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Deadline Approaches for Compliance with Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulations

On July 1, 2009, pharmaceutical and medical device manufacturers of FDA-approved drugs or medical devices doing business in Massachusetts or doing business with health care practitioners ("HCPs")[1] licensed in Massachusetts (regardless of where benefits are provided or expenditures are made) ("Companies") must be in compliance with the Massachusetts Code of Conduct Law.[2] This requirement is contained in regulations issued by the Massachusetts Department of Public Health (the "DPH") on March 11, 2009 (the "Regulations")[3]. The Regulations require such Companies to adopt a code of conduct based upon, and no less restrictive than, the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America ("PhRMA Code") or the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association ("AdvaMed Code"), as applicable.

Massachusetts has joined a number of states in passing laws which govern the marketing activities of pharmaceutical and medical device manufacturers. At the Federal level, Senators Grassley and Kohl introduced a bill in January 2009 which would require disclosures of payments and gifts to physicians and physicians' practices. More recently, Vermont passed a strict pharmaceutical marketing conduct law and at least Minnesota, Oregon, Texas and Connecticut are contemplating proposed legislation in this area. Furthermore, various hospitals and medical institutions have adopted or are in the process of adopting their own code of conduct regulating their employees' contacts with pharmaceutical and other vendors.

Compliance Overview

Each Company will be required to comply with the following provisions commencing on July 1, 2009:

- adopt and be compliant with a marketing code of conduct as set forth in the Code of Conduct Law and Regulations ("Marketing Code of Conduct");

[1] "A person who prescribes prescription drugs for any person and is licensed to provide health care in the Commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and board members of pharmaceutical or medical device manufacturers are not health care practitioners." 105 CMR 970.004.

[2] MGL c. 111N.

[3] 105 CMR 970.000.

- adopt a training program for sales and marketing staff informing them of the prohibitions and obligations imposed by the Marketing Code of Conduct;

- perform annual audits of compliance with the Marketing Code of Conduct;

- adopt policies and procedures for investigating non-compliance with the Marketing Code of Conduct;

- appoint a compliance officer to monitor compliance with the Marketing Code of Conduct; and

- submit a "Compliance Filing Form in Accordance with MGL c. 111N," together with a $2,000 filing fee, certifying under the pains and penalties of perjury that Company has complied with each of the foregoing requirements.

In addition, by July 1, 2009, each Company must begin tracking expenditures on certain sales and marketing activities for an annual disclosure report to be filed with DPH on or before July 1st of each year, covering such expenditures made during the previous calendar year. The first required disclosure report will be due on or before July 1, 2010, covering the period from July 1, 2009 through December 31, 2009.

Companies Subject to the Regulations

Companies subject to the Regulations are defined as companies "(a) engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (b) directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices."[4] The DPH Office of General Counsel has stated that the definition of Companies

[4] The definitions of "prescription drugs" and medical devices appear to limit the definition of a Company to those companies with FDA-approved products. The definition of "biologics" is less clear regarding the approval status of the product (see below).

"Prescription Drugs" are defined as "drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription".

Medical Device" is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in persons or animals or (3) intended to affect the structure of the body of a person or animal, and which does not achieve its primary intended purpose through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

"Biologic" is defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product or analogous product, as defined in Section 351 of

is intended to be limited to companies that manufacture or distribute commercially available products that have been cleared, approved or exempted by the FDA[5] to HCPs that are licensed in Massachusetts.

Specifically excluded from the definition of Companies are pre-commercial companies,[6] HCPs, physician practices, home health agencies, licensed hospitals, licensed wholesale drug distributors or registered retail pharmacies.[7]

In addition to the actual manufacturers of pharmaceuticals and medical devices, individuals, business or other organizations who are employed by, or contracted to distribute and market such products on behalf of, a Company ("Company Agents")[8] are subject to the Regulations in that the Company of which a Company Agent is an agent is still responsible for complying with its Marketing Code of Conduct provisions and reporting any payments to HCPs, including payments made by its Company Agent.[9] Therefore, Companies that have no sales force of their own and market solely through a Company Agent are subject to the Regulations as if they were engaging in such conduct themselves.[10]

Marketing Code of Conduct

The Code of Conduct Law requires the adoption of a code of conduct by the DPH that is no less restrictive than the most recent version of the PhRMA Code or the AdvaMed Code, as the case may be,[11] and Companies must incorporate the requirements of the Regulations in their respective Marketing Codes of Conduct. The Massachusetts Regulations are among the most restrictive in the country in terms of the marketing obligations and prohibitions it places upon Companies. The Regulations require that each Company include the following provisions in its Marketing Code of Conduct.[12]

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the Public Health Service Act applicable to the prevention, treatment or cure of disease or condition of human beings and regulated as a drug under the Food Drug and Cosmetic Act." Id. At 1.

[5] See Frequently Asked Question Pharmaceutical and Medical Device Manufacture Conduct at http://www.mass.gov/Eeohhs2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_faq.pdf

[6] Id. at 5.

[7] Id. at 1.

[8] Id. at 1.

[9] Id. at 5.

[10] The following persons are excluded from the definition of a Company Agent: a licensed pharmacist, licensed physician or any other licensed HCP with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he or she is licensed, a licensed wholesale drug distributor, or a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a registered retail pharmacist if such person is not engaging in such practices under contract with a manufacturing company. Id. at 1.

[11] While the Code of Conduct Law and the Regulations refer to a state-authored code of conduct, the DPH has not actually adopted such a code.

[12] Note that some of the provisions distinguish between pharmaceutical Companies and medical device Companies.

Prohibition on Meals and Entertainment.[13] Except as otherwise provided in the Regulations, no Company that employs or contracts with a Company Agent may provide or pay for meals for HCPs that are (a) part of an entertainment or recreational event; (b) offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; (c) offered, consumed, or provided outside of the HCP's office or a hospital setting; or (d) provided to an HCP's spouse or other guest. To the extent that a Company is permitted to pay for meals under the Regulations, such meals must be modest and occasional in nature.

Limitations on Company support for CME.[14]

1. A Company that employs or contracts with a Company Agent may not provide:

(a) financial support for costs of travel, lodging, or other personal expenses of non-faculty HCPs 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;

(b) funding to compensate for the time spent by HCPs participating in any CME event, third-party scientific or educational conferences, or professional meetings;

(c) payment for meals directly to an HCP at any CME event, third-party scientific or educational conferences, or professional meetings, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a Company for the event to provide meals for all participants; or

(d) sponsorship or payment for CME that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education ("ACCME") or equivalent commercial support standards of the relevant continuing education accrediting body, or that provides payment directly to an HCP.

2. A pharmaceutical Company shall separate its CME grant-making functions from its sales and marketing departments.

3. A pharmaceutical Company shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the Company.

4. Notwithstanding the foregoing, the Regulations allow a Company to:

(a) compensate or reimburse an HCP 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, provided that

[13] 105 CMR 970.006.
[14] 105 CMR 970.007.

the payment is reasonable, based on fair market value, and complies with the standards for commercial support as established by the relevant accreditation entity;

(b) sponsor or pay for any portion of a 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; and

(c) pay for 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.

Other Prohibited Payments to HCPs.[15] Companies that employ or contract with a Company Agent are prohibited from providing to HCPs:

(a) 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 HCP who is not a salaried employee of the Company;

(b) payments of any kind including cash or cash equivalents, equity, "in kind" or tangible items including any "complimentary" items such as pens, coffee mugs, gift cards, etc. either directly or indirectly, except as compensation for bona fide services;

(c) any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items 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; or

(d) any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under applicable federal or state "fraud and abuse" laws or regulations including the federal "Anti-Kickback Statute" (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws such as M.G.L. c. 118E, sec. 41 and M.G.L. c. 175H, sec. 3.

Permissible Activities.[16] The following activities are permitted under the Regulations:

(a) distribution of peer-reviewed academic, scientific or clinical information;

(b) purchasing of advertising in peer-reviewed journals;

(c) payment for reasonable expenses necessary for technical training on the use of medical devices if such expense is part of the purchase contract for the device;

[15] 105 CMR 970.008(1).
[16] 105 CMR 970.008(2).

(d) compensation for consulting services in connection with a genuine research project or clinical trial;

(e) reasonable compensation for bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by an HCP directly as a result of the performance of such services, provided that the compensation and reimbursement is specified in, and paid for under, a written agreement;

(f) the provision of prescription drugs to an HCP solely and exclusively for use by the HCP's patients;

(g) the provision of reasonable quantities of medical device demonstration and evaluation units provided to an HCP to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future;

(h) the provision of price concessions, such as rebates or discounts, in the normal course of business;

(i) provision of reimbursement information regarding products in support of accurate and responsible billing to Medicare and other payors and provision of information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products, provided that such technical or other support shall not be offered or provided for the purpose of inducing HCPs to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of products;

(j) the provision of payments, or the provision of free outpatient prescription drugs, to HCPs for the benefit of low income individuals, through established "patient assistance programs" ("PAPs"), provided such PAP meets the criterion for a permissible program in accordance with the relevant published guidance available from the U.S. Department of Health and Human Services Office of the Inspector General, or is otherwise permitted under applicable federal laws and regulations including the "Anti-Kickback Statute" (42 USC 1320a-7b); and

(k) the provision of charitable donations provided that the donation (a) is not 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, and (b) does not otherwise violate the provisions of the Regulations.

Disclosure Obligations.[17] Any Company that employs or contracts with a Company Agent must disclose to the DPH 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 Company

[17] 105 CMR 970.009.

provides, directly or through its Company Agents, to any HCP in connection with the Company's sales and marketing activities. For the purposes of computing the $50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Disclosures must be made on or before July 1st for the previous calendar year using a standardized reporting format developed by the DPH and shall be accompanied by a fee of $2,000. The first annual payment of $2,000 shall be due to the DPH on July 1, 2009. The first required disclosure report shall cover the period from July 1, 2009 through December 31, 2009. Finally, a Company must certify that to the best of its knowledge, information and belief, the report is true and accurate.

In addition to the restrictions set forth above, pharmaceutical Companies must include the following additional requirements into their Marketing Code of Conduct:

Use of Prescriber Data.[18] Each pharmaceutical Company that uses non-patient identified prescriber data to facilitate communications with HCPs must (a) maintain the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about these policies; (d) designate an internal contact person to handle inquiries regarding the use of the data; (e) identify appropriate disciplinary actions for misuse of the data; and (f) comply with the request of any HCP not to make his or her prescriber data available to the Company sales representatives.[19] Notwithstanding the foregoing, a pharmaceutical Company may use prescriber data to disseminate safety and risk information to prescribers of a particular drug or device, conduct research, comply with FDA mandated risk management plans that require manufacturers to identify and interact with HCPs who prescribe certain drugs or devices; or track adverse events of marketed drugs, biologics or devices.

Interaction with HCP Consultants.[20] In all speaker and commercial consultant contracts, a pharmaceutical Company must require any HCP who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for such pharmaceutical Company to disclose to the committee the nature and existence of his or her relationship with such pharmaceutical Company. This disclosure requirement must be complied with for at least two years beyond the termination of any speaker or consultant arrangement.

July 1, 2009 Requirements

As of July 1, 2009, each Company that employs or contracts with a Company Agent will be required to identify a compliance officer responsible for monitoring the Company's Marketing Code of Conduct and such compliance officer much submit a "Compliance Filing

[18] 105 CMR 970.005(2).
[19] Further, before utilizing HCP prescriber data for marketing purposes, Companies must give HCPs the opportunity to request that their prescriber data (i) be withheld from Company sales representatives, and (ii) not be used for marketing purposes. Id. at 17.
[20] 105 CMR 970.005(3).

Form in Accordance with MGL c. 111N" ("Compliance Form") certifying under pains and penalties of perjury that the Company:

(i) has adopted and is in compliance with a Marketing Code of Conduct that addresses the obligations and prohibitions set forth above;

(ii) has adopted a training program for employees and sales and marketing staff, which includes training in:

1. the Marketing Code of Conduct;

2. general science;

3. product-specific information;

(iii) will conduct annual audits to monitor compliance with its Marketing Code of Conduct; and

(iv) has adopted policies and procedures to investigate instances of non-compliance with its Marketing Code of Conduct.[21]

As stated above, each Company must pay a $2000 filing fee when submitting the Compliance Form.

Finally, July 1, 2009 marks the date on which Companies must start tracking items for disclosure on its annual disclosure report.[22]

Penalties and Traps for the Unwary

Any individual, business or other organization that knowingly and willfully violates the Regulations shall be subject to a fine of not more than $5,000 for each transaction, occurrence or event.[23] For example, failure to file a disclosure report *and* failure to pay the $2000 filing fee will result in a $10,000 penalty. Likewise, each prohibited meal or other payment will carry a $5000 penalty.

It bears repeating that prohibited conduct applies to HCPs who are licensed in Massachusetts regardless of whether an HCP practices in Massachusetts or whether the conduct occurs in Massachusetts.

[21] 105 CMR 970.005(1).
[22] 105 CMR 970.009.
[23] 105 C.M.R. 970.010.

Enforcement

The Regulations shall be enforced by the attorney general and the DPH. No Company is permitted to take any adverse action against an employee, applicant, HCP or other applicable individual or entity because such employee, applicant, HCP or other applicable individual or entity has taken any action to enforce the Regulations.

On-Going Obligations

Companies have on-going obligations under the Regulations, including the annual filing of disclosure reports, paying the annual fee and internal monitoring of compliance. Pharmaceutical and medical device companies that are not subject to the Regulations as of July 1, 2009 must become compliant after receiving marketing approval for its first prescription drug or medical device.

Next Steps

Prior to July 1, 2009, each Company should, as applicable, (a) have its existing Marketing Code of Conduct and related policies reviewed by counsel or (b) consult with counsel regarding the development of such a Marketing Code of conduct and related policies to ensure that all such policies meet the requirements of the Regulations.

If you would like further information, please contact the one of the Edwards Angell Palmer & Dodge LLP attorneys listed below:

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