

The Massachusetts Law Governing Pharmaceutical and Medical Device Manufacturer Conduct:

A Guide for the Hospitality Facilities and Professional Meeting Hosts, Planners and Sponsors

The information contained in this manual is intended to serve as a general resource and guide. It is not to be construed as legal advice. Attorneys with knowledge of Massachusetts General Law, Chapter 111 and laws regulating pharmaceutical and medical device company marketing should be consulted regarding the application of these laws to specific situations.

This manual was prepared by William M. Mandell, Esq. of the law firm of Pierce & Mandell, P.C. (Boston, MA) in conjunction with the Greater Boston Convention & Visitors Bureau.

©2009 Greater Boston Convention & Visitors Bureau. All rights reserved.

I. Introduction

As part of its mission to promote the development of meetings, conventions and tourism-related business in the greater Boston area, the Greater Boston Convention & Visitors Bureau (GBCVB) has prepared this Guide on the Massachusetts Law governing **Pharmaceutical and Medical Device Manufacturer Conduct (the Mass. Law)**. This law which is effective July 1, 2009 establishes a variety of rules that apply to conventions, meetings and other events sponsored by pharmaceutical and medical device companies.

Since the enactment of this law in August, 2008, there has been a lot of information, not all of it accurate, regarding how it will impact the holding of conventions and events in Massachusetts, including the greater Boston market.

GBCVB has prepared this Guide on the Mass. Law as a resource for our hospitality, members and convention and event planning. We are also making it available on-line so it may serve as a source of reliable information for professional associations, continuing medical education (CME) organizers, exhibitors and pharmaceutical and medical device manufacturer and distributors. It has been drafted with the intent to provide clear and concise summary of the Mass. Law in an easy-to-read and reference format.

Once you read this Guide, we believe you will agree with GBCVB's assessment that the Mass. Law -- while presenting some new procedures to follow -- will not result in significant cost or impediment to any professional association or event organizer that seeks to hold professional conventions and meetings in the greater Boston area.

In addition to this Guide, GBCVB will also post on its website, www.BostonUSA.com/plan any future developments or additional agency guidance on the Mass. Law as it may become available.

GBCVB is continuing its efforts by keeping open lines of communication with legislative leaders and the Mass. DPH on any further developments with the Mass. Law.

GBCVB has engaged in and will continue a vibrant outreach effort to professional associations, exhibitors, event organizers, and the local and national hospitality industry to answer their questions about the Mass. Law and to highlight the reasons why the Mass Law should not cause organizations any hesitation to plan and hold future events in the greater Boston area.

II. Background of the Law

On August 10, 2008, Massachusetts enacted **Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare**. Section 14 of this Act added a new chapter to the **Massachusetts General Laws, Chapter 111N**, entitled **“Pharmaceutical and Medical Device Manufacturer Conduct.”**

The stated purposes of the Mass. Law are to benefit patients, enhance the practice of medicine, and to 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.

On March 11, 2009 the Massachusetts Department of Public Health (“Mass. DPH”) issued regulations for Pharmaceutical and Medical Device Manufacturer Conduct (the “Mass. Rules”). They were issued to implement the restrictions, limits and reporting obligations on pharmaceutical and medical device companies that are required under the Mass. Law.

Complete copies of the Mass. Law and Mass. Rules can be found as Appendices to this Guide.

Both the Mass. Law and Rules are intended to follow in large part the voluntary trade association codes on conduct on interactions with health care professionals -- the PhRMA Code and AdvaMed Codes established by the Pharmaceutical and Medical Device industries. The Massachusetts legislature required Mass. DPH to use these voluntary trade association codes, as well as the Accreditation Council for Continuing Medical Education (ACCME) Standards For Commercial Support as the minimum standard in devising the required code of conduct under the Mass. Rules. The PhRMA Code is short for the **Pharmaceutical Research and Manufacturers of America (“PhRMA”) Code on Interactions with Healthcare Professionals**¹. The AdvaMed Code is short for the **Advanced Medical Technology Association (“AdvaMed”) Code of Ethics on Interactions with Health Care Professionals**².

¹ Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, January 1, 2009
<http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

² Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, July 1, 2009,
<http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.

Meeting and event planners are already very familiar with the specific rules for CME and other professional meetings that are found in the latest 2009 versions of the PhRMA and AdvaMed Codes and in the ACCME Standards for Commercial Support.

III. Summary and Scope of the Massachusetts Law

The Mass. Law can be found in the Massachusetts General Laws as **Chapter 111N** entitled **Pharmaceutical and Device Manufacturer Conduct**. The implementing agency regulations for the Mass. Law appear as Mass. **DPH Regulations, 105 Code of Massachusetts Regulations (CMR) Section 970.000**, finalized on March 11, 2009.

Since the issuance of the final regulations, the Mass DPH has engaged in an on-going effort to answer questions about the scope and application of the Mass. Law and its implementing regulations. The Mass. DPH has issued two sets of FAQs, and other materials, which are available on the DPH website at the address listed below at the footnote.³

There are two basic mandates under the Mass. Law:

- pharmaceutical and medical device manufacturing companies (PMDMCs) must have a Code of Conduct/Compliance Plan that meets the requirements set out by DPH in its regulations, 105 CMR 970.000, in effect by July 1, 2009; and,
- PMDMCs must start tracking certain financial relationships they have with health care practitioners and certain other providers starting on July 1, 2009 for financial reporting commencing on July 1, 2010.

Who is required to follow the Mass Law?

Only pharmaceutical and medical device manufacturing companies that market their products in Massachusetts are subject to the Mass. Law. Distribution companies that take title to products and market them in Massachusetts are also covered and defined as PMDMCs by DPH.

In particular, 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.

This could include any affiliate of a PMDMC that has offices or branches based in other states or countries if the company has interactions with Massachusetts doctors and licensed health care practitioners. PMDMCs, and not their agents, are responsible for compliance.

DPH has stated that the Mass. Law applies to PMDMCs that are physically located in Massachusetts as well as those that have agents in Massachusetts and market to Massachusetts health care practitioners.

3

http://www.mass.gov/?pageID=eohhs2modulechunk&L=4&L0=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_conduct_code&csid=Eeohhs2

If a PMDMC is subject to the Mass Law due to its marketing activities in Massachusetts, the PMDMC must follow the Massachusetts marketing code of conduct and public reporting requirements under the Mass. Law in its interactions with Massachusetts licensed professionals taking place both inside and outside of Massachusetts. This is true even for physicians and other practitioners who are licensed in Massachusetts but practice outside of Massachusetts. DPH has stated that PMDMCs are responsible for making a good faith effort to determine where a health care practitioner is licensed.

This means that PMDMCs will need to track attendees at major professional meetings occurring anywhere, and not just inside Massachusetts, to ensure compliance with the Mass. Law's required Code of Conduct and reporting requirements. The subsequent Section V. in this Guide (see pages 21 to 24) on the reporting requirements describes the Mass. DPH tracking system in detail.

It should be noted that CME organizations, event planners and professional societies **are not** regulated parties under the Mass. Law. These enterprises and organizations, however, will want to be conversant on the Mass. Law to effectively work with their commercial sponsors who are subject to the Mass Law.

Licensed wholesale drug distributors and registered retail pharmacists are exempt from the Mass. Law requirements.

What does the Mass Law require?

Massachusetts Marketing Code of Conduct

By July 1, 2009 each PMDMC covered by the Mass. Law must adopt a marketing code of conduct and establish a compliance and training program that comply with the Mass. Law. Specifically, the regulated companies must:

- Adopt a marketing code of conduct that complies with the Mass. Law;
- 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. Law;
- Adopt and submit to the Mass. DPH policies and procedures for investigating non-compliance with the Mass. Law;
- 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;

- Beginning on July 1, 2010 and annually on or before July 1 of each year thereafter, certify to the Mass. DPH that it has conducted an annual audit to monitor compliance with the Mass. Law

DPH has posted on its website a Compliance Filing Form for PMDMCs to file on or before July 1, 2009 to certify accomplishment of these required steps. This Form states that companies need not actually file copies of their training programs and policies and procedures for investigating non-compliance to DPH. DPH is allowing PMDMCs to simply certify on the Form that they are available to DPH on request.

A copy of this Compliance Filing Form is attached as an appendix to this Guide.

Massachusetts Financial Reporting of Sales and Marketing Activities

Each PMDMC is also required to submit an annual disclosure listing all fees, payments, subsidies, or other economic benefits with a value of at least \$50 involving “sales and marketing activities” it has with any “covered recipient” defined to include any Massachusetts physician, medical practice or its non-physician officers, employees and agents, health care practitioner, hospital, nursing home, pharmacist, health benefit plan administrator or other person authorized to prescribe, dispense or purchase a prescription drug or medical device in Massachusetts, first starting on July 1, 2010 for the period July 1, 2009 through December 31, 2009, and thereafter for each immediately past calendar year by each July 1.

All PMDMCs subject to the Mass. Law by virtue of marketing their products in Massachusetts are required to pay an annual fee of \$2,000 to the Commonwealth of Massachusetts to be submitted to DPH with the Compliance Filing Form due by July 1, 2009.

In subsequent years, the \$2,000 annual fee must be paid by companies making an annual disclosure. Starting with 2010 only companies that file reports must pay the fee, but if a company files an annual disclosure after one or more years of non-reporting DPH reserves the right to collect back payment of \$2,000 per year.

The reporting requirements are described in more detail in Section V. of this Guide.

Under the Mass. Rules who is defined as a “health care practitioner”?

Any health care professional licensed in Massachusetts who has the authority to prescribe prescription drugs, even if that health care practitioner does not practice in Massachusetts. For example, a medical device company’s interactions with an orthopedic surgeon who practices primarily in Providence Rhode Island, but who maintains a Massachusetts license to cover emergencies at a Massachusetts hospital would be subject to the Mass. Law.

In addition to physicians, DPH has defined health care practitioner to include, physician assistants, practical nurses, nurse practitioners, nurse midwives, nurse mental health clinical specialists, dentists, optometrists and podiatrists.

Therefore, dental professional meetings and interactions directly between PMDMCs and these types of health and dental professionals are covered by the Mass. Law.

In addition to individual Massachusetts health care practitioners, the Mass. Law covers interactions between PMDMCs and any partnership or corporation comprised of Massachusetts health care practitioners, as well as any officer, employee, agent or contractor of such a partnership or corporation acting in the course and scope of his or her duties related to or in support of the provision of health care to individuals. These professional practice organizations and employees and agents are included in the definition of “health care practitioner.”

Full time employees and board members of PMDMCs are excluded from the definition of health care practitioners.

Thus, PMDMCs must conform their marketing practices (and follow reporting requirements) under the Mass. Law involving Massachusetts medical and other professional practices, as well as those practices’ non-clinical administrators.

Does the law apply to interactions between out of state practitioners and drug or device companies at events held inside Massachusetts?

No. The Mass. Law only requires a PMDMC to adopt a Marketing Code of Conduct consistent with the Mass. Law covering its interactions with Massachusetts health care practitioners and to report sales and marketing activities it has with Massachusetts health care practitioners, as well as Massachusetts hospitals, nursing homes, pharmacists and health benefit plan administrators made in connection with the PMDMC’s sales and marketing activities.

Does the law apply to Massachusetts practitioners at events taking place outside Massachusetts?

Yes. The Mass. Law requires PMDMCs to follow a Mass. compliant Marketing Code of Conduct and to track and annually report each financial relationship, worth at least \$50 relating to “sales and marketing activity” in any interactions with a “covered recipient” which includes Massachusetts physicians and health care practitioners taking place either inside or outside Massachusetts.

If an event follows the standard established under either the PhRMA or AdvaMed Codes will it automatically comply with the Mass. Law?

No. Simply following the PhRMA and AdvaMed Codes will generally but not always result in compliance with the Mass. Law. Thus, PMDMCs are best advised to modify their Codes

of Conduct and policies to conform to the Massachusetts Code of Conduct , and most of them have or are in the process of doing so.

Although most of the provisions relating to PMDMC – health care practitioner interactions in the Mass Law, including those related to conferences and meetings, do follow the corresponding PhRMA and AdvaMed Code standards, the Mass. Law in some instances imposes more stringent standards on PMDMCs. These primarily relate to meals in restaurants and direct sponsorship of scholarship programs.

IV. The Massachusetts Required Marketing Code of Conduct

The Mass. Law has been referred to as a “gift ban” law. Does it actually ban all gifts to physicians?

No, it is not a total gift ban. DPH has clarified that PMDMCs will be compliant with the Mass. Law if they have a Marketing Code of Conduct that permits the occasional giving of certain educational gifts allowed under both the PhRMA and AdvaMed Codes. Thus, the scope of permitted gifts is limited to occasional items that benefit patients or serve a genuine educational function for the health care practitioner (e.g. a medical textbook or anatomical model but not a DVD player). The PhRMA and AdvaMed Codes state that any such permitted gift for purposes of the education of health care professionals or patients should generally not have a value of over \$100. “Occasional” is not defined and there is no annual stated limit per recipient in either the PhRMA or AdvaMed Codes. The giving or receiving of any item intend as an inducement to order or prescribe products that are reimbursable by any government program or private insurers, however, is illegal under federal and Massachusetts anti-kickback laws.

The Mass Law does explicitly prohibit the following:

- 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 (these however are permitted for salaried employees of PMDMCs);
- 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 compensation for bona fide services;
- any “complimentary” items such as pens, coffee mugs, gift cards, etc., except as compensation for bona fide services;
- 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.

It should also be noted that the PhRMA and AdvaMed Codes, and thus the Mass. Law, prohibit the giving of any non-educational and practice –related branded items with company logos.

This scope of limited permissible gifts now must govern the practices of PMDMCs within exhibit halls at medical conventions taking place both inside and outside Massachusetts when a Massachusetts health care practitioner is the recipient.

Is the provision of meals directly by drug or device companies totally prohibited under the Mass. Law?

No. Meals can be directly provided or funded by a PMDMC as part of an informational presentation but only if a PMDMC marketing agent or representative is present and the program takes place at a medical office, hospital (hospital restaurants are OK), academic medical center, clinic or other health care facility where a health care practitioner practices, or a “specialized training facility.” In other words, if a PMDMC wants to provide food and beverages to Massachusetts physicians and practitioners directly, it can only do so if it is part of an informational presentation held on-site at a medical office or health care facility, or otherwise at a specialized training facility.

DPH has defined “specialized training facility” to be based on the activity that occurs within it and not by its actual location. Thus, the Mass. DPH would accept the establishment of a specialized training facility by a PMDMC inside a convention or hotel facility. The Mass. DPH does not require any specific pre-operational certifications or inspections for such “facilities.” DPH simply requires PMDMCs to annually submit a completed compliance filing form -- which includes a statement from the PMDMC certifying to the Mass. DPH to the best of the company’s knowledge, information, and belief that it is in compliance with the Mass. Law -- and to keep a description of each specialized training facility on file and available for review by the Mass. DPH or Massachusetts Attorney General’s office. PMDMC would have to be prepared to demonstrate to the Mass. DPH , if requested , that the “facility” approximates the conditions of a surgical suite or a working clinical laboratory, or is a site at which the PMDMC directly provides medical training on large and/or technical medical devices.

Meals, however, cannot be directly provided or funded by a PMDMC under the Mass. Law if they are part of an entertainment or recreational event or offered without an informational presentation at a medical office, or health care facility setting (including a “specialized training facility”).

Meals may not be directly provided or funded by a PMDMC at a restaurant or provided under any circumstances to a spouse or guest.

The Mass. Law prohibition on the direct provision of meals to Massachusetts health care practitioners by PMDMCs at restaurants or convention centers does not apply to any practitioners who are company employees or as part of reimbursement for bona fide services. It also does not prevent PMDMC sponsorship of professional meetings and conventions and CME and non-CME events where food is available as long as the PMDMC provides its funds to the professional society or event organizer which determines how to use it for the meeting or event and the meals are available to all participants.

Comparatively, the PhRMA and AdvaMed Codes do permit the provision or payment for meals at restaurants or convention centers by PMDMCs if the practitioner meets with a non-sales representative of the PMDMC or attends a company speaker educational meeting. These are not permitted under the Mass. Law.

This more restrictive aspect of the Mass. Law will affect restaurants which can no longer be the host of meetings directly funded or presented by PMDMCs. Given the continued permissibility of PMDMC-provided meals during informational meetings at medical office and hospital locations, local catering companies and restaurants with take-out/delivery capacity can continue to serve the needs of PMDMCs accordingly.

All permitted meals must be modest and occasional in nature. The Mass. Law does not define what “modest” means. Each company will need to decide how to apply the “modest meal” standard. The PhRMA and AdvaMed Codes reference permissible meals during an educational presentation as having to be conducive to the exchange of information.

The Mass. Law does not define “meals” but the Mass. DPH has indicated that it would view beverages to come within that definition.

The Mass. Law does not preclude the provision of meals at any conference or meeting sponsored by a PMDMC as long as the PMDMC does not pay for the meal directly and the event organizer or professional association applies the commercial support to provide meals for all participants at its own discretion.

How does the Mass. Law effect event planners, hotels, convention centers and other venues that host events sponsored by pharmaceutical and medical device companies?

The Mass. Law does not impose any legal obligations on such parties, only on the PMDMCs.

Virtually all major PMDMCs are fully aware of the Mass Law and already have a compliance officer and compliance and training programs in place under the existing PhRMA and the AdvaMed Codes.

A list of the companies that have signed on to the PhRMA Code are included as an appendix to this Guide.

PMDMCs that market their products in Massachusetts are required to have a Marketing Code of Conduct that complies with the Mass. Law and to follow it during any interactions the company has with Massachusetts health care practitioners, even if they occur outside of Massachusetts. Thus, the Mass. Law will regulate PMDMC hosted and sponsored events at venues outside, as well as inside, Massachusetts.

What Does the Mass. Law Require and Prohibit at Scientific, Educational or Professional Meetings or Conferences?

CME conferences are independent educational gatherings at which attending health care professionals can earn CME credits which they must obtain every year to continue to hold licenses to practice medicine but can be sponsored by PMDMCs grants or advertisements and can include PMDMC exhibitors in exhibit halls. Non-CME events may be held by third party event organizers or professional associations and have an educational component but

are not run in accordance with CME accreditation standards, or may be provided directly by a PMDMC as part of its company's marketing efforts, and would include a satellite event or user group gathering convened and funded directly by a PMDMC within or at the same time and venue as a professional society meeting.

The Mass Law does not establish specific rules for non-CME events funded directly by pharmacy or device companies, other than a prohibition on providing free meals to Massachusetts health care practitioners if they are held at a restaurant, hotel or other meeting hall, and not at a medical office or health care facility (including a specialized training facility). Where a third party, such as an event planner or CME educational company, however, organizes a meeting event or conference and determines how to allocate funds modest free meals can be served if made available to all attendees.

The Mass. Law does explicitly bless both CME and non-CME conferences and meetings where the responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event organizer in accordance with its guidelines..

■ The following practices are prohibited:

- financial support for the costs of travel, lodging, or other personal expenses of attending non-faculty/organizing committee Massachusetts 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 Massachusetts health care practitioners for time spent participating in the event
- payment for meals directly to any attending Massachusetts health care practitioner at the event

■ The following practices are permitted under the Mass. Law:

- a conference or meeting organizer, at its own discretion, may request and disperse funds from PMDMCs for the event as the conference or meeting organizer deems appropriate, including meals for all participants (which can be provided at hotel and convention function rooms and restaurants)
- 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
- the 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 organizer

- 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 if CME credit is to be granted to attendees

- any conferences or meetings sponsored by PMDMCs where the responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event’s organizers in accordance with its guidelines, as long as the event is held in a venue that is appropriate and conducive to informational communication and training about medical information, where:
 - 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
 - the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented

It is noteworthy that DPH used the word “primarily” (and not exclusively) as to the scientific and educational focus of the event. This does give some leeway to event organizers to include some level of recreation within the schedule of a conference that otherwise meets these Mass. Law standards for conferences as long as the recreational portion is not directly provided by a PMDMC. For example, the offering of duck boats tours or performance by an entertainer at a discounted cost, subsidized by some level of commercial sponsorships, during a professional society annual meeting would not appear to violate these standards under the Mass Law).

Under this standard established by the Mass. DPH event venues and organizers can continue to hold meetings and conferences organized by third parties in convention centers, hotels and other special event venues and provide attendees with meals and recreation as long as such parts of the event do not come to dominate the educational portion of the gathering.

The drug and medical device companies, however, cannot pay for such events directly and must underwrite the costs through a third party event organizer. For example, if a CME educational company holds a national summit on breast cancer, secures funding from four pharmaceutical and biotech companies, uses the funds without any strings attached by the

granting companies, and has independence in the selection of the event topics, panels and speakers, than the event can include modest meals and recreation as well as educational meetings. PMDMCs can also provide grants to professional societies for their annual meetings, and even sponsor or pay for any portion of a professional meeting as long as the payment is made directly to the conference or meeting organizer.

The Mass. Law prohibition on direct funding of meals at conferences is more restrictive than the PhRMA and AdvaMed Codes which do allow companies to provide modest meals directly at conferences if they are provided either to (i) all professional attendees, in a manner consistent with sponsor and CME accrediting body standards, or (ii) to fewer than all professional attendees if the company providing the meals and refreshments does so over scientific, educational or business discussions with non-sales representatives from the company.

Therefore, while the voluntary trade association codes permit a drug or device company to invite a select group of physicians to a non-sales/non-recreational informational satellite event and provide free food and refreshments, Massachusetts health care practitioners could not be provided the free food and refreshments.

The Mass. Law, as well as the PhRMA and AdvaMed Codes, do not prohibit PMDMCs from hosting user conferences or other satellite events at annual meetings to discuss scientific, educational and business issues about company products with company non-sales personnel as long as free meals are not provided to Massachusetts health care practitioners. They also do not prohibit PMDMCs from putting on product theatres or sales-related presentations inside or outside exhibit halls as long as they are clearly labeled as non-educational marketing and provided without free food or refreshments.

The Mass Law does permit meals to be funded through the event organizer if the meals are made available to all attendees. For example, at the annual meeting of a specialty society PMDMC sponsor funds could be used to underwrite the costs of box lunches available during CME programs or coffee stations inside the exhibit hall as long as such food and refreshments were available to all meeting attendees.

When integrating the Mass. Law into their Marketing Codes and Compliance Plans, PMDMCs will need to decide whether to apply the more stringent Mass. Law standards to all conference attendees, or to have separate rules apply to attending Massachusetts health care practitioners. This is true whether the event is held inside or outside of Massachusetts as the Mass. DPH has stated that the Mass. Law does not apply to interactions occurring inside of Massachusetts between PMDMCs and doctors and other health care practitioners not licensed by Massachusetts

In addition to these Rules for Scientific, Educational or Professional Meetings or Conferences, are there Additional Special Rules for CME Events under the Mass. Law?

Yes. In order to ensure the absolute independence of the educational content at CME programs, the Mass. Law establishes additional standards for CME programs funded by drug and device companies.

All health care practitioners must obtain continuing medical education credits each year in order to maintain their licenses and facility privileges. Physicians are given CME allowances by their employers and practices to spend to attend CME events.

CME events are organized by either professional societies or education companies that are accredited CME providers, often around a type of disease or treatment topic.

In addition to the above described prohibitions and requirements for meetings and conferences, PMDMCs are also subject to the following additional requirements for any event they sponsor at which attending Massachusetts health care practitioners can earn CME credit:

- Pharmaceutical manufacturers must separate their CME grant-making functions from sales and marketing departments;
- Pharmaceutical manufacturers 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;
- Any PMDMC commercial support must meet the Accreditation Council for Continuing Medical Education (ACCME) Standards For Commercial Support, or equivalent commercial support standards of the relevant continuing education accrediting body (i.e. although the CME Program attended by Massachusetts health care practitioners does not have to be ACCME accredited, the PMDMC commercial support must follow ACCME or other accrediting entity commercial support standards.
- Physicians 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 and the program otherwise satisfies the CME accreditation body commercial support standards;

The Mass. Law serves to codify and legally mandate commercial support standards for industry-sponsored CME events attended anywhere by Massachusetts health care practitioners. The most widely used of these are ACCME Standards, which are as follows:

- The content, faculty, objectives, and methods for the program must be decided free of the control of commercial sponsors;
- No joint sponsorship with commercial interest is permitted;
- Disclosure of financial interests by faculty and by those who control content is required;
- Disclosure of the sources of commercial support is required;

- The CME event organizer must have a mechanism to identify and resolve conflicts of interests before program;
- Commercial support of the CME program must be given with full knowledge and approval of CME event organizer;
- There must be a written agreement between each commercial supporter and CME event organizer;
- The CME event organizer 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;
- No honoraria or reimbursement for portion of any session attended by faculty as a learner is permitted;
- Social events or meals cannot take precedence over educational events;
- No reimbursement for non-faculty participants is permitted except for CME event organizer employees and volunteers;
- Adequate documentation must be prepared of the receipt and expenditure of commercial support;
- Separation of promotional materials and commercial exhibits from CME program and content is required;
- Schedules and program descriptions may include promotional materials or ads;
- Commercial interests cannot be used as an agent to provide CME activities; and,
- The program content must be balanced and impartial

The Mass. DPH has made it clear that other than compliance with these ACCME Standards for Commercial Support (or equivalent standards of another CME accrediting body) the Mass. Law does not regulate the manner in which conference or event organizers use their funds contributed by PMDMCs. PMDMCs, however, are required to track and report any sales and marketing activity related payments or items worth at least \$50 provided to Massachusetts health care practitioners, as well as to Massachusetts hospitals and nursing homes, but not to professional societies or other CME event organizers.

In addition to ACCME commercial support standards, event planners should also be aware of the United States Food and Drug Administration (FDA) 1997 Guidance on Industry-

Supported Scientific and Educational Activities. Under this Guidance the FDA adopted the following positions related to CME events:

- 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 assistance, or in response to an unsolicited request for assistance from either the organizer or a presenter (note the Mass. Law is more restrictive as to pharmaceutical companies);
- Full disclosure of all financial relationships by presenters and vetting of presenters' financial relationships is required by event organizers; and,
- Exhibitor booths must be outside of the educational presentation meeting rooms.

Does the Mass. Law absolutely prohibit scholarships programs to fund the costs of attendance at CME events for fellows, interns, residents, medical students and other trainees?

No. In its final regulations under the Mass. Law the Mass. DPH opted not to explicitly permit PMDMCs to directly fund scholarship programs to pay for the attendance by fellows, interns, residents, medical students and other trainees at meetings. Yet, the PhRMA and AdvaMed Codes do permit company funded scholarships for major medical association meetings as long as the grantees are selected by their academic or training institution.

Even though these directly funded programs are not sanctioned by the Mass. DPH, the Mass. Law does permit PMDMCs to make educational grants and charitable contributions as long as they are not provided in exchange for prescribing or dispensing of any prescription drug, biologic or medical device.

The Mass. DPH has stated that a PMDMC may provide funding to a third party, such as an academic medical center or a professional society, for a fellowship to send a Massachusetts health care practitioner in training to a national meeting, as long as the third party selects the health care practitioners in training who will benefit from the grants. If the grants are provided to a Massachusetts facility or academic medical center they would be subject to the financial disclosure requirements.

Under the Mass. Law there is no explicit prohibition on an event planner or medical society using unrestricted funds contributed by a drug or medical device company for a meeting or conference toward the cost of a scholarship program as long as the program is run independently by a medical society or academic medical center without any company attribution or influence.

For example, a medical society could establish its own system of selecting worthy medical students, residents and fellows to receive a grant to underwrite the cost of attending a major national meeting of the society. If funding for this grant program came from the society's

general annual operating budget, and it was not funded directly by a drug or device company and the company made grants or charitable contributions for CMEs, fellowships or training to the society to use as it saw fit, the Mass Law does not explicitly prohibit such a practice.

Thus, the Mass. Law would not prohibit an educational grant recipient from using such a grant to fund a scholarship program.

Can a Drug or Device Company Make a Charitable Donation under the required Massachusetts Code of Conduct?

Yes. The Mass. Law permits charitable donation by PMDMCs in the form of financial support to a Section 501(c)(3) organizations or the in-kind provision of drugs, biologics or medical devices for the charity care of patients, as long as such contributions may not be provided in exchange for prescribing.

Does the Mass. Law Establish Specific Requirements for Speaker and Consultant Contracts between Physicians and Drug and Device Companies?

Yes. The Mass. Law requires pharmaceutical manufacturing companies to require any Massachusetts health care practitioner who is a member of a committee that sets formularies (e.g. prescription drugs to be covered by an HMO) or develops clinical guidelines and also serves as a speaker or commercial consultant for the pharmaceutical manufacturing company to disclose to the formulary or clinical guidelines committee the nature and existence of his or her relationship with the pharmaceutical manufacturing company. This disclosure requirement extends for at least two years beyond the termination of any speaker or consultant arrangement.

The PhRMA Code sets forth the same provision and suggests that practitioners who concurrently serve in these roles should recuse themselves from decisions relating to their speaking or consulting services for the pharmaceutical manufacturing company.

In addition, while PMDMCs are permitted to contract with Massachusetts physicians and other health care practitioners and pay them reasonable compensation and expense reimbursements for bona fide services, including services as a company speaker, inventor, consultant or company advisory board member, the following requirements must be satisfied:

- there must be a legitimate need for the services identified in advance;
- the parties enter into a written contract specifying the services and compensation;
- compensation is based on the fair market value of the services;
- there is a connection between MD competence and purpose;
- only a reasonable number of practitioners are retained to achieve identified purpose;

- the venue and circumstances of any meeting with the practitioner is conducive to the services and activities related to the services are the primary focus of the meeting;
- the company maintains records concerning the arrangement and makes appropriate use of the services; and,
- the decision to retain the practitioner is not unduly influenced by the company's sales personnel.

Are There Other Rules Under the Mass. Law That Apply to the Interactions Between Drug And Device Companies And Massachusetts Physicians and Other Health Care Practitioners?

Yes, Under the Massachusetts Marketing Code of Conduct the following practices by PMDMCs are permitted:

- 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;
- The provision of price concessions, such as rebates or discounts, in the normal course of business;
- The provision of reimbursement information regarding products in support of accurate and responsible billing;
- The 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; and,
- 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 Federal Anti-Kickback Statute)

V. The Massachusetts Public Reporting by Drug and Device Companies of Sales and Marketing Activity

All PMDMCs must file with the Mass. DPH an annual disclosure listing the value, nature, purpose and particular recipient of each fee, payment, subsidy, or other economic benefit, including gifts, food and beverages, if it has a value of at least \$50 per recipient and transaction that is provided directly by the PMDMC or through its agents to any “covered recipient”. The Mass. Law defines “covered recipient” to be any Massachusetts physician or health care practitioner, hospital, nursing home, pharmacist, health benefit plan administrator, or other person authorized to prescribe, dispense or purchase prescription drugs or devices in Massachusetts in connection with the PMDMCs “sales and marketing activities.”

The Mass. DPH has stated that payments or items provided to agents or employees of covered recipients are not subject to the reporting requirements unless they are in a position to act on behalf of the covered recipient in making purchasing, prescribing or dispensing decisions. Thus, the provision of a meal by a medical device company at a planning meeting with an event organizer acting on behalf of a Massachusetts academic medical center’s CME event would not be subject to reporting, but a meal provided by such company at the AMC campus, including AMC executives and consultants, who are in a position to help decide whether the AMC will acquire equipment from the company, would be subject to disclosure.

“Sales and marketing activities” is 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, or
- to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force

“Sales and marketing activities” 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.

Payments made to universities or hospitals through charitable donations or commercial support for CME, meetings and conferences is reportable to the extent it constitutes sales and marketing activities.

The Mass. DPH has clarified that payments to CME and third-party professional or scientific meeting or conference organizers that are not professional practices, hospitals, nursing homes, pharmacists, or health benefit plan administrators are not reportable under any circumstances.

PMDMCs will have to report any payment or benefit related to sales and marketing activities worth \$50 or over per transaction made directly to any Massachusetts physician and other health care practitioner, or to any Massachusetts health care facility or academic medical center, or its employees or agents in a position to act its behalf in making purchasing, prescribing or dispensing decisions.. The Mass. DPH has specifically identified reimbursement of expenses in conjunction with a product training, compensation for serving as a faculty at a CME, participating on a Speaker's Bureau, and compensation for bona fide services as being reportable.

PMDMCs will also have to track and report meals they pay for or provide to any covered recipient that cost \$50 or more per recipient. For example, if a pizza lunch is provided in a medical office in conjunction with an informational presentation by a drug company sales representative that costs a total of \$100 and the presentation is attended by three Massachusetts physicians it would not be reportable. If, however, the company offers the same presentation with a catered complete meal that costs a total of \$500 and is attended by four Massachusetts physicians and one of the meals is provided to the company sales representative, the company would have to report a \$100 meal for each of the four physicians in its next annual financial report to the Mass. DPH.

The Mass. DPH has clarified that it looks at the per covered recipient value of each total expenditure for its sales and marketing activity payment or benefit, to determine if a report is required. The DPH has also stated that 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 on an annual basis. So three gifts or meals given in one year to a physician, each with a value of \$30 and delivered at different times by the same pharmaceutical company, would not cross the \$50 reporting threshold.

The Mass. Law establishes several blanket exemptions from the annual reporting requirement. These include:

- payments in conjunction with clinical trials and genuine research (Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure);
- the provision of prescription drugs solely and exclusively for use by patients;
- 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; and,

- intellectual property agreements and related payments, such as licensing fee royalty or title transfer payments

PMDMCs are prohibited from structuring fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the Mass. reporting requirements.

The 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 reportable payments made during the previous calendar year. All disclosed data will be made publicly available and easily searchable on the Mass. DPH website. Mass. DPH will report to Mass. Attorney General any items provided in violation of the DPH code.

To assist PMDMCs in tracking “covered recipients” (i.e. persons and entities authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts) for purposes of the required financial reporting, the Mass. DPH has created and posted a master list data base that assigns a unique ID number for each individual covered recipient. The file is available on the Department’s Marketing Code of Conduct website at www.mass.gov/dph/pharmamed. Manufacturers are instructed by the Mass. DPH to use the information on this list when creating the disclosure report for the Department. The disclosure report lists which covered recipients the manufacturer has made payments to during the previous reporting period.

The Mass. DPH has established the required format for the annual disclosure report. It must be sent in a comma-separated value (CSV) format. Each row will represent total payments to a particular covered recipient within a particular payment category. The required fields on the report include, the pharmaceutical and medical device manufacturer, the unique ID assigned of the covered recipient, the full name of the covered recipient, the Category of Payment ID assigned by DPH, which include:

Payment Category Name	Payment to Covered Recipients (“CRs”) Category Description
Compensation for Bona Fide Services	Consulting, Speaker's Bureaus, etc.
CMEs, third-party Conferences, or Meetings	Payments to CRs in Conjunction with CMEs, third-party conferences and meetings
Grants/Educational Gifts	Grants and Educational Gifts to CRs
Food	Meals Provided to CRs
Education/Training	Payments to CRs in Conjunction with education and training
Marketing Studies	Payments to CRs in conjunction with research other than genuine research
Charitable Donation	Donations other than donations of prescription drugs, biologics or medical devices
Other	Non-exempt payments to CRs of \$50 or more

The fields also include the amount of payment in US dollars rounded to the nearest dollar using standard rounding guidelines, representing the sum total of payments to a particular covered recipient within a particular payment category. Finally, the report also include a field for number of events reflected i.e. the number of individual payment events that were provided to a particular covered recipient for a particular payment category (for example: Company Y provides three lunches at \$100 each to Dr. X – “amount of payment” = 300, “number of events reflected” = 3).

VI. How is the Mass. Law Enforced?

Anyone who knowingly and willfully violates the Mass. Law can be subject to a fine of up to \$5,000 for each violating transaction, occurrence or event. Enforcement may be pursued through civil action by the Massachusetts Attorney General, a District Attorney with jurisdiction, or the DPH. Alleged violators must be granted notice and opportunity to dispute the proposed fine ten (10) days prior to issuance and have a right of judicial review in Massachusetts 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.

VII. Compliance Steps

Pharmaceutical and medical device manufacturers and distributors that market their products in Massachusetts and are thus subject to the Mass. Law will clearly need to make changes to their Compliance Plans and Codes of Conduct to include the Mass. Law required Marketing Code and reporting requirements.

Professional Societies will need to review and possibly update their Conflict of Interest Policies relating to industry grants and their CME activities, and should review and possibly update their Conflict of Interest Policies for members.

Event organizers and educational companies will need to reconsider their practices for programs inside and outside Massachusetts and adopt commercial support policy changes.

Do the event venues or planners in Massachusetts need to notify pharmaceutical and medical device manufacturing and distribution companies about the Mass Law and/or instruct them on how to comply?

No. Event venues and planners do not need to instruct pharmaceutical and medical device manufacturing and distribution companies on how to comply with the Mass Law.

What if the company does not know about the Mass. Law?

Virtually all major pharmaceutical and medical device manufacturing and distribution companies are fully aware of the Mass Law by now and already have a compliance officer and compliance and training programs in place. Under the PhRMA and the AdvaMed Codes, pharmaceutical and medical device manufacturing companies are supposed to have compliance officers, compliance plans and training programs. So Massachusetts is not asking the major companies to do substantially more than they are already doing.

It is possible that some smaller or foreign companies may not be aware of the Mass. Law. In such cases, the company representative can be advised to have its compliance officer or legal counsel consult the Mass. DPH website to secure a copy of the Mass Law and the DPH regulations and other materials, but the Mass. Law imposes no legal duties or obligations on event organizers.

Does the Mass Law only apply to activities that occur inside of Massachusetts?

No. The Mass Law requires any pharmaceutical and medical device manufacturing and distribution company that markets its products in Massachusetts to adopt a marketing code of conduct and compliance plan consistent with the Mass. Law. It must follow the code in all of its interactions with doctors and other health care practitioners who are licensed in Massachusetts even if the interactions take place outside of Massachusetts.

For instance, a Massachusetts cardiologist serving as a paid faculty member at a CME conference in San Diego, underwritten in part by a pharmaceutical company that has sales agents in Massachusetts, would be an interaction that is covered by the Mass. Law as applied by the DPH.

If a company underwrites the cost of an event at a location outside of Massachusetts will it have to comply with the Mass. Law?

Yes. If Massachusetts licensed physicians and health care practitioners are invited to an event outside of Massachusetts funded by a drug or device company that markets its products in Massachusetts, the company is required to follow a code of conduct and have a compliance program in place that meets the Mass. Law.

It would also have to report its sales and marketing activity payments having a value of \$50 or more made to Massachusetts health care practitioners, as well as Massachusetts hospitals, nursing homes, and any other persons authorized to prescribe, dispense or purchase prescription drugs or medical devices in Massachusetts.

The Mass. DPH has made it clear that reportable sales and marketing activity must be reported by the paying PMDMC even if the activity occurred outside of Massachusetts.

APPENDICES

- A. Massachusetts General Law Chapter 111N
- B. 105 CMR 970.000
- C. DPH Compliance Filing Form
- D. List of the pharmaceutical companies that have signed on to the PhRMA Code
- E. Relationship between the Drug and Medical Device Industry

E. The Relationship between the Drug and Medical Device Industry and the Medical Profession: Conflicts of Interest

Health care professionals, namely physicians, serve in a variety of roles, beyond treating patients, in which they are key to the development, study and marketing of prescription medications and medical devices. Dental professionals play similar roles with dental devices.

These include:

- Editor
- Author
- Peer Reviewer
- Company Advisory Board
- FDA Committee
- CME Presenter/Organizer
- Company Speakers Bureau
- Company Trainer
- Inventor
- Licensor
- Royalty Rights
- Equity Holder
- Researcher - PI
- Consultant
- Clinical Guideline and Formulary Committee member

The question therefore arises to what extent do such physicians, and other licensed professionals who are authorized to prescribe medications or purchase medical devices, have a conflict of interest arising from their financial relationships with drug and device companies? Will the financial relationship with a drug or device company unduly influence the independence of the physician's judgment in carrying out his or her research, educational or clinical responsibilities?

Starting in the late 1990s and early 2000s, the legality of such financial relationships began to be questioned through government prosecutions and private whistleblower cases under the Federal and State **Anti-kickback Laws** and **False Claims Acts**. These investigations and prosecutions, which are continuing and have resulted in multi-million dollar settlements with the federal and state health care programs and private whistleblowers, include the following:

- Neurontin: Off-label promotion, including company ghost writing and CME activities, resulted in civil and criminal settlement of \$430 million in 2004.
- Serostim: Physicians were 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 .

In 2003, the Office of Inspector General ("OIG") for the United States Department of Health and Human Services ("HHS") issued **Compliance Guidance for Pharmaceutical Companies**. This OIG Guidance led to many reforms in industry practices, including the

cessation by most major companies of paying for the attendance by physicians and spouses to recreational events.

In reaction to the growing focus on the potential for conflict of interest, both the federal and state legislative branches have jumped into fray to regulate such financial relationships with the intent to protect patients and lower health care costs.

The U.S. Senate Finance Committee has mounted some widely publicized congressional investigations of prominent physician leaders who did not disclose financial relationships with drug companies. Also, in April 2007 the Senate Finance Committee issued a Report on company grant-making practices. Its findings included that:

- 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

In this 2007 Report the Senate Finance Committee recommended that physicians and organizations seeking grants from drug and device companies 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.

The leaders of the Senate Finance Committee, Senators Charles Grassley and Max Baucus, have also proposed a major piece of federal legislative: **the Physician Payment Sunshine Act of 2009.**

If enacted the Sunshine Act would establish a national reporting and public access system on financial relationships between drug and medical device companies and physicians involving payments/items to physicians in excess of \$100 per year. The information reported by drug and device manufacturing companies would be posted on a HHS website. Consideration is being given to expanding the Sunshine Act reporting to payments and other items given to hospitals, medical schools and medical societies. The Sunshine Act, if passed by Congress, could in large part serve to pre-empt state disclosure laws, including the Massachusetts public reporting system established under Massachusetts General Law, Chapter 111N. Unless and until such a federal law is ever passed, the current reporting obligations under the Mass. Law are in effect.

Some drug and device manufacturing companies are already publicly disclosing on their websites the amount of educational grants they are making for professional association events.

There is also a growing impetus toward major changes to the ethical standards applicable to the proper management of the relationship between the medical profession and the pharmaceutical and medical device industries. These include tougher voluntary trade association codes, such as the new 2009 PhRMA and AdvaMed Codes, as well as more stringent medical school/academic medical center and professional medical association conflict of interest policies.

As of July, 2009 both the PhRMA and AdvaMed Codes instruct drug and device companies to refrain from providing or paying for any entertainment or recreational activities. They also prohibit the giving of non-educational branded promotional items, such as pens, notepads and mugs, even if the items are of minimal value and related to the professional's work. Meals that are not provided as part of bona fide interaction involving the presentation of scientific, educational or business information are also no longer permitted under these Codes.

Both the 2009 PhRMA and AdvaMed Codes, however, do continue to permit commercial funding of CME programs if the grants go to the professional association or event organizer directly and the content of the program is independently controlled by the professional association or event organizer. (These newer versions of the Codes are discussed in more detail in Section IV. of this Guide).

The Institute of Medicine, which advises the US government on health policy, issued a report in 2009 recommending major changes to the CME funding system and interactions between industry and medicine, including:

- Development of a new system of funding accredited CME free of industry influence, enhancing public trust in the integrity of the system and providing high-quality education;

- Physicians should not accept items of material value from pharmaceutical, medical device, and biotechnology companies except when a transaction involves payment at fair market value for a legitimate service;

- Physicians should not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;

- Physicians should not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation;

- Professional societies and health care providers should amend their policies and codes of professional conduct to support these recommendations; and, .

- Pharmaceutical, medical device, and biotechnology companies and their company foundations should have policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value.

Although as of mid-2009 the federal government stands poised and ready to regulate in this area, the major legislative enactments has been at the state level. Massachusetts is one of a growing number of states that have decided to regulate financial relationships between industry and medicine. The states have taken a variety of approaches that include:

- Gift Bans and limits
- Registry and Reporting Laws
- Marketing Codes
- Licensing of Detailers
- Limits on prescription data-mining

In 2007 there were over 500 pending bills in state legislatures. As of July 1, 2009, Massachusetts as well as California, District of Columbia, Maine, Minnesota, Vermont and West Virginia have actually passed laws regulating pharmaceutical and medical device company marketing to physicians and other health care prescribers.

Massachusetts is the first state to require a marketing code of conduct on financial relationships between both medical device and pharmaceutical companies and MDs. It is also the first state to adopt a public disclosure system for both medical device and pharmaceutical companies.

There is now much uncertainty for health care event planning with so much regulatory activity on marketing practices to health care professionals and the public disclosure of such financial relationships.

Clearly, we are in the middle of an evolutionary process. Governments, professional and trade organizations, and teaching institutions are struggling to achieve the right balance in identifying those practices that are acceptable on a national level. Many more states are expected to enact their own laws in the coming years on acceptable marketing practices and disclosure. If national health reform is passed, the federal government is likely to pass the Sunshine Act and possibly other mandates and prohibitions on marketing practice to health care professionals.

This environment of uncertainty may continue for some time. Keeping up with the changes is vital for organizations, businesses and individuals that are involved with conventions, conferences and events with health care professionals.

The Mass. Law does represent mainstream thinking and practice on marketing to health care professionals. In this current fluid situation Massachusetts now has a distinct advantage over other states that have either enacted much tougher standards, or do not have any law on their books yet. Massachusetts has a comprehensive law that sets out definitive standards consistent for the most part with the voluntary trade association codes and national trends. For events that are scheduled in Massachusetts there is an authoritative source under the rule of law as to what practices are legal or ethical.

GBCVB, together with the Massachusetts Lodging Association, and a substantial number of individual Massachusetts hotels and hotel chains, provided testimony on the proposed Mass.

DPH regulations implementing Chapter 111N. We joined with Massachusetts convention centers and hotels to raise concern about the potential impact of the Mass Law on the scientific or medical conference business in Massachusetts.

The Mass. DPH addressed our concerns by including a provision in its regulations explicitly allowing CME, third-party professional and scientific meetings to be held in convention centers, hotels or other special event venues.

DPH also clarified in its public comments accompanying its final regulations that neither the statute nor the regulations prohibit the commercial sponsorship of CME, as long as the third-party conference or meeting organizers remain responsible for the content, selection of speakers and distribution of monies.

Additionally, DPH announced 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.