Medical Conventions in Boston: The Massachusetts Hospitality Industry Responds to the Healthcare Marketing Law

Summary of the New Massachusetts Law

2009 Healthcare Convention & Exhibitors Association

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This summary of various legal sources is intended for general education purposes and is not intended to advertise or solicit legal services. Please note that it also should not be construed or read to serve as legal advice. Anyone having legal questions about the content of these materials should consult their own legal counsel for specific advice.

Industry Relationships Subject to Scrutiny

- Editor
- Author
- Peer Reviewer
- Advisory Board
- FDA Committee
- CME Presenter/Organizer
- Company Speakers Bureau
- Company Trainer

Industry Relationships Subject to Scrutiny

- Inventor
- Licensor
  - Royalty Rights
- Equity Holder
- Researcher - PI
- Consultant
- Clinical Guideline Committee

The CME System: Who are the Players?

- Physicians and other professionals
- Professional Societies
- Academic Medical Centers
- Community Hospitals
- Pharma and Device Companies
- Medical education and communication companies (MECCs) and other event planners
- Other CME Providers (e.g. on-line, publications)
- Disease Advocacy Organizations
- Federal and State Governments
- Hospitality Industry

Nature of Conflict

- Does the MD have a financial relationship with a drug or device company concurrent with having an R & D, clinical, product approval, academic or publication role that could unduly influence the independence of the MD's judgment in carrying out that role?

New Developments – 2009

- Tougher Voluntary Trade Associations Codes
  - PhRMA Code – (1/1/09)
  - AdvaMed Code – (7/1/09)
- Medical School/AMC CoI Policies
- Professional Medical Association Policies
  - AMA CEJA
  - Specialty Societies (APA)
- Institute of Medicine CoI Report
- New CME Accreditation Standards (ACCME?)
- Proposed federal laws
- Enacted and proposed state laws

New Developments – 2009

- Gift Bans and limits
- Limits on funding meals on and off-site
- Legal and ethical barriers to direct commercial funding of CME
- Voluntary limits on speakers' bureaus
- Multiple reporting and disclosure systems

Sources of Legal and Ethical Rules for Industry Relationships

- Federal and State Anti-kickback Laws
  - OIG 2003 Compliance Guidance for Pharmaceutical Companies
- Federal (Stark) and State Self-Referral Laws
- Federal and State False Claims Acts
  - Violations of Anti-kickback/Stark Laws
  - Claims for off-label uses
  - Whistleblower Provisions

Sources of Legal and Ethical Rules

- 1997 FDA Guidance on Industry-Supported Scientific and Educational Activities
  - Industry support of CME is legal if it is independent of company influence
  - CME cannot include promotional activities regarding off-label uses that are not truly independent of company influence
  - No company technical assistance is permitted beyond limited technical, or in response to an unsolicited request for assistance from either the organizer or a presenter.
  - No company edited or supplied materials
  - Full disclosure of all financial relationships and vetting of presenters
  - Exhibitor booths to be outside educational presentation meeting rooms.

Sources of Legal and Ethical Rules

- FDA Regulation of Information on Off-Label Uses
  - 1997 Food and Drug Administration Modernization Act – permitted limited company distribution of journal articles with off-label info -- expired in 2006
  - Current FDA Guidance - Jan. 2009 “Good Reprint Practices” allows such distribution
    - Unabridged reprints of peer reviewed journal articles that address off-label uses of their drugs in reputable medical journals
    - Accompanied by the FDA approved labeling for the product
    - not written, edited or significantly influenced by anyone with a financial relationship
    - not distributed with promotional materials or during promotional talks by company representatives.
    - Not in the form of a company funded special supplement
    - Is also generally available through independent distribution channels (e.g. internet, subscription)

Sources of Legal and Ethical Rules

- Federal Public Financial Disclosure
  - Terms of Settlement with federal government
  - Proposed: *The Physician Payments Sunshine Act of 2009*
    - Financial disclosure by drug and device manufacturers of payments/items to MDs in excess of $100 per year - posted on HHS website
    - Consideration being given to expand legislation to payments/items paid an given to hospitals, medical schools and medical societies as recommended by MedPAC
    - Would pre-empt state disclosure laws except for those that require reporting of information not required under the PPSA.
- Voluntary Company and Health System Disclosure
    - *E.g.* Eli Lilly; Merck; Pfizer
    - E.g. Cleveland Clinic; Park Nicollet Health Services

Sources of Legal and Ethical Rules

- Voluntary Company Public Disclosure of Grants and other Financial Relationships
- Elimination of Funding Through MECCs
  - e.g. Pfizer 2008 Policy
    - CME programs will have to meet stricter criteria
    - No direct funding commitments for CME programs by MECCs
    - Competitive grant review period for grant applicants to encourage more innovative, high-quality grant applications
    - Support balanced funding in CME by establishing financial caps on grant support
    - Requires all major grant applicants to meet criteria equivalent to ACCME's highest level of accreditation.

Sources of Legal and Ethical Rules for CME

- April 2007 Senate Finance Committee Report on company grant-making practices - Findings:
  - Drug and device companies give educational grants for CME in excess of $1 billion annually
  - Some CME programs do not actually operate with true independence from commercial interests
  - The off-label promotion risk of educational grants poses the greatest threat but is the most difficult to define because of the fine line between illegal company promotion and legal company-sponsored education that happens to recommend an off-label use

Sources of Legal and Ethical Rules for CME

- April 2007 Senate Finance Committee Report on company grant-making practices - Recommendations:
  - Physicians and organizations seeking grants from drug and device companies should not accept grants that come from a company's sales department and only consider those grants that are reviewed and approved by the company's medical affairs staff.

Sources of Legal and Ethical Rules for Industry Relationships

- The states react:
- State Laws Regulating Marketing to Prescribers
  - In 2007 there were over 500 pending bills
  - Registry and Reporting Laws
    - Gifts
    - All Financial Relationships Over Certain $ Limit
  - Marketing Codes
  - Licensing of Detailers
  - Gift Bans
  - Prescription data-mining

Sources of Legal and Ethical Rules for Industry Relationships

- MA, VT, ME, WV, CA, MN and DC to date regulate pharma and device company marketing to MDs
- Massachusetts is the first state to require a marketing code of conduct on, and public disclosure of, financial relationships between both medical device and pharmaceutical companies and MDs

Massachusetts Law: Drug and Device Marketing

- M.G.L. c. 111N: Pharma and Device Manufacturer Conduct (Enacted under Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care)
- Mass DPH Final Regulations, 105 CMR 970.000 finalized on March 11, 2009
  - Drug and device manufacturers and distributors must have a Code of Conduct/Compliance Plan that meets 105 CMR 970.000 in effect by July 1, 2009
  - Financial reporting by July 1, 2010

Massachusetts Law: Drug and Device Marketing

- Stated Purposes:
  - benefit patients
  - enhance the practice of medicine
  - ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners do not interfere with the independent judgment of health care practitioners
  - without compromising companies' legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

Massachusetts Law: Drug and Device Marketing

- The Mass law applies to pharmaceutical or medical device manufacturing companies ("PMDMCs") and some times distributors
- PMDMCs are subject to the law if they:
  - employ or contract with agents that engage in any marketing of products in Massachusetts to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices

Massachusetts Law: Drug and Device Marketing

- CME and Event Planners and Professional Societies are not regulated parties under the Mass law
- Only distributors that take title to products are covered
- Licensed wholesale drug distributors and registered retail pharmacists are exempt
- PMDMCs not their agents are responsible for compliance

Massachusetts Law: Drug and Device Marketing

- **Companies Subject to the Mass. Law must by July 1, 2009:**
  - Adopt a marketing code of conduct that complies with the Mass. Rules
  - Adopt and submit, if requested, to the Mass. DPH a description of a training program to provide regular training on the marketing code of conduct to appropriate employees including, all sales and marketing staff
  - Certify to the Mass. DPH that it is in compliance with the Mass. Rules (Form is available on DPH Website)
  - Adopt and submit, if requested, to the Mass. DPH policies and procedures for investigating non-compliance with the Mass. Rules
  - Take corrective action in response to noncompliance and reporting instances of noncompliance to the appropriate state authorities
  - Submit to the Mass. DPH the name, title, address, telephone number and electronic mail address of its compliance officer responsible for ensuring compliance with the Mass. Rules and monitoring and enforcing its required marketing code of conduct

Massachusetts Law: Drug and Device Marketing

- Beginning on July 1, 2010 and annually on or before July 1 of each year thereafter, each company must also certify to the Mass. DPH that it has conducted an annual audit to monitor compliance
- DPH is required to updated its required Code of Conduct standards no less than every two years but has stated it will do so within the next year

Massachusetts Law: Drug and Device Marketing

- DPH imposes the law so that companies subject to the Mass. law:
  - Must follow their Mass. compliant Marketing Code of Conduct in any interactions inside or outside Massachusetts with:
    - any Massachusetts licensed practitioner who prescribes drugs
    - a partnership or corporation compromised of such persons
    - an officer, employee, agent or contractor of such person acting within scope of duties related to provision of health care
    - Full time employees and board members of drug and device manufacturers are excluded

Massachusetts Law: Drug and Device Marketing

- Mass requires PMDMCs to establish Code standards no less restrictive than the most recent versions of:
  - Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals
    - January 1, 2009 version
      - http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf.
  - Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals
    - July 1, 2009 version
      - http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf.

Massachusetts Law: Drug and Device Marketing

- Many of the provisions in the Mass Law follow corresponding PhRMA and AdvaMed Code provisions
- But --- it imposes more stringent standards on PMDMCs in several instances
- Simply following the PhRMA and AdvaMed Codes will generally but not always result in automatic compliance with the Mass. law

Massachusetts Law: Drug and Device Marketing

- **Payments and gifts**
- Not a total gift ban
- Marketing Code of Conduct must prohibit:
  - entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips (OK for salaried employees of companies)
  - meals that are part of an entertainment or recreational event
  - payments of any kind including cash or cash equivalents, equity, “in kind” or tangible items, except as consideration for permissible service contracts
  - any “complimentary” items such as pens, coffee mugs, gift cards, etc.
  - any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items given in exchange for prescribing, or using any drug or devices
  - Any other remuneration prohibited under federal or Mass. fraud and abuse laws
- Mass law <u>does not</u> prohibit the giving of educational items worth no more than $100 permitted by the PhRMA and AdvaMed Codes

Massachusetts Law: Drug and Device Marketing

- **Meals**
- If directly funded by a drug or device company (i.e. not through third party event sponsor) a meal may not be:
  - part of an entertainment or recreational event
  - offered without an informational presentation or marketing agent present
  - offered, consumed or provided outside an office, hospital setting (hospital restaurants are OK) or device training facility, or
  - provided to a spouse or guest
- All permitted meals must be modest and occasional in nature
- PhRMA and AdvaMed Codes permit off-site meals with non sales reps and at company speaker educational meetings -- but Mass law prohibits such off-site meals unless MD recipients are employed or contracted

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. prohibits:
  - financial support for the costs of travel, lodging, or other personal expenses of attending non-faculty/organizing committee health care practitioners, either directly to the individuals participating in the event or indirectly to the event's sponsor
  - funding to compensate non-faculty/organizing committee health care practitioners for time spent participating in the event
  - payment for meals directly to any health care practitioner at the event

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. Permits:
  - a conference or meeting organizer, at its own discretion, to request and disperse funds from PMDMCs for the event as it feels appropriate, including meals for all participants, and hotel restaurants are OK.

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. permits:
  - "the 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"

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. permits:
  - conferences or meetings where the responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizer's in accordance with their guidelines.
  - "meetings or conferences" are defined as those held in a venue that is appropriate and conducive to informational communication and training about medical information, where
    - (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and
    - (b) the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. permits:
  - Compensation or reimbursement to a practitioner who serves as a company speaker or provides actual and substantive services as organizer/consultant if it:
    - is reasonable and based on fair market value; and,
    - complies with the standards for commercial support as established by the relevant accreditation entity

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. permits:
  - reimbursement of reasonable expenses, including travel and lodging related expenses, in order for a practitioner to attend a technical training session on the use of a medical device if the company's commitment to pay expenses, and the amounts or categories of reasonable expenses to be paid, are described in the written contract between the attending practitioner and the device vendor for the purchase of the device

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. permits:
  - sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting – commonly known as “satellite events” -- as long as the payment is made directly to the conference or meeting organizers

Massachusetts Law: Drug and Device Marketing

- **CME Meetings or Conferences**
- Mass. prohibits:
  - PMDMC commercial support that does not meet the ACCME Standards For Commercial Support, or equivalent commercial support standards of the relevant continuing education accrediting body – but it is OK if the program is not ACCME accredited
  - PMDMC sponsorship or payment directly to a health care practitioner

ACCME Standards for Commercial Support

- Content, faculty, objectives, and methods to be decided free of control of commercial interest
- No joint sponsorships with commercial interest
- Disclosure of financial interests by faculty and by those who control content and disclosure of source of commercial support by CME provider
- Mechanism to identify and resolve conflicts of interests before program

ACCME Standards for Commercial Support

- Commercial support of CME must be given with full knowledge and approval of CME provider
- Written agreement between commercial supporter and CME provider
- CME provider must have written policies and procedures on granting honoraria and reimbursement for planners, teachers and authors
- No other payments to CME director, planning committee, teachers, authors or others involved is permitted

ACCME Standards for Commercial Support

- No honoraria or reimbursement for portion of any session attended by faculty as a learner
- Social events or meals cannot take precedence over educational events
- No reimbursement for non-faculty participants except for CME provider employees and volunteers
- Adequate documentation of receipt and expenditure of commercial support

ACCME Standards for Commercial Support

- Separation of promotional materials and commercial exhibits from CME program and content
- Schedules and program descriptions may include promotional materials or ads
- Commercial interest cannot be used as agent to provide CME activities
- Content to be balanced and impartial

Massachusetts Law: Drug and Device Marketing

- **CME Meetings or Conferences**
- Pharmaceutical companies must separate CME grant-making functions from sales and marketing departments
- Pharmaceutical companies are prohibited from providing any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company
- MDs and scientists employed by PMDMCs may participate in CME meetings and present on specific products or treatment methodologies as long as it is in the context of providing attendees a balanced and objective presentation of all alternative treatments and therapies

Massachusetts Law: Drug and Device Marketing

- **CME Meetings or Conferences – Grants/Scholarships**
- **Mass. permits grants as long as they are not provided in exchange for prescribing**
- **Mass prohibits PMDMC direct funded scholarship programs to allow medical students, residents and interns to attend major educational/policy making medical association meetings**
- **Mass permits a grant recipient (e.g. AMC) to use the grant to fund a scholarship program**
- **PhRMA and AdvaMed Codes permit company funded scholarships for major medical association meetings as long as the grantees are selected by the academic or training institution**

Massachusetts Law: Drug and Device Marketing

- **Bona fide services**
- Mass permits:
  - Reasonable compensation/expense reimbursement for bona fide services (including research, IP licensing agreements, advisory boards, company speaker presentations) but only if there is:
    - A legitimate need for the services identified in advance
    - Written contract specifying the services and compensation
    - Compensation at FMV
    - Connection between MD competence and purpose
    - Reasonable # of consultants are retained to achieve purpose
    - Venue and circumstances appropriate
    - Company maintains adequate records
    - Decision to retain is not unduly influenced by sales personnel

Massachusetts Law: Drug and Device Marketing

- **Speaker/Consultant Conflicts**
- Mass. Requires pharmaceutical companies to:
  - require any practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company
  - This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement
- PhRMA Code sets forth the same provision and suggests such practitioners concurrently serving in these roles should recuse themselves from decisions relating to their speaking or consulting services

Massachusetts Law: Drug and Device Marketing

- **Additional Permitted Practitioner Interactions:**
  - The provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information
  - The purchase of advertising in peer reviewed academic, scientific or clinical journals
  - The provision of prescription drugs to a health care practitioner solely and exclusively for the benefit of the health care practitioner's patients
  - The provision of reasonable quantities of medical device demonstration and evaluation units provided to a health care practitioner to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future

Massachusetts Law: Drug and Device Marketing

- **Additional Permitted Practitioner Interactions:**
  - The provision of price concessions, such as rebates or discounts, in the normal course of business
  - Provision of reimbursement information regarding products in support of accurate and responsible billing
  - Provision of information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products as long as not be offered or provided as an inducement
  - The provision of payments, or the provision of free outpatient prescription drugs, to health care practitioners for the benefit of low income individuals, through established "patient assistance programs" ("PAPs"), as long as it meets OIG Guidance or is otherwise permitted under applicable law (including the Anti-Kickback Statute)

Massachusetts Law: Drug and Device Marketing

- **Charitable Contributions**
  - Mass. permits:
  - charitable donations
  - which are broadly defined as any financial support to a 501(c)(3) organization or the in-kind provision of drugs, biologics or medical devices for the charity care of patients
  - in-kind items used for charity care are exempt from the disclosure requirements
  - But: such contributions may not be provided in exchange for prescribing

Massachusetts Law: Drug and Device Marketing

- **Annual Financial Disclosure to DPH**
  - All manufacturers and distributors that market product in Massachusetts must file with DPH an annual disclosure listing:
    - the value, nature, purpose and particular recipient of any fee, payment subsidy, or other economic benefit
    - with a value of at least $50 per transaction (no aggregation)
    - provided directly or through its agents to
    - any MD, hospital, nursing home, pharmacist, HBP Admin., practitioner, or other person authorized to prescribe, dispense or purchase prescription drugs or devices in Mass.
    - In connection with its “sales and marketing activities”

Massachusetts Law: Drug and Device Marketing

- **Annual Financial Disclosure to DPH**

- "Sales and marketing activities" defined as advertising, promotion, or other activity intended:
  - to influence sales or the market share
  - to influence or evaluate the prescribing behavior
  - to promote a prescription drug , biologic, or medical device
  - to market a prescription drug, biologic, or medical device
  - to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force

- Also includes any product education, training, or research project that is designed or sponsored by the marketing division or has marketing, product promotion, or advertising as its purpose

Massachusetts Law: Drug and Device Marketing

- **Annual Financial Disclosure to DPH**
  - payments made to practitioners indirectly
    - through charitable donations or commercial support for CME, meetings and conferences to universities or hospitals
    - But payments to CME, third-party professional or scientific meeting or conference organizers that are not MD practices, hospitals, nursing homes, pharmacists, health benefit plan administrators <u>are not reportable</u>
  - payments made to practitioners directly
    - pursuant to a bona fide services agreement (except for genuine research or clinical trials), as compensation for serving as a faculty at a conference or meeting, for meals or for any other permissible activity

Massachusetts Law: Drug and Device Marketing

- **Annual Financial Disclosure to DPH**
- **Exemptions from disclosure**:
  - clinical trials and genuine research (Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure)
  - the provision of product samples, including demonstration or evaluation units, in-kind items used for the provision of charity care
  - confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan's formulary

Massachusetts Law: Drug and Device Marketing

- Annual Financial Disclosure to DPH
- For the purposes of computing the $50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated.
- PMDMCs are prohibited from structuring fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the Mass. reporting requirements

Massachusetts Law: Drug and Device Marketing

- **Annual Financial Disclosure to DPH**
  - First annual disclosure must be made by July 1, 2010 for the period July 1, 2009 through December 31, 2009.
  - Following 2010, the disclosure must be annually on or before July 1 of each year listing all disclosable payments made during the previous calendar year
  - $2,000 annual filing fee payable even if no reports
  - All disclosed data to be made publicly available and easily searchable on DPH website
  - DPH reports to Mass. AG any items provided in violation of the DPH code

Massachusetts Law: Drug and Device Marketing

- Violations by pharmaceutical or medical device manufacturers and distributors
  - knowing and willful violations are punishable by a fine of up to $5,000 for each violating transaction, occurrence or event
  - Enforcement may be pursued through civil action by the Mass. AG, a District Attorney with jurisdiction, or the DPH
  - Alleged violators must be granted notice and opportunity to dispute proposed fine ten days prior to issuance and have right of judicial review in Mass. Superior Court
  - Companies are subject to an anti-retaliation rule protecting any employee, applicant, health care practitioner, hospital, nursing home or other provider that has taken any action in furtherance of the enforcement of the Mass. Rules

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps --**
- **Pharma/Device Manufacturers**
  - Subject to Mass Law?
  - Changes in practices inside and outside Massachusetts
  - Compliance Plan/Code of Conduct Changes
  - Staff training
  - Prepare to commence tracking reportable transactions

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps --**
- **Pharma/Device Distributors**
  - Subject to Mass Law?
  - Changes in practices inside and outside Massachusetts
  - Establish (or update) Compliance Plan/Code of Conduct
  - Staff and sub-distributor training
  - Prepare to commence tracking reportable transactions

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps --**
- **Medical Societies**
  - Review and possible update to Conflict of Interest Policies for industry grants to society and CME activities
  - Review and possible update to Conflict of Interest Policies for members
  - Educate staff and membership

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps –**
- **Educational Companies**
  - Are company sponsors subject to Mass Law?
  - Changes in practices for programs inside and outside Massachusetts
  - Commercial Support Policy Changes
  - Staff training

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps –**
- **Hospitals**
  - Review and possible update to Conflict of Interest Policies for institution, medical staff and employed physicians and other prescribers /affiliated practices
  - Review and possible update to CME Policies for members
  - Educate staff and membership
  - Monitor industry relationships that will be subject to pubic disclosure

Massachusetts Law: Drug and Device Marketing

- **Compliance: Next Steps –**
- **Physicians and other prescribers**
  - Review and possible update to outside activity policies and changes to employment agreements
  - Review and possible update to policies on office interactions with sales reps
  - Monitor industry relationships that will be subject to pubic disclosure

Questions & Thank You

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