

Massachusetts Enacts Final Rules Governing Pharmaceutical and Medical Device Manufacturer Conduct: Manufacturers Must Prepare for a New Regime of State Law Compliance

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Massachusetts, which has distinguished itself as the state with the most comprehensive and stringent sales and marketing practices law, recently adopted final regulations, available at <http://www.mass.gov/Eeohhs2/docs/dph/regs/105cmr970.pdf>, implementing the Pharmaceutical and Medical Device Manufacturer Conduct established under “An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.” Massachusetts is the first state to enact a law requiring *both* pharmaceutical and medical device manufacturers¹ to adopt and comply with a state-authored code of conduct and to require disclosure of economic benefits provided to health care practitioners² (HCPs) and certain other persons or health care entities.

Other states, however, are moving rapidly to meet Massachusetts’s new standard of compliance and disclosure. On May 9, 2009, the Vermont legislature approved a bill to amend its state marketing disclosure law to restrict further activity with prescribers, such as flatly prohibiting meals and expanding the scope of the law to require compliance and financial reporting by medical device manufacturers.³ As of this writing it is anticipated that the bill will be signed by Governor Jim Douglas in early June.⁴

Pharmaceutical and medical device manufacturers must act quickly to meet the July 1, 2009, deadline for implementing a wide array of compliance requirements, such as:

- Restrictions on meals provided to HCPs
- Restrictions on support for, or provision of meals at, continuing medical education (CME) programs, other third-party scientific or educational conferences or professional meetings
- Appropriate conflicts disclosures for all speakers and consultants who also serve on a formulary or other committee

Separately, pharmaceutical and medical device manufacturers must also have sophisticated systems in place to track certain financial payments or other economic benefits provided on or after July 1, 2009, in connection with the company’s “sales and marketing activities.” The broad definition of “sales and marketing activities” in the final regulations creates a significant challenge for identifying, tracking, accounting for and reporting payments and other economic benefits.

Penalties for knowing and willful violations are punishable by a fine of up to \$5,000 for each transaction, occurrence or event. The final regulations provide that manufacturers will be given notice and have an informal opportunity to dispute the issuance of any fine. Manufacturers may seek judicial review of the imposition of a fine in the Superior Court.

Importantly, the Massachusetts Department of Public Health (DPH) is taking a proactive approach to providing compliance guidance and has posted two sets of FAQs on its website.⁵

¹ The regulations define a “pharmaceutical or medical device manufacturing company” as any entity that is “engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of a chemical synthesis; or is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices.” 105 CMR § 970.004. On May 22, 2009, the Massachusetts Department of Health published a second set of FAQs addressing certain compliance questions. These FAQs indicate that the manufacturers of prescription devices as well as manufacturers of Class II and Class III devices are required to comply. Manufacturers of medical devices that are exempt from the Premarket Notification requirements under the federal Food Drug and Cosmetic Act are not required to comply. See DPH FAQ(A)(8) (May 22, 2009).

² The regulations define a “health care practitioner” as a person who prescribes prescription drugs and is licensed to provide health care in the commonwealth, or a partnership or corporation of such persons, or an officer, employee, agent or contractor of such persons acting in the course and scope of employment. Hospitals and full time employees or board members of pharmaceutical or medical device manufacturers are not health care practitioners. 105 CMR § 970.004.

³ See S.48, 2009 Gen. Assem., Reg. Sess. (Vt. 2009). Prior to this amendment, the Vermont disclosure law applied to pharmaceutical manufacturers only. See generally Vt. Stat. Ann. tit. 22, § 4632 (2008).

⁴ If signed by the governor, the new law will become effective July 1, 2009.

⁵ The first set of FAQs and other information, such as presentations made by DPH, were published on March 11, 2009, and are *available at* http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_faqs.doc. The second set of FAQs was published on May 22, 2009, and is *available at*

http://www.mass.gov/?pageID=eohhs2terminal&L=4&L0=Home&L1=Provider&L2=Certification%2c+Licensure%2c+and+Registration&L3=Programs&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_conduct_code&csid=Eeohhs2.

The Big Picture – Transparency is the New Standard

The issue of conflicts of interest between a physician's ethical responsibility to patient care and the profit motives of pharmaceutical companies has received extensive media coverage and has triggered congressional investigations and legislative reform initiatives over the last several years. Indeed, on April 29, 2009, the Institute of Medicine (IOM) issued an extensive report that offers 16 specific recommendations to reduce conflicts of interest between doctors and industry. One recommendation is to create a national disclosure program requiring pharmaceutical, medical device and biotechnology companies to report publicly payments to physicians.⁶

STATE LAW REFORM INITIATIVES

To date, Massachusetts, six other states and the District of Columbia have passed laws addressing pharmaceutical and medical device manufacturer sales and marketing conduct and/or requiring disclosure of economic benefits provided to health care professionals and other persons or entities that prescribe or dispense prescription drugs.⁷

SALES AND MARKETING COMPLIANCE

The pharmaceutical and medical device industry associations have responded to media and government concerns over manufacturer relationships with health care professionals by revising their respective industry codes of conduct, which now set forth stricter limits and guidelines for industry interactions with health care professionals, such as prohibiting distribution of branded promotional items (*e.g.*, pens, mugs or notepads) bearing a company or product name. The revised Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (PhRMA Code) became effective in January of this year.⁸ The revised AdvaMed Code of Ethics on Interactions with Health Care Professionals (AdvaMed Code) will become effective on July 1, 2009.⁹

POSSIBLE NATIONAL TRANSPARENCY REQUIREMENTS

Looming large in the background is the recent reintroduction of the Federal Physician Payments Sunshine Act of 2009, which would require pharmaceutical and medical device manufacturers to report payments and other economic benefits provided to physicians on a national level.¹⁰

PREPARE TODAY

Given the clear signals that there will be a continued push for transparency both at the federal and state levels, in preparing to comply with the Massachusetts requirements, pharmaceutical and medical device manufacturers may wish to undertake a detailed examination of the company's policies and procedures for monitoring and managing compliance oversight not only for the company's own employees, but also with respect to the processes, checks and balances in place for interacting with HCPs and other health care entities.¹¹

⁶ Institute of Medicine, *Conflict of Interest in Medical Research, Education and Practice* (Apr. 2009), available at http://www.nap.edu/catalog.php?record_id=12598#toc.

⁷ Other states and jurisdictions with marketing disclosure laws are: California, the District of Columbia, Maine, Minnesota, Nevada, Vermont and West Virginia. *See generally*, Cal. Health & Safety Code §§ 119400, 119402; D.C. Code Ann. §§ 48-833.01, 48-833.09; Maine Rev. Stat. Ann. tit. 22, § 2698-A; Minn. Stat. §§ 151.461, 151.47; Nev. Rev. Stat. §639.570; Vt. Stat. Ann. tit. 22, § 4632; W. Va. Code § 5A-3C-13. Two states, California and Nevada, have requirements that apply to device manufacturers; however, neither requires reporting of marketing gifts or other economic benefits. *See* Cal. Health & Safety Code § 19402(a), (b) (requiring development and publication of a Comprehensive Compliance Plan); Nev. Rev. Stat. § 639.570(2) (requiring annual submission of a company's marketing code of conduct and other information regarding training and investigation policies).

⁸ The revised PhRMA Code became effective on January 1, 2009, and is available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.

⁹ The revised AdvaMed Code is available at <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.

¹⁰ The Federal Physician Payments Sunshine Act of 2009 (S.301) is available at <http://thomas.loc.gov/cgi-bin/query/z?c111:S.301>.

¹¹ In a recent speech at the National Disclosure Summit in Washington, D.C., Christopher J. Christie, Esq., Former United States Attorney for the District of New Jersey, Newark made an important comment with respect to his involvement with the highly publicized settlements and Deferred Prosecution Agreements (DPA) with four medical device companies in 2007. In particular, Mr. Christie noted that a common issue among the device manufacturers was that the company's product growth and success outstripped its management's skills and sophistication to

The tables below set forth the scope of the Massachusetts compliance, reporting and certification requirements and provide practical compliance considerations and tips to assist with that effort. The tables also include key guidance from the DPH FAQs published through May 22, 2009.

TABLE 1: GENERAL REQUIREMENTS

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
<p>TRAINING AND COMPLIANCE</p> <p>Training Requirements</p>	<p>The training program must ensure appropriate employees have sufficient knowledge of:</p> <ul style="list-style-type: none"> ▪ The Marketing Code of Conduct ▪ General science ▪ Product-specific information to provide accurate information consistent with state law and Food and Drug Administration (FDA) requirements <p>The training program must include regular assessments of compliance with the Marketing Code of Conduct.</p>	<p>Ensure that top level management and field sales employees understand the Marketing Code of Conduct restrictions and limitations, in addition to the financial tracking requirements.</p> <p>Review current training policies and procedures and incorporate relevant Massachusetts requirements.</p> <p>Consider developing travel size compliance cards for field sales representatives with Massachusetts specific guidance.</p>
<p>Policies, Procedures and Certification Requirements</p>	<p>By July 1, 2009, manufacturers must:</p> <ul style="list-style-type: none"> ▪ “Adopt” and submit a description of a training program to provide regular training to appropriate employees ▪ “Adopt” and submit policies and procedures for investigating non-compliance with the regulations, taking corrective action in response to non-compliance and reporting instances of non-compliance to the appropriate state authorities ▪ Submit the following information regarding the compliance officer responsible for certifying compliance with the regulations, and implementing, monitoring and enforcing the company’s marketing code of conduct: <ol style="list-style-type: none"> 1. Name 2. Title 3. Address 4. Phone number 5. E-mail address ▪ Certify to the DPH “to the best of the company’s knowledge and belief” that it is in compliance with the regulations 	<p>Review (and amend if necessary) current policies and procedures for training programs and investigating instances of non-compliance.</p> <p>Tip 1: <i>The DPH Code of Conduct Compliance Form (due July 1, 2009) is available on the DPH website.¹² The form requires manufacturers to indicate that the required policies and procedures are in place. The form indicates that manufacturers will be required to make copies of these policies and procedures available to DPH upon request. A hard copy submission is not required.</i></p>

track and account for activity with health care professionals in a meaningful manner. Mr. Christie advised other companies to start tracking this information early. The investment of time and effort to develop tracking mechanisms and management tools is worth the effort.

¹² The form is available at

http://www.mass.gov/?pageID=eohhs2terminal&L=4&L0=Home&L1=Provider&L2=Certification%2c+Licensure%2c+and+Registration&L3=Programs&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_conduct_code&csid=Eeohhs2.

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
<p>Limitations on Financial Support</p>	<p>Manufacturers are <i>prohibited</i> from providing:</p> <ul style="list-style-type: none"> ▪ Financial support for travel, lodging or other expenses of non-faculty HCPs attending any CME or third-party scientific or educational conference or professional meeting, either directly to the individual, or indirectly to the event sponsor ▪ Funding to compensate time spent by HCPs in any CME or third-party scientific or educational conference or professional meeting 	<p>Tip 3: <i>Requirements are consistent with PhRMA and AdvaMed Codes.</i></p> <p>Tip 4: <i>Although such activity is addressed by the PhRMA and AdvaMed Codes, the final regulations do not include an exception for providing financial assistance for scholarships or other educational funds to permit medical students, residents or fellows to attend educational conferences.</i></p>
<p>No Provision of, or Payment for Meals Directly</p>	<p>Payment for meals directly to an HCP is prohibited. CME providers or conference or meeting organizers may apply any financial support to provide meals for all participants at its own discretion.</p>	<p>Review all contracts or plans to provide meals at CME or other events occurring after July 1, 2009.</p> <p>Tip 5: <i>Both the PhRMA and AdvaMed Codes permit meals that are provided separate from the CME, so long as the meal is consistent with sponsor guidelines. Such meals are not permissible under the Massachusetts Code of Conduct.</i></p>
<p>Compensation to HCPs Serving as Faculty Organizers or Program Consultants Permitted</p>	<p>Speakers or health care practitioners providing substantive services as faculty organizers or program consultants for CME events, professional meetings or other educational conferences may receive compensation or reimbursement that is:</p> <ul style="list-style-type: none"> ▪ Reasonable ▪ Based on fair market value ▪ Compliant with the standards for commercial support established by the relevant accredited CME provider 	<p>Consider this in light of industry code requirements and company policy.</p> <p>Tip 6: <i>The AdvaMed code provides that manufacturers may make grants to conference sponsors for reasonable honoraria, travel and lodging for HCPs who are bona fide conference faculty members.</i></p>
<p>Payments Directly to Conference Organizers and Use of Hotels or Other Venues Permitted</p>	<p>Sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting or professional meeting, where the payment is made directly to the conference or meeting organizers is permitted.</p> <p>Use of hotel or convention center facilities or other venues for CME or third-party scientific, educational or professional meetings or conferences is permitted.</p>	<p>Tip 7: <i>Such sponsorship is also permitted by the PhRMA and AdvaMed Codes.</i></p> <p>DPH FAQs:</p> <p>Manufacturers do <i>not</i> need to report payments to third-party scientific, educational or professional meeting organizers, unless the organizer is a “covered recipient” as defined by the regulations.</p>

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
<p>NON-PATIENT IDENTIFIED PRESCRIBER DATA</p>	<p>Pharmaceutical manufacturers using non-patient identified prescriber data to facilitate communications with health care practitioners must:</p> <ul style="list-style-type: none"> ▪ Maintain the confidential nature of the prescriber data ▪ Develop policies regarding the use of the data ▪ Educate employees and agents regarding these policies ▪ Designate an internal contact person to handle inquiries regarding the use of the data ▪ Identify appropriate disciplinary action for misuse of the data ▪ Comply with the request of any health care practitioner <i>not</i> to make his or her prescriber data available to company sales representatives <p>Before utilizing HCP prescriber data for marketing purposes, manufacturers must give HCPs an opportunity to request that their prescriber data be withheld from company sales representatives and not be used for marketing purposes.</p> <p>Pharmaceutical manufacturers are permitted to use prescriber data to provide safety information, conduct research, comply with FDA mandated risk management plans and track adverse events of marketed drugs.</p>	<p>Develop policies and procedures regarding the use of prescriber data.</p> <p>Consider how the company will track HCP requests restricting use of prescribing data and how those restrictions will be available and accessible to field sales representatives.</p>

TABLE 3: PERMISSIBLE ACTIVITY

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
DRUG SAMPLES/ DEMONSTRATION AND EVALUATION UNITS	Prescription drugs provided to an HCP for use by the HCP’s patients, and reasonable quantities of medical device demonstration and evaluation units provided to an HCP to assess appropriate use and function and to determine whether to use or recommend the product in the future, are permissible.	<p>Tip 8: <i>Requirements are consistent with PhRMA and AdvaMed Codes.</i></p> <p>DPH FAQs:</p> <p>Medical device manufacturers may provide medical devices for the benefit of patients, such as glucose monitors.</p>
PRICE CONCESSIONS	Price concessions such as rebates or discounts in the normal course of business are permissible.	<p>Tip 9: <i>Not addressed by PhRMA or AdvaMed Codes.</i></p>
CHARITABLE DONATIONS	Charitable donations are permissible, so long as they are not provided in exchange for, or for a commitment to, prescribe, dispense or use prescription drugs, biologics or medical devices.	<p>Tip 10: <i>Requirements are consistent with the PhRMA and AdvaMed Codes.</i></p>
REIMBURSEMENT INFORMATION	Manufacturers may provide certain reimbursement information and technical support.	<p>Tip 11: <i>Requirements are consistent with the AdvaMed Code. There is no comparable provision in the PhRMA Code.</i></p>
PEER-REVIEWED LITERATURE	<p>Manufacturers may distribute peer reviewed academic, scientific or clinical journals.¹⁴</p> <p>Manufacturers may purchase advertising in peer reviewed academic, scientific or clinical journals.</p>	<p>Consider whether purchase costs for distribution or advertising is reportable.</p> <p>Tip 12: <i>Not addressed by PhRMA or AdvaMed Codes.</i></p>
PATIENT ASSISTANCE PROGRAMS	Payments or the provision of free outpatient prescription drugs to benefit low income individuals through established “patient assistance programs” are permissible provided the program meets guidance published by the U.S. Department of Health and Human Services Officer of Inspector General (OIG) or is otherwise permissible under applicable federal laws and regulations.	<p>Tip 13: <i>Not addressed by the PhRMA or AdvaMed Codes.</i></p> <p><i>OIG has issued various advisory opinions addressing Patient Assistance Programs. See, e.g., Advisory Ops. 02-13 (Oct. 4, 2002), 06-14 (Sept. 26, 2006), 06-21 (Nov. 9, 2006) & 08-17 (Oct. 21, 2008).</i></p>

¹⁴ In January 2009, the FDA published its final “Good Reprint Practices” guidance, which addresses the FDA’s principles for distribution of medical journal articles or medical reference publications that discuss off-label uses of FDA approved drugs and medical devices. See U.S. Food & Drug Administration, Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009), available at <http://www.fda.gov/oc/op/goodreprint.html>.

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
TECHNICAL TRAINING ON THE USE OF A MEDICAL DEVICE	Manufacturers may pay or reimburse reasonable expenses, including travel and lodging for technical training of HCPs on the use of a medical device if the commitment to provide such expenses, and the amounts or categories of reasonable expenses, are included in the written agreement between the HCP and the device vendor for the purchase of the device.	Consider what, if any revisions must be made to current contracting processes and procedures for medical device purchases and training. Tip 14: <i>This requirement is more restrictive than the AdvaMed Code.</i>

TABLE 4: INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
PAYMENTS AND ACTIVITY WITH HEALTH CARE PRACTITIONERS Payments, Grants, Scholarships, Subsidies, Educational or Practice Related Items	The regulations prohibit: <ul style="list-style-type: none"> ▪ Payments of any kind, including cash or cash equivalents, equity or “complimentary” items such as pens, coffee mugs or gift cards except as compensation for <i>bona fide</i> services ▪ Any other remuneration, direct or indirect, including any rebate or “kickback” prohibited under applicable federal or state “fraud and abuse” laws or regulations, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b) ▪ Entertainment or recreational items of any value including, but not limited to, tickets to the theater or sporting events, concerts or vacation trips to any HCP who is not a salaried employee ▪ Grants, scholarships, subsidies, consulting contracts, or educational or practice related items in exchange for, or for a commitment to, prescribe, dispense or purchase prescription drugs, biologics or medical devices 	Tip 15: <i>Requirements are consistent with PhRMA and AdvaMed Codes.</i> DPH FAQs: Educational items consistent with the PhRMA or AdvaMed Codes are permitted.
COMPENSATION FOR BONA FIDE CONSULTING SERVICES	HCPs may be paid for <i>bona fide</i> services (and reimbursed for reasonable out-of-pocket expenses), so long as there is a written agreement specifying the services to be provided and the fair market value of the services. The arrangement must also be characterized by the following factors: <ul style="list-style-type: none"> ▪ A legitimate need for the services clearly identified in advance 	Tip 16: <i>Requirements are consistent with the PhRMA and AdvaMed Codes.</i>

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
<p>Key Definition</p>	<ul style="list-style-type: none"> ▪ A connection between the competence and expertise of the health care practitioner and the purpose of the arrangement ▪ The number of health care practitioners retained is reasonably necessary to achieve the identified purpose ▪ The retaining company maintains records of the arrangement and makes appropriate use of the services provided by the health care practitioner ▪ The circumstances of meetings with the health care practitioner are conducive to the services, and the services are the primary focus of the meeting ▪ The decision to retain a health care practitioner is not unduly influenced by the company's sales personnel <p>“Bona fide services” include, but are not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to promotion of health and prevention of disease and presentations at pharmaceutical or medical device company-sponsored medical education and training including FDA required education and training.</p>	
<p>CONFLICT DISCLOSURE BY FORMULARY OR COMMITTEE MEMBERS</p>	<p>Pharmaceutical manufacturers (only) must obligate any HCP who serves as a speaker or commercial consultant and also is a member of a committee that sets formularies or develops clinical guidelines 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 termination of the speaker or consulting arrangement.</p>	<p>Review all speaking and consulting contracts with Massachusetts HCPs and assess whether the HCPs are also committee members.</p> <p>Determine and document whether disclosure has been made or is required and will be made.</p>

Marketing Code of Conduct Provision	Regulatory Requirement	Compliance Considerations and Tips
<p>Key Definitions</p>	<p>manufacturers and insurers, pharmacies, pharmacy benefit managers or health plan administrators offered in connection with the acquisition of drugs, biologics, medical devices or the management of a health plan's formulary.</p> <p>“Covered recipient” is defined as a person authorized to prescribe, dispense or purchase prescription drugs in the commonwealth including a hospital, nursing home, pharmacist, health benefit plan administrator or a health care practitioner. <i>Bona fide</i> employees of a pharmaceutical or medical device manufacturing company and consumers who purchase prescription drugs or medical devices are not “covered recipients.”</p> <p>“Clinical trial” is defined as a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the drug, biologic or medical device in the prevention, screening, diagnosis, evaluation or treatment of a disease, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, has been approved by an Institutional Review board.</p> <p>“Genuine research project” is defined as a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to HCPs or scientists working in the field.</p>	<p><i>reportable.</i></p>
<p>ANNUAL COMPLIANCE AUDIT SUBMISSION</p>	<p>Beginning July 1, 2010, and annually each July 1, each pharmaceutical and medical device manufacturer must certify to the DPH that it has conducted annual audits to monitor compliance with the regulations.</p>	<p>Consider the scope of activity that must be covered by the annual audit, the covered period, and the time required to prepare, conduct and document the audit.</p>

Conclusion

State and federal lawmakers will continue the movement towards transparency and accountability in the marketing practices of pharmaceutical and medical device manufacturers because, in their view, “the practice of allowing pharmaceutical and device manufacturers (or anyone with a vested interest in the decisions of prescribers) to make gifts or payments of cash or goods creates an unacceptable conflict of interest” that drives up costs of prescription drugs and devices.¹⁵ According to Sharon Anglin Treat, Executive Director, National Legislative Association on Prescription Drug Prices, the state and federal government as purchasers of prescription drugs, should not have to compete with manufacturer marketing tactics that put profits over scientific rigor.¹⁶

In light of the significant compliance and reporting considerations required by the final regulations, it is critical to begin an early evaluation of the effect the regulations may have on a company’s marketing and promotional activities in Massachusetts. A critical piece of this evaluation should include a comprehensive assessment of technology capabilities and whether additional personnel are necessary to manage the compliance and reporting requirements. Companies must work quickly to ensure that the proper policies and procedures are in place to ensure compliance with the final regulations by July 1, 2009.

For more information, please contact your regular McDermott lawyer, or:

Bernadette M. Broccolo: +1 312 984 6911 bbroccolo@mwe.com

Kate W. Feola: +1 202 756 8388 kfeola@mwe.com

April Timko: +1 617 535 4043 atimko@mwe.com

For more information about McDermott Will & Emery visit www.mwe.com

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¹⁵ See Testimony of Sharon Anglin Treat, Executive Director, National Legislative Association on Prescription Drug Prices Before the Health Care Committee, Oregon Legislature (Mar. 9, 2009) available at www.reducedrugprices.org/av.asp?na=497.

¹⁶ *Id.*