ARNOLD & PORTER LLP

CLIENT ADVISORY

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MASSACHUSETTS FINALIZES REGULATIONS ON PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT

In August 2008, Massachusetts enacted "An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare" which contained a new chapter entitled "Pharmaceutical and Medical Device Manufacturer Conduct." The purpose of the new law was to address potential undue influence in interactions between pharmaceutical or medical device manufacturing companies and healthcare practitioners. Lawmakers desired an increased level of transparency in these interactions, but acknowledged the need to protect manufacturers' legitimate confidentiality interests, trade secrets, and other intellectual property rights.

The Massachusetts law contains basic instructions on permissible and prohibited conduct related to the sales and marketing of drugs and devices and requires the Massachusetts Department of Public Health (DPH) to promulgate and update a code of conduct for pharmaceutical and medical device companies every two years. The Massachusetts law also requires companies employing persons in the sales/marketing of a drug or device in the Commonwealth to adopt the code of conduct and to create a training program regarding the code of conduct for those employees. Annual compliance audits are required, as well as investigations into and reporting of any breaches of the code of conduct. These actions must be certified annually to the DPH.

The other key portion of the new law is the requirement of an annual report to the DPH of the value, nature, purpose, and particular recipient of any fee, payment, subsidy, or economic benefit with any value of at least US$50 provided to a covered healthcare provider[1] by agents of a pharmaceutical or device company. The DPH was required to promulgate regulations that would adopt a detailed standard marketing code of conduct for all manufacturers that employ persons to sell or market prescription drugs and medical devices in Massachusetts, with the new law specifically noting that regulations should be "no less restrictive" than the most recent versions of the Pharmaceutical

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Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) Codes.[2] The DPH was to establish a public database to enable listing payments to healthcare practitioners by manufacturers that employ persons to sell or market prescription drugs and to set fees in conjunction with the disclosure requirements of the chapter. The DPH, the Massachusetts attorney general, and district attorneys with jurisdiction were charged with enforcement of the new law.

After releasing proposed regulations in December 2008, the Public Health Council held two public hearings and received written comments during the comment period that closed January 19, 2009. Based on the input received during this period from industry stakeholders (including pharmaceutical and medical device companies, PhRMA, AdvaMed, and other advocacy organizations), the DPH modified the proposed regulations. On March 11, 2009, the Massachusetts Public Health Council adopted the final set of implementing rules, setting forth the requirements that pharmaceutical and medical device manufacturers must comply with pursuant to the new law on Pharmaceutical and Device Manufacturer Conduct.

As more fully discussed in this advisory, the regulations require companies by July 1, 2009 to adopt a code of conduct, as specified in the regulations, to adopt a training program for the code, certify compliance with the regulations, and establish policies and procedures for investigation and corrective action. The regulations also require companies to make annual disclosures starting July 1, 2010 of certain payments to recipients in connection with sales and marketing activities.

Though the Code of Conduct provisions only apply to interactions between industry and healthcare practitioners licensed in Massachusetts, this new law has attracted national attention because of its unprecedented scope. Following is a summary of the new rule, highlighting changes from the proposed and final regulations. Next is a comparison of the Massachusetts disclosure law and regulations to the proposed Physician Payments Sunshine Act (Sunshine Act)[3] and the current PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code).

I. THE MASSACHUSETTS FINAL REGULATIONS

A. Marketing Code of Conduct

The final regulations confirm the prohibitions on the provision of meals outlined in the Massachusetts law, as well as the entertainment or recreation prohibitions. The final regulations also add an allowance for the use of hotel facilities, convention centers, or other special event venues for continuing medical education (CME) or related conferences, likely in response to criticism that the implementation of the Massachusetts law would have a chilling effect on the Commonwealth's ability to attract conferences going forward.

The final regulations prohibit leave-behind and reminder items, any grants or supports designed to induce prescriptions, and any payments that could implicate the anti-kickback statute. The final regulations do allow for the provision of reasonable quantities of medical device demonstration and evaluation units to assess the appropriate use and functionality of the product and the provision of charitable donations.

A Summary of the Massachusetts Code of Conduct	
Permitted Conduct	**Prohibited Conduct**
Compensation for the substantial professional or consulting services of a healthcare practitioner in connection with a genuine research project or a clinical trial Payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device Provision or receipt of peer reviewed academic, scientific, or clinical information Purchasing advertising in peer-reviewed academic, scientific, or clinical journals Provision of drug samples solely for patient use	Payments for or Provision of Meals: ■ related to entertainment or recreation ■ offered without the marketing agent and an informational presentation ■ offered/consumed outside of the practitioner's office/hospital setting Provision of Entertainment/Recreation other than to salaried employees of the pharmaceutical or device company Sponsorship of CME that does not meet Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support or that offers direct payment to a practitioner Direct or indirect financial support for travel, lodging, or personal expenses of non-faculty CME attendees Direct payments to practitioners except for bona fide service agreements Providing grants, scholarships, subsidies, support, consulting contracts, or educational/practice items to any practitioner in exchange for prescription or use of a drug or medical device

B. Compliance Requirements

The final regulations require each manufacturer to adopt a compliant code of conduct and to submit a training program on code to the DPH by July 1, 2009. One new provision was added related to prescriber data, allowing healthcare practitioners the ability to request withholding of their data from company sales reps and for it to not be used for marketing purposes, a concept traceable to the PhRMA code discussed more broadly in Part III. Prescriber data may still be used to relate important safety and risk information, to conduct research, to comply with FDA mandated risk management plans, and to track adverse events.

C. Disclosure Requirements

The disclosure section of the regulations impose a July 1, 2010 reporting deadline for the commencement of the filing of annual reports. The regulations define a healthcare practitioner rather broadly as "a person who prescribes prescription drugs for any person and is licensed to provide healthcare in the commonwealth or a partnership or corporation comprised of such persons, or an officer, employee, agent, or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision

of healthcare to individuals." The regulations do not require aggregate reporting, meaning that for purposes of computing the US$50 reporting trigger, fees, payments, subsidies, and other economic benefits that relate to separate events or transactions are to be calculated on a transactional, not aggregate, basis for the covered recipient. Specifically exempted from the reporting requirement are the following: reasonable compensation for bona fide services (including related expenses) pursuant to a written agreement; reimbursement for expenses related to technical training of healthcare practitioners on the use of a medical device (per written purchasing agreement); dissemination or receipt of peer reviewed academic, scientific or clinical information; purchasing advertising in peer reviewed academic, scientific or clinical journals; provision of samples (including medical device demonstration units); rebates and discounts; reimbursement information; patient assistant program support (financial or free product); and charitable donations. Manufacturers are prohibited from structuring payments to avoid reporting requirements.

D. Enforcement

The penalty section specifically targets knowing and willful violations of the regulations under the Massachusetts law and reinforces the US$5,000 per transaction penalty per violation. The attorney general, the district attorney with jurisdiction over a violation, or the DPH are provided with authority for enforcement of the law and regulations, and are allowed to issue fines and notice via mail for violations. Recipients are afforded the opportunity to dispute the fine, including judicial review related to issued fines. The enforcement authorities are allowed to pursue a civil action for recovery of lodged and unpaid fines.

II. FEDERAL SUNSHINE ACT

The federal Physician Payments Sunshine Act (Sunshine Act) was re-introduced in the 111th Congress after failing to progress out of committee in the 110th. One key distinction between the federal legislation and the Massachusetts law is in the underlying purpose of their provisions; where both are interested in preventing inappropriate influence over healthcare practitioners by manufacturers in the form of payments or other remuneration, the Massachusetts law is primarily concerned with the interaction of sales and marketing personnel with healthcare professionals and its focus is mandating a code of conduct. The Sunshine Act has a wider scope than just the marketing and sales departments when looking at a myriad of ways that funding can affect practitioner decision-making. The Sunshine Act's primary purpose is facilitating the public reporting of payments made to physicians.

Another key aspect of the proposed Sunshine Act is its provision on federal preemption, which would require adherence to the federal law should a conflict arise with state laws related to payment reporting. The legislation would not prevent states from requiring more than what is provided in the federal bill, however. Therefore, manufacturers would still have to comply with the Massachusetts provisions that go above and beyond those contained in the Sunshine Act.

Several important distinctions between the Massachusetts law and the proposed Sunshine Act are described as follows:

- The Massachusetts law applies to manufacturers of prescription drugs, biologics, and medical devices; the Sunshine Act adds medical supply manufacturers to that list.
- The Sunshine Act's reporting trigger is US$100 per calendar year per covered recipient, aggregated (versus US$50 per covered recipient, per transaction in Massachusetts).

- The Sunshine Act includes more exempted items from the reporting requirements, such as educational materials that directly benefit patients, short-term device loans (90 days), items/services under warranty, and dividends or other profits from a publicly traded security and mutual fund.
- The Sunshine Act has a more specific list for reportable payments (including honoraria, royalties or licenses, and ownership and investment interests) versus the Massachusetts regulation's more general "any fee, payment, subsidy, or other economic benefit and provision of a definition for "bona fide services."[4]
- The Massachusetts regulations contain a disclosure requirement for members of formulary committees with speaker or consulting agreements with manufacturers, where the Sunshine Act does not have a similar conflict of interest provision.
- The Sunshine Act also requires the reporting of fees or payments at the request of or designated on the behalf of a covered recipient, where the Massachusetts law does not address designee payments.
- The Sunshine Act includes a reporting requirement for physician ownership interest in an applicable manufacturer including the amount invested, the value and terms of the investment, and any payment related to that interest over the past reporting year.
- The Sunshine Act contains a provision on delayed reporting for payments made pursuant to product development agreements and clinical investigations.
- Massachusetts charges a fee of US$2,000 per annual disclosure report (the Sunshine Act does not charge a fee).
- Massachusetts has a US$5,000 penalty per violation of its law/regulations and the Sunshine Act assesses a civil monetary penalty in a range of US$1,000-10,000 for each payment not reported with a maximum penalty of US$150,000 for each annual submission per manufacturer (the fines increase to US$10,000-100,000 for knowing failures to report, with a cap of US$1 million per submission period).
- The Sunshine Act does not allow judicial review over its implementation and otherwise does not have an enforcement section like the Massachusetts law (which does allow judicial review of assessed penalties).

III. THE PhRMA AND ADVAMED CODES

The Massachusetts legislation recognizes the influence of the PhRMA and AdvaMed Codes, but qualifies them as "the floor" in restricting marketing activities. The most significant difference between the Massachusetts Disclosure Law and the PhRMA and AdvaMed Codes is that the Massachusetts law is mandatory, while the PhRMA and AdvaMed Codes are voluntary.

Overall, the mandatory/voluntary distinction makes the Massachusetts law more restrictive than the PhRMA and AdvaMed Codes. Many of PhRMA's and AdvaMed's guidelines are reflected in the Massachusetts law and regulations, including the allowance of samples for patient use, a prohibition on reminder items (e.g., pens, pads, etc.), the ban on providing entertainment and recreation, and the rules related to funding CME and other educational events. Distinctions do exist, however, and include the following:

- The industry codes allow for the provision of educational funds for medical students, residents, fellows, or healthcare professionals in training. The

Massachusetts proposed regulations included that allowance, but the final rule excluded it.

- The PhRMA Code allows the provision of appropriate educational items if the items are not of substantial value (US$100 or less), while the AdvaMed Code permits medical textbooks and anatomical models even if they exceed US$100 in value. The Massachusetts final regulations do not contain these allowances.

IV. CONCLUSION

Now that the Massachusetts regulations are in final form, companies must turn their attention to the code of conduct related reporting requirements due in July 2009 and begin preparation for compilation of payment information for the first deadline in 2010, which covers payments made between July 1 and December 31, 2009. Should the Sunshine Act pass in the near future, companies will have to reconcile their obligations in Massachusetts with those of the federal government in the very near term. And while Massachusetts has enacted the most vigorous state provisions to date, it certainly will not have the last word on the subject.

We hope that you have found this client advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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1 Covered providers include any physician, hospital, nursing home, pharmacist, health benefit plan administrator, healthcare practitioner, or other person authorized to prescribe, dispense, or purchase prescription drugs or devices in the Commonwealth.

2 PhRMA's Code on Interactions with Healthcare Professionals most recent version has an effective date of January 1, 2009. AdvaMed's most recent version of its Code of Ethics on Interactions with Healthcare Professionals has an effective date of July 1, 2009.

3 S. 301 was introduced on January 22, 2009 by Senators Charles Grassley (R-IA) and Herb Kohl (D-WI).

4 Bona fide services includes arrangements for services related to research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including US Food and Drug Administration (FDA) required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and characterized by the following factors:

- a legitimate need for the services clearly identified in advance;
- a connection between the competence and expertise of the healthcare practitioner and the purpose of the arrangement;
- the number of healthcare practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the healthcare practitioner;
- the venue and circumstances of any meeting with the healthcare practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and
- the decision to retain a healthcare practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel.