MANAGING PHYSICIAN INDUSTRY RELATIONSHIPS: MASSACHUSETTS AND BEYOND IN 2009

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William M. Mandell, Esq.
Pierce & Mandell, P.C.
11 Beacon Street, Ste. 800
Boston, MA 02108
Tel. 617-720-2444
www.piercemandell.com
Email: bill@piercemandell.com

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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.

Medical Innovation: From the Bench to the Bedside - Relevant Legal Areas

- FDA Approvals
- Intellectual Property
  - Patent
  - Confidentiality Agreements
- Licensing –Technology Transfer
- Industry Relationships
  - Internal Rules
    - Academic Medical Centers Conflict of Interest Policies
  - External Laws and Rules

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?

Sources of Legal and Ethical Rules for Industry Relationships

- Federal and State Anti-kickback Laws
  - OIG 2003 Compliance Guidance for Pharmaceutical Companies
- Federal Stark Law
- 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
  - 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

- State Self-Referral Laws
- 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

- Six states and D.C. in total 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

Sources of Legal and Ethical Rules for Industry Relationships

- State Laws Regulating Pharma/Device Marketing
  - California, Massachusetts, Nevada and D.C. to date have adopted marketing laws that incorporate by reference voluntary trade associations codes
  - Such laws serve to convert aspirational voluntary goals into minimum standards mandated by law

State Law

- State Licensing Boards
  - Disciplinary Action for Ethical Violations
  - Rules and Conditions on Licensure

Professional Ethics

- National and State Medical Society Ethical Codes
  - AMA
  - American College of Physicians
- Specialty Society Ethical Codes
- Health System, Hospital and Medical Practice Policies

AMA Ethical Guidelines - Ethical Opinion E-8.061 and clarifying guidelines on Gifts

- Physicians may only accept nominal gifts that primarily entail a benefit to patients (e.g. textbooks, modest meals, and other gifts if they serve a genuine educational function)
- Cash payments should not be accepted
- The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples.

AMA Ethical Guidelines - Ethical Opinion E-8.061 and clarifying guidelines on CME

- Defines a legitimate CME conference as any activity held at an appropriate location where the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse, and the main incentive for bringing attendees together is to further their knowledge on the topics being presented
- Organizers and faculty members must make disclosure of the financial support or any conflict
- Prohibits any faculty member from accepting any subsidy directly from a sponsoring company
- Company financial support must be payable exclusively to the event-organizing entity

ACCME Accreditation Standards

- ACCME Standards for Commercial Support
  - Self-disclosure of financial interests
  - Commercial support to organizers not presenters/no influence on content or speaker selection
  - Mechanism to identify and resolve conflicts of interests before program

ACCME Accreditation Standards

- **ACCME Standards for Commercial Support**
  - intended to ensure that the content of presentations and the learning space surrounding CME live events and printed materials are free of promotional content and undue influence from any commercial supporter
  - standards seek to distinguish truly independent CME activities, regardless of their commercial support, from CME-like programs that are not independent and are promotional in nature
  - Required by Massachusetts law (105 CMR 970.007 1. d.) for any CME program as of 7/1/09 if the program is funded by a company that markets in Massachusetts and is attended by MDs or other health care practitioners licensed in Massachusetts

ACCME Accreditation Standards

- 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 Accreditation Standards

- 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 Accreditation Standards

- 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 Accreditation Standards

- 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

Voluntary Trade Association Codes of Conduct

- PhRMA Code on Interactions with Health Care Professionals issued in 2003 – updated effective January 1, 2009
- AdvaMed Code of Ethics on Interactions with Health Care Providers issued in 2004 – updated effective July 1, 2009
- International and EU Codes

PhRMA Code – 2009 Version

- Principle: In interacting with health care professionals pharma companies are to follow the highest ethical standards as well as legal requirements in marketing their products
- Establishes annual company certification and staff training on compliance

PhRMA Code – 2009 Version

- Prohibits the giving of any non-educational and practice –related items (e.g. “reminder items” with company logos) or other gifts
- Permits the giving, if allowed by applicable law, of items designed primarily for the education of patients or professionals with a value of $100 or less and without value to the professional outside his or her practice (e.g. anatomical model – OK; DVD player – not OK)
- No meals outside office/hospital setting if meeting with a sales rep– but OK if meeting with other company reps or MD speaker (with sales rep in attendance) if modest meal provided and not at a resort
- Entertainment/Recreational items prohibited

PhRMA Code – 2009 Version

- Consultants
  - Must be chosen based on established selection criteria for seeking expertise
  - Reasonable, FMV compensation
  - Written contract required
  - Appropriate venue and circumstances/no resorts
  - No more than reasonably necessary number of MDs retained

PhRMA Code – 2009 Version

- CME
  - Financial support for CME must be given to CME provider and not directly to a healthcare professional
  - Separate CME grant-making and sales and marketing functions
  - Develop objective criteria for making CME grant decisions that meets ACCME Standards and OIG Guidance

PhRMA Code – 2009 Version

- No support for costs of travel, lodging or other personal expenses of non-faculty attendees either directly or to CME provider
- Except for scholarships to trainees selected by academic institutions to attend major meetings of medical associations
- No funding to compensate for time spent by a professional participating in the CME event

PhRMA Code – 2009 Version

- Non-CME Third Party Educational or Professional Meetings
  - Must be at an appropriate location (no resorts)
  - Primarily dedicated to promoting objective scientific and educational activities and discourse
  - Financial support should be given to event sponsor and non-faculty attendees should not be reimbursed/compensated for attending

AdvaMed Code – 2009 Version

- Recognizes uniqueness of “hands on” interactions with MDs related to Medical Technologies

AdvaMed Code – 2009 Version

- Principles:
  - First duty to act in best interests of patients is not incompatible with beneficial collaborations with health care professionals MDs
  - Companies shall not use any unlawful inducement in order to sell, lease, recommend or arrange for the sale, lease or prescription of their products.

AdvaMed Code – 2009 Version

- Product education and training to professionals OK if:
  - held in venues conducive to the effective transmission of knowledge, with staff that have the proper qualifications and expertise
  - only modest meals and receptions
  - reimbursement for reasonable and modest travel and lodging for attendees but not guests

AdvaMed Code – 2009 Version

- Educational grants
  - only to sponsoring organization/institution to offset total cost
  - only for primarily objective scientific and educational activities and discourse.
  - Speaker/content selection left to sponsoring organization/institution
  - Can provide grants so medical students, residents, fellows, or HCPs-in-training (but not HCPs) may attend

AdvaMed Code – 2009 Version

- Conference meals
  - Companies may provide funding to event sponsor
  - Companies may provide modest meals directly if they are:
    - Provided to all Professional attendees, except for modest meals over scientific, educational or business discussions
    - provided in a manner consistent with sponsor and CME accrediting body standards

AdvaMed Code – 2009 Version

- Sales & Promotional Meetings
  - OK if focus is product features, contract negotiations, and sales terms
  - only occasional modest meals and receptions for HCPs (not guests) if conducive to exchange of info
  - appropriate location to business being conducted (not resort locations)

AdvaMed Code – 2009 Version

- Entertainment & Recreation
  - Focus of interactions must be on education and information exchange
  - Payments for entertainment and recreation should not be made
  - Avoidance of appearance of impropriety

AdvaMed Code – 2009 Version

- Gifts
  - Permits occasional giving of items that benefit patients or service genuine educational function
  - FMV of item must be less than $100, except for medical textbooks or anatomical models
  - Gift cannot have non-educational/patient-related purposes (e.g. MP3 Player)
  - Non-educational branded items not permitted

AdvaMed Code – 2009 Version

- *bona fide* consulting arrangements permitted if:
  - FMV compensation not based on volume or value of consultant's past, present or anticipated business
  - Written contract describing services
  - Legitimate need for service contracted
  - Consultant selected based on qualifications
  - Reimbursement only for reasonable and actual expenses
  - Related hospitality is modest in value and subordinate in time and focus to the primary purpose of the meeting
  - Venue of meetings appropriate to subject matter of consultation

AdvaMed Code – 2009 Version

- Royalties
  - Meets consulting contract standards
  - Only if professional is expected to make or has made a novel, significant or innovative contribution to product, technology, process or method development
  - Calculation of royalty based on factors preserving medical decision-making objectivity

AdvaMed Code – 2009 Version

- Product-Related Reimbursement and Technical information to HCPs OK if:
  - It is accurate and objective
  - Does not interfere with independent clinical decision-making
  - identifies appropriate coverage, coding or billing of products or related procedures
  - technical or other support for the appropriate and efficient use or installation of a product
  - But cannot be for the purpose of unlawfully inducing HCPs to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of company's products

AdvaMed Code – 2009 Version

- Research/Educational Grants and Charitable Donations:
  - Permitted if not provided as an unlawful inducement
  - Provided under adopted objective criteria for making grants
  - Appropriately documented
  - Not controlled or unduly influenced by sales personnel
  - independent medical research
  - Indigent care
  - patient education and public education,
  - sponsorship of events where proceeds are charitable

AdvaMed Code – 2009 Version

- Evaluation and Demonstration Products
  - Reasonable quantities of products at no charge permitted for professionals to assess appropriate use and whether to use or order in the future if:
    - Single use products not in excess of amount needed to do adequate evaluation
    - Multiple use products if company retains title and items are returned and terms set out in advance in writing
    - Demos

AMC Conflict of Interest Policies

"It's really been an honor system thing. If somebody tells us that a pharmaceutical company pays them $80,000 a year, I don't even know how to check on that"

- **Dr. Robert Alpern, Dean, Yale School of Medicine (Boston Globe, "Researchers Fail to Reveal Full Drug Pay," June 8, 2008)**

AMC Conflict of Interest Policies

- Association of American Medical Colleges 2008 Report of the AAMC Task Force on Industry Funding of Medical Education
- AAMC issued guidelines for industry relationships in 2008 and urged US medical schools and teaching hospitals to implement updated policies and procedures by July 1, 2009

AAMC Report - CME

- **AMCs should adopt and implement policies that address specific interactions between academic medical personnel and industry**
- **AMCs offering CME programs should develop audit mechanisms to assure compliance with ACCME Standards, including those with respect to content validation and meals.**
- **AMCs should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.**
- **Educational programs for physicians supported by any commercial entity should be offered only by ACCME-accredited providers according to ACCME standards.**
- **Educational programs should be developed to raise the awareness among students, trainees, and faculty of challenges to professionalism presented by interactions with industry**

Sample Enforcement Action – Medical Devices

- 2007: Zimmer, Inc., DePuy Orthopaedics, Inc., Biomet, Inc., Smith & Nephew, Inc., Stryker Orthopedics, Inc., entered into settlement agreements with federal govt. over allegations of excessive consulting arrangements with MDs
  - $311 million civil settlement
  - Deferred criminal charges if compliance plan followed
  - MD Investigations on-going

Sample Enforcement Action – Medical Devices

- Govt. Allegations:
  - orthopedic surgeons retained as “consultants” but "did little or no work" but agreed to use the company's products exclusively
  - “Consulting fees” up to hundreds of thousands of dollars per year, plus lavish trips, and other perks
  - Consultants did not disclose these financial arrangements to the hospitals where surgeries were performed or to patients receiving the implants

Sample Enforcement Actions – Off-Label & CME Activities

- Neurontin: Off-label promotion, including company ghost writing and CME activities, resulted in civil and criminal settlement with Company of $430 million in 2004

- An Alabama neurologist was named as a co-defendant in two class action lawsuits filed in 2006 in Alabama state court by health insurance companies arising out of the Neurontin off-label case, alleging the doctor was a knowing participant in an illegal effort to promote off-label uses through alleged company controlled presentations at CME programs for which the doctor was invited to speak by a medical education company

- Serostim: Physicians offered all-expense-paid trips to a medical conference in Cannes, France, if they agreed to write or influence the prescription of the drug: resulted in criminal and civil settlement in 2005 for $704 million

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

- Purpose:
  - 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

- DPH Regulation imposes requirements upon:
  - Pharmaceutical or medical device manufacturing companies and distributors
  - that 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
  - Licensed wholesale drug distributors and registered retail pharmacists are exempt
- Note: C. 111N limits application to manufacturers that "participate[ ] in a commonwealth health care program" but DPH removed this phrase from the definition of "pharmaceutical and medical device manufacturer" in the regulation

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 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
  - Adopt and submit 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. required 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

- 105 CMR 970.000 sets forth DPH requirements for the mandated marketing Code of Conduct
- M.G.L. c. 111N requires DPH 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

- In 105 CMR 970.000 DPH was required under M.G.L. c. 111N to adopt certain prohibited and permissible interactions with practitioners for the mandated Marketing Code of Conduct
- Many of the provisions in 105 CMR 970.000 follow corresponding PhRMA and AdvaMed Code provisions
- But --- DPH has imposed more stringent standards in several instances

Massachusetts Law: Drug and Device Marketing

- 105 CMR 970.000 does not address all facets of the required marketing code and does not state that following PhRMA and AdvaMed Codes will result in automatic compliance with Mass. law
- DPH stated that it intends 105 CMR 970.000 to reflect the balance struck by Chapter 111N which does list a number of permissible activities recognizing that some industry interactions are beneficial and should be allowed to continue
- DPH stated it supports this premise by limiting its regulatory prohibitions to those clearly enunciated in the statute

Massachusetts Law: Drug and Device Marketing

- **Payments and gifts**
- DPH stated it declined to impose an across the board 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
- PhRMA and AdvaMed Codes permit the giving of certain educational items

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 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

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- Mass. required Marketing Code of Conduct must prohibit:
  - 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 , although a 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.

Massachusetts Law: Drug and Device Marketing

- **CME or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- The Mass required Marketing Code may permit:
  - 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**
- The Mass required Marketing Code may permit:
  - 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**
- The Mass required Marketing Code may permit:
  - 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**
- The Mass required Marketing Code may permit:
  - 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 or other Third-Party Scientific, Educational or Professional Meetings or Conferences**
- The Mass required Marketing Code may permit:
  - "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 Meetings or Conferences**
- The Mass required Marketing Code must prohibit:
  - drug or device company sponsorship that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education (“ACCME”) or equivalent commercial support standards of the relevant continuing education accrediting body.
  - drug or device company sponsorship or payment directly to a health care practitioner

Massachusetts Law: Drug and Device Marketing

- **CME Meetings or Conferences**
- Each pharmaceutical manufacturing company must separate its CME grant-making functions from its sales and marketing departments
- Each pharmaceutical manufacturing company shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company
- DPH has stated that scientists employed by pharmaceutical or medical device manufacturing companies may participate in such 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**
- DPH opted to not permit:
  - **drug or device company funded scholarship programs to allow medical students, residents and interns to attend major educational/policy making medical association meetings**
- The DPH regulations do not have any explicit prohibition on an event planner using unrestricted funds contributed by a drug or device company for a meeting or conference toward the cost of 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**
- The Mass required Marketing Code may permit:
  - 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**
- Any pharmaceutical manufacturing company subject to the Mass. Law in its Code of Conduct must:
  - 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**
- DPH Rules state that there is no prohibitions on the following activities and thus they can be permitted in a Marketing Code of Conduct:
  - 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**

- DPH Rules state that there is no prohibitions on the following activities and thus can be permitted in a marketing Code of Conduct:
  - 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**
  - DPH allows companies in their Code of Conduct to permit:
  - 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, 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” or otherwise violate 105 C.M.R. 970.000

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**
- DPH interprets this mandate to require annual disclosure of:
  - payments made to practitioners indirectly
    - through charitable donations to universities or hospitals where a health care practitioner is employed or affiliated,
    - through the sponsorship of a CME, third-party professional or scientific meeting or conferences
  - 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, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval. (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.
- Pharmaceutical or medical device manufacturing companies are prohibited from structuring fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the Mass. Rules 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
  - 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

- **Non-patient identified prescriber data**

- The DPH rules require any pharmaceutical manufacturing company subject to the Mass. Law that that uses non-patient identified prescriber data to facilitate communications with practitioners to:
  - maintain the confidential nature of prescriber data
  - develop policies regarding the use of the data
  - educate employees and agents about these policies
  - designate an internal contact person to handle inquiries regarding the use of the data
  - identify appropriate disciplinary actions for misuse of the data
- Before utilizing practitioner prescriber data for marketing purposes manufacturers must give practitioners the opportunity to request that their prescriber data not be available to company sales representatives or used for marketing purposes and must comply with such requests
- Pharmaceutical manufacturing companies may use prescriber data to:
  - impart important safety and risk information to prescribers
  - conduct research;
  - comply with FDA mandated risk management plans
  - track adverse events of marketed dugs, biologics or devices

- These requirements were not established in Mass. G.L.C. 111N

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
  - Accreditation and 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