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FREQUENTLY ASKED QUESTIONS PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CODE OF CONDUCT

Updated and Revised 03/29/2012

FAQ items are now organized by topic

(Revisions to previous items have the word “Updated” along with the corresponding date before the question)

1) General Information

1) How does Massachusetts regulate pharmaceutical and medical device companies?

M.G.L. c. 111, which took effect on January 1, 2009, regulates the pharmaceutical and medical device industry in two ways:

- It requires that the Massachusetts Department of Public Health adopt a standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth, which in turn must be adopted by those companies.
- It requires all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth to annually report bona fide payments (i.e., permissible payments under the code of conduct) made to Massachusetts-licensed health care practitioners.

2) What are the requirements for the pharmaceutical and medical device manufacturing company code of conduct based on?

The code of conduct incorporates requirements from two voluntary industry codes of conduct: the PhRMA code and the AdvaMed code, and contains numerous additional restrictions contained in Massachusetts General Law Chapter 111N. These requirements, restrictions and prohibitions establish ground rules for interactions between the pharmaceutical and medical device industry and health care providers. The code expressly prohibits certain activities and in some cases places restrictions on how activities may be conducted.

3)When will the Department issue its Code of Conduct?

The regulation, 105 CMR 970.000, is the Department's Code of Conduct for pharmaceutical and medical device manufacturing companies ("PMDMCs"). The regulation includes marketing restrictions, compliance requirements and disclosure requirements for pharmaceutical and medical device manufacturers and distributors.

4)What does this regulation do?

The regulation:

- Establishes a code of conduct that must be adopted by pharmaceutical and medical device companies. Included in this code of conduct is the so-called "gift ban" that prohibits certain types of payments and interactions between pharmaceutical and medical device companies and Massachusetts health care practitioners.
- Requires companies to designate a compliance officer and to establish a compliance program pursuant to the regulatory requirements.
- Requires disclosure of certain financial interactions between the industry and covered recipients.

5) What are the penalties for failing to comply with the law?

A knowing and willful violation of the regulation may be punishable by a fine of up to \$5,000 for each transaction, occurrence, or event (see 105 CMR 970.010(1)).

6) How does the Department's regulation affect physicians or other providers?

The statute and the regulation apply to the conduct of pharmaceutical and medical device companies. They do not directly regulate the conduct of health care practitioners. A fine for a violation of the regulation would be assessed against the pharmaceutical or medical device company, not the health care practitioner who received a prohibited payment. Health care practitioners are cautioned, however, that their licensing boards, professional associations, employers and workplaces may have similar codes of conduct that prohibit receipt of payments or other benefits from pharmaceutical and medical device companies.

7) Where can companies submit additional questions?

Questions on the regulation can be submitted to: Pharmamedreg@massmail.state.ma.us

Questions on submission of disclosure reports and manufacturer registration can be submitted to: Pharmameddata@state.ma.us

8) Does the Department have an 800 line or other call-in number so that I can speak with a regulator about my questions?

No, the Department asks that you direct your questions to the above-noted email addresses so that the Department can reply in writing. The Department will periodically update this FAQ with questions that it receives of general interest.

9) Would a risk assessment auditing system satisfy the audit requirement in the Department's regulations?

Yes. The Department does not mandate a particular type of auditing system, just a compliance auditing system consistent with existent auditing practices and federal guidelines.

10) The regulation states that manufacturers must "give health care practitioners the opportunity to request that their prescriber data: i. be withheld from sales representatives and ii. not be used for marketing purposes." Are manufacturers who comply with the PhRMA Code data provisions providing the required opportunity to prescribers to opt out of the use of their data in compliance with the DPH requirements?

The opt-out provision in the Department's regulations comes from the PhRMA voluntary code of conduct and was added pursuant to the statutory requirement that the Department's regulations set the PhRMA and Advamed Voluntary Codes as the regulatory floor. The PhRMA Code provisions require pharmaceutical manufacturers to respect the confidentiality of physician's prescriber identified data (PI), and to refrain from sharing the data with sales representatives if the prescriber has indicated he or she does not want the data shared. Under the PhRMA Code, the manufacturer has the option of relying on voluntary programs to identify the prescribers who "opt-out" of the use of their data. The Department has been informed that many manufacturers rely on the AMA Prescription Data Restriction Program (PDRP), pursuant to which the names of prescribers enrolling in the PDRP are made available to participating manufacturers and data intermediaries. (Note that a practitioner need not be member of the AMA to avail himself or herself of the data protections of the PDRP, which is explained in helpful documentation at:

http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp_brochure.pdf.)

The Department considers participation in the PDRP or similar voluntary programs as satisfying the regulatory obligation to provide Massachusetts physicians with an opportunity to "opt-out" of the use of their prescriber data, as long as the pharmaceutical manufacturing company honors "opt-outs" under such programs. The Department did not intend to create a new regulatory process for pharmaceutical manufacturing companies to track and honor opt-outs.

11) Section 970.005(2)(g) of the regulation requires that manufacturers give health care practitioners the opportunity to request that their prescriber data be withheld from company sales representatives and not be used for marketing purposes. Is there a list on file with Massachusetts (or in a database) concerning which physicians have requested that their prescriber data be withheld? If so, what is the process for getting that list? Is there a particular method by which PMDMCs are supposed to provide physicians with the "opportunity" to request that their prescriber data be withheld? If so, how?

Answer: The Department of Public Health will neither collect information on nor maintain a list of health care practitioners that request that their prescriber data be withheld from sales and marketing representatives. The Department advises Massachusetts physicians to opt-out through the AMA Prescription Data Restriction Program ("PDRP"). A practitioner need not be a member of the AMA to avail himself or herself of the AMA PDRP, which is explained in helpful documentation at:

http://www.ama-assn.org/ama1/pub/upload/mm/432/pdrp_brochure.pdf

2) Registration and Disclosure Report Submission Process

1) What are the deadlines for compliance and disclosure?

Pharmaceutical and medical device manufacturing companies were required to come into compliance with the regulation by July 1, 2009. The first disclosure report was due July 1, 2010 for the time period July 1, 2009 through December 31, 2009. In subsequent years, the disclosure will cover the entire previous calendar year. See below for the first three years of reporting:

Report Due	Covering activities that take place during the following time period
July 1, 2010	July 1, 2009 to December 31, 2009
July 1, 2011	January 1, 2010 to December 31, 2010
July 1, 2012	January 1, 2011 to December 31, 2011

The annual deadline for disclosure is July 1. The disclosure must report any covered transactions from the previous calendar year, with the exception of the initial disclosure in 2010, which only covered transactions occurring between July 1 – December 31 of 2009. (See 105 CMR 970.009.)

2) (Updated 08-24-11) Is there a fee required for submission of the disclosure information?

Manufacturers subject to the regulation are required to register annually with the Department as part of the regulation. Annual registration includes paying a fee of \$2000. While manufacturers subject to the regulation are required to submit both a disclosure report annually and register annually, the two requirements are separate processes, and the time frames for the two are different. However, the annual fee is connected to the calendar year reporting period. For example, the 2009 annual registration fee is connected to the July 1st – December 31st reporting period; any company subject to the regulation during this time frame would be required to pay the 2009 annual registration fee, as well as submit a disclosure report for that period.

3) (Updated 08-24-11) Can a company designate one person to be responsible for all reporting or must each division of a company report?

A company must designate a compliance officer and may submit one overall disclosure report or several reports at the divisional level. If a company decides to do separate reports for each division, the company is required to register each division separately with the Department, and each division will be required to register annually and pay the annual registration fee of \$2000.

4) What happens to disclosed information?

The disclosed information is posted on a searchable, publicly available website on www.mass.gov/dph/pharmamed.

5) (Updated 08-24-11) If a company has nothing to report, does it have to pay the \$2,000 fee?

All manufacturers subject to the Massachusetts law must register and pay the annual registration fee, even if there are no data items on their disclosure report. The annual registration renewal fee is due annually during July and August and may be paid electronically through the on-line system established for manufacturer's annual registration and compliance certification. If a manufacturer does not have any data to disclose for a given period, it should send an e-mail stating that fact to: pharmameddata@massmail.state.ma.us. The Department will deem such emails as meeting the requirement for filing an annual disclosure report. The subject line of emails should contain only the manufacturer's Department-assigned ID number (the number beginning with CC) and company name.

6) If a company reports at the divisional level, how is the fee applied?

Each division submitting an individual report needs to register with the Department and be assigned a unique registration ID number. Each division will be required to pay the annual registration fee of \$2000.

7) How can or should a company that has more than one separate but unincorporated business unit or division within the company comply with the Massachusetts law? Should the company comply at the company level (as one manufacturer) or at the business unit/division level (as more than one manufacturer) or may the company choose? What if only one business unit/division engages in activities that fall within the scope of the pharmaceutical or medical device manufacturing company definition?

A company with more than one business unit/division may choose to comply either at the company level as one manufacturer or at the business unit/division level as more than one manufacturer. A compliance officer needs to be identified and annual filing fee paid for each business unit/division that files separately. Further, the company should disclose the position taken with respect to compliance with the law (e.g., that X manufacturer is a business unit of Y company) with annual submissions. If only one business unit/division within a company engages in activities that fall within the scope of the “pharmaceutical or medical device manufacturing company” definition, the company may treat only that business unit/division as the manufacturer. That business unit/division would have to comply with the code of conduct and track/report financial interactions with “covered recipients” but other business units would not.

8) Must disclosure reports be provided electronically or are print submissions allowed?

Disclosure reports must be provided electronically. Print submissions will not be accepted.

9) (Updated 08-24-11) If a PMDMC does not have any products on the market as of July 1, 2009, but intends to launch a product at some point thereafter, does the company need to be in compliance and pay the \$2,000.00 fee by July 1, 2009, or the date they launch the product? In other words, if they launch their first marketed product on December 1, 2009, would they pay the fee immediately prior to launch, or must they comply with the July 1, 2009 deadline?

A company that anticipates being subject to the Department’s regulations during a disclosure period should submit an initial registration form and the annual fee to the Department as soon as their product launches.

10) If a company has a parent/subsidiary relationship, can the company designate one person to be responsible for all reporting or must each subsidiary of a company report?

Companies that have a parent/subsidiary relationship may submit a single annual report, and pay a single registration fee, where the subsidiary is covered by and implementing the same marketing code of conduct and training and reporting requirements as the parent. In this

instance, the parent is responsible for determining and reporting all payments made by its subsidiary to covered recipients.

11) Scenario: A modest lunch is provided in a physician's office in conjunction with an informational presentation by a PMDMC sales representative

5 MDs

1 Office Staff

1 Sales Representative

7 Total attendees with a \$315 dollar total bill

Which allocation is correct and thus reportable for this event?

Answer: The \$315 total cost would be divided equally among the 7 attendees. Each health care practitioner in attendance would receive a benefit of \$45.00, which is below the \$50.00 per transaction reporting threshold. Thus, no disclosure would be required of the PMDMC in this instance. Note: if the cost per participant exceeded the \$50 threshold for reporting, the payment on behalf of the office staff member would have to be attributed to an identifiable covered recipient.

12) Is there a mechanism in place for health care practitioners and other covered recipients to review the financial data the companies provide before it is posted on the website? Will there be a means to correct any data that was misrepresented by the companies?

No. Health care practitioners or other covered recipients that dispute any of the reported information should contact the manufacturer who submitted the reports. Manufacturers will be afforded an opportunity to correct data submitted to the Department of Public Health in error.

3) Questions On Allowable Transactions

1) Does the regulation apply to activities outside Massachusetts?

The Massachusetts Code of Conduct provisions apply to activities that involve a Massachusetts-licensed "health care practitioner" regardless of where such activity takes place. The disclosure requirements apply to any "sales and marketing activity" directed at and benefiting a Massachusetts covered recipient. Therefore, activities occurring outside of Massachusetts are subject to the regulation if they involve a Massachusetts-licensed "health care practitioner" or covered recipient.

2) What financial payments for health care providers by pharmaceutical or medical device manufacturing companies are prohibited or restricted ?

The regulation specifies the following:

Gifts of entertainment or recreation and meals in conjunction with entertainment or recreation are prohibited.

Complimentary items such as pens, mugs, calendars, etc. are prohibited.

Meals are restricted and in most instances prohibited. Generally, meals provided to health care providers must be modest and occasional in nature, cannot occur outside of a practitioner's office or hospital setting, and must be part of an informational presentation by the pharmaceutical or medical device marketing agent. For more information, see 105 CMR 970.006 and 970.008.

3) Can CME or other scientific and professional meetings and conventions still be held in Massachusetts?

Yes. The code of conduct provisions allow 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" (105 CMR 970.007(4)(c)). Additionally, pharmaceutical or medical device companies may sponsor or provide payments for such meetings or conferences, provided they are organized by third-parties who remain responsible for the content, selection of speakers and distribution of monies. (See 105 CMR 970.007(4)(b).)

4) May pharmaceutical or medical device manufacturers sponsor meals at conventions, meetings and receptions if such occur outside of a "hospital setting?"

Pharmaceutical or medical device manufacturers may not directly pay for meals that are part of an entertainment or recreational event, that are offered without an informational presentation made by a pharmaceutical marketing agent, are offered outside of a "hospital setting," or that are provided to a health care practitioner's spouse or other guest. However, third-party organizers of CME or other meetings may use general funds from such manufacturers to provide meals.

5) May charitable organizations receive economic benefits from pharmaceutical or medical device manufacturers? Must such benefits be disclosed pursuant to the regulations?

Yes. Charitable organizations may receive donations from pharmaceutical or medical device manufacturers, provided such donations are not meant to influence the prescribing patterns or other medical decisions of the organization. Charitable donations are not subject to the disclosure requirements of the regulation if they are "in-kind items used for the provision of charity care." (See "sales and marketing" definition in 105 CMR 970.004.)

6) May a company representative, other than a sales representative or immediate supervisor, take a doctor out for a meal, outside of the hospital setting?

No, unless the doctor is a bona fide employee or board member of the company and payment for the meal is reasonable compensation for bona fide services or the compensation is specified under a written agreement.

7) May a manufacturer provide educational items to a health care practitioner?

Yes, the Massachusetts law does not ban all gifts. The provision of educational items consistent with the PhRMA and Advamed Codes is permitted.

8) May a PMDMC reimburse a health care practitioner for travel and reasonable expenses associated with a plant tour or product evaluation of a medical device?

The pharmaceutical and medical device manufacturer conduct regulation prohibits payments to health care practitioners except as compensation for bona fide services. Payment of expenses in conjunction with bona fide services as defined in the regulation or in connection with product training pursuant to a contract to purchase a medical device is permissible.

9) May a PMDMC provide a grant to a covered recipient?

Grants are not prohibited unless 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 or unless the grant otherwise violates the regulatory requirements. For example, a pharmaceutical or medical device manufacturer may provide a grant to an academic medical center or university for fellowship training or educational purposes.

10) If a PMDMC has a contract with a health care practitioner that provides for entertainment or any other prohibited activity under the regulation, will the contract be valid after July 1, 2009?

No. If the contract allows for prohibited activities to continue beyond the July 1, 2009 deadline for compliance, it must be voided or re-negotiated to come into compliance with state law.

11) May medical device manufacturers provide medical devices “solely and exclusively for the benefit of a health care practitioner’s patients?”

Yes. Medical device manufacturers may provide demonstration and evaluation units for a health care practitioner’s use and may provide medical devices, such as glucose monitors, for the benefit of patients. Medical device manufacturers are not required to disclose the provision of such product samples.

12) May a PMDMC provide meals to health care practitioners pursuant to a consulting agreement?

A PMDMC may provide meals to health care practitioners if the provision of meals:

(a) complies with the specific meal restrictions of 105 CMR 970.006,
or

(b) represents compensation to the health care practitioner for bona fide services, as that term is defined in 105 CMR 970.004.

13) May meals be provided to health care practitioners at restaurants located in hospitals?

The Massachusetts statute and regulation prohibit the provision of or payment for a meal that is “offered, consumed or provided outside of the health care practitioner’s office or a hospital setting.” A restaurant located in a hospital qualifies as a hospital setting. The Department interprets this provision to permit meals within the four walls of the main hospital building, but would not extend that permission to buildings on or contiguous to a hospital campus. Please also note that the same sections of the statute and regulation prohibit the provision of or payment for any meal that is offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such agent being present.

14) Are restaurants in hotels considered by DPH to be appropriate facilities for meals in conjunction with CME or other third-party scientific, educational or professional meetings or conferences?

Yes, meals in conjunction with CME or other third-party scientific, educational or professional meetings or conferences may be provided in hotel restaurants. Please note however that the meals cannot be provided directly by a pharmaceutical or medical device company.

15) May a “health care practitioner’s office” include other health facilities where the health care practitioner is based or has an office?

Yes. Under the regulation, a clinic or other health care facility where a health care practitioner practices qualifies as a “health care practitioner’s office” where meals may be provided in conjunction with informational presentations by marketing agents of a PMDMC.

16) Is the provision of coffee or other snacks or refreshments at a booth at a conference considered a prohibited meal?

No.

17) Does the Massachusetts regulation permit a PMDMC to cover reasonable expenses (including travel, lodging, and meal expenses) of Massachusetts-licensed health care practitioners in connection with bona fide employment recruitment activities?

PMDMCs may reimburse costs and provide meals to Massachusetts-licensed health care practitioners in connection with bona fide recruitment activities, but must disclose such reimbursements and expenditures as “bona fide services.”

18) Does a CME program have to be ACCME accredited in order to be considered a CME program for the purposes of the Massachusetts regulation?

No. The program itself need not be accredited by ACCME, but if it receives support from a pharmaceutical or medical device manufacturing company, the commercial support must comply with the ACCME standards for commercial support.

19) Is a conference or event organizer free to request and dispense funds as they feel appropriate for implementation of their own conference?

Yes, other than compliance with ACCME Standards for Commercial Support, the regulation does not regulate the manner in which conference or event organizers use their funds.

20) Is DPH going to expect a report on payments to third-party scientific or educational conference or meeting organizers?

No. PMDMCs need not report payments to third-party scientific, educational or professional meeting organizers unless the meeting organizer is a covered recipient.

21) How do manufacturers ensure that a site qualifies as a “specialized training facility” in compliance with the regulation?

Manufacturers must certify in their annual compliance statement that they are in compliance with the regulation, including the requirement that “specialized training facilities” meet the regulatory definition. Under the regulation, a “specialized training facility” is not limited to certain locations, but is defined by the activity that occurs within it. PMDMCs need not submit a description of the “specialized training facility” and the activities that occur within it to the Department, but should keep such a description on file, available for review upon request by the Department or the Attorney General’s Office.

22) With regards to providing reimbursements in conjunction with training on a medical device, what is meant by the phrase “pursuant to a contract to purchase a medical device?” Does it include agreements to lease medical devices? Must the agreement to purchase or lease a device be between a manufacturer and a health care practitioner?

As used in the Department’s regulation, a “contract to purchase a medical device” includes an agreement to purchase a medical device pending an evaluation of the device to assess the appropriate use and functionality of the product as well as an agreement to lease a medical device, provided that such agreements do not otherwise violate Chapter 111N and the Department’s regulation. Additionally, the contract to purchase or lease the medical device need not be between the health care practitioner and the manufacturer, but the PMDMC must receive assurance from the health care practitioner that a contract to purchase or lease the device has been entered into subject to which the health care practitioner will be evaluating or operating the device, (e.g., a contract between the facility with which the health care practitioner is associated and the PMDMC) before the PMDMC may provide reimbursements for reasonable expenses related to training on the device.

Reimbursements for reasonable expenses, including travel, meals and lodging, associated with FDA required training and other product consultation, demonstration and training may also be

provided pursuant to a contract between a PMDMC and a health care practitioner for “bona fide services,” as long as the contract is based on fair market value and is characterized by the following factors:

- (a) a legitimate need for the services clearly identified in advance;
- (b) a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement;
- (c) the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- (d) the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner;
- (e) the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and
- (f) the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company’s sales personnel.

23) May demonstration and evaluation units be provided to hospitals, academic medical centers and other facilities?

Yes, reasonable quantities of demonstration and evaluation units may be provided for the benefit of patients, or to a health care practitioner, hospital, academic medical center, or other facility to assess the appropriate use and functionality of the product and to determine whether or not to use or recommend the device in the future.

24) May a PMDMC provide funding to an academic medical center for a fellowship to send health care practitioners in training to a national meeting?

Yes. A third party such as an academic medical center may receive grants from a PMDMC for CMEs, fellowships or training and may use the grant to benefit health care practitioners in training as long as the third party selects the health care practitioners in training who will benefit from the grants. Additionally, because an academic medical center is a covered recipient under the regulations, the grant must be disclosed to the Department by the PMDMC.

4) Which Transactions Need To Be Disclosed?

1) What must be disclosed?

A pharmaceutical or medical device manufacturing company must disclose “the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to any covered recipient in connection with the company’s sales and marketing activities” (105 CMR 970.009(1)). This includes reimbursement of expenses in

conjunction with a product training, compensation for serving as faculty at a CME or participation on a Speaker's Bureau, and compensation for bona fide services.

2) What activities are “sales and marketing activities” for the purposes of disclosure?

Sales and marketing activities include:

1. Advertising, promotion, or other activity that is intended to be used or is used to:
 - a. Influence sales or market share of a prescription drug, biologic, or medical device;
 - b. Influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device;
 - c. Market a prescription drug, biologic or medical device;
 - d. Evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force;
2. Product education, training, or research 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
3. Other payments with a value of \$50 or more to a covered recipient, except as expressly excluded.

3) What activities are exempt from disclosure?

1. Payments in conjunction with genuine research and clinical trials.
2. The provision of:
 - a. prescription drugs to a covered recipient solely and exclusively for use by patients,
 - b. demonstration or evaluation units, or
 - c. in-kind items used for the provision of charity care.
3. Price concessions such as rebates and discounts.

4) Is the \$50 threshold for disclosure based upon a single expense or an annually aggregated basis?

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 basis and shall not be aggregated.

5) Must licensing fees and royalties be disclosed under the regulation?

The regulation does not apply to intellectual property agreements and related payments.

6) Is an industry payment to a physician licensed in MA, but practicing in Rhode Island subject to disclosure? Is the company responsible for determining everywhere the practitioner is licensed to practice?

Yes, as long as the payment is made to a health care practitioner licensed to practice in Massachusetts and authorized to prescribe, it is subject to disclosure under 105 CMR 970.000. PMDMCs are responsible for making a good faith effort to determine where a health care practitioner is licensed.

7) The regulation states that price concessions such as rebates and discounts are exempt from disclosure where they are “established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan’s formulary.” Does the Massachusetts law generally exempt price concessions offered by a manufacturer to a covered recipient from disclosure, or is the exemption limited to these circumstances?

The Massachusetts law does generally exempt price concessions offered by a manufacturer to a covered recipient from disclosure. The language in the regulation provides examples of contracts in which the exemption applies, but the exemption is not limited to these examples.

8) If a charitable donation is made to an organization that is not a covered recipient, is the donation subject to disclosure?

Not unless the charitable donation directly or indirectly benefits a covered recipient. If a charitable donation is made to an organization that is not a covered recipient, but is made for the purposes of providing an economic benefit of \$50 or more to a covered recipient, or does provide an economic benefit of \$50 or more to a covered recipient, it is subject to the disclosure requirements of 105 CMR 970.000.

9) (Updated 08-24-11): If a PMDMC #1 has a user’s conference, attended by employees of PMDMC #2 that also happen to be Massachusetts licensed health care practitioners, is

PMDMC #1 subject to the code of conduct provisions and must PMDMC #1 disclose the payments made to the employees of PMDMC #2?

Yes. Employees of a PMDMC who are also covered recipients are exempt from having payments made to them by their employer reported, but not exempt from reporting by other PMDMCs.

10) What if a PMDMC has a contract with a national company with a presence in Massachusetts (e.g., a national provider of laboratory services with several laboratories located in Massachusetts) and takes out individuals at the headquarters level to dinner? Must a portion be attributed to Massachusetts, because the company has a presence and does business in Massachusetts? How would that be apportioned and reported for Massachusetts?

Benefits provided by a PMDMC at the headquarters level of a national or multinational corporation are not subject to the code of conduct restrictions unless they are provided to a Massachusetts health care practitioner and if permissible need not be disclosed unless they are provided to a Massachusetts health care practitioner or other individual or organization that otherwise qualifies as a Massachusetts covered recipient.

11) Are payments made by PMDMCs to health care practitioners or other covered recipients in conjunction with pre-clinical trial activities and post-market trials subject to disclosure?

Payments in conjunction with pre-clinical trials are exempt from disclosure pursuant to the clinical trials exemption in the regulation as long as the payments are related to the design and development of a clinical trial, as that term is defined in the regulation. However, PMDMCs must disclose any payments made to a health care practitioner or other covered recipient in conjunction with post-market trials.

12) If a PMDMC hires a market research company to conduct a double-blind study of health care practitioners, where the health care practitioners are paid an honorarium by the market research company, but the PMDMC does not know which health care practitioners participated in the study and the health care practitioners who participated do not know what pharmaceutical or medical device manufacturing company was involved, is the information subject to disclosure?

No. The regulations seek to create transparency around payments to health care practitioners by PMDMCs that may influence prescriber behavior. Where the health care practitioner participates in a market research study, but is not paid by the PMDMC and is not aware of the PMDMC involved, the payment need not be reported.

13) May manufacturers report on employees of a physician that fall within the regulatory definition of “health care practitioner” by name, without providing a unique identifier?

No. A unique identifier must accompany all disclosures. If a payment of \$50 or more is made to an employee of a physician, it must be reported. If the employee does not have a unique

identifier and no facility identifier is available, payments to employees of physicians may be reported under the physician's unique identifier.

14) (Updated 08-24-11): Company A manufactures a product (covered by the regulation). Company B markets and sells the product. Does Company A need to report the marketing activities of Company B? Or, is Company B responsible for reporting its payment activities?

All marketing activities subject to 105 CMR 970.000 must be reported. Manufacturers are responsible for reporting payments to Massachusetts covered recipients, even if those payments are made by the manufacturer's agent. In this instance, the manufacturer responsible for disclosure is Company A and the manufacturer's agent is Company B. Thus, Company A should report all payments made to Massachusetts covered recipients on its behalf by Company B.

15) When a pharmaceutical company's Office of Medical Affairs responds to a healthcare professional's unsolicited request for information regarding the company's products, is this excluded from the Massachusetts definition of required reporting since the information provided is scientific, not sales or marketing related?

Any provision of marketing or other product-related materials to a Massachusetts health care practitioner must comply with the Code of Conduct restrictions in the regulations and may be subject to disclosure, regardless of whether the manufacturer or the healthcare professional initiated the contact.

16) Are manufacturers required to report any aggregated expense (such as advertising) that cannot be tied back to a specific covered recipient (e.g., TV, journal ads, news print, radio) as opposed to a "direct mailing" where a PMDMC will use their customer list/HCP list to send out a mailing directly to the HCP?

Advertising expenses that cannot be tied to any health care practitioner or other Massachusetts covered recipient need not be disclosed.

17) Does the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct require disclosure of a payment made by a medical device manufacturer to a hospital in the Commonwealth of Massachusetts for the right to have a promotional exhibit at an educational symposium sponsored by the hospital?

Yes.

18) Is the cost of the meal strictly the charge for the food and beverages consumed, or does the "meal" cost also include tax and gratuities as well?

The cost of the meal would include all taxes and gratuities and any other charges associated with the meal.

5) Definition of Covered Recipient and Health Care Practitioner

1) Does the regulation apply to all interactions in Massachusetts when they occur between industry and doctors licensed in other states, such as Connecticut?

No, the Code of Conduct provisions only apply to interactions between industry and health care practitioners licensed in Massachusetts and apply regardless of where the interaction takes place.

2) Who are “covered recipients” for the purposes of disclosure?

Any person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices in the commonwealth. This includes hospitals, nursing homes, pharmacists, health benefit plan administrators, and health care practitioners. Full time employees and board members of pharmaceutical and medical device manufacturing companies acting in that capacity, and consumers who purchase prescription drugs, biologics or medical devices are excluded.

3) What classes of individuals may be considered a “health care practitioner” for the purposes of 105 CMR 970.000?

The regulation defines a “health care practitioner” as “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.”

To be a “health care practitioner”, an individual must be duly licensed by a professional board of registration and possess a valid Massachusetts Controlled Substances Registration (MCSR) or be authorized to prescribe pursuant to the MCSR of a health care facility (i.e., residents). Classes of individuals in the Commonwealth who may be both licensed to provide health care (i.e., by a professional board of registration) and registered to prescribe prescription drugs (i.e., possess a MCSR), and therefore may be a “health care practitioner”, include the following:

Advanced Practice Nurse
Certified nurse-midwife
Nurse Practitioner
Psychiatric nurse mental health clinical specialist
Dentist

Optometrist
Physician
Physician Assistant
Podiatrist

4) Are health insurers covered recipients?

No, health insurers are not covered recipients.

5) Is a distributor a covered recipient?

A distributor is not considered a covered recipient, even though it purchases prescription drugs, biologics or medical devices. The regulation is directed at creating transparency around industry payments to prescribers and health care providers, and others who interact with patients or affect patient care in Massachusetts.

6) Is CVS or Walgreens a covered recipient?

No, for the same reasons as described above.

7) Are agents of hospitals, nursing homes and other covered recipients also covered recipients? What if an employee of a hospital who is not an agent of a health care practitioner receives an economic benefit of \$50 or more from a PMDMC? Must it be disclosed?

A hospital employee is not a covered recipient unless he or she is in a position to act on behalf of the hospital (or other covered recipient) in making or recommending purchasing, prescribing or dispensing decisions.

8) Many physicians have Massachusetts licenses, but have never practiced here (e.g., foreign medical graduates, physicians who did their training in Massachusetts, etc.). Do the code of conduct restrictions apply to health care practitioners practicing outside of Massachusetts?

Any physician with an active license may practice medicine in Massachusetts. Thus, the regulation applies to industry interactions with all physicians who have an active Massachusetts license and are authorized to prescribe, even if they practice elsewhere or are not currently in active practice.

9) I had a question regarding the PCOC. I am currently doing a fellowship in MA and am a licensed physician here in MA. Does the PCOC still apply to me after I leave the state of MA? Does having an inactive MA license change the applicability of PCOC?

The PCOC regulation applies to pharmaceutical and medical device companies' interactions with all actively licensed Massachusetts physicians, regardless of where they practice. The regulation would not apply to interactions with a practitioner with an inactive license.

10) Are professional trade organizations that represent various types of health care practitioners considered health care practitioners and/or covered recipients under this regulation? If so, how are they affected by the regulation?

There are two components to the Massachusetts law: The first is a gift ban, which prohibits certain conduct on the part of manufacturer. The second is a reporting requirement.

A professional organization such as a medical society could be a health care practitioner if it is acting as an agent of a health care practitioner. Thus, if a pharmaceutical or medical device manufacturer provided prohibited items to the medical society, which then distributed those items to its members, the Department would view this as a violation of the law. Example: a pharmaceutical manufacturer provides trips to Hawaii, or Red Sox tickets, to the medical society for its officers. This would be prohibited.

Currently, the Department does not define entities like a medical society as a covered recipient, even if its members are health care practitioners. What this means is that if permissible and reportable payments are made to a medical society, which then directs the payments to health care practitioners within its organization, the payments are not required to be reported (unless, of course, a manufacturer has actual knowledge of the ultimate recipient).

For the purposes of the gift ban, then, although a medical society itself is not a health care practitioner, a manufacturer cannot make prohibited payments to the medical society for distribution to its health care practitioner members. For reporting purposes, a medical society is not a covered recipient.

11) Are covered recipients who are employed by a pharmaceutical or medical device manufacturer exempt from having disclosures reported on them by all pharmaceutical and medical device manufacturers?

No. In this case, the covered recipient would only be exempt from having disclosures reported on them by their own employers; other pharmaceutical and medical device manufacturers are still required to report payments to them.

12) I understand that currently, a person who is a covered recipient by virtue of performing drug and medical device purchasing on behalf of a hospital, but does not otherwise qualify as a covered recipient, is to have disclosures on them attributed to the hospital they work for. Is it possible to have such a person added to the covered recipient list and assigned a unique covered recipient ID, so that payments can be attributed directly to them and not to the hospital?

No. In this case, payments to the person would need to be attributed to the health care facility for which he or she works.

13) I am licensed to practice in Massachusetts but do not actively practice in the commonwealth. Am I subject to the law?

The law applies to the conduct of pharmaceutical and medical device manufacturers as it relates to interactions with “covered recipients,” which includes any physician licensed in Massachusetts. It does not matter if the physician is not currently practicing, or does not practice in Massachusetts, he or she is still a covered recipient and as such the manufacturer must comply with the Massachusetts Code of Conduct in its interactions with this provider.

6) Which Companies Are Considered “Manufacturers” That Are Required To Register With The Program?

1) Who is subject to the requirements of the regulation?

The regulation applies to any pharmaceutical or medical device manufacturing company, which includes any pharmaceutical or medical device manufacturing company or distributor as defined in 105 CMR 970.004. Health care practitioners, physician practices, home health agencies, hospitals, wholesale drug distributors, or retail pharmacists are not required to comply with the code of conduct provisions or to disclose information pursuant to the disclosure requirements, but may be otherwise affected by the regulation.

2) Does the regulation apply to manufacturers and distributors of veterinary drugs or devices?

No. The regulation applies to manufacturers and distributors of drugs, biologics and medical devices intended for use in humans.

3) Is the manufacturer of a commodity medical device that does not provide compensation to a health care practitioner or any other covered recipient, subject to the disclosure requirements?

Such manufacturers are subject to the disclosure requirements, but need not file a disclosure report or filing fee if the manufacturer has not made any payments to a covered recipient. If a manufacturer fails to file a disclosure report and filing fee for a year in which such payments are made, however, the manufacturer will be in violation of 105 CMR 970.000 and subject to penalties.

4) Is a company that develops 510(k) exempt software products that are considered “unclassified medical devices” by the federal Food and Drug Administration, considered PMDMCs under the Department’s regulation?

No. With respect to medical devices, the Department's regulation applies to manufacturers of prescription devices as well as Class II and Class III devices, as such classes are determined by the FDA. Software manufacturers are not subject to the Department's regulation unless the software constitutes a medical device or a component, part or accessory of a medical device regulated by the FDA under the federal Food, Drug, and Cosmetic Act. Manufacturers of unclassified medical devices that are exempt from Pre-market Notification under the federal Food, Drug & Cosmetic Act (510(k) exempt medical device manufacturers) are not subject to 105 CMR 970.000.

5) What if a device qualifies as a Class I 510(k) exempt device under federal FDA regulations, but the device manufacturer, for whatever reason, has filed a 510(k)?

The manufacturer of a device that qualifies as a Class I 510(k) exempt device is not a PMDMC subject to the Department's regulation, regardless of whether it chooses to file a 510(k).

6) I am looking for confirmation that 105 CMR 970.000 does not apply to research-stage companies that do not manufacture or market any FDA-approved or cleared drugs or devices. I'm requesting this clarification because of the use of the term "exempted" in the Department's recent guidance. On the one hand, "exempted" could refer to commercially available devices that are, for instance, exempted from the 510(k) clearance requirements. On the other hand, "exempted" could refer to investigational drugs and devices, which are "exempted" from the otherwise applicable approval or clearance requirements via the Investigational New Drug (IND) application and Investigational Device Exemption (IDE) processes. Because INDs and IDEs technically are "exemptions," I want to get clarification regarding the meaning of the Department's interpretation.

The Department's regulation applies only to companies that have at least one commercially available product. The regulations do not apply to research-stage companies that do not manufacture or market any FDA approved or cleared devices. The Department does not interpret the term "exempted" in its guidance to include investigational drugs or devices.

7) A drug/device manufacturer established and endowed a charitable foundation many years ago that provides a variety of charitable donations to U.S. charities, including to local civic organizations (such as local Boys and Girls Clubs), to organizations that serve and help the homeless and migrant workers, underprivileged children, family support groups, local schools and school-based educational programs, advanced medical education programs (including fellowships), volunteer organizations, national patient groups, and provide scholarships for children of company employees . Although the charitable organization was endowed by a manufacturer required to comply with the Massachusetts disclosure requirements, and that manufacturer makes occasional ongoing donations to the foundation, the charitable foundation itself is a separate legal entity, with a separate board of directors. The foundation is recognized by the U.S. Internal Revenue Service as tax exempt pursuant to Section 501(c)(3) of the Internal Revenue Code. Further, the foundation's IRS Form 990 filings are available via the public website, www.guidestar.org.

These filings include descriptions of the foundation's charitable activities and the recipient, purpose and amount of each donations made by the foundation.

Does the charitable foundation, as a separate legal entity that has no involvement in the manufacturing of drugs or devices, qualify as a "manufacturer" for purposes of the tracking and disclosure requirements? Is the charitable foundation required to report its donations, if those donations are made to Massachusetts health care professionals who are recognized by the IRS as tax-exempt pursuant to Section 501(c)(3) of the Internal Revenue Code?

The charitable foundation may be considered an agent of the pharmaceutical or medical device manufacturing company (“PMDMC”) if for compensation or reward, it does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices or engages in detailing, promotional activities or other marketing of prescription drugs 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. Thus, the drug or device manufacturer is responsible for ensuring that the charitable foundation is acting in compliance with the Department’s regulation and must report any donations to Massachusetts covered recipients.

8) A pharmaceutical or medical device manufacturer is comprised of a number of different business units, many of which manufacture and/or market prescription drugs. It also has a clinical laboratory. Must the clinical laboratory have a compliance program, a training and auditing system and generally comply with the marketing code of conduct its other divisions are subject to?

No, unless the clinical laboratory for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices or engages in detailing, promotional activities or other marketing of prescription drugs 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.

9) Are private (not affiliated with any hospitals) MRI company service providers subject to the regulation?

No, unless the MRI service provider for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices or engages in detailing, promotional activities or other marketing of prescription drugs 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.

10) Is running a reimbursement hotline considered “sales and marketing activities?” A company runs a reimbursement hotline that contracts with PMDMCs to provide services. After a doctor makes a decision to use a specific drug or a specific medical device, and after

the patient’s insurance carrier refuses to authorize payment, the doctor then calls the reimbursement hotline. Staff at the hotline handle the appeal of the rejection, and are usually successful. Does this service conflict with the new Massachusetts pharmaceutical and medical device marketing law and regulation?

The Department would consider a reimbursement hotline to be “sales and marketing activities” and it would not be permissible under Massachusetts law because it offers “in kind” services to influence prescribing behavior .

11) Is a manufacturer of dental implants or other devices used in dental care a PMDMC?

Yes. A manufacturer of a dental device is a PMDMC if the device is a “medical device” under Massachusetts law and is not a Class I 510(k) exempt device under federal law. The regulation defines “medical device” 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 or function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Additionally, payments made by manufacturers of dental devices to Massachusetts-licensed dentists with prescribing authority are restricted by the conduct restrictions of 105 CMR 970.006-970.008 and subject to disclosure under 105 CMR 970.009.

12) Are clinics PMDMCs?

A clinic defined under M.G.L. c. 111, §52 is not a PMDMC.

13) Why did the Department eliminate the phrase “participates in a commonwealth health care program?” Does the state have jurisdiction over companies that do not participate in a commonwealth health care program?

This phrase caused confusion among regulated parties without advancing any of the goals of the statute. Chapter 111N is directed at regulating both pharmaceutical and medical device manufacturing companies. The statute and regulation apply to all pharmaceutical and medical device manufacturing companies, even those that are neither reimbursed by the Commonwealth of Massachusetts nor the federal government. The Department’s jurisdiction over out-of-state manufacturers and activities arises from the fact that the pharmaceutical or medical device manufacturer is interacting with Massachusetts-licensed health care practitioners with prescribing authority.

14) Are specialty and nuclear pharmacies PMDMCs?

No. Specialty and nuclear pharmacies are not PMDMCs and are not subject to the requirements of 105 CMR 970.000 unless such pharmacies are acting to promote, oppose or influence the prescribing of a particular prescription drug, biologic, or medical device, or category of prescription drugs, biologics or medical devices.

15) Is an oxygen dispenser a PMDMC?

No. Companies that merely dispense medical gases such as oxygen are not PMDMCs and are not subject to the requirements of 105 CMR 970.000 unless such companies are acting to promote, oppose or influence the prescribing of a particular prescription drug, biologic or medical device, or category of prescription drugs, biologics or medical devices. However, manufacturers of medical oxygen generators, concentrators, or those that fill medical gas cylinders are PMDMCs.

16) Does the regulation apply only to PMDMCs that are physically located in Massachusetts or does it apply to any manufacturer that performs promotions in the Commonwealth, regardless of their physical location?

The regulation applies to PMDMCs that are physically located in Massachusetts as well as PMDMCs that have agents in Massachusetts and PMDMCs that market to Massachusetts health care practitioners and regulates interactions between the PMDMC and Massachusetts health care practitioners regardless of where the interaction takes place.

17) Does the regulation apply to pre-commercial companies?

The regulation applies only to companies that manufacture or distribute commercially available products that have been cleared, approved or exempted by the Food and Drug Administration. If the company is marketing a drug, biologic or medical device to Massachusetts health care practitioners and engages in any of the activities outlined in 105 CMR 970.000, it is subject to the regulation. If the company has at least one drug or device that has been cleared, approved or exempted by the Food and Drug Administration, then it must disclose to the Department payments to covered recipients in conjunction with any pre-commercial activities not otherwise exempted by the regulations.

18) Does the regulation apply only to the manufacturers of prescription medical devices?

No. The regulation applies to manufacturers of prescription medical devices as well as to manufacturers of Class II and Class III devices, as determined by the Food and Drug Administration. Medical devices are defined broadly in the statute and in the regulation to include components, parts or accessories of instruments, machines, or contrivances and to include devices used solely for diagnostic purposes. However, manufacturers of Class I medical devices that are exempt from Premarket Notification under the federal Food, Drug and Cosmetic Act (510(k) exempt device manufacturers) are not subject to 105 CMR 970.000.

19) Is a company that has a marketing agreement with another drug company for its product, but does not employ any sales or marketing representatives of its own, subject to the regulation?

Yes. The second drug company would be considered a “pharmaceutical or medical device manufacturer agent” of the first company, and any PMDMC that employs or contracts with a “pharmaceutical or medical device manufacturer agent” is subject to 105 CMR 970.000.

20) When is a distributor a PMDMC as opposed to a PMDMC agent?

A distributor that takes title to a prescription drug, biologic or medical device and is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices is a PMDMC.

A distributor that operates merely as a sales force for a PMDMC or assists in the distribution or marketing of a PMDMC’s products, or does any act to promote, oppose or influence the prescribing of a particular prescription drug, biologic or medical device, or category of prescription drugs or medical devices is a PMDMC agent. The PMDMC of which a PMDMC agent is an agent of is responsible for complying with the code of conduct provisions and reporting any payments to health care practitioners, including payments made by its PMDMC agent.

21) Is a wholesale distributor who is exempt from the Massachusetts licensure requirement a PMDMC?

No, a wholesale distributor who is exempt from the MA licensure requirement is not a PMDMC. The statute and regulation are intended to exempt wholesale distributors from the definition of PMDMC.