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TO: Interim Commissioner Lauren A. Smith, MD, MPH and Members of the Public Health Council

FROM: Madeleine Biondolillo, MD, Director
Bureau of Health Care Safety and Quality

DATE: November 21, 2012

RE: Request to Promulgate Final Amendments to 105 CMR 970.000 (Pharmaceutical and Medical Device Manufacturer Conduct)

INTRODUCTION

The purpose of this memorandum is to request the Public Health Council's approval of final amendments to 105 CMR 970.000, *Pharmaceutical and Medical Device Manufacturer Conduct*. The proposed amendments implement changes to M.G.L. c. 111N that were enacted as part of the FY 2013 budget and that went into effect on July 8, 2012, and reflect changes following public comment on emergency regulations approved by the Council on September 19, 2012.

BACKGROUND AND PROPOSED REVISIONS TO AMENDMENTS

M.G.L. c. 111N sets forth requirements for pharmaceutical and medical device manufacturers. Among other provisions, the statute required the Department to promulgate a manufacturer code of conduct in regulation, based on existing industry codes of conduct and also incorporating specific statutory requirements. The Department originally promulgated 105 CMR 970.000 in April of 2009.

In July of 2012, the legislature enacted several changes to chapter 111N, which necessitate amendments to the existing regulation. On September 19, 2012, staff presented emergency amendments that were approved by the Council. The emergency amendments were filed with the Secretary of the Commonwealth that same day. Emergency amendments take effect when filed, and remain in effect for three months. During the three-month period, the Department must comply with all hearing and notice requirements of M.G.L. c. 30A. Staff must file final regulatory documents with the Secretary of the Commonwealth before the expiration of

the emergency regulations on December 19, 2012 and thereby make permanent changes to 105 CMR 970.000.

The regulation with the proposed changes noted is appended as Attachment 1. The public comment and staff responses, including proposed revisions to the emergency amendments, are summarized below.

Public Comment and Staff Response and Recommendations

Staff conducted the public hearing on October 19, 2012 and accepted written comments until October 26, 2012. Approximately 100 people attended the hearing and 19 offered oral testimony. There were seventy-seven (77) written submissions from organizations, individuals or groups of individuals. Council members can view the written testimony on the Department's website (go to www.mass.gov/dph; click on "Regulations and Policies," then "Proposed Amendments to Regulations" and then click on the link to "Pharmaceutical and Medical Device Manufacturer Code of Conduct." The url for this section is <http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/pharmaceutical-and-medical-device-manufacturer-code.html>). The majority of the comments focused on the following topics.

1. Provision of meals. Chapter 111N originally prohibited the provision of meals to health care practitioners outside of a hospital or the practitioner's office. The legislature removed that prohibition, and chapter 111N now permits a pharmaceutical or medical device manufacturer to provide modest meals and refreshments outside of such a healthcare setting in connection with non-CME educational presentations for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to informational communication. The statute directs the Department to define "modest meals and refreshments." The definition in the emergency regulation defined "modest meals and refreshments" as "food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense." This definition is consistent with the definitions contained in industry codes of conduct and allows the manufacturers to adjust for regional or other variations in costs.

In general, the regulated manufacturers, several medical associations and representatives of the Massachusetts hospitality industry supported the definition as fair and consistent with existing codes of conduct. Consumer advocates and professional groups representing providers and medical students objected to the definition as vague and unenforceable. Most recommended that the Department specify a particular dollar limit on meals, with many recommending that the Department base the dollar limits on per diem allowances for government employees.

Staff response and recommendation: Chapter 111N directs that the Department's regulation be "no less restrictive than the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of

America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association.” The definition as adopted is consistent with these codes, and also with the American Medical Association’s ethical guidelines.

Imposing a specific dollar cap is a simplistic approach to a complex regulatory provision. The statutory change permits meals outside of physician office or hospital settings, i.e., in restaurants or other facilities with function rooms. The per-person cost for the meal component of a presentation or group event is often more than the menu price of similar meals because the cost of the room and attendant amenities (audio-visual equipment, for example) may be included, as may be beverages, taxes and gratuities. In order to take into account variations in costs based on regional differences, number of participants, etc, the Department would have to establish a ceiling that was at such a high level so as to invite criticism that in many lower-cost areas or events, it would exceed any reasonable interpretation of “modest.” Additionally, among any regulated group, a defined upper limit often as a practical matter becomes the average, and a figure high enough to account for regional variations could have the unintended consequence of encouraging additional spending beyond what would otherwise be considered modest.

Comparison to government employee “per diems” is not apt for a number of reasons. When government employees travel on business, the travel allowance is intended to cover a personal meal, not a meal that is part of any seminar or conference event. Also, the per diem amount does not limit the amount of the cost of a meal but rather limits the amount of reimbursement to the employee – the employee is free to spend additional amounts at his or her own cost.

Staff appreciate concerns about enforceability, but must reiterate that the statute is permissive. Meals that were previously prohibited are now allowed to be provided. Past cases of noncompliance were related to impermissible activities, and not to disputes about the dollar value of reported payments. Staff are confident that any complaints regarding provision of meals that do not meet the definition will be investigated, and staff will continue to work with the Office of the Attorney General on all complaints or reports of non-compliance with any provision of 105 CMR 970.000.

Staff are recommending no change to the definition.

2. Alcohol as part of modest meals. Consumer advocates and groups representing medical students stated that alcohol should not be permissible as part of modest meals and refreshments. For some, the objection was that the pharmaceutical and medical device manufacturers should not be paying for alcohol to physicians and other providers as part of modest meals. Others stated that any provision of alcohol, whether paid for by the manufacturer or the provider, is inconsistent with the statutory requirement that modest meals are permitted “for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information,” and must occur “in a venue and manner conducive to informational communication.” In contrast, other commenters noted that physicians and other providers as adults are entitled to a glass of wine or other beverage of choice with dinner.

Staff response and recommendation: The new statutory language is silent on the provision of alcoholic beverages, although staff note that the legislature chose the term “modest meals and refreshments” rather than simply “modest meals.” As a practical matter, nearly every venue with function rooms or conference capacity serves alcoholic beverages, and it would be unrealistic to expect either the host site or the manufacturer to police the contents of participants’ glasses. As such, staff are not proposing any language around the provision of or payment for alcohol.

3. Expenses related to training. Previously, chapter 111N and the regulation had permitted payment or reimbursement for expenses, including travel and lodging related expenses, necessary for technical training of health care practitioners on the use of a medical device if the commitment to provide such expenses, and the amounts or categories of reasonable expenses to be paid, were described in the written agreement between the health care practitioner and the device vendor for the purchase of the device. The 2012 changes to chapter 111N removed the requirement that the reimbursable expenses appear in the written contract. Accordingly, the proposed amendment to 105 CMR 970.008(2)(b) removed this condition.

Consumer advocates commented that the legislature did not authorize this change. The original language regarding this provision in section 2 of c. 111N follows:

The marketing code of conduct adopted by the department shall allow:

- (1) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;
- (2) the purchase of advertising in peer reviewed academic, scientific or clinical journals;
- (3) prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner’s patients;
- (4) compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or a clinical trial;
- (5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor’s purchase contract for the device.

The new language in the 2013 budget follows:

SECTION 111. The third paragraph of said section 2 of said chapter 111N, as so appearing, is hereby amended by striking out clause (5) and inserting in place thereof the following 2 clauses:-

- (5) payment for reasonable expenses necessary for technical training on the use of a medical device ice [sic, later corrected]; and
- (6) the provision of or payment for modest meals and refreshments in connection with non-CME educational presentations for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to informational communication; and provided further, that any such provision of or payment for modest meals and refreshments complies with the requirements set forth in section 2A; provided that the department shall define modest meals and refreshments through regulation.

Staff is therefore recommending that the revised statutory language continue to be part of the amended regulation.

4. Federal preemption of reporting requirements. An additional component of chapter 111N required disclosure to the Department of payments by pharmaceutical and medical device manufacturers to covered recipients. Federal provisions in the Affordable Care Act known as the Physician Payments Sunshine Act (“the Sunshine Act”) require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare, Medicaid and the Children’s Health Insurance Program to report payments and other transfers of value made to physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (“CMS”) for subsequent public disclosure. The Sunshine Act also preempts any state law that requires the collection and reporting of the same type of data. Thus, current provisions in chapter 111N that require disclosures of certain payments by pharmaceutical and medical device manufacturers to certain covered recipients will be preempted once federal regulations are finalized and federal reporting goes into effect. The Sunshine Act also provides that the federal Secretary of Health and Human Services will send reports of payments to each state. The 2012 changes to chapter 111N acknowledge the federal preemption and that the Department will receive the federal reports, and requires the Department to make all disclosed data in annual reports publicly available and easily searchable on its website not later than 90 days following the receipt from the Secretary.

The emergency amendments had stated that manufacturers would no longer have to make any required annual disclosures after the federal preemption begins. Additionally, the regulation stated that the Department would deem any manufacturer to have met any requirements regarding the quarterly disclosure of payments if that manufacturer complies with all federal reporting requirements and the federal Secretary subsequently sends the data to Massachusetts. .

Many commenters objected to the Department’s treatment of the federal preemption on two grounds: first, the federal reporting requirements apply to payments to physicians and teaching hospitals, while the original Massachusetts requirements under c. 111N apply to all prescribers and health care providers. Commenters want the Department to continue to collect data on payments to providers other than physicians and teaching hospitals, (primarily nurse practitioners and physician assistants) and payments by manufacturers who do not have to report under the federal law (e.g., for drugs and devices that are not reimbursable by federal insurance programs because they are strictly for cosmetic purposes and not covered by insurance). Second, commenters want the Department to enforce the quarterly reporting inserted in c. 111N as a condition for the provision of modest meals, notwithstanding any federal preemption issues.

Staff response and recommendation: Although the vast majority of reporting will be preempted by federal law¹, staff are recommending that the regulation be amended to require all annual reporting of information that is not reported pursuant to federal requirements. Staff are also recommending that the regulation require the quarterly reporting set forth in the statute, despite the fact that much of the information is of the type required to be reported under the Sunshine Act and therefore likely to be found to be preempted if challenged.

4. Annual fee. Previously, c. 111N had linked the fee that manufacturers must pay to the Department with the required disclosure. The statutory change added authority for the fee to the

¹ Reported payments to nurse practitioners and physician assistants represented 0.8% of the total reported payments for FY2010 and 0.7% of the reported payments for FY2011.

section regarding the provision of modest meals and refreshments; the emergency amendment had separated the fee from the required disclosures, many of which will be preempted by federal law.

Certain commenters appeared to misunderstand the Department's intent in moving the fee and thought that the Department was doing away with the fee.

Staff response and recommendation: Staff are recommending that the current amount of the fee (\$2000) be added to the new section where the fee now appears in order to make it more readily apparent that regulated companies must pay an annual fee with their registration with the Department.

5. Venue and manner conducive to informational communication. Consumer advocates urged the Department to define or otherwise regulate the places outside of the office or hospital setting where modest meals may be provided, by specifically prohibiting such meals at recreational sites like resorts, sporting clubs, casinos or other vacation destinations.

Staff response and recommendation: Meals (or any other types of gifts or payments) in connection with entertainment or recreation are already prohibited by both the statute and regulation. There are many examples of dual-purpose venues that provide conference services in addition to functioning as sites for recreation or entertainment. Likewise, non-recreational sites can provide entertainment within their function rooms. Staff are confident that the current statutory and regulatory language provide limitations that prohibit inappropriate gifts or payments from being provided to practitioners.

CONCLUSION

Staff requests approval for promulgation of the final amendments as noted. Following PHC approval the Department will file the amendments with the Secretary of the Commonwealth for final promulgation.

Attachment 1

105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct

Section

- 970.001: Purpose
- 970.002: Regulatory Authority
- 970.003: Citation
- 970.004: Definitions
- 970.005: General Requirements
- 970.006: Provision of Meals
- 970.007: CME, Third-party Scientific or Educational Conferences, or Professional Meetings
- 970.008: Other Payments to Health Care Practitioners
- 970.009: Reporting to the Department
- 970.010: Penalties
- 970.011: Enforcement

970.001: Purpose

105 CMR 970.000 implements M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct. 105 CMR 970.000 is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners. Pursuant to M.G.L. c. 111N, 105 CMR 970.000 seeks to accomplish these objectives without compromising companies' legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

970.002: Regulatory Authority

105 CMR 970.000 is adopted under the authority of M.G.L. c.111, § 3 and M.G.L. c.111N.

970.003: Citation

105 CMR 970.000 shall be known, and may be cited, as *The Pharmaceutical and Medical Device Manufacturer Code of Conduct* or the *Marketing Code of Conduct*.

970.004: Definitions

The following terms as used in 105 CMR 970.000 shall have the following meanings, unless the context or subject matter clearly require a different interpretation:

Annual Reports, the annual reports submitted by the Secretary of Health and Human Services to Massachusetts pursuant to Sec. 1128G(d)(2) of Part A of title XI of the federal Social Security Act.

Authorized Entity, the attorney general, the district attorney with jurisdiction over a violation, or the department of public health.

Biologic, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product, or analogous product, as defined by Section 351 of the Public Health Service Act applicable to the prevention, treatment, or cure of a disease or condition of human beings and regulated as a drug under the Federal Food, Drug, and Cosmetic Act.

Bona Fide Services, an arrangement for services including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including U.S. Food and Drug Administration (FDA) required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and 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.

Charitable Donation, the provision of financial support to a 501(c)(3) or the in-kind provision of drugs, biologics or medical devices for charity care of patients.

Clinical Trial, a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency.

Covered Recipient, a person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner. A person who otherwise meets this definition but is a *bona fide* employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient for the purposes of payments by that company. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.

Conference or Meeting, any convening where responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizers in accordance with their guidelines, held in a venue that is appropriate and conducive to informational communication and training about medical information, where

- (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and
- (b) the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

Department, the department of public health.

Genuine Research Project, a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry.

Health Care Practitioner, a person who prescribes prescription drugs for any person and is licensed to provide health care in Massachusetts, 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.

Hospital Setting,

- (a) a hospital;
- (b) academic medical center; or
- (c) pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company, is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.

Medical Device, an instrument, apparatus, implement, machine, contrivance,

implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is:

- (a) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto;
- (b) 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
- (c) 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.

Modest Meals and Refreshments, food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.

Non-faculty, a health care practitioner who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education (CME) event, third-party scientific or educational conference, or professional meeting.

Person, a business, individual, corporation, union, association, firm, partnership, committee or other organization.

Pharmaceutical or Medical Device Manufacturer Agent, a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in Massachusetts to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices; provided, however, that "pharmaceutical or medical device manufacturer agent" shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner 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 wholesale drug distributor licensed under M.G.L. c. 112, § 36A, 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 retail pharmacy registered under M.G.L. c. 112, § 37 if such person is not engaging in such practices under contract with a manufacturing company.

Pharmaceutical or Medical Device Manufacturing Company," any entity that:

- (a) is 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) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices; provided, however, that “pharmaceutical or medical device manufacturing company” shall not include a health care practitioner, physician practice, home health agency, hospital licensed under M.G.L. c. 111, § 51, a wholesale drug distributor licensed under M.G.L. c. 112, § 36A or a retail pharmacy registered under M.G.L. c. 112, §§ 37 through 39C.

Prescription Drugs, 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.”

Sales and marketing activities, for the purposes of disclosure under 105 CMR 970.009, sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose.

Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a covered recipient except as follows: Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or “new use” or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions 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.

Secretary, the Secretary of the United States Department of Health and Human Services.

970.005: General Requirements

- (1) By July 1, 2009, each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall:
 - (a) adopt a marketing code of conduct in compliance with the requirements of 105 CMR 970.000;
 - (b) adopt and submit to the Department a description of a training program to provide regular training to appropriate employees including, without limitation,

all sales and marketing staff, on the marketing code of conduct. The training program must:

1. ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of:
 - a. the marketing code of conduct,
 - b. general science, and
 - c. product-specific information to provide accurate, up-to-date information, consistent with state law and FDA requirements; and
 2. provide for regular assessments of persons who are employed by or acting on behalf of the companies to ensure that they comply with the requirements of 105 CMR 970.000 and other relevant company policies.
- (c) certify to the Department to the best of the company's knowledge, information and belief that it is in compliance with 105 CMR 970.000;
- (d) adopt and submit to the Department policies and procedures for investigating non-compliance with 105 CMR 970.000, taking corrective action in response to noncompliance and reporting instances of non-compliance to the appropriate state authorities; and
- (e) submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for certifying compliance with 105 CMR 970.000 and implementing, monitoring, and enforcing the company's marketing code of conduct.

(2) Each pharmaceutical manufacturing company that uses non-patient identified prescriber data to facilitate communications with health care practitioners shall:

- (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 health care practitioner not to make his or her prescriber data available to company sales representatives.
- (g) Before utilizing health care practitioner prescriber data for marketing purposes, manufacturers must give health care practitioners the opportunity to request that their prescriber data:
 1. be withheld from company sales representatives, and
 2. not be used for marketing purposes.
- (h) Nothing in 105 CMR 970.005(2) shall prohibit pharmaceutical manufacturing companies from using prescriber data to:
 1. impart important safety and risk information to prescribers of a particular drug or device;
 2. conduct research;
 3. comply with FDA mandated risk management plans that require manufacturers to identify and interact with health care practitioners who prescribe certain drugs or devices; or

4. track adverse events of marketed drugs, biologics or devices.

(3) In all speaker and commercial consultant contracts, pharmaceutical manufacturing companies shall require any health care practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.

(4) Beginning on July 1, 2010, and annually on or before July 1st of each year thereafter, each pharmaceutical and medical device manufacturing company must certify to the Department that it has conducted annual audits to monitor compliance with 105 CMR 970.000.

(5) Each pharmaceutical and medical device manufacturing company must report all incidents of non-compliance with 105 CMR 970.000 to the Department and to the Office of the Attorney General in a format specified by the Department.

(6) Each pharmaceutical and medical device manufacturing company must register with the Department annually and must pay the \$2000 annual registration fee ~~established by the Department~~. The annual registration fee replaces the disclosure fee described in 105 CMR 970.009(2), which is no longer required after July 1, 2012.

970.006: Provision of Meals

(1) Except as otherwise provided in 105 CMR 970.000, no pharmaceutical or medical device manufacturing company or its agent may provide or pay for meals for health care practitioners that:

- (a) are part of an entertainment or recreational event;
- (b) are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; or
- (c) are provided to a healthcare practitioner's spouse or other guest.

(2) Pharmaceutical or medical device manufacturing companies and agents may provide or provide payment for modest meals to health care practitioners in the health care practitioner's office or hospital setting in connection with informational or educational meetings or presentations.

(3) Pharmaceutical or medical device manufacturing companies and agents may provide or provide payment for modest meals and refreshments to health care practitioners outside of the health care practitioner's office or hospital setting for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to

informational communication. For the purposes of 105 CMR 970.006(3), “appropriate uses” may not include the promotion of off-label uses of prescription drugs or medical devices.

(4) No pharmaceutical or medical device manufacturing company may provide or provide payment for such meals and refreshments permitted under 105 CMR 970.006(3) unless such pharmaceutical or medical device manufacturing company files quarterly reports detailing all non-CME educational presentations at which such meals or refreshments are provided. Reports shall include:

- (a) the location of the non-CME presentation;
- (b) a description of any pharmaceutical products, medical devices or other products discussed at such presentation;
- (c) the total amount expended on such presentation; and
- (d) an estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation.

970.007: CME, Third-Party Scientific or Educational Conferences, or Professional Meetings

(1) No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:

- (a) financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners attending any CME event, third-party scientific or educational 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 health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;
- (c) payment for meals directly to a health care practitioner 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 pharmaceutical or medical device manufacturing company for the event to provide meals for all participants.
- (d) sponsorship or payment for CME, also known as independent medical education, 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 a health care practitioner.

(2) A pharmaceutical manufacturing company shall separate its CME grant-making functions from its sales and marketing departments.

(3) A pharmaceutical manufacturing 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) Nothing in 105 CMR 970.000 shall prohibit:

(a) compensation or reimbursement made to a health care practitioner 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 the payment:

1. is reasonable;
2. is based on fair market value; and
3. complies with the standards for commercial support as established by the relevant accreditation entity.

(b) sponsorship or payment 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;

(c) 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.

970.008: Other Payments to Health Care Practitioners

(1) No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:

(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 health care practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing 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.* to health care practitioners 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;

(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, § 41 and M.G.L. c. 175H, § 3.

(2) Nothing in 105 CMR 970.000 shall prohibit the following:

(a) Reasonable compensation for *bona fide* services, or the reimbursement of other reasonable out-of-pocket costs incurred by the health care practitioner directly as a result of the performance of such services, where the compensation and reimbursement is specified in, and paid for under, a written agreement;

- (b) Payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of health care practitioners on the use of a medical device;
- (c) The provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;
- (d) The purchase of advertising in peer reviewed academic, scientific or clinical journals;
- (e) The provision of prescription drugs to a health care practitioner solely and exclusively for use by the health care practitioner's patients;
- (f) The provision of reasonable quantities of medical device demonstration and evaluation units provided to a health care practitioner 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;
- (g) The provision of price concessions, such as rebates or discounts, in the normal course of business;
- (h) Provision of reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products, or of procedures using those products and information, in support of accurate and responsible billing to Medicare and other payers 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, however, that this technical or other support shall not be offered or provided for the purpose of inducing health care practitioners to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of products; or
- (i) The provision of payments, or the provision of free outpatient prescription drugs, to health care practitioners for the benefit of low income individuals, through established "patient assistance programs" (PAPs), provided the program 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).
- (j) The provision of charitable donations provided that the donation:
 - 1. 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
 - 2. does not otherwise violate the provisions of 105 CMR 970.000.

970.009 Reporting to the Department

- (1) Beginning July 1, 2010, and annually on or before July 1st of each year thereafter, every pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall disclose to the Department 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

provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities. ~~No reporting pursuant to 105 CMR 970.009(1),(3) and (5) is required after reporting for the calendar year 2012.~~

(2) Each annual disclosure report shall be accompanied by a fee of \$2,000. The first annual payment of \$2,000 shall be due to the Department on July 1, 2009. No payment pursuant to 105 CMR 970.009(2) shall be required after July 1, 2012.

(3) Disclosures shall be made for the previous calendar year using a standardized reporting format developed by the Department. The first required disclosure report shall cover the period from July 1, 2009 through December 31, 2009. Each annual disclosure report may be submitted to the Department electronically.

(4) Pharmaceutical or medical device manufacturing companies shall certify that to the best of the company's knowledge, information and belief, that any report is true and accurate.

(5) 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. Pharmaceutical or medical device manufacturing companies shall not structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements of M.G.L. c. 111N, §6 and 105 CMR 970.009.

(6) ~~The Department shall deem a pharmaceutical or medical device manufacturing company to meet the reporting requirement specified in 105 CMR 970.006(4)(a) through (e) if said company makes all disclosures required under federal law that are then provided by the Secretary to the Department in annual reports.~~ Notwithstanding the provisions of 105 CMR 970.009, no pharmaceutical or medical device manufacturing company is required to disclose information to the Department that has been disclosed to a federal agency pursuant to federal law and that is then provided by the Secretary to the Department in annual reports.

970.010 Penalties

(1) A person who knowingly and willfully violates 105 CMR 970.000 shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event.

(2) No pharmaceutical or medical device manufacturing company shall discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse action against any employee, applicant, health care practitioner or covered recipient because such employee, applicant, health care practitioner, or covered recipient takes or has taken any action in furtherance of the enforcement of 105 CMR 970.000.

970.011 Enforcement

- (1) Fines pursuant to 105 CMR 970.000 shall be issued by an authorized entity.
- (2) Ten days prior to the issuance of any fine pursuant to 105 CMR 970.000, the authorized entity shall provide notice and an informal opportunity to dispute the issuance of the fine in person or by counsel or other representative as to the proposed action.
- (3) Notice shall be provided by mail, postage prepaid, to the person's usual place of business or, if unavailable, to the person's last known address.
- (4) A person aggrieved by the issuance of a fine by an authorized entity pursuant to 105 CMR 970.000 may seek judicial review in the Superior Court.
- (5) An authorized entity may file a civil complaint in Superior Court following the failure of any person to pay a fine issued by the authorized entity.

REGULATORY AUTHORITY

105 CMR 970.000: M.G.L. c. 111, § 3 and c. 111N.