

MA Regulations Regarding Compliance with Pharmaceutical and Medical Device Manufacturer Conduct Take Effect

On July 1, 2009 the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct regulations (the “Marketing Code of Conduct”) went into effect.¹ The Marketing Code of Conduct governs the behavior of manufacturers of pharmaceuticals and medical devices that commercialize FDA-approved products in the Commonwealth (collectively “Manufacturers”). In particular the Marketing Code of Conduct addresses the relationships between those Manufacturers and health care practitioners who are licensed to practice in the Commonwealth (“Practitioners”).

With the enactment of the Marketing Code of Conduct, Massachusetts has joined the District of Columbia and six other states, all of which have enacted laws that address the interactions between Manufacturers and Practitioners.² The Marketing Code of Conduct,

which incorporates requirements from the voluntary PhRMA and AdvaMed industry codes as the regulatory floor, represents the most comprehensive and stringent of the state laws addressing the Manufacturer-Practitioner relationship.³

In implementing the Marketing Code of Conduct, the objectives of the Massachusetts Department of Public Health (“DPH”) are, among other things, to minimize potential conflicts of interest, to enhance the transparency of relationships between Manufacturers and Practitioners and to preserve the independent judgment of Practitioners.⁴ In furtherance of these objectives, the Marketing Code of Conduct imposes specific compliance requirements, marketing restrictions and disclosure obligations on Manufacturers that employ or contract with an agent⁵

to commercialize their products in the Commonwealth.

Adoption of Marketing Code of Conduct

The Marketing Code of Conduct provides that by July 1, 2009, all Manufacturers must:

- o establish and adopt a marketing code of conduct which is consistent with the Marketing Code of Conduct and certify to DPH that they are in compliance;
- o implement and submit to DPH a program that provides regular training to the Manufacturer’s employees and sales and marketing staff, and that provides for regular assessments of persons who are employed by, or acting on behalf of, the Manufacturer;
- o adopt and submit to DPH

1. The Marketing Code of Conduct is codified at 105 C.M.R. § 970.000 and is the implementation of Mass. Gen. Laws ch. 111N § 2, which is entitled “Pharmaceutical and Medical Device Manufacturer Conduct”, as enacted under Ch. 305 of the Acts of 2008.

2. In addition to Massachusetts, currently California, Maine, Minnesota, Nevada, Vermont, West Virginia and the District of Columbia have enacted laws governing the activities of pharmaceutical and/or medical device manufacturers.

3. See M.G.L. CH. 111N and DPH Presentation entitled Massachusetts DPH Pharmaceutical and Medical Device Manufacturer Conduct.

4. See DPH Informational Briefing on Proposed Regulation 105 C.M.R. § 970.000 to DPH Commissioner Auerbach and Members of the Public Health Counsel (Dec. 10, 2008).

5. See 105 C.M.R. § 970.004 which defines a “pharmaceutical or medical device manufacturer agent” as a person either employed by, or under contract with a Manufacturer who “engages in detailing, promotional activities or other marketing or prescription drugs, biologics, or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices”.

policies and procedures for investigating non-compliance with the Marketing Code of Conduct and taking corrective action in response to identified non-compliance; and

o identify a compliance officer who is responsible for certifying compliance with the Marketing Code of Conduct and for implementing, monitoring and enforcing that Manufacturer's code of conduct.⁶

Mandatory Marketing Restrictions

Unlike the voluntary PhRMA and AdvaMed industry codes of conduct, the Marketing Code of Conduct imposes mandatory restrictions on the conduct of Manufacturers. With the exception of compensation provided in exchange for bona fide services,⁷ the Marketing Code of Conduct restricts both direct and indirect payments of cash or cash equivalents to Practitioners.⁸ Consistent with the restrictions articulated by both the PhRMA and AdvaMed industry codes of conduct, the Marketing Code of Conduct's prohibitions on compensation preclude the distribution of items to Practitioners which have entertainment or recreational value, as well as the distribution of reminder items such as pens, calendars and mugs. The

Marketing Code of Conduct also prohibits the distribution of grants, scholarships, consulting contracts or educational or practice-related items to Practitioners if such items are provided in exchange for prescribing or using that Manufacturer's products.

The Marketing Code of Conduct does not restrict the distribution of prescription drug samples to Practitioners, where such samples are exclusively intended for use by that Practitioner's patients, nor does it restrict the provision of reasonable quantities of medical device demonstration or evaluation units that are used to assess the appropriate use of such device.⁹

As is the case with both the PhRMA and AdvaMed industry codes of conduct, the Marketing Code of Conduct addresses the provision of meals to Practitioners, and provides that permitted meals must be modest in nature and occasional in frequency.¹⁰ Manufacturers are prohibited from providing meals to Practitioners in association with an entertainment or recreational event, or in the absence of an accompanying informational presentation. Also restricted are the provision of meals to Practitioners in the absence of a Manufacturer's agent, meals which are provided

outside of a Practitioner's office or hospital setting,¹¹ or meals which are provided to a Practitioner's spouse or guest.

The Marketing Code of Conduct also limits Manufacturer funding of continuing medical education ("CME") events.¹² Manufacturers are precluded from providing payments directly to a Practitioner attending CME events where such payments are being provided to compensate that Practitioner for his or her attendance, for the reimbursements of travel, lodging or personal expenses or for the payment of meals. Manufacturer funding of CME or independent medical education is limited to those events which meet the commercial support standards of the relevant CME accrediting entity, and Manufacturers that fund these programs are precluded from directing the content or selecting the faculty of such programs. DPH has clarified that the Marketing Code of Conduct expressly permits Manufacturer sponsorship or support of third-party scientific or educational conferences where payments are made directly to third-party meeting organizers who "remain responsible for the content, selection of speakers and distribution of monies".¹³

6. 105 C.M.R. § 970.005.

7. See 105 C.M.R. § 970.005, which provides that "bona fide services" (as that term relates to the provision of services by Practitioners on behalf of Manufacturers) include, among other things, participation on advisory boards, collaborations with charitable organizations, or presentations at Manufacturer-sponsored medical education events that are formalized in a written agreement identifying the nature of services to be provided.

8. 105 C.M.R. § 970.008.

9. *Id.*

10. 105 C.M.R. § 970.006.

11. See 105 CMR 970.004, which provides that a "hospital setting" is a hospital, academic medical center or a specialized training facility specifically designed to approximate the conditions of a surgical suite, a working laboratory and/or to provide training on large or technical medical devices.

12. 105 C.M.R. § 970.007.

13. See Guide to 105 C.M.R. 970.000: Pharmaceutical and Medical Device Manufacturer Conduct (Mar. 11, 2009).

The Marketing Code of Conduct restricts pharmaceutical manufacturing companies' use of non-patient identified prescriber data as a tool to facilitate communications with Practitioners. The provisions addressing the use of prescriber data remain limited to pharmaceutical manufacturing companies, and impose requirements on such companies to maintain the confidentiality of non-patient identified prescriber data, to develop policies regarding the use of Practitioner-specific data, to train their agents regarding these policies and to identify disciplinary actions for misuse of such data. Prior to using Practitioner-specific data for marketing purposes, pharmaceutical manufacturing companies must extend Practitioners an opportunity to request that their data be withheld from company sales representatives and that such data not be used for marketing purposes. Furthermore, pharmaceutical manufacturing companies must comply with a Practitioner's request that his or her data be withheld from the pharmaceutical company's sales representatives or agents.

DPH has clarified that its intentions, as they relate to non-patient identified prescriber data, are not to create unique mechanisms for

pharmaceutical manufacturers to monitor and track Practitioner requests that their data be withheld. Rather, DPH intended to set the voluntary PhRMA code, which permits pharmaceutical manufacturers to rely on programs to identify Practitioner requests that their data be withheld (such as the AMA Prescription Data Restriction Program), as the "regulatory floor" and that accordingly participation in such programs would satisfy the obligations of the Marketing Code of Conduct.¹⁴

Mandatory Financial Disclosure Requirements

In furtherance of DPH's objective to increase the transparency of the Manufacturer-Practitioner relationship and representing a departure from the requirements of the voluntary PhRMA and AdvaMed industry codes of conduct, the Marketing Code of Conduct imposes mandatory financial disclosure requirements upon Manufacturers that employ or contract with agents to conduct sales and marketing activities in Commonwealth.¹⁵ Beginning on July 1, 2009 and thereafter on an annual basis, every Manufacturer must disclose to DPH the "value, nature, purpose and particular

recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50" where such \$50 threshold is calculated on a transactional basis, rather than on an aggregate basis.

The first of such submissions must be reported to DPH by July 1, 2010 in electronic format and must incorporate all reportable activities for the period commencing on July 1, 2009 and ending on December 31, 2009. Information disclosed to DPH, including the value, nature and recipient of the economic benefit, will be compiled and published by DPH on a comprehensive, searchable public website.¹⁶

The annual disclosure must be accompanied by an annual \$2,000 fee, the first of which was due by July 1, 2009, and a certification statement providing that to the best of the Manufacturer's knowledge, information and belief the information contained in the report is true and accurate.¹⁷ Manufacturers that knowingly and willfully violate the Marketing Code of Conduct may subject themselves to fines of not more than \$5,000 per violation.

Expressly excluded from the broad

14. See Frequently Asked Questions Pharmaceutical and Medical Device Conduct (June 30, 2009).

15. As it relates to a Manufacturer's disclosure obligations, 105 CMR § 970.004 provides a very broad definition of "sales and marketing activities" which "include[s] advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose."

16. 105 C.M.R. § 970.009.

17. *Id.*

definition of “sales and marketing activities” and accordingly exempt from the financial disclosure requirements are:

- o Manufacturer supported clinical trials and research, particularly where the primary purpose of such clinical trials or research are to support a filing with the FDA;
- o the provision of prescription drug samples solely for use by patients or demonstration or evaluation units; and
- o price concessions or rebates that are offered in connection with the acquisition of the product.¹⁸

The Marketing Code of Conduct also addresses the relationships of pharmaceutical manufacturing companies and Practitioners with whom such companies also have a consulting arrangement or speaker engagement while that Practitioner serves as a member of a committee responsible for the selection of formularies or the development of clinical guidelines. Pharmaceutical manufacturing companies must require that such Practitioners disclose their affiliation with that pharmaceutical manufacturing company to their respective committees, and continue to do so for at least two years beyond the termination of that speaker or consulting engagement.¹⁹ The provisions addressing the disclosure of affiliations are limited to pharmaceutical manufacturing companies and generally remain consistent with the PhRMA code of

conduct.

Conclusion

Manufacturers that are subject to the requirements of the Marketing Code of Conduct should have implemented the formal policies and procedures necessary to ensure compliance in advance of the July 1, 2009 deadline, or risk the imposition of fines. To comply with the Marketing Code of Conduct, on or before July 1, 2009 Manufacturers should have, among other things, submitted to DPH the required certification statement and accompanying fee. Manufacturers should also have implemented procedures on or before July 1, 2009, which allow them to track the value of economic benefits conferred upon Practitioners.

On or before July 1, 2009, Manufacturers’ conduct should also be in compliance with the Marketing Code of Conduct. For example, Manufacturers may continue to provide modest meals to Practitioners on or after July 1, 2009, as long as such meals are, among other things, accompanied by an informational presentation, are provided in the presence of a Manufacturer’s agent and are provided in an appropriate office or hospital setting.

While the Marketing Code of Conduct represents a significant step by Massachusetts towards preserving the independent judgment of Practitioners, compliance will likely present challenges to Manufacturers.

In particular, the implementation of the mandatory Marketing Code of Conduct may prove especially difficult for those Manufacturers that have yet to adopt their respective voluntary industry code of conduct. Implementation of, and compliance with, the Marketing Code of Conduct may also present unique challenges to pharmaceutical or medical device manufacturers that are anticipating commercialization of FDA-approved products in the Commonwealth for the first time.

For additional information, questions or advice regarding maintaining compliance with the Marketing Code of Conduct, please contact Stan Chalvire at schalvire@mbbp.com.

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18. 105 C.M.R. § 970.004.

19. § 970.005.