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MEMORANDUM

TO: Members of the Public Health Council

FROM: Melissa J. Lopes, Deputy General Counsel

DATE: March 11, 2009

RE: Request for Final Promulgation of 105 C.M.R. 970.000
Pharmaceutical and Medical Device Manufacturer Conduct

I. Introduction and Background

The Department of Public Health (the “Department”) requests final promulgation of 105 CMR 970.000, as amended. (A redlined copy of the proposed regulation is attached as Appendix D). This regulation is issued pursuant to 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 II). 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.

Chapter 111N and 105 CMR 970.000 regulate pharmaceutical and medical device manufacturer conduct in three ways, requiring pharmaceutical and medical device manufacturers to: (1) adopt and comply with a state-authored code of conduct, (2) provide compliance information to the Department, and (3) disclose sales and marketing related payments to covered recipients. Sections 970.006-970.008 of the Department's proposed regulations set out what is and is not permissible for pharmaceutical and medical device manufacturers with respect to providing meals, sponsoring continuing medical education and other conferences, and otherwise providing payments or other items of economic benefit to Massachusetts health care practitioners. Additionally, the Department's proposed regulation outlines the statutory compliance directives in Section 970.005 and interprets the contours of the disclosure requirements for pharmaceutical and medical device manufacturers in Section 970.009. Finally, the Department's proposed regulation reiterates the penalties outlined in Chapter 111N and provides procedures for enforcing the code of conduct, compliance and disclosure requirements of 105 CMR 970.000. The Department's proposed regulations seek 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 Massachusetts health care consumers' access to clinical trials and new discoveries and treatments arising from legitimate and beneficial industry interactions with health care practitioners.

After initially presenting the proposed regulations to the Council at its December meeting, the Department held two public hearings on 105 CMR 970.000. Notice was published on December 11, 2008 in the Boston Herald and the Republican. The Department held public hearings on the proposed regulations on January 9, 2009 in Boston, Massachusetts and January

12, 2009 in Worcester, Massachusetts. Twenty-five people presented oral testimony at the Boston hearing, which was attended by over 150 people. Eleven people provided oral testimony at the Worcester hearing, which was attended by approximately 80 people. The period for written testimony closed on January 19, 2009. Prior to the close of the comment period, the Department received 109 letters of written testimony from individuals, practitioners, consumer groups, trade organizations and pharmaceutical and medical device manufacturers.

The proposed regulations and the letters of testimony were subjected to an in-depth review by the Department, in conjunction with the Executive Office of Health and Human Services and the Office of the Attorney General. The proposed changes are the result of this vigorous review.

II. Summary of Written Testimony

The Department received written comments and oral input from a number of individuals and groups regulated or otherwise affected by the proposed regulations. (A list of individuals providing testimony and in-depth chart of their concerns is attached as Appendix III). Such groups include consumer advocacy groups; pharmaceutical, biotech and medical device industry trade groups and individual companies; health care practitioners including nurse practitioners and physicians; the visitor industry, including convention centers and hotels; charitable organizations; and payors and purchasers of drugs, biologics or medical devices such as insurers and chain drug stores.

A. The Consumer Perspective

From the consumer perspective, the Department received testimony from advocacy groups such as Healthcare for All, AARP and the Prescription Reform Coalition as well as from Senators Richard Moore and Mark Montigny. Rooted in concerns that pervasive industry

interaction affects prescribing patterns, such testimony called for broad transparency with respect to the disclosure of industry payments to health care practitioners and strict limitations regarding payments by pharmaceutical and medical device manufacturers to health care practitioners. In particular, consumer advocacy groups requested that the regulations impose an across the board gift ban, including a ban on all meals, branded items such as pens and mugs, and gifts given for educational and practice related purposes and that the \$50 threshold for disclosure be calculated on an annual basis. Further, such groups oppose the Department's proposed language exempting clinical trials and genuine research from disclosure, maintaining that transparency is necessary to guard against sham clinical trials and the exploitation of patients purely for marketing purposes.

B. The General Industry Perspective

From the industry perspective, the Department received testimony from pharmaceutical, biotechnology medical device industry trade organizations such as the Pharmaceutical Research Manufacturers of America ("PhRMA"), Bio and the Massachusetts Biotechnology Council ("MBC"), the Advanced Medical Technology Association ("AdvaMed"), the Massachusetts Medical Device Industry Council ("MassMedic"), and individual pharmaceutical and medical device manufacturers, such as Astrazeneca and Smith and Nephew. Much of this testimony sought clarification on how these regulations might achieve the goals of transparency and eliminating conflicts of interest without impeding the development of new drugs, biologics or medical devices. Industry representatives raised a number of concerns ranging from the difficulty of complying with differing state laws and the need for an extension of the timeline for compliance with chapter 111N, to the applicability of chapter 111N, the permissibility of certain activities not explicitly referenced in chapter 111N and the depth and reach of the disclosure requirements. In particular, industry representatives suggested a 6 month extension for the date

of compliance, the opportunity to designate some information disclosed to the Department as confidential, clarification of terms such as “genuine research” and “hospital setting” to reflect actual research and training practices, clarification that the \$50 disclosure threshold will be calculated on an individual transactional basis and additional exemptions from the disclosure requirements, including exemptions for product samples, price concessions, bona fide services, all permissible activities under 105 CMR 970.000, and reflecting the exemptions contained in the proposed federal sunshine act.

C. Issues Specific to the Medical Device Industry

Medical device companies and trade groups suggested in their testimony that the pharmaceutical and medical device industries differ from one another in a number of ways and that the regulations should account for such differences. The medical device industry points to the fact that medical device manufacturers rely heavily upon health care practitioner input and feedback in developing and training health care practitioners on medical devices. Thus, the medical device industry raised a number of concerns specific to their industry. In particular, the medical device industry requested that the definitions of “clinical trials” and “hospital setting” be amended to reflect the fact that clinical trials for medical devices do not and cannot always involve human subjects and that training on medical devices does not always use human tissue or cadavers. Additionally, the medical device industry requested allowing for the provision of demonstration and evaluation units for a health care practitioner’s use, as such items are often used by the health care practitioner for the benefit of the patient. Also, the medical device industry opposes the Department’s inclusion of medical device distributors as subject to the regulations, maintaining that Chapter 111N intentionally omitted such distributors. Further, the medical device industry requested that the Department employ a sliding scale for the imposition

of fees, in recognition of the fact that a number of medical device companies are smaller and less profitable than pharmaceutical companies and many start-up companies cannot afford a \$2,000 annual fee.

D. The Visitor Industry Perspective

The Greater Boston Convention Center, together with the Massachusetts Lodging Association, a number of individual Massachusetts hotels, and the Promotional Products industry provided testimony as to the indirect economic effects of the Department's proposed regulations. Massachusetts convention centers and hotels raised concerns that the restrictions in Sections 970.006 (The Provision of Meals) and 970.007 (CME, Third-Party Scientific or Educational Conferences, or Professional Meetings) of the regulations would diminish or discourage scientific or medical conference business in Massachusetts. The Promotional Products industry raised concerns that the prohibition against complimentary items such as pens and mugs in Section 970.008(1)(b) of the proposed regulations directly and adversely impacts their business.

E. The Perspective of Charitable Organizations

Organizations such as the Schwartz Center, the Asthma and Allergy Foundation of America and the Massachusetts Association for Mental Health, Inc. stressed in their testimony that charitable donations by pharmaceutical and medical device manufacturing companies should be allowed to continue and be encouraged. Such organizations also requested clarification that they do not fall within the definitions of "pharmaceutical or medical device manufacturing company" and "health care practitioner" for the purposes of the regulations.

F. The Perspective of Payors, Pharmacy Benefit Managers and Purchasers of Drugs, Biologics or Medical Devices

The Massachusetts Association of Health Plans, Pharmaceutical Care Management Association, and the National Association of Chain Drug Stores provided testimony regarding

the disclosure of price concessions such as rebates and discounts. Citing a Federal Trade Commission opinion that disclosure of rebates may lead to “tacit collusion among manufacturers,” these groups suggested that the regulatory language explicitly exempt such payments from disclosure and from the definition of “sales and marketing activities.”

III. The Department’s Response

After conducting a thorough analysis of the issues raised by the testimony received, the Department concludes that the proposed regulations, with a few clarifying and substantive amendments, represent an appropriate balance of interests. In drafting these regulations, the Department intended to implement Chapter 111N with three goals in mind:

1. To limit industry interactions with health care practitioners that may influence prescribing patterns and/or adversely affect the care patients receive.
2. To increase transparency surrounding industry payments to health care practitioners.
3. To not unduly restrict beneficial industry interactions with health care practitioners that increase access to advances in the diagnosis, treatment and prevention of disease.

The proposed amendments include grammatical edits, language changes to increase clarity and ensure the consistent use of terminology and substantive changes that respond to the testimony received during the public hearing and comment period with these three goals in mind.

A. Response to Consumer Advocacy Concerns

The Department responds to the consumer concerns by largely tracking 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, explicitly prohibiting “complimentary” items such as pens consistent with the PhRMA Code of Conduct and the recently amended AdvaMed Code of Conduct, and prohibiting manufacturers

from knowingly structuring fees, payments, subsidies or other economic benefits to circumvent the reporting requirements.

Additionally, the Department accepted the validity of the argument proffered by consumer advocacy groups that some research projects and clinical trials are not undertaken to answer a scientific question, but rather to promote sales. Such clinical trials, often referred to as seeding trials, are generally designed or sponsored by a manufacturer's marketing department and clearly fall within the ambit of "sales and marketing activities." As such, the Department determined that these research projects or clinical trials should be subject to the disclosure requirements. Thus, the Department amended the definition of "sales and marketing activities" to specifically include research projects that are designed or sponsored by marketing departments of manufacturers or that are undertaken to increase sales of a particular drug, biologic or medical device, subjecting such research to the light of disclosure.

The Department declined to impose an across the board gift ban, reflecting the balance struck by Chapter 111N. By listing a number of permissible activities, Chapter 111N recognizes that some industry interactions are beneficial and should be allowed to continue. The Department supports this premise by limiting its regulatory prohibitions to those clearly enunciated in the statute.

B. Response to Industry Concerns

The Department amended the definitions of genuine research, clinical trials and hospital setting in response to the valid points raised by industry that the proposed definitions did not reflect the actual conduct of research and training. Also, the Department made explicit Chapter 111N's implicit requirement that the \$50 threshold be calculated on an individual transactional basis.

Additionally, the Department explicitly provided for exemptions from disclosure for the provision of price concessions such as rebates and discounts, prescription drugs provided to a covered recipient solely and exclusively for use by patients, and demonstration and evaluation units. In view of the comments proffered by payors, health benefit plan administrators, and purchasers of drugs, biologics and medical devices, the Department determined that requiring disclosure of price concessions such as rebates and discounts may lead to a restraint of trade in violation of Federal Trade Commission requirements and lead to increases in the costs of prescription drugs, biologics or medical devices without any corresponding benefit to consumers, who seek to understand whether industry payments affect the prescribing patterns of their physician.

Further, the Department interprets Chapter 111N's disclosure requirements as limited to "sales and marketing activities" directed at and benefiting covered recipients. The provision of prescription drugs to a covered recipient solely and exclusively for use by patients, inures to the benefit of patients rather than health care practitioners or other covered recipients. Similarly, the provision of demonstration and evaluation units to covered recipients inure to the benefit of patients. Concerns were raised that the administrative burden of tracking and reporting these items would increase the cost of prescription drugs, biologics and medical devices and may discourage manufacturers from providing such items to Massachusetts health care practitioners for the benefit of Massachusetts patients. As a policy matter, the Department determined that characterizing these items as "sales and marketing activities" for the purposes of disclosure would create a regulatory burden without any corresponding benefit to Massachusetts health care consumers.

The Department declined to include a provision that all activities allowed under the proposed regulations would be exempt from disclosure, however, as such a provision would contravene the intent of Chapter 111N to require disclosure and increase transparency around sales and marketing activities directed at and benefiting covered recipients. The statute specifically allows pharmaceutical or medical device manufacturing companies to engage in certain sales and marketing activities directed at and benefiting health care practitioners as long as the activities are made transparent. Exempting such activities from disclosure would undermine this goal. Thus, industry payments made to health care practitioners indirectly through charitable donations to universities or hospitals where a health care practitioner is employed or affiliated, and through the sponsorship of a CME, third-party professional or scientific meeting or conferences; or directly, pursuant to a bona fide services agreement (except for genuine research or clinical trials), as compensation for serving as a faculty at a conference or meeting, for meals or for any other permissible activity under 105 CMR 970.000, are subject to disclosure.

The proposed regulations respond to the industry compliance concerns by providing 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 Code of Conduct largely mirror those imposed by each industry's own codes, the Department is confident that the 6 month lead time is unnecessary and that manufacturers can come into compliance by July 1, 2009.

C. Response to Medical Device Industry Concerns

The Department accepts the validity of the argument proffered by medical device manufacturers that medical device demonstration and evaluation units are generally provided to

health care practitioners for their use and training for the benefit of patients. Thus, the Department added subsection 970.008(2)(f) allowing for the provision of such items for a health care practitioner's use. Chapter 111N limits the provision of drug samples "solely for a patient's use," but is silent as to the provision of demonstration and evaluation units. In the interests of parity and in recognition that Chapter 111N regulates two industries that differ in significant ways, the Department included this provision to place medical device manufacturers on equal footing with pharmaceutical manufacturers.

The Department declined to make any changes to Section 970.008(2)(b) regarding reimbursements in conjunction with training on a medical device pursuant to a sales agreement. While the Department understands the nature of the argument that training sometimes predates the signing of a sales contract and that health care practitioners are not involved in the structuring or signing of such contracts, Chapter 111N specifically requires this limitation.

There appeared to be some confusion among medical device manufacturers regarding where training on medical devices may occur. There is no limitation on where training may occur in the regulations. The only limitation is on where meals may occur. Meals may only be provided in a "hospital setting," which is defined, for the purposes of training, not in terms of venue, but in terms of the activity which is taking place. As long as a facility is specially designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, the facility meets the conditions of a "hospital setting" where medical training and meals in conjunction with such training may occur.

The Department declined to include a provision that it will employ a sliding scale for the imposition of the \$2,000.00 disclosure fee on smaller medical device companies and start-ups.

After some consideration, the Department determined that it set its disclosure fee at a reasonable rate for all regulated parties.

The Department also declined to remove medical device distributors from the definition of “pharmaceutical and medical device manufacturers.” The Department added medical device distributors in recognition that Chapter 111N and the defined term itself is directed at activity conducted by both the pharmaceutical and medical device industries equally. Pharmaceutical distributors are subject to Chapter 111N and the regulations and thus, so are medical device distributors. The Department interprets the failure of Chapter 111N to reference medical device distributors as a mere oversight.

Along the same lines of providing clarity as to the reach of Chapter 111N and the proposed regulations, the Department also removed the phrase “participates in a commonwealth health care program” from the definition of “pharmaceutical and medical device manufacturer.” This term was included in Chapter 111N, but was undefined. It is particularly perplexing because it appears in the definition of “pharmaceutical or medical device manufacturing company” only in reference to manufacturers, but not distributors of drugs, biologics or medical devices. A number of individuals and groups who provided testimony raised questions as to the meaning of this phrase. What precisely is a “commonwealth health care program?” Is it a limitation on the applicability of the statute and regulations? Why would a manufacturer have to participate in a commonwealth health care program and not a distributor? The Department attempted to define this phrase in the proposed regulations, but its proposed definition did little to alleviate the confusion surrounding the term. As the Department received no guidance as to the intent or meaning of this phrase, nor could the Department find the phrase defined anywhere

else, and as the term serves only to create greater confusion for regulated parties without advancing any relevant public health policy, the Department eliminated this term.

D. Response to Visitor Industry Concerns

The visitor industry raised concerns that conference organizers may choose to site conferences outside of Massachusetts, because of a concern that such conferences held within Massachusetts must be held in a "hospital setting." The Department determined that this was not the intent of Chapter 111N. There is no specific requirement in the statute that CME, conferences and meetings be held in hospital settings, only a requirement that meals generally be limited to hospital settings. To eliminate any confusion concerning this issue in the proposed regulations, the Department included a provision explicitly allowing CME, third-party professional and scientific meetings to be held in convention centers, hotels or other special event venues.

Other issues raised by the visitor industry reflect fundamental misinterpretations of Chapter 111N and the proposed regulations. Neither the statute nor the regulations prohibit the sponsorship of CME, as long as the third-party conference or meeting organizers remain responsible for the content, selection of speakers and distribution of monies. Additionally, scientists employed by pharmaceutical or medical device manufacturing companies may participate in such meetings and present on specific products or treatment methodologies as long as it is in the context of providing attendees a balanced and objective presentation of all alternative treatments and therapies.

E. Response to Concerns Raised by Charitable Organizations

Charitable contributions by pharmaceutical and medical device manufacturing companies serve the public interest by increasing access to health education, services and health care for the

medically underserved and the public generally. Charitable organizations dedicated to the promotion of health and the education of patients rely heavily upon donations from a number of sources, including pharmaceutical and medical device manufacturers. Additionally, charitable contributions of drugs, biologics or medical devices in response to a public health crisis or natural disaster provide immeasurable relief to those affected. In an effort to ensure that such contributions are allowed and encouraged to continue under its proposed regulations, the Department included an allowance for the industry provision of charitable donations, a broad definition of charitable contributions, and exempted the provision of in-kind items used for charity care from the disclosure requirements. The Department sought to prevent abuse of this broad allowance by requiring that such contributions “not [be] provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices.”

IV. Conclusion

The Department respectfully requests final adoption of 105 CMR 970.000, as amended. If approved, the Department will file 105 CMR 970.000, as amended, with the Secretary of State for publication in the Code of Massachusetts Regulations on April 3, 2009.