The Final DPH Pharmaceutical and Medical Device Manufacturer Conduct Regulations: The Industry Perspective

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On March 11, 2009, the Massachusetts Department of Public Health (DPH) issued its final regulations, 105 CMR 970.000 (the "Final Regulations"), implementing Massachusetts General Law, Chapter 111N. Chapter 111N, which sets forth the most comprehensive state law to date regulating pharmaceutical and medical device marketing to physicians and other prescribers, was enacted under Chapter 305 of the Acts of 2008 (An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care).

The Final Regulations present a mixed bag to industry and thus will lead to a variety of responses and reactions from industry once they become effective on July 1, 2009. While industry welcomes the efforts of DPH to safeguard trade secrets and proprietary information, there remain significant concerns that the scope of Chapter 111N and the Final Regulations will have a detrimental overall impact on the viability of the biotechnology industry in the Commonwealth.

Overview of the New Law

Massachusetts is now the sixth state to enact its own law regulating financial relationships between industry and medicine, and it is the first state to do so in such a comprehensive fashion.

While Chapter 111N and the Final Regulations have become known as the "Gift Ban" law, this shorthand reference is a misnomer. In fact, the Massachusetts law does not prohibit all forms of gifts and meals.

As confirmed in DPH's second set of FAQs issued on May 22, 2009, and available on its website,[1] Chapter 111N does not ban educational items that are consistent with the PhRMA and AdvaMed Codes of Conduct.[2] The 2009 versions of these voluntary trade association codes, while prohibiting recreational items and even minimal non-educational items such as notepads, pens and mugs with company logos, do permit pharmaceutical and medical device companies to offer items designed primarily for the education of patients or healthcare professionals, if the items are not worth more than $100 and have no value outside of a professional's practice (e.g., a text book would be OK, but a DVD player would not). Furthermore, meals can be provided if modest, accompanied by an educational or training presentation and provided at a hospital, medical office or medical-device training site, but Massachusetts goes beyond the PhRMA and AdvaMed Codes of Conduct to prohibit the direct provision of meals by pharmaceutical and medical device companies in restaurants unless such a restaurant is within a hospital.

The Final Regulations require both pharmaceutical and medical device manufacturers and distributors to: (i) adopt and comply with a compliance program and Marketing Code of Conduct (which in many respects is more stringent than the standards set forth in the 2009 versions of the PhRMA Code and AdvaMed Code); (ii) annually submit compliance plan information and certifications to DPH; and (iii) beginning on July 1, 2010, annually disclose to DPH – for posting on a public website – the value, nature, purpose, and recipient of any sales and marketing activity payment, or other benefit, with a value of at least $50 to physicians, prescribers, hospitals, nursing homes, pharmacists, and other prescribers.

Pharmaceutical manufacturers and distributors are further required to (i) comply with limitations and requirements on the use of non-patient identified prescriber data, including an "opt-out" for physician and other prescribers on having their prescriber data used for marketing purposes, and (ii) obligate all contracted speakers and consultants who serve on a formulary or clinical guideline committees to disclose their company relationship to the committee.

Industry Reaction to the Final Regulations

The variety of industry perspectives on the DPH's implementation of Chapter 111N are reflected in the myriad views expressed through the extensive written comments submitted to DPH between the proposed version of 105 CMR 970.000, issued in December 2008 (the "Proposed Regulations"), and

the promulgations of the Final Regulations. Although many company advocates and trade associations were highly critical of the proposed regulations, a significant percentage of these comments focused on requirements and limitations already mandated by the statute itself. DPH has worked toward addressing many of industry's ongoing questions and concerns about the elements of the Massachusetts-mandated Code of Conduct and scope of the reporting obligations by issuing two sets of FAQs.[3]

Local research institutions and biotech interest groups were satisfied to see that the Final Regulations excluded company funding of clinical trials and genuine research from the public disclosure requirement. DPH further confirmed that certain post-FDA approval research would not be subject to public reporting if a market research company funded by a pharmaceutical or medical device company pays physicians to participate in the market research study, provided that the physician is not paid directly by the funding company and is not aware of the company involved.

DPH has also made it clear that the Massachusetts law does not prohibit continued commercial funding for CME, as well as other non-CME conferences and meetings. This is an important aspect of the law, given the major ongoing efforts by many advocacy groups to eliminate even indirect funding of CME by pharmaceutical and medical device companies.[4] Company underwriting of CME events is permitted as long as certain safeguards are followed, such as adherence to the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support (even if ACCME accreditation is not secured), and the separation of CME grant-making functions from company sales and marketing departments. However, company underwriting of CME events, as well as other conferences and meetings, cannot include payment for meals directly to any health care practitioner (except as part of reimbursement for speakers and event organizers), although the Final Regulations allow "a CME provider or conference or meeting organizer" to apply company financial support for the event or meeting to provide meals for all participants. [5]

Furthermore, both Chapter 111N and the Final Regulations prohibit the provision of meals by companies outside of a medical office or hospital/device training setting. This off-site meal prohibition is absolute, even if the meal is offered with an informational presentation.[6] Thus, Massachusetts now outlaws the very common practice of hosting informational presentations that include meals at restaurants and hotels — activities that are permitted even in the more stringent 2009 updated versions of the PhRMA and AdvaMed Codes.

It is also to important to note that DPH and the Massachusetts Attorney General's Office view Chapter 111N and the Final Regulations to apply to any financial relationships between pharmaceutical and medical device manufacturers and distributors that market their products in Massachusetts or to Massachusetts prescribers outside of Massachusetts, and any Massachusetts licensed prescribers, regardless of the location of the relationships. Thus, the Massachusetts-mandated Code of Conduct restrictions and disclosure requirements must be understood and followed by companies in their efforts with meetings, contracts, and relationships that take place outside of Massachusetts if they are with Massachusetts-licensed physicians and other prescribers.[7]

The Future of the Law

Even though DPH has worked hard to consider the concerns of industry in issuing the Final Regulations and providing additional agency guidance, Chapter 111N and the Final Regulations could still have a deleterious impact on the local economy, including loss of biotech activities and the patronage of convention centers, hotels, and restaurants.

DPH was sensitive to this latter concern, and added a provision to the Final Regulations stating that there is no prohibition on the "use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences."[8] Notwithstanding DPH's efforts to protect the Massachusetts convention and event business, and the fact that the Massachusetts law applies equally to conventions and meeting both inside and outside Massachusetts, there may thus be a perception and reality disconnect that could still hurt the local economy of the state.

DPH and the Legislature will need to consider in the required reevaluation of the law (which DPH has announced it plans to conduct on or about July 2010) whether the statute and its Final Regulations have had the unintended consequence of harming the state's economy in excess of the intended savings to the cost of health care in the Commonwealth. It is hard to imagine that the legislative leaders who brought Chapter 111N into existence intended to support a law that could save certain costs

within the health care system while causing substantially more lost dollars to the local economy. Whether that scenario plays out is yet to be seen.

The Massachusetts law also is understood by industry to be part of the growing national trend toward more mandatory, as well as voluntary, reform of industry's relationships with medicine. In addition to the more restrictive PhRMA and AdvaMed Codes that are going into effect this year, several other states are likely to pass laws similar to Chapter 111N. The federal government is also proposing to become involved in this area, with Senators Charles Grassley and Herbert Kohl promoting a bipartisan bill (entitled the Physician Payment Sunshine Act of 2009) that would create a national public reporting system of industry-physician payments.[9] Finally, a growing number of academic medical centers are adopting very stringent conflict of interest and disclosure policies; and, professional societies are starting to tighten their policies on the permissible scope of accepting financial support for CME and other activities. As of mid-2009 the Institute for Medicine, Association of American Medical Colleges, American Medical Association, as well as the ACCME, have established more stringent standards, or are all in the process of modifying their positions, on permissible industry relationships and managing conflicts.

Conclusion

The Massachusetts efforts to regulate financial relationships between industry and medicine are just part of an ongoing evolution toward tougher legal and ethical standards intended to protect the integrity of medicine and lower health care costs.

The largest pharmaceutical and medical device manufacturers with in-house compliance officers and legal counsel are generally well aware of Chapter 111N and the Final Regulations and are already in the process of devising strategies to comply. Compliance with the Massachusetts mandatory Code of Conduct and reporting requirements will be more challenging for the smaller biotech start-ups and medical device distributors.

While it is inevitable that drug and device companies, physicians, and other regulated parties will be subject to a growing number of internal and external laws, rules, and policies establishing conflicting limits and reporting obligations, there is one absolute that can be stated:

> The best approach to addressing financial conflicts for physicians maintains the primacy of the physician's role in medicine and research and allows physicians to pursue their professional calling and commitment with integrity; placing the best interest of each patient and of medicine as a whole ahead of any financial self-interest.[10]

1 See http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_faq.pdf.
2 Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009; Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009.
3 See http://www.mass.gov/pageID=eohhs2modulechunk&L=4&L0=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_ph_mdm_conduct_code&csid=Eeohhs2.
4. See e.g., David J. Rothman, ph.D., et. al., *Professional Medical Associations and Their Relationships with Industry*, JAMA, April 1, 2009.
5 105 CMR 970.007 1.c.
6 105 CMR 970.006.
7 DPH Guide to 105 CMR 970.000: Pharmaceutical And Medical Device Manufacturer Conduct http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_faq_090311.pdf.
8 105 CMR 970.007 4.c.
9 Physician Payments Sunshine Act of 2009 (S.301) (http://thomas.loc.gov/cgi-bin/query/z?c111:S.301.).
10 Steve Schachter, William Mandell, Scott Harshbarger & Randall Grometstein, *Managing Relationships with Industry: A Physician's Compliance Manual* 246 (2008).