

## CLIENT ADVISORY

### MASSACHUSETTS HEALTH CARE REFORM LAW LIMITS GIFTS TO PHYSICIANS

#### I. Introduction

On August 10, 2008, Massachusetts Governor Deval Patrick signed into law Massachusetts Senate Bill 2863, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the “Bill”)<sup>1</sup>, which sets strict limits on gifts provided to physicians by pharmaceutical and medical device manufacturing companies. The debate over the gift ban language was the most contentious measure contained in a broad statute intended to improve healthcare safety and control growing costs. In its original form, the gift ban language prohibited gift-giving altogether with the intent to ending undue influence exerted by pharmaceutical and medical device manufacturing companies on medical professionals’ judgment in deciding which drugs or devices to utilize. As enacted, the Bill bans only certain types of gifts such as tickets to athletic events and free travel. It also requires public disclosure of gifts worth more than \$50.

#### II. Background

The gift ban provision was initially proposed by Massachusetts State Senators Mark Montigny and Richard Moore in Section 22 of Senate Bill 2526. It would have banned outright any pharmaceutical or device manufacturer from knowingly offering anything of value to any medical professional or health care facility, and imposed both civil and criminal liability on those who did. The gift ban allowed for no exceptions, *de minimis* provisions, or safe harbors. If enacted, these provisions would have established the strictest gift ban statute in the nation.

The Bill is a compromise between Senate and House versions of the legislation. It will apply to any pharmaceutical and medical device manufacturer who “participates in a commonwealth health care program.” The Bill requires the Massachusetts Department of Public Health (“DPH”) to promulgate a marketing code of conduct that is “no less restrictive” than the PhRMA<sup>2</sup> and AdvaMed<sup>3</sup> codes of ethics and requires that manufacturers adopt the DPH Code, train their employees in compliance with the code, and submit an annual compliance audit to DPH. Additionally, the Bill will require annual disclosure of all items

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<sup>1</sup> A copy of Massachusetts Senate Bill 2863 can be accessed at:

<http://www.mass.gov/legis/bills/senate/185/st02/st02863.htm>.

<sup>2</sup> Pharmaceutical Research and Manufacturers of America (“PhRMA”) represents pharmaceutical research and biotechnology companies.

<sup>3</sup> The Advanced Medical Technology Association’s (“AdvaMed”) member companies produce the medical devices, diagnostic products and health information systems.

with a value of \$50 or more that a manufacturer provides to a physician or other health care practitioner, and requires DPH to post this disclosure on its website. The Bill provides for civil penalties of up to \$5,000 per violation.

### **III. New Chapter 111N**

The Bill regulates the provision of gifts by pharmaceutical and medical device manufacturers to physicians by adding a new Chapter – 111N: Pharmaceutical and Medical Device Manufacturer Code of Conduct – to the Massachusetts General Laws. Chapter 111N requires DPH to promulgate regulations developing a “standard marketing code of conduct”. The DPH Code must include restrictions on a number of activities, including limits on the provision of meals for health care practitioners, continuing medical education (“CME”) sponsorship, grants and subsidies, and entertainment. Specifically, the Bill proscribes pharmaceutical and medical device manufacturers from providing or paying for entertainment or recreational items of any value, including tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the company. The DPH Code will allow dissemination of peer reviewed information, advertising in peer reviewed journals, drugs provided solely for the use of the practitioner’s patients, compensation for consulting services connected with research or clinical trials, and payment for technical training on medical devices.

Pursuant to Chapter 111N, manufacturers employing sales representatives in Massachusetts will now be required to adopt and comply with the DPH Code. Manufacturers must adopt a regular training program for employees, conduct annual compliance audits, adopt procedures for investigating and reporting noncompliance, and identify a compliance officer. Section 5 of Chapter 111N requires manufacturers to submit annually to DPH the following: descriptions of their training program and investigation policies; contact information for their code compliance officer; and certification of a successful compliance audit.

Chapter 111N also requires every manufacturer to disclose to DPH, by July 1 of each year, the “value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth.” This section also requires DPH to make this data publicly available on its website and to report any improper transactions to the Office of the Attorney General. Those violating the above provisions are subject to a fine of not more than \$5,000 per incident.

### **IV. Conclusion**

All pharmaceutical and medical device manufacturers who participate in a Commonwealth health care program, and employ individuals to sell or market drugs, medicines, or medical devices in the Commonwealth, will be required to adopt and comply with the DPH code.

It should be noted that the Bill also provides \$25 million to promote electronic medical record-keeping in physicians’ offices, requires the University of Massachusetts to graduate

more primary care doctors, and gives regulators the power to hold hearings when health insurers want to raise premiums. The Bill also establishes a medical-home demonstration project aimed at reducing healthcare costs through preventive, coordinated care of patients. Under the legislation, hospitals and community health centers will be required to adopt computerized physician order-entry systems by 2012 and electronic health-record systems by 2015. In addition, the Bill requires that hospitals report to DPH all healthcare-associated infections. Furthermore, state payers will no longer reimburse providers for certain so-called “never events” such as wrong-site surgeries.

The Rogers Law Firm will monitor DPH’s promulgation of regulations related to the Bill. Meanwhile, if you should have any questions regarding the Bill, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

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