Health Law Advisory

April 13, 2009

Review of the Massachusetts Marketing Code of Conduct for Pharmaceutical and Medical Device Manufacturers

The Massachusetts Department of Public Health (DPH) recently adopted some of the nation's most stringent regulations (the "Final Regulations") restricting the marketing activities of pharmaceutical and medical device manufacturers ("Manufacturers").[1] Mintz Levin summarized the Final Regulations in a Health Law Client Alert entitled "Massachusetts DPH Releases Final Rules for Pharmaceutical and Medical Device Manufacturers' Conduct." In response to the tremendous interest in the Final Regulations, this Advisory expands upon our Client Alert and offers information responsive to questions frequently asked by clients.

This Advisory:

- highlights important submissions that Manufacturers must make to DPH by July 1, 2009;
- highlights changes to the Final Regulations in response to public comments on the proposed regulations, dated December 10, 2008 ("Proposed Regulations"); and
- compares, for purposes of example, several key provisions of the Final Regulations to the PhRMA Code on Interactions with Healthcare Professionals ("PhRMA Code")[2] and the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code").[3]

Introduction

On March 11, 2009, DPH approved the Final Regulations adopting a Massachusetts Marketing Code of Conduct for Manufacturers operating in Massachusetts.[4] Effective July 1, 2009, the Final Regulations apply to "pharmaceutical or medical device manufacturing" companies.[5] The Final Regulations contain several groundbreaking requirements, including the following:

- ***Disclosure Requirements:*** Manufacturers must make annual disclosures to DPH of any payment, subsidy, or economic benefit of at least $50 (calculated on an individual transactional basis) made to covered recipients, including certain prescribers and purchasers;

- ***Gift Bans:*** Manufacturers' ability to give any type of gift or payment to health care providers is limited;
- ***Code of Conduct:*** Manufacturers must adopt the Code of Conduct set out in the Final Regulations, and implement a training program;
- ***Compliance Program:*** Manufacturers must annually certify compliance with the Final Regulations; and
- ***CME, Third-Party Scientific or Educational Conferences, or Professional Meetings:*** Manufacturers' ability to provide financial support for health care providers is limited.

July 1, 2009: Important Deadline for Submissions to DPH is Fast Approaching

By July 1, 2009, Manufacturers that employ or contract with a pharmaceutical or device manufacturer agent must:

- adopt a marketing Code of Conduct in compliance with the Final Regulations;
- adopt and submit to DPH a description of a training program to provide regular training to appropriate employees;
- certify compliance with the Final Regulations;
- adopt and submit to DPH policies and procedures for investigating non-compliance with the Final Regulations; and
- submit to DPH certain information about the Manufacturer's Chief Compliance Officer.

Beginning July 1, 2010, Manufacturers must annually disclose to DPH the value, nature, purpose and particular recipient of any economic benefit with a value of at least $50, which the Manufacturer provides, directly or through its agents, to any covered recipient in connection with sales and marketing activities. Manufacturers should begin to track this information in preparation for the first annual disclosure, which must be submitted to DPH by July 1, 2010.

Public Comments Incorporated into the Final Regulations

DPH held public hearings and accepted comments on the Proposed Regulations. Numerous groups and organizations commented on the Proposed Regulations, including consumer advocacy groups, pharmaceutical and medical device industry groups and manufacturers, health care practitioners, the tourism industry, charitable organizations, payors, and purchasers of drugs and medical devices. In response to these comments, DPH made several key changes, guided by a focus on limiting interactions that influence prescribing patterns, and increasing transparency surrounding industry payments, while not unduly restricting beneficial industry interactions with health care practitioners.[6] Some noteworthy revisions[7] include the following:

- Clarified that *all Manufacturers* must comply with the Final Regulations;
- *Expanded the definition of "sales and marketing activities"* to require Manufacturers to disclose research that is sponsored by a Manufacturer's marketing department, or has marketing, product promotion, or advertising as its purpose;
- Clarified that a *health care practitioner may be hired as a consultant* if the consulting services do not amount to serving as a sales representative for the Manufacturer;
- Eliminated provisions allowing Manufacturers to provide financial assistance to *health care professionals in training*;
- Clarified that medical device Manufacturers *may provide demonstration and evaluation units to*

health care practitioners for their own use;

- Clarified definitions to *avoid restricting research and clinical trials* on medical devices;
- Clarified that the $50 threshold is calculated on a *per transaction basis*;
- Retained an exemption from disclosure for *genuine research and clinical trials*;
- Added an exemption from disclosure for *prescription drugs provided at no cost* solely for use by patients, and demonstration and evaluation units for benefit of patients;
- Added an exemption from disclosure for *rebates and discounts*;
- Added an exemption from disclosure for in-kind items for charity care; and
- Broadly defined "charitable donation."

DPH declined to make certain changes to the Proposed Regulations in response to public comments. DPH declined to:[8]

- impose an across-the-board gift ban;
- exempt from disclosure all activities allowed under the Proposed Regulations;
- remove medical device distributors from the definition of "pharmaceutical and medical device manufacturers;"
- make any changes regarding reimbursements in conjunction with training on a medical device pursuant to a sales agreement; and
- include a provision that it will employ a sliding scale for the imposition of the $2,000 disclosure fee on smaller medical device companies and start-ups.

In addition, DPH removed the phrase "participates in a Commonwealth health care program" from the definition of "pharmaceutical and medical device manufacturer."

Comparison of Massachusetts Marketing Code of Conduct with PhRMA Code and AdvaMed Code[9]

The Final Regulations specifically incorporate requirements from the PhRMA Code and AdvaMed Code as mandated by M.G.L. c. 111N, while setting the PhRMA and AdvaMed Codes as the baseline, and imposing more stringent requirements.[10] The following examples compare certain key provisions of the Massachusetts Marketing Code of Conduct with both the PhRMA and AdvaMed Codes.

To Whom Does the Code Apply?

1. **MA:** A "[p]harmaceutical or device manufacturing company." 105 C.M.R. 970.004.
2. **PhRMA:** The PhRMA Code does not explicitly define the covered entities. But PhRMA represents research-based pharmaceutical and biotechnology companies. (PhRMA Code, Preamble).
3. **AdvaMed:** The AdvaMed Code does not explicitly define the covered entities. But AdvaMed represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. (AdvaMed Code, Preamble).

Adoption of a Code of Conduct

1. **MA:** Adoption of Massachusetts Code of Conduct is *mandatory*. Manufacturers "shall adopt a marketing Code of Conduct…" 105 C.M.R. 970.005.
2. **PhRMA:** Adoption of the PhRMA Code is *permissive*. The PhRMA Code is "voluntary." (PhRMA Code, Preamble).
3. **AdvaMed:** Adoption of the AdvaMed Code is *permissive*. Manufacturers are "strongly encouraged" to adopt the AdvaMed Code. (AdvaMed Code, Section II).

Certify Compliance and Investigate Non-Compliance

1. **MA:** A Manufacturer must certify to DPH that to the best of its knowledge, information, and belief, it is in compliance with the Final Regulations. Manufacturers must also "adopt and submit to [DPH] policies and procedures for investigating non-compliance with" the Final Regulations, taking corrective action, and reporting non-compliance to the appropriate state authorities. 105 C.M.R. 970.005.
2. **PhRMA:** The PhRMA web site identifies Manufacturers that "publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code…" (PhRMA Code, Section 15). Manufacturers "should adopt procedures to assure adherence to" the PhRMA Code. (PhRMA Code, Section 15).
3. **AdvaMed:** The AdvaMed web site lists those Manufacturers that have submitted the annual certification. (AdvaMed Code, Section II). In addition, "[Manufacturers] are strongly encouraged to follow the seven elements of an effective compliance program…" (AdvaMed Code, Section II).

Disclosures

1. **MA:** Requires annual disclosure to DPH of 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 [Manufacturer] provides, directly or through its agents, to any covered recipient in connection with the [Manufacturer's] sales and marketing activities." 105 C.M.R. 970.009(1).
2. **PhRMA**: No disclosure requirement.
3. **AdvaMed:** No disclosure requirement.

Payments

The Massachusetts Marketing Code of Conduct, PhRMA Code, and the AdvaMed Code all include provisions addressing payments for entertainment, complimentary items, and lodging, meals, and other payments related to Continuing Medical Education (CME), and third-party conferences. Some examples are given below.

Travel or Lodging

1. **MA:** Manufacturers *cannot* provide "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 conferences, or professional meetings, either directly to the

individuals participating in the event or indirectly to the event's sponsor." 105 C.M.R. 970.007(1)(a).

2. **PhRMA:** "Financial support *should not* be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor," with some exceptions. (PhRMA Code, Section 4).
3. **AdvaMed:** "Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies *may pay* for reasonable travel and modest lodging costs of the attending Health Care Professionals." (AdvaMed Code, Section III).

Meals

1. **MA:** With certain exceptions, no [Manufacturer] may provide or pay for meals for health care practitioners that are part of an entertainment or recreational event or offered without an informational presentation. 105 C.M.R. 970.006; *see also* 105 C.M.R. 970.007(1)(c) (prohibition against providing payment for meals directly to a healthcare practitioner at any CME event, third-party scientific or educational conferences, or professional meetings).
2. **PhRMA:** "In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication." (PhRMA Code, Section 2). In addition, a Manufacturer "should not provide meals directly at CME events." (PhRMA Code, Section 4).
3. **AdvaMed:** "[M]odest meals may be provided as an occasional business courtesy consistent with…limitations," including purpose, setting, location, and participants. (AdvaMed Code, Section VIII)

Entertainment

1. **MA:** Manufacturers *cannot* provide "entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the [Manufacturer]…" 105 C.M.R. 970.008(1)(a).
2. **PhRMA:** Manufacturers "*should not* provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company." (PhRMA Code, Section 3).
3. **AdvaMed:** A Manufacturer "*should not* provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional." (AdvaMed Code, Section VII).

Penalties

1. **MA:** "A person who knowingly and willfully violates [the Final Regulations] shall be punished by a fine of not more than $5,000 for each transaction, occurrence or event." 105 C.M.R. 970.010.
2. **PhRMA:** No penalty provisions.
3. **AdvaMed:** No penalty provisions.

Price Concessions

1. **MA:** Includes a provision protecting "price concessions such as rebates or discounts in the normal course of business." 105 C.M.R. 970.008(2)(g).
2. **PhRMA:** No price concession or rebate provisions.
3. **AdvaMed:** No price concession or rebate provisions.

* * *

To assure compliance with the Final Regulations, Manufacturers seeking to transact business in Massachusetts should analyze their current practices and compliance plan, as well as the code of conduct under which the Manufacturer currently operates (*e.g.* PhRMA Code or AdvaMed Code) in the context of the requirements imposed by the Final Regulations. This analysis will form the basis for developing and implementing a compliance plan that meets the requirements of the Final Regulations. Physicians, hospitals, nursing homes, pharmacists, health benefit plan administrators, and others authorized to prescribe, dispense, or purchase drugs should familiarize themselves with the Final Regulations to understand how Manufacturers will be affected, and should be aware that benefits conferred upon them will be publicly disclosed.

Endnotes

[1] The Final Regulations are codified as 105 C.M.R. 970.000.

[2] Pharmaceutical Research and Manufacturers of America, "Code on Interactions with Healthcare Professionals," PhRMA, January 2009.

[3] Advanced Medical Technology Association, "Code of Ethics on Interactions with Health Care Professionals," AdvaMed, July 1, 2009.

[4] The Final Regulations implement M.G.L. c. 111N, the law enacted in August 2008 that governs marketing activities by pharmaceutical and medical device manufacturers operating in Massachusetts.

[5] 105 C.M.R. 970.004.

[6] Melissa J. Lopes, Deputy General Counsel, DPH, Presentation to PHC (March 11, 2009).

[7] *See id.*

[8] Melissa J. Lopes, Deputy General Counsel, DPH, Memorandum to PHC re: Request for Final Promulgation of 105 C.M.R. 970.000, 8-11, (March 11, 2009).

[9] Please note that this summary is meant to highlight a limited number of the important elements of each code. Please consult the relevant code for additional detail.

[10] "In promulgating regulations for a marketing code of conduct, the department [*sic*] adopt regulations that shall be no less restrictive than the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association." M.G.L. c. 111N, § 2.

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

MEMBERS

Robert D. Clark
Managing Member, Health Law Practice
(202) 434-7402
RDClark@mintz.com

Stephen M. Weiner

Chairman, Health Law Practice
(617) 348-1757
SWeiner@mintz.com

Susan W. Berson
Managing Member,
Washington, D.C. Office
(202) 661-8715
SBerson@mintz.com

Thomas S. Crane
(617) 348-1676
TSCrane@mintz.com

Stephen C. Curley
(212) 692-6217
SCCurley@mintz.com

Deborah A. Daccord
(617) 348-4716
DADaccord@mintz.com

Hope S. Foster
(202) 661-8758
HSFoster@mintz.com

Ellen L. Janos
(617) 348-1662
EJanos@mintz.com

Karen S. Lovitch
(202) 434-7324
KSLovitch@mintz.com

M. Daria Niewenhous
(617) 348-4865
DNiewenhous@mintz.com

Andrew B. Roth
(212) 692-6889
ARoth@mintz.com

OF COUNSEL

Michael D. Bell
(202) 434-7481
MDBell@mintz.com

Margaret D. Kranz
(212) 692-6882
MKranz@mintz.com

ASSOCIATES

Stephen R. Bentfield
(202) 585-3515
SRBentfield@mintz.com

Dianne J. Bourque
(617) 348-1614
DBourque@mintz.com

Shawneequa L. Callier
(202) 585-3551
SLCallier@mintz.com

Theresa C. Carnegie
(202) 661-8710
TCCarnegie@mintz.com

Brian P. Dunphy
(617) 348-1810
BDunphy@mintz.com

Garrett G. Gillespie
(617) 348-4499
GGGillespie@mintz.com

Lauren N. Haley
(202) 434-7386
LNHaley@mintz.com

Rachel M. Irving
(617) 348-4454
RMIrving@mintz.com

Krietta Bowens Jones
(617) 348-3042

Sarah A. Kaput
(202) 434-7423
SAKaput@mintz.com

Katina W. Lee
(202) 661-8729
KLee@mintz.com

Carrie A. Roll
(202) 434-7350
CARoll@mintz.com

Tara E. Swenson
(202) 585-3504
TESwenson@mintz.com

Andrea P. Testa
(617) 348-4407
ATesta@mintz.com

Melissa O'Neill Thatcher
(617) 348-3015
MOThatcher@mintz.com

Heather L. Westphal
(202) 585-3538
HLWestphal@mintz.com

Jennifer E. Williams
(202) 585-3542
JEWilliams@mintz.com

Nili S. Yolin
(212) 692-6799
NSYolin@mintz.com

www.mintz.com