Pharmaceutical and Medical Device Code of Conduct

Request to Promulgate Final Amendments to 105 CMR 970.000

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Public Health Council Meeting

Wednesday, November 21, 2012
Proposed Regulations: Background

• 2008: Legislature passed Chapter 111N, requiring pharmaceutical and medical device companies to comply with a Massachusetts Code of Conduct.

• March 2009: PHC promulgated regulations, 105 CMR 970

• July 2012: Legislature amended Chapter 111N, allowing modest meals

• September 2012: PHC amended regulations through emergency vote

• October 2012: public hearing and public comment period held
  – Hearing: October 19
  – Public Comment period ended October 26
<table>
<thead>
<tr>
<th></th>
<th>State Code of Conduct</th>
<th>Attestation of Compliance</th>
<th>Disclosure Requirement</th>
<th>Public Disclosure</th>
<th>Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massachusetts</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√ (with disclosure)</td>
</tr>
</tbody>
</table>
MA Law Governing Pharmaceutical & Medical Device Manufacturers

- Industry must adopt the **Massachusetts Marketing Code of Conduct**

- **Training program** on the Code for employees

- Sets requirements for the **industry’s use of prescriber data**
  - Data must be kept confidential
  - Providers can request data be kept from sales reps or not be used for marketing purposes

- Requires that providers who set formularies or develops clinical guidelines and who work for the industry as a speaker or consultant disclose the relationship

- Requires companies to conduct an annual audit that it is in compliance with the regulation
Massachusetts Code of Conduct

Current

**PROHIBITED**

- Entertainment/recreational items (tickets to shows, golf outings, concerts, etc.)
- Cash, gift cards, pens, mugs, calendars, etc.
- Payment to non-faculty HCPs for attending CME events

**ALLOWED**

- Payment for “bona-fide services”
- “technical training” for medical devices, and associated travel and lodging
- Rx drugs for use by patients
- Medical device demonstration units
- Charitable donations

**Meals**

- Meals outside hospital / office setting
- Meals for spouses/guests

**Meals**

- Modest meals inside hospital & office setting
Massachusetts Code of Conduct, After Amendment

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• Entertainment/recreational items (tickets to shows, golf outings, concerts, etc.)
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Meals
- Modest meals inside hospital & office setting
- Meals outside hospital & office setting
How other codes of conduct approach provision of meals
Sources of Codes of Conduct

- A small number of professional organizations publish codes of conduct for their members
  - Codes are voluntary, and contain broad guidelines meant to promote ethical interactions among members
- Professional organizations, individual institutions, such as hospitals, also enforce their own codes of conduct
  - often more stringent than association codes
  - usually required as a condition of employment
- The legislation governing these regulations specifically mentions two codes of conduct as a basis for MA law:
  - **PhRMA** (Pharmaceutical Research & Manufacturers Association)
  - **AdvaMed** (Advanced Medical Technology Association)
## Professional Codes of Conduct

<table>
<thead>
<tr>
<th>Profession</th>
<th>Applicable Code</th>
<th>Alcohol Specifications</th>
<th>Meals Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>American Medical Association</td>
<td>None</td>
<td>Meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense</td>
</tr>
<tr>
<td>Dentists</td>
<td>ADA Principles of Ethics and Code of Professional Conduct (April 2012)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Psychologists</td>
<td>American Psychological Association. Ethical Principles of Psychologists and Code of Conduct, (June 2010)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Medical Device Companies</td>
<td>AdvaMed Code of Ethics on Interactions with Health Care Professionals</td>
<td>None</td>
<td>Modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>PhRMA Code on Interactions with Healthcare Professionals, 2008</td>
<td>None</td>
<td>Modest: as judged by local standards</td>
</tr>
</tbody>
</table>
Summary of Public Comments
Overview of Public Testimony

Public Hearing held on October 19, 2012:

– 19 oral testimonies

– 84 written comments

– 92 total comments
  • Some individuals submitted both oral and written comments
  • Some letters were signed by multiple people/parties
Testimony

- Consumer advocacy groups and individual consumers
- Legislators
- Medical and healthcare associations
- Pharmaceutical, biotech and medical device industry companies and trade groups
- Health care practitioners, including physicians and medical students
- Restaurant owners
### Organization’s Response to Amendments as Proposed

<table>
<thead>
<tr>
<th>SUPPORT</th>
<th>OPPOSE</th>
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</thead>
<tbody>
<tr>
<td><strong>Healthcare-related Associations:</strong></td>
<td><strong>Consumer Advocacy Organizations</strong></td>
</tr>
<tr>
<td>• American Assoc. of Clinical Endocrinologists</td>
<td>• AARP</td>
</tr>
<tr>
<td>• Arthritis Foundation</td>
<td>• Community Catalyst</td>
</tr>
<tr>
<td>• Asthma &amp; Allergy Foundation of America</td>
<td>• Health Care For All</td>
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<tr>
<td>• Coalition for Healthcare Communication</td>
<td>• MASSPIRG</td>
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<tr>
<td>• Massachusetts Association for Mental Health</td>
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<tr>
<td>• Massachusetts Medical Society</td>
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<table>
<thead>
<tr>
<th>Pharma / Medical Device Companies:</th>
<th><strong>Healthcare-related Associations</strong></th>
</tr>
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<tbody>
<tr>
<td>• Biotechnology Industry Organization (BIO)</td>
<td>• American Medical Student Association</td>
</tr>
<tr>
<td>• MassBio</td>
<td>• National Physicians Alliance</td>
</tr>
<tr>
<td>• MassMEDIC</td>
<td>• National Medical Students Association</td>
</tr>
<tr>
<td>• Medical Imaging and Technology Alliance</td>
<td></td>
</tr>
<tr>
<td>• Novartis Pharmaceutical Corporation</td>
<td><strong>Healthcare Institution</strong></td>
</tr>
<tr>
<td>• Organogenesis</td>
<td>• Umass Memorial Health Care</td>
</tr>
<tr>
<td>• Otsuka American Pharmaceutical</td>
<td></td>
</tr>
<tr>
<td>• Pfizer</td>
<td></td>
</tr>
<tr>
<td>• PhRMA</td>
<td></td>
</tr>
<tr>
<td>• Sunovion Pharmaceuticals Inc.</td>
<td></td>
</tr>
</tbody>
</table>

| **Restaurant / Hospitality Industry** | |
|--------------------------------------| |
| • Davios Restaurant | |
| • Greater Boston Chamber of Commerce | |
| • Massachusetts Restaurant Association | |
| • Restaurant and Business Alliance | |
Testimony:

- Approximately half of testimony received asked for a different definition of modest meals, stating in general:
  - Definition needs to include a specific dollar amount to allow enforceability.
  - When a specific dollar amount was recommended, it ranged from $25 to $50 or to base on government per diem meal allowances.

- Many testified in support of the definition of modest meals as written. Comments included:
  - definition is consistent with PhRMA and AdvaMed codes of conduct
  - any flat cap on the cost of a "modest" meal would be arbitrary; there is no existing standard for this type of activity
  - “Modest Meals and Refreshments” recognizes regional variations in costs by providing that modest meals and refreshments are determined by local standards.
  - original law resulted in an unanticipated consequence of hurting the restaurant and hospitality industry
Feedback: Definition of modest meals

• Proposal:
  – maintain definition included in the emergency regulation

• Rationale:
  – None of the professional codes reviewed specify dollar amount for meals
  – The per diem rates proposed would not be appropriate for the kinds of educational venues envisioned with the law change.
  – Because the venues must be appropriate for educational meetings, this would mean generally a private area with audio-visual capacity, the cost of which would generally be included in the per/person cost of the meal.
  – If the Department were to propose a rate that would reflect a/v costs, tax and gratuity, as well as geographical variation, the result would be a high meal rate.
  – Have a high rate could have the opposite effect, i.e. a rate of over $100 could cause industry to use that as the base rate as opposed to the ceiling
Feedback: alcohol

- **Testimony**
  Approximately half of testimony received asked for a prohibition on alcohol, stating in general:
  - Alcohol is not a component for learning.
  - Should not be paid for or even available as cash bar.

- **Proposal**
  - Maintain definition as included in the emergency regulation

- **Rationale**
  - The law does not explicitly prohibit alcohol, or any other specific food or beverage. In fact, the law does not describe alcohol at all.
  - None of the professional codes address alcohol.
  - It is not appropriate for the Department to preclude the presence of alcohol, however the Department expects use will be appropriate.
Feedback: fees

• Testimony
  – A small number of people testified stating in general that the removal of the dollar amount was confusing. Some interpreted the change as the Department removing the fee altogether.

• Proposal:
  – Add the $2000 back into the reg

• Rationale:
  – This will eliminate any confusion.
  – It was never the Department’s intention to eliminate the fee.
• **Testimony**
  – A small number of people testified that certain venues should be prohibited from hosting educational forums with meals, specifically country clubs, golf clubs, casinos.

• **Proposal:**
  – No change

• **Rationale:**
  – The law and regulation already explicitly prohibit any recreation or entertainment (i.e. no golf games, shows, sporting events.)
  – Many of these venues are dual-purpose locations, i.e. Golf clubs often rent out appropriate space for private meetings
  – Given the prohibition on entertainment, and the various uses for different venues, it would be unfair to start prohibiting a small number of types of venues.
Feedback: reporting and disclosure

- **Testimony**
  Approximately half of testimony asked for expanded reporting, stating in general:
  - While the federal law requires disclosure of payments to physicians and teaching hospitals, the MA law also requires the disclosure and reporting of payments to all prescribers including NPs and PAs and that reporting should be maintained.
  - The amended law requires quarterly reporting, which is not reflected in the emergency regs.

- **Proposal**
  - Amend to maintain information not required by federal law (e.g., NPs and PAs)
  - Amend to include quarterly reporting

- **Rationale**
  - Massachusetts has had the strongest disclosure requirements in the country which could be slightly weakened with the original proposal
  - Maintaining disclosure will allow the Department to monitor spending on meals, allowing analysis by institution, provider and pharmaceutical company
Federal Transparency Law

- Part of National Health Care Reform

- Requires annual reporting of any payment > $10 to physicians and teaching hospitals

- Will be administered by the Secretary of Health and Human Services
Federal Transparency Law

• Information Required:
  – Name
  – Address
  – Amount of payment
  – Date of payment
  – Type of Payment (i.e. cash, stock, etc)
  – Nature of payment (14 categories)
  – Name of relevant drug, device, etc
Federal Transparency Law

- Information must be available on a searchable website and be “easily aggregated and downloaded”
- Information can be searched by company, provider, address, date, nature of payment and name of covered drug/device
- Provides 45 day review period for providers to review/correct payment report
- Requires federal government to send reports to states
Impact of Federal Disclosure on Massachusetts Reporting Requirements

• Because the federal government has not implemented its reporting structure, the Department will continue to collect reports from industry until the federal law is implemented.
• DPH will continue to collect reports on providers not covered by the federal law, such as Nurse Practitioners and Physician Assistants
• New quarterly reports specific to the new modest meals provision will show:
  – location of the presentation;
  – description of any pharmaceutical products, medical devices or other products discussed at such presentation;
  – total amount expended on such presentation; and
  – an estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation.
In summary

• In depth analysis of testimony received

• Clarified the regulations where necessary

• Further amended with 4 goals in mind:
  – To maintain the high level of public information available by keeping disclosure requirements for nurse practitioners, physician assistants and other prescribers not covered by federal law.
  – To implement regulations that would not be unduly burdensome on the Department, in terms of receipts, audits and other requirements
  – To align state law with standards set by the legislature, specifically the two industry codes of conduct (PhRMA and AdvaMed.)
  – To increase transparency surrounding industry payments to covered recipient
Additional Amendments

- Clarify that there is one $2000 annual fee as part of registration.

- Require annual reporting of all information that is not pre-empted by the federal Sunshine Act (i.e., continued reporting of information that is not included in federal reports).
  - PAs, NPs, etc

- Require quarterly reporting.
With the changes, MA remains:

- 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.
- One of few states to have its own website making disclosure data part of the public record.
- Broadest definition of “Sales and Marketing” of any state.
# State Comparison of Pharmaceutical Gift Laws

<table>
<thead>
<tr>
<th>State</th>
<th>State Code of Conduct</th>
<th>Limit on Gifts</th>
<th>Certify Compliance w/ a Code of Conduct</th>
<th>Reporting Required ($)</th>
<th>Reporting Public</th>
<th>Applies to Medical Device Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>California[1]</td>
<td>✓</td>
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<td>✓</td>
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<td>W. Virginia</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>🔴</td>
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</table>

[2] [http://www.phcybrd.state.mn.us/main_pay.htm](http://www.phcybrd.state.mn.us/main_pay.htm)
[3] [http://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/AB_128_CompliancePacket.pdf](http://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/AB_128_CompliancePacket.pdf)
[7] [http://doh.dc.gov/node/185802](http://doh.dc.gov/node/185802)
The Department Respectfully Requests Final Approval of 105 CMR 970.000.
The Department Respectfully Requests Final Approval of 105 CMR 970.000.
Dispensing Procedures for Pharmacists – A Strategy to Minimize Potential Drug Shortages

Request to Promulgate Emergency Regulations at 105 CMR 722.000

Iyah K. Romm
Director of Policy, Health Planning, and Strategic Development

Public Health Council Meeting

Wednesday, November 21, 2012
Overview of Need

- Multi-State Meningitis Outbreak
- Overview of Compounding
  - New England Compounding Center/Ameridose Actions
- Board of Pharmacy Actions – Emergency Regulations
- Concern for Drug Shortages
  - No concrete reports at present
  - Collaboration with MHA and hospitals
Proposed Regulations: Background

- 105 CMR 722.090 restricts hospital pharmacies from dispensing medications to anyone other than the hospital’s patients and staff.

- DPH has received requests to waive these requirements

- DPH currently has no authority to grant a waiver.

- The amendment to 105 CMR 722.000 adds a new section authorizing the Commissioner, or the Commissioner’s designee, to waive requirements imposed by 105 CMR 722.000 during temporary drug shortage or other emergencies.
The proposed regulation authorizes the Commissioner, or the Commissioner’s designee, to grant time-limited waivers to any requirements imposed by 105 CMR 722.000 when:

1. The Commissioner determines that there is an emergency that affects public health and safety;
2. Waiver of a requirement will alleviate the emergency;
3. Waiver of a requirement will not jeopardize the health or safety of patients; and
4. The emergency is expected to be temporary in nature.

Commensurate with waiver authority under other regulations.
Proposed Regulations: Conditions

- Temporary waivers granted under this new section may be accompanied by conditions with which the registrant must comply.

- Failure to comply with the conditions of a waiver may result in immediate termination of the waiver.

- The Drug Control Program plans to hold a public hearing on the proposed changes to 105 CMR 722.000 in December 2012.
Public Hearing and Actions

• The Drug Control Program plans to hold a public hearing on the proposed changes to 105 CMR 722.000 in December 2012.

• The Department Respectfully Requests Final Approval of Amendments to 105 CMR 722.000.