufacturers on equal footing with respect to the specific requirements of Chapter 111N**
- **Specifically incorporates requirements from the PhRMA and AdvaMed Codes of Conduct as mandated by Chapter 111N.**

4

## Massachusetts: A Robust Approach

Massachusetts law is the most stringent of the existing state laws.


- **Code of Conduct** provisions that restrict 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.

5

## State Comparison

State	State Code of Conduct	Compliance Requirement	Disclosure Requirement	Disclosure Public?	Medical Devices
California		√			√ (without disclosure)
Maine			√		
Massachusetts	√	√	√	√	√ (with disclosure)
Minnesota			√	√	
Nevada		√			√ (without disclosure)
Vermont			√		
W. Virginia			√		
District of Columbia			√		

6



## Proposed Regulations: Process

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- Presented at December 2008 PHC meeting.
- Held two public hearings in January 2009
- Comment period closed on January 19, 2009

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## Summary of Public Comments

8

## Who Submitted Comments?

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- Consumer advocacy groups and individual consumers
- Pharmaceutical, Biotech and Medical Device Industry Trade Groups
- Individual Pharmaceutical, Biotechnology and Medical Device Manufacturers
- Health Care Practitioners
- Visitor Industry
- Charitable Organizations
- Payors, Pharmacy Benefit Managers and Purchasers of Drugs, Biologics or Medical Devices

9

## Consumer Perspectives

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- **Representative Groups:**
  - Massachusetts Prescription Reform Coalition, Health Care For All, AARP, Individual Consumers, Senators Richard Moore and Mark Montigny.
- **Concern:**
  - Pervasive industry interaction affects prescribing patterns
- **Suggested changes:**
  - Set limitations on industry interaction with practitioners in training
  - Require disclosure of purely marketing research
  - Include across the board gift ban
  - Ban all meals
  - Eliminate detailing provisions

10

## General Industry Perspectives

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- **Representative Groups:**
  - PhRMA, AdvaMED, MassMedic, Astrazeneca, Wyeth, Boston Scientific, Smith and Nephew, etc.
- **Concerns:**
  - Difficulties of complying with Massachusetts-specific requirements in a national marketplace, and
  - Ensuring the protection of product development and research.
- **Suggested Changes:**
  - Include 6 month extension for compliance
  - Clarify the \$50 threshold for disclosure
  - Exempt from disclosure all activities deemed permissible under the Massachusetts code of conduct provisions.
  - Exclude industry employees and boardmembers from the definition of health care practitioner.
  - Expand protections for trade secrets and not unduly restrain genuine research and clinical trials.

11

## Specific Medical Device Industry Perspectives

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- **Representative Groups:**
  - AdvaMed, MassMedic, MDMA
- **Concerns:**
  - Regulations should reflect the fact that medical device manufacturers differ substantially from pharmaceutical companies:
    - Size
    - Training, and
    - Diversity of products
- **Suggested changes:**
  - Impose sliding scale for \$2,000 fee.
  - Allow the provision of demonstration and evaluation units for a health care practitioner's use.
  - Allow manufacturers to reimburse travel costs associated with training on medical devices.
  - Amend definitions to reflect that clinical trials and research on medical devices do not always use human subjects or human tissue.

12

## Visitor Industry Perspectives

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### ○ Representative Groups:

- The Greater Boston Convention Center, the Massachusetts Lodging Association, Massachusetts Hotels and the Promotional Products industry.

### ○ Concerns:

- The Department's regulations on CME, conferences and meetings may deter pharmaceutical and medical device meetings from taking place in Massachusetts
- Indirect effects may adversely impact the local economy.

### ○ Suggested Changes:

- Permit the provision of promotional products such as pens, mugs, etc.
- Eliminate requirements surrounding CME, conferences and meetings.

13

## Charitable Organizations Perspectives

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### ○ Representative Groups:

- The Schwartz Center, the Massachusetts Association for Mental Health and the Asthma and Allergy Foundation of America.


### ○ Concerns:

- The Department's regulations may chill charitable giving by pharmaceutical and medical device manufacturers.

### ○ Suggested changes:

- Allow:
  - Charitable donations to 501(c)(3)s
  - Donations of drugs and supplies in the event of an emergency or national disaster.

14



## The Perspective of Payors, Pharmacy Benefit Managers and Purchasers

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### ○ **Representative Groups:**

- Massachusetts Association of Health Plans, Pharmaceutical Care Management Association and National Association of Chain Drug Stores.

### ○ **Concerns:**

- The Department's regulations may discourage pharmaceutical and medical device manufacturers from offering bulk discounts and rebates.
- The costs of drugs, biologics and medical devices will increase.

### ○ **Suggested Changes:**

- Specifically exempt price concessions from disclosure requirements.


15



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## The Department's Response

16




## Balancing the Interests

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- In depth analysis of testimony received
- Clarified the regulations where necessary
- Made substantive changes with 3 goals in mind:
  - To limit industry interactions with health care practitioners that may influence prescribing patterns and/or adversely affect the care patients receive.
  - To increase transparency surrounding industry payments to covered recipients
  - To not unduly restrict beneficial industry interactions with health care practitioners/other covered recipients that increase access to advances in the diagnosis, treatment and prevention of disease.

17



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**The Proposed Final Regulations  
Remain the Strongest in the  
Nation**

18

## With the Proposed Changes, MA remains:

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- Only state to require adoption of and compliance with state-authored Code of Conduct requirements
- Only state to prohibit certain payments to health care practitioners by both pharmaceutical and medical device manufacturers.
- Only state to require disclosures by medical device manufacturers.
- One of only two states to make disclosure data part of the public record.


19

## Adoption and Compliance with a State-Authorized Code of Conduct

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- Department Responded to Consumer Concerns by:
  - Making explicit the broad mandate implicit in Chapter 111N
    - Clarify that all pharmaceutical and medical device manufacturers and distributors must comply with the Department's regulations.
  - Limiting the influence of marketing in health care consulting agreements.
    - Clarify that a health care practitioner may be hired as a consultant as long as the consultancy does not amount to purely serving as a sales representative for the company.
  - Limiting industry influence on health care practitioners in training.
    - Eliminate the provision allowing manufacturers to provide financial assistance to healthcare professionals in training.

20



## Disclosure of Industry Payments

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- The Department responded to consumers' transparency concerns by:
  - Expanding the already broad definition of "sales and marketing activities."
    - Require manufacturers to disclose research that:
      - ◆ Is designed or sponsored by a manufacturer's marketing department
      - ◆ Has marketing, product promotion, or advertising as its purpose.

21



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## Protecting Beneficial Relationships

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## Response to Industry Concerns Regarding the Code of Conduct Provisions

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- Department responded to general industry concerns by:
  - ✦ Clarifying that manufacturers need not restrict payments provided to full-time employees and boardmembers.
- Department responded to specific medical device manufacturer concerns by:
  - ✦ Providing that medical device manufacturers may provide demonstration and evaluation units to health care practitioners for their own use.
  - ✦ Clarifying definitions so as not to restrict research and clinical trials on medical devices.

23



## Response to Groups Indirectly Impacted by the Code of Conduct Provisions

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- Department responded to the concerns of charitable organizations by:
  - ✦ Allowing for the provision of charitable donations and the donation of drugs or devices in the event of a public health crisis, natural disaster, or other charitable need.
- Department responded to visitor industry concerns by:
  - ✦ Clarifying that CMEs, conferences and meetings, and meals in conjunction with CMEs, conferences, and meetings, could be conducted at hotels or convention centers.

24

## Response to Industry Concerns Regarding Disclosure

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- Department responded to industry concerns by:
  - Making explicit the statutory requirement that the \$50 threshold will be applied per individual transaction.
  - Clarifying that manufacturers need not disclose payments made to full-time employees and boardmembers.
  - Retaining the exemption from disclosure for genuine research and clinical trials
  - Providing a new exemption from disclosure for prescription drugs provided at no cost to covered recipients solely and exclusively for use by patients, and demonstration and evaluation units provided for the benefit of patients.

25

## Response to Groups Impacted by Disclosure Requirements

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- Department responded to the concerns of payors, prescription benefit plan administrators and purchasers by:
  - Providing an exemption for the provision of rebates and discounts.
- Department responded to concerns of charitable organizations by:
  - Providing an exemption for the provision of in-kind items for charity care.

26

## Regulations Continue to Require Broad Transparency of Industry Payments

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- Proposed Regulations, as amended, require disclosure of the following:
  - ⊛ 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 health care practitioner to promote a drug, biologic, or medical device;
    - Evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force;
  - ⊛ Product education and training
  - ⊛ Charitable donations to hospitals, universities, 501(c)(3)s
  - ⊛ Sponsorship of CME, third-party conferences, scientific or professional meetings
  - ⊛ Consulting payments in conjunction with marketing-based research
  - ⊛ Any other economic benefit with a value of \$50 or more directed at and benefiting a covered recipient.

27

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## Consumer-Friendly Website

28




## MA Will Have the Most Accessible and Comprehensive Website on Disclosures

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- Each annual disclosure report filed by manufacturers will be made publicly available on an easily searchable website established by the Department.
- The Department is committed to making this information accessible to a diverse population of healthcare consumers.
- Other states requiring disclosure either:
  - Fail to make such information publicly available, or
  - Fail to make such information accessible to the public.

29



## What Is Required of Manufacturers?

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- Disclosure of:
  - Individual fees, payments, subsidies and other economic benefits over \$50 related to sales and marketing activities. \$50 threshold shall be calculated on a per transaction basis and shall not be aggregated.
  - the value, nature, purpose and **particular recipient**.
- Payment of a \$2,000 annual fee:
  - The first payment of this fee is due on July 1, 2009, which pre-dates the first submission of disclosure reports by pharmaceutical and medical device manufacturers. Starting July 1, 2010, the fee shall accompany the disclosure report.
  - No sliding scale for imposition of the fee.

30

## Specific Data Elements in Report

- Company Identifier
  - FDA number
- Provider Identifier
  - MA specific license numbers for individuals and organizations such as those from BORIM and Health Profession Licensure
  - Provider or organization name may also be provided for verification purposes
- Dollar amount
  - Amount given by company to this provider or organization
- Category
  - Marketing Research, Product Training and Education, Consulting Services, CME and Third Party Conferences or Meetings, Meals, Charitable Donations, Other
- Number of events
  - Number of unique events represented by this dollar amount in this category for the specific provider

31

## Example of Data Submitted by Company XYZ

Company ID	Provider ID	Dollar Amount	Category	Number of Events
XYZ	3784213 (Dr. J. Smith)	125.00	Marketing/ Research	1
XYZ	3784213 (Dr. J. Smith)	800.00	Meals	10
XYZ	3412321 (S. Adams, NP)	75.00	Consulting Services	1

32

## Website View:

A consumer could look up Dr. John Smith (Provider ID 3784213) on the DPH Website and see the following summary:


Company ID	Dollar Amount	Category	Number of Events
XYZ	125.00	Marketing/ Research	1
XYZ	800.00	Meals	10
ABC	135.00	Third Party Conferences	1

33

## 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.
- Fines shall be issued and enforced by the Department in conjunction with the Office of the Attorney General.
- Non-retaliation provision: No manufacturer or other person shall retaliate or take any adverse action against any applicant, health care practitioner, or covered recipient who takes action in furtherance of the enforcement of 105 CMR 970.000.

34




## Summary

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### Proposed Regulations Break New Ground in Industry Oversight

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## Most Comprehensive State Regulation

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- \* Only state to require adoption of and compliance with a state-authored Marketing Code of Conduct.
- \* Only state to prohibit certain payments to health care practitioners by both pharmaceutical and medical device manufacturers.
- \* Only state to require financial disclosures by medical device manufacturers.
- \* One of only two states to make disclosure data part of the public record.
- \* Broadest definition of "Sales and Marketing" of any state.

36

## Implementation Dates

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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


37

## A Balanced Approach

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- DPH, with the advice of the Executive Office of Health and Human Services and the Office of the Attorney General, engaged in an in-depth review of the regulations and the various comments received during the hearing and comment period and interests of impacted groups.
- The regulations, with the proposed changes, clarify Department policy and provide a balanced approach towards addressing the conflicts of interest issue.

38



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**The Department Respectfully  
Requests Final Approval of 105  
CMR 970.000.**