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TO: Commissioner Auerbach and Members of the Public Health Council

FROM: Melissa J. Lopes, Deputy General Counsel

DATE: December 10, 2008

RE: Informational Briefing on Proposed Regulation 105 CMR 970.000, *Pharmaceutical and Medical Device Manufacturer Conduct*

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## I. Introduction

On August 10, 2008, the Governor signed into law 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 General Laws, Chapter 111N, entitled "Pharmaceutical and Medical Device Manufacturer Conduct," a copy of which is attached. (Appendix I). With a focus on preventing undue influence in the relationship between health care practitioners and pharmaceutical and medical device manufacturers, Chapter 111N requires that manufacturers adopt and comply with a state-authored marketing code of conduct, establish compliance and training programs pursuant to the state code of conduct, and disclose marketing payments made by pharmaceutical or medical device manufacturers to health care practitioners.

## II. Background

Chapter 111N presents the Department of Public Health (the "Department") with a number of responsibilities to implement the statute and enforce its provisions. Section 2 of Chapter 111N directs the Department to promulgate regulations adopting a standard marketing code of conduct for all pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs in the commonwealth. Section 6 of Chapter 111N requires that the Department establish a public database of payments to health care practitioners by pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs in the commonwealth. Further, section 6 requires that the Department set fees in conjunction with the disclosure requirements of the chapter. And, pursuant to section 7 of the Chapter 111N, the Department is charged with enforcing chapter 111N in its entirety, along with the Attorney General's Office and the district attorney with

jurisdiction over a violation. The Department reads this combination of responsibilities as explicitly and implicitly conferring authority to promulgate regulations clarifying all sections of Chapter 111N. The proposed regulation, 105 CMR 970.000, sets out what is and is not permissible with respect to marketing prescription drugs or medical devices in the commonwealth, outlines the statutory compliance directives, and interprets the contours of the disclosure requirements for pharmaceutical and medical device manufacturers. (Appendix II). In doing so, the Department seeks to address potential undue influence in interactions between pharmaceutical or medical device manufacturing companies and health care practitioners, and increase transparency with respect to such relationships 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.

### **III. Comments from Consumer Advocacy Groups and Industry**

The Department is presenting 105 CMR 970.000 for informational purposes. Although public hearings have not yet been held, the Department encouraged an open process for commentary during the drafting stages of the proposed regulations. As a result, the Department received a number of written comments and oral input from consumer advocates such as Healthcare for All and the Prescription Reform Coalition; pharmaceutical and medical device industry trade organizations such as Pharmaceutical Research Manufacturers of America ("PhRMA"), and the Advanced Medical Technology Association ("AdvaMed"), the Massachusetts Medical Device Industry Council ("MassMedic"), the Medical Device Manufacturers Association ("MDMA") and the Medical Imaging and Technology Alliance ("MITA"); biotechnology trade organizations such as Bio and the Massachusetts Biotechnology Council ("MBC"); general business organizations such as the Greater Boston Chamber of Commerce; and individual pharmaceutical and medical device manufacturers, such as Astrazeneca and Smith and Nephew.

The Department's proposed regulation largely tracks the statutory provisions of Chapter 111N regarding permissible and prohibited activities of pharmaceutical and medical device manufacturers in their financial relationships with health care practitioners. Where clarification was clearly required, the Department provided interpretation of the statutory language in Chapter 111N.

### **IV. Compliance Timeline**

To ensure that the regulation is implemented fairly and that the Department receives accurate and pertinent data pursuant to chapter 111N's disclosure requirements, the proposed regulation specifically outlines a compliance schedule. The proposed regulation provides 6 months lead time from the date of the Department's initial presentation of the proposed regulations and approximately 3 months lead time from the date of final promulgation of the regulations for coming into compliance with the Department's Code of Conduct. Because the requirements of Department's proposed Marketing Code of Conduct largely mirror those imposed by each industry's own codes, the Department is confident that manufacturers can come into compliance by July 1, 2009. Additionally, the Department, through its regulation, has set July 1, 2010 as the date for pharmaceutical and medical manufacturers' first submission of the disclosure report required by chapter 111N. This first report shall include only data collected from July 1, 2009 to December 31, 2009, so as not to hold companies responsible for the portion of 2009 prior to the effective compliance date.

## **V. Clarification of Undefined Terms in Chapter 111N**

There are a number of terms referenced in the statute or implicit in the statutory language that required definition and/or explicit reference. The Department, in section 970.004, proposes to define “biologic” as a drug in reference to the federal Food Drug and Cosmetic Act and Public Health Service Act and references manufacturers of biologics throughout the regulations as subject to the reach of Chapter 111N, includes a definition for “covered recipient” to clarify the regulated parties for which reports are required pursuant to Section 6 of the statute, proposes to define “genuine research project” and “clinical trial” based upon federal rules to give some context and clarity to manufacturers, adds a caveat to the definition of “health care practitioner” to exclude bona fide employees of a manufacturer, includes a definition for “non-faculty” to avoid confusion regarding the use of this term, and details what it means to “participate in a commonwealth health care program” so as to clarify who is subject to the requirements of chapter 111N.

## **VI. Distinction Between Pharmaceutical and Medical Device Manufacturers.**

The Department recognizes that the pharmaceutical and medical device manufacturing industries differ in a number of ways. The Department interprets the requirements of chapter 111N, however, as applying to both pharmaceutical and medical device manufacturing companies. The title of the chapter, in conjunction with the fact that the chapter references both pharmaceutical and medical device manufacturers throughout as a single defined term supports this interpretation. Thus, the Department declined to issue regulations with two separate codes of conduct, but where appropriate sought to place the two industries on equal footing. At times this imposed requirements on medical device manufacturers that were not explicitly imposed by chapter 111N and at times this carved out permissible activities that were not clearly granted by chapter 111N. For example, the Department noted that, while pharmaceutical distributors were included in the definition of “pharmaceutical and medical device manufacturers,” medical device distributors were omitted. Reading this as an oversight by the Legislature, the Department included medical device distributors in its regulatory definition of “pharmaceutical and medical device manufacturers” in section 970.004. Conversely, the Department noted that pharmaceutical manufacturers were specifically permitted to provide free samples to health care practitioners, but no such allowance was provided for medical device manufacturers to provide demonstration and evaluation units. The Department addresses this issue in section 970.008(2)(e), with an allowance that medical device manufacturers may provide such units to health care practitioners.

Chapter 111N clearly requires that the Department’s Marketing Code of Conduct be as strict as the PhRMA and AdvaMed Codes of Conduct. Where the Department included provisions directly from the PhRMA Code of Conduct that are absent from the AdvaMed Code of Conduct, the Department limited those provisions to conduct by pharmaceutical manufacturers. The Department’s intent was to recognize the difference between the two industries and not subject medical device manufacturers to standards absent from both the statute and their own code of conduct.

In another effort to place pharmaceutical and medical device manufacturers on equal footing with respect to Chapter 111N, the Department accounted for the difference between the pharmaceutical and medical device industries as it relates to informational presentations on their respective products. Chapter 111N clearly intended to allow for informational presentations by pharmaceutical and medical device manufacturing representatives and to allow for modest meals in conjunction with such presentations. Medical device manufacturers often must provide such informational presentations at centralized facilities due to the fact that the size and/or interoperability of their products makes it

difficult if not impossible to move such devices from physician office to physician office or from hospital to hospital. Thus, the Department interprets “hospital setting” to include a pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturer, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory and to provide medical training that uses human tissue or cadavers, on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment. The Department interprets the legislature’s use of the term “hospital setting” instead of simply “hospital” in section 2 as encompassing more than simply a traditional hospital facility.

## **VII. Explication of the Reach of Chapter 111N Prohibitions.**

The statutory prohibition against payments in cash or cash equivalents to health care practitioners either directly or indirectly could be read broadly to impede research and the development of treatments and new products. Chapter 111N does allow for an exception to this prohibition for “bona fide services.” Chapter 111N does not, however, define “bona fide services.” The Department defines “bona fide services” so as not to inhibit or impede certain relationships between manufacturers and health care practitioners. The Department’s definition allows for consulting services, including but not limited 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 company-sponsored training including U.S. Food and Drug Administration (“FDA”) required education and training involved in producing safe and effective medical devices.

Chapter 111N also prohibits financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event’s sponsor, except in cases as determined by the department. The Department interpreted the exception to this prohibition as conferring authority to specifically allow the following financial support, subject to a number of conditions:

1. scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend educational conferences;
2. compensation or reimbursement made to a health care practitioner serving as a speaker, or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting; and
3. sponsorship or payment for any 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.

## **VIII. Disclosure Requirements**

The Department interprets Chapter 111N, section 6 as limited to disclosures of sales and marketing activities. The Department bases its interpretation, inter alia, on the fact that the term “pharmaceutical or medical device manufacturer” is modified by the phrase “that employs a person to sell or market a drug, medicine, chemical, device or appliance in the commonwealth” in section 6, suggesting an intent to regulate the disclosure of marketing related payments to physicians. The fact that chapter 111N also requires the adoption of a “marketing code of conduct” establishing “practices and standards [to] govern the marketing and sale of prescription drugs or medical devices” offers

additional support for the Department's interpretation. References to the "marketing code of conduct" and sales and marketing appear throughout chapter 111N, including in section 6, which further serves to corroborate the Department's interpretation of the legislative intent behind section 6.

The Department defines "sales and marketing activities" broadly, to include activities beyond those traditionally considered to be pure "sales and marketing activities," such as advertisements, "sales pitches," customer satisfaction studies and promotional messages for communication to consumers and health care practitioners. The Department's definition of "sales and marketing" also includes activities such as product education, training and the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a health care practitioner for any purpose other than reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial. The Department concludes that a number of pharmaceutical or medical device manufacturer interactions with health care practitioners may influence sales or the market share of a prescription drug, biologic or medical device, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, biologic, or medical device, market a prescription drug, biologic, or medical device, or evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Further, a broad interpretation of marketing is consistent with the statute's conception of a "marketing code of conduct" that covers such diverse activities as consulting services, education and training; funding for CME, third-party scientific or educational conferences or professional meetings; the provision or dissemination of peer reviewed academic, scientific or clinical journals; the provision of pharmaceutical drugs provided to health care practitioners solely and exclusively for use by the health care practitioner's patients; and technical training on the use of a medical device subject to a purchase contract for the device.

## **IX. Process**

Following the presentation, the Department will release the proposed regulations for public hearing and comment. The Department intends to hold two hearings to ensure that interested parties have access and ample opportunity to comment on the proposed regulations. The public hearings are scheduled for January 9, 2009 at the Public Health Council Room, 250 Washington Street, Boston, MA, 02108 at 9:00 A.M. and January 12, 2009 at UMASS Medical School, Amphitheater I, 2<sup>nd</sup> Floor, 55 Lake Avenue North, Worcester, MA 01655 at 1:00 P.M. The Department will consider the comments received as part of the formal notice and comment period, revisit the language set forth in these proposed regulations as well as, potentially, the reasoning set forth in this memorandum, and return to the Council with a final set of regulations for approval and final promulgation.