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**FREQUENTLY ASKED QUESTIONS
PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT**

A. Pharmaceutical or Medical Device Manufacturing Company (“PMDMC”):

1. Is a manufacturer of dental implants or other devices used in dental care a PMDMC?

Answer: 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 regulations define “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 970.006-970.008 and subject to disclosure under 970.009.

2. Are clinics PMDMCs?

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

3. **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?**

Answer: 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 regulations 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.

4. **Are specialty and nuclear pharmacies PMDMCs?**

Answer: 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.

5. **Is an oxygen dispenser a PMDMC?**

Answer: 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.

6. **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?**

Answer: 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.

7. **Do the regulations apply to pre-commercial companies?**

Answer: The regulations apply 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.

8. **Does the regulation apply only to the manufacturers of prescription medical devices?**

Answer: 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.

9. **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?**

Answer: 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.

10. **When is a distributor a PMDMC as opposed to a PMDMC agent?**

Answer: 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.

11. **Is a wholesale distributor who is exempt from the Massachusetts licensure requirement a PMDMC?**

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

B. Health Care Practitioner:

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

Answer: The regulations define 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

C. Code of Conduct:

1. **When will the Department issue its Code of Conduct?**

Answer: The regulation, 105 CMR 970.000, is the Department’s Code of Conduct for pharmaceutical and medical device manufacturing companies. The regulation includes marketing restrictions, compliance requirements and

disclosure requirements for pharmaceutical and medical device manufacturers and distributors.

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

Answer: No, unless the doctor is a bona fide employee or board member of the company.

3. **May a manufacturer provide educational items to a health care practitioner?**

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

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

Answer: The pharmaceutical and medical device manufacturer conduct regulations prohibit 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 regulations and in connection with product training pursuant to a contract to purchase a medical device is permissible.

5. **May a PMDMC provide a grant to a covered recipient?**

Answer: 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.

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

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

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

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

D. Meals:

1. **May a PMDMC provide meals to health care practitioners pursuant to a consulting agreement?**

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

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

or

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

2. **May meals be provided to health care practitioners at restaurants located in hospitals?**

Answer: Yes, a restaurant located in a hospital qualifies as a hospital setting.

3. **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?**

Answer: Yes, meals in conjunction with CME or other third-party scientific, educational or professional meetings or conferences may be provided in hotel restaurants.

E. CMEs, Conferences and Meetings:

1. **Does a CME program have to be ACCME accredited?**

Answer: 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.

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

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

3. **Is DPH going to expect a report on payments to third-party scientific or educational conference or meeting organizers?**

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

F. Disclosure Fees:

1. **If a company has nothing to report, does it have to pay the \$2,000 fee?**

Answer: The filing fee accompanies the disclosure report, so if the company does not file a disclosure report, it needn't submit a fee. However, for the first year, we are requiring companies to pay the fee even though no report is required. If a company does not submit a fee this July because it does not anticipate it will have anything to report next year, and the same company eventually does submit a report next year, then the Department reserves the right to collect \$4,000 with that report (\$2,000 for the 2010 filing fee and backpayment of the 2009 filing fee), in addition to any penalties for non-compliance (under the regulation, non-compliance can result in a fine of up to \$5,000.00 per incident).

2. **If a company reports at the divisional level, how is the fee applied?**

Answer: The fee accompanies the report. If a multi-divisional corporation submits 3 reports at the divisional level, the company must submit \$6,000 to the Department, \$2,000.00 per report.

G. Reporting:

1. **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?**

Answer: 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 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.

2. **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?**

Answer: 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.

5. **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?**

Answer: 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.

6. **Must disclosure reports be provided electronically or are print submissions allowed?**

Answer: Disclosure reports must be provided electronically. The Department will establish a reporting format for electronic submissions.

7. **Scenario:** A lunch is provided in a hospital setting (in compliance with Massachusetts Regulations).

5 MDs

1 Office Staff

1 Rep

7 Total attendees with a \$240 dollar total bill

Which allocation is correct and thus reportable for this event?

Answer: Because the total cost exceeds the \$50 per instance threshold, it is reportable under Massachusetts law. For purposes of allocation, the manufacturer would divide the total among health care practitioners (as that term is defined in the regulations) only. So, in this instance, a pharmaceutical or medical device manufacturer would disclose its payment of \$240 to the physician practice (as a covered recipient) or divide the \$240 payment by 6, and provide 6 separate disclosures of \$40.00 for each health care practitioner.

8. **The regulations state 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?**

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

9. **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 know what pharmaceutical or medical device manufacturing company was involved, is the information subject to disclosure?**

Answer: 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.

H. Covered Recipients:

1. **Are health insurers covered recipients?**

Answer: No. health insurers are not covered recipients.

2. **Is a distributor a covered recipient?**

Answer: 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.

3. **Is CVS or Walgreens a covered recipient?**

Answer: No, for the same reasons as described above.

4. **If a charitable donation is made to an organization that is not a covered recipient, is the donation subject to disclosure?**

Answer: 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.