

MA Healthcare Reform Legislation: Assessment of Massachusetts Department of Public Health Regulations

Pri-Med Institute

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MA Department of Public Health (DPH): Intent of the Regulations

- Identify and minimize potential conflicts of interest between healthcare professionals (HCP) and those in the position to influence medication acquisition or prescription practices
- Ensure transparency around industry payments to HCP without compromising legitimate and beneficial industry-healthcare practitioners
- Hold pharmaceutical and medical device manufacturers equally accountable to the regulations
- Incorporate requirements from PhRMA and AdvaMed Codes of Conduct

Other states with disclosure or pharma/device marketing and sales regulations: MN, VT, ME, WV, CA, NV, DC

DPH Regulations: Principles of the Code

- Based on applicable legal standards and incorporate principles of healthcare
- Cover activities of pharmaceutical reps or medical device manufacturer agents
- Intended to benefit patients, enhance practice of medicine, and not interfere with independent judgment of healthcare practitioners
- Align with standards outlined in the current PhRMA and AdvaMed Code and be no less restrictive
- Reporting requirement applies to all MA HCP based on their interactions with pharma and medical device industry and their representatives
- To be updated at least every two years

DPH Regulations in MA

- Require adoption of and compliance with a state-specific Code of Conduct
 - All pharmaceutical and medical device manufacturers and distributors must comply with the regulations
- Prohibit certain payments to HCP by both pharmaceutical and medical device manufacturers
 - “HCP may be hired as a consultant so long as the consultancy does not amount to purely serving as a sales representative for the company”
- Require disclosures by both pharmaceutical and medical device manufacturers
 - Research payments must be disclosed if the research is designed/sponsored by the manufacturer’s marketing department and/or has marketing, product promotion or advertising purpose
- One of two states to make disclosure data available to the public and part of the public record
- Law makes provisions to compel enforcement through state Attorney General, who can apply civil penalties for violations

Industries/Personnel Subject to MA 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 are **subject** to the Marketing Code of Conduct
- Persons who Prescribe prescription drugs for any person, and are licensed to provide health care in the commonwealth and Partnerships or corporations comprised of such persons and their agents are affected by the Marketing Code of Conduct
 - Physicians
 - Hospitals
 - Nursing homes
 - Pharmacists
 - Health benefit administrators
 - Health care practitioners, or
 - Any other person authorized to prescribe, dispense, or purchase prescription drugs or medical devices
- This does not include bona fide employees of PMDMC

DPH Website and Reportable Items

Annual Disclosure Report per Manufacturer

- \$2000 annual fee to state
- Annual Reports due by July 1
 - First report due July 1, 2010
- Reports will be made public on DPH website
 - Report only covers payments made to individual HCP or covered institutions identified in the law
 - Number of events
 - Unique events for each payment to each HCP or covered institutions
- Implementation
 - By July 1, 2009: Attestation of compliance with Code of Conduct, Submission of Compliance Officer and Policies, Payment of Fee
 - By July 1, 2010: Submission of first reportable activities for period July 1-December 31, 2009

Disclosure Specifics: What Must be Disclosed

- Individual fees, payments, subsidies and other economic benefits over \$50 related to sales and marketing activities
 - Includes payments made directly by covered company or through its agents, to covered recipient in connection with the company's sales and marketing activities
- \$50 threshold per transaction
- Transactions are not to be aggregated
- The disclosed information will be posted on website www.mass.gov portal
 - Database intended to be publically available and easily searchable

Disclosure Specifics: Allowable Items

What is ALLOWED

- **Compensation or reimbursement made to HCP serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, provided that the payment:**
 - is reasonable;
 - is based on fair market value; and
 - complies with the standards for commercial support as established by the relevant accreditation entity
- **Sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers**
- **Use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences**

Additional Details on What is Allowed

MEALS

- CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants
- Meals pursuant to a written consulting agreement for bona fide services, sponsored genuine research or clinical trials
- Meals that are allowed, including those offered with an informational presentation, must be modest and occasional in nature

OTHER ALLOWED ITEMS

- Provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information
- Advertising in peer reviewed journals
- Provision of prescription drug or medical device demonstration and evaluation units
- Provision of free outpatient prescription drugs through established “ patient assistance programs” for the benefit of low income individuals
- Technical assistance concerning reimbursement information regarding products, including indentifying appropriate coverage, coding, or billing of products

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Industry Payments/Meals to HCP

What is **NOT** Allowed

- *Can not* provide entertainment or recreational items of any value, including, but not limited to, tickets to theater/sporting events/concerts/sporting equipment, or leisure or vacation trips, to any HCP who is not a salaried employee of the pharmaceutical or medical device manufacturing company
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
 - **NOTE: Per the DPH FAQ Document: “Pharmaceutical or medical device manufacturers may not directly pay for meals outside of a “hospital setting.” However, third-party organizers of CME or other meetings may use general funds from such manufacturers to provide meals”**
- *Can not* provide payments of any kind including cash/cash equivalents/equity, “in kind” or tangible items including any “complimentary” items such as pens, coffee mugs, gift cards, etc. to HCP either directly or indirectly, except as compensation for bona fide services
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
- *Can not* provide any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**

Note: Please consult each Code for specific details relevant to each item as there are wording and contextual differences between the Codes

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Industry Payments/Meals to HCP

What is **NOT** Allowed

- *Can not provide* financial support for the cost of travel, lodging, attendance or other personal expenses of non-faculty HCP's
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
- *Can not provide* sponsorship of CME that is not compliant with the appropriate standards set by ACCME or other equivalent accrediting body
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
 - **NOTE: MA Code expressly prohibits sponsorship of CME under specific conditions while the PhRMA Code encourages companies to support CME, with certain restrictions and AdvaMed Code describes various ways as to how companies may support CME conferences**
- *Can not* directly provide meals at CME events
 - **CONSISTENT WITH PhRMA Code; There are additional allowable provisions for meals at CME events in AdvaMed Code**
 - **NOTE: While MA and PhRMA Codes prohibits direct payment or sponsorship of meals, a provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide modest meals for all participants**

Note: Please consult each Code for specific details relevant to each item as there are wording and contextual differences between the Codes

Industry Payments/Meals to HCP

What is **NOT** Allowed (Cont'd)

- *Can not* provide for any other payment or remuneration to HCP, in cash or in kind, directly or indirectly,
 - **CONSISTENT WITH PhRMA and AdvaMed Codes and Federal and State Laws**
 - NOTE: MA Code includes specific language that this includes any rebate or “kickback” that is prohibited under applicable federal or state “fraud and abuse” laws or regulations:
- Meals that *are not* allowed:
 - Part of an entertainment or recreational event
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
 - Offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**
 - Offered, consumed, or provided outside of the HCP’s office or a hospital setting
 - **Meal can not outside of HCP office or healthcare institution**
 - **INCONSISTENT WITH PhRMA and AdvaMed Codes but MA Code allows meals at hotels and convention venues in conjunction with CME or third-party conferences**
 - Provided to a HCP’s spouse or other guest
 - **CONSISTENT WITH PhRMA and AdvaMed Codes**

Note: Please consult each Code for specific details relevant to each item as there are wording and contextual differences between the Codes

Reporting Accountabilities and Penalties

- Pharmaceutical or medical device manufacturing companies shall certify that to the best of the reporter's knowledge and belief, the report is true and accurate
- Pharmaceutical or medical device manufacturing companies shall not knowingly structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements
- A company who violates MA Law/Regulations (105 CMR 970.000) shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event
- For more detailed information on penalties, please visit the Massachusetts Department of Public Health's website at www.mass.gov/dph

Permissible Payments

- Reasonable compensation for substantial professional and consulting service 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
- Provision of price concessions, such as rebates or discounts in the normal course of business
- Payments for bona fide services Consulting Services
 - Including but not limited to bona fide clinical research; participation on Advisory Boards; presentations at company-sponsored trainings; royalties or licensing fees

Presentation References

- State's press release:
http://www.mass.gov/?pageID=eohhs2pressrelease&L=4&L0=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&sid=Eeohhs2&b=pressrelease&f=090311_tough_new_rules&csid=Eeohhs2
- List of information including FAQs: <http://tinyurl.com/azocku>
- State's overview presentation:
http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_presentation_march11.ppt

Pri-Med Institute

- Pri-Med Institute (PMI) is the accreditation and compliance arm of M|C Holding Company group. PMI is an accredited provider of education for medical, pharmacy and nursing professionals. PMI is structured to provide continuing medical education (CME) programs to physicians that will advance health care practice and patient outcomes. Established in 2001, PMI is accredited by the ACCME (Accreditation Council for Continuing Medical Education), ACPE (Accreditation Council for Pharmacy Education), AANP (American Academy of Nurse Practitioners) and ANCC (American Nurse Credentialing Center) to provide CME. In addition, PMI oversees adherence to all relevant policies and practices including FDA, OIG, PhRMA and AMA, to which the M|C Holding Corp. is required to comply. Pri-Med Institute is committed to providing relevant, evidence-based education and educational intervention strategies that are innovative in design and motivate physicians to adopt appropriate, up-to-date clinical practices. For more information on PMI, visit www.pri-medinstitute.org.
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