

## Massachusetts Gift Ban Narrowed to Allow Meals During Education Programs

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As part of the annual state budget process, the Massachusetts legislature has narrowed several of the most contentious provisions of its so-called physician gift ban, Mass. Gen. L. c. 111N. These changes will have a significant effect on interactions between industry and health care providers in Massachusetts.

The most notable change is the elimination of the prohibition on restaurant meals. The revised statute now permits “the provision of or payment for modest meals and refreshments in connection with non-CME educational presentations for the purpose of educating and informing healthcare practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and matter conducive to information communication.”

This change is tempered by two qualifications. First, any meals or refreshments that are provided must be “modest,” and the Department of Public Health has the authority to determine, by regulation, what “modest” means. Consumer advocacy groups and industry groups alike have already promised to be involved in that rule-making process.

Second, the amended statute requires pharmaceutical and medical device companies to report these meals and refreshments on a quarterly basis. However, in light of the existing Massachusetts reporting provisions for other industry-provider interactions, as well as the preemption reporting provisions in the Federal Sunshine Act that take effect in January 2013, this burden is likely to be fairly minimal.

Another new statutory change that will impact the medical device community is that training related to medical devices can now be provided without having a signed sale agreement.

### Amendments to Massachusetts “Gift Ban” Law, M.G.L. c. 111N

Sections 108 through 114 of the FY 2013 Budget Conference Committee report that was released on June 27, 2012 (“FY13 Report”) propose certain amendments to the Pharmaceutical and Medical Device Manufacturer Conduct Law, M.G.L. c. 111N (“Chapter 111N”). These amendments were signed into law by Governor Patrick on July 8, 2012. A summary of these amendments is provided below.

- **Sections 108, 109 and 114** (*DPH Reporting of Sunshine Expense Data*)

As of January 1, 2012, pharmaceutical and medical device manufacturing companies are required to begin collecting certain marketing expenses under the federal Sunshine Act (42 U.S.C. 1320a-7h) for annual reporting to the U.S. Department of Health and Human Services (“HHS”). The Sunshine Act requires HHS to submit annually to each state a summary of the information disclosed by companies with respect to covered recipients in that state. Sections 108, 109 and 114 of the FY13 Report require the Department of Public Health (“DPH”) to annually disclose on its website the Massachusetts-related expense data contained in the HHS summary report.

- **Section 113** (*Codification of Sunshine Act Pre-emption Provision*) The Sunshine Act pre-empts any state law requiring manufacturers to report to a state any marketing expense information that also must be reported to HHS. Section 113 of the FY13 Report simply codifies this pre-emption provision in Massachusetts law. Note: The adoption of Section 113 would not prevent DPH from continuing to require the disclosure of expenses under Chapter 111N that are not otherwise reportable to HHS under the Sunshine Act, including, for example, payments made to non-physician drug prescribers.

- **Sections 110, 111 and 112** (*Payment for and Reporting of Meals at Educational Events Outside of the Practitioner’s Office or Hospital Setting*)

Chapter 111N currently prohibits the provision of, or payment for, any meals for health care practitioners outside of the practitioner's office or hospital setting. Sections 110 and 111 of the FY13 Report would permit a manufacturer to pay for "modest meals and refreshments" outside of the practitioner's office or hospital setting in connection with non-CME educational presentations for the purpose of educating and informing practitioners about prescription drugs, medical devices, disease states or other scientific information. Section 111 also requires the DPH to define "modest meals and refreshments" by regulation. Section 112 requires manufacturers to report to the DPH on a quarterly basis the cost of such payments per "participant," the location of the presentation, and the drugs or devices discussed. Section 112 section also allows DPH to require payment of a fee to administer this new reporting requirement.

■ **Section 111** (*Payment of Medical Device Training Expenses*)

Chapter 111N currently allows a manufacturer to pay a health care practitioner's reasonable expenses necessary for technical training on the use of a medical device only when such payment is part of a purchase contract for that device. Section 111 of the FY13 Report would allow such payments regardless of the existence of any purchase contract.

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