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Regulatory Summary of 105 CMR 970.000

Final Pharmaceutical and Medical Device Manufacturer Conduct Regulations

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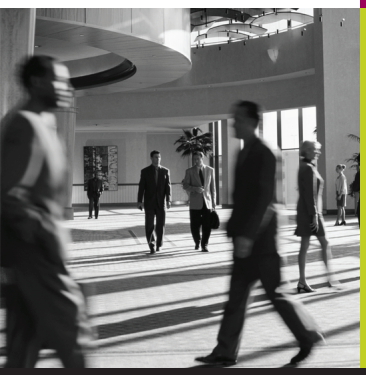
FOLEY HOAG LLP
Driving Business Advantage



I. Overview of the Final Regulations

On March 11, 2009, the Massachusetts Public Health Council promulgated final regulations (105 CMR 970.000) for the administration of Chapter 111N of the Massachusetts General Laws, which governs the marketing activities of pharmaceutical and medical device manufacturing companies. When the Legislature passed Chapter 111N in August 2008 (as Section 14 of Chapter 305 of the Acts of 2008) (the "Law"), Massachusetts joined the District of Columbia and six other states in regulating the relationships between the pharmaceutical and medical device industries and physicians.

Understanding these final regulations is of significant importance to anyone involved in the Massachusetts biotechnology, health care, and drug and device sectors. The regulations apply broadly to pharmaceutical or medical device manufacturing companies ("PMDMCs"), including companies that are "directly" engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices. In accordance with the requirements of the Law, the regulations establish a fine of $5,000 for each knowing and willful violation.

As summarized in greater detail below, the final regulations generally track the substance and organization of the Law, in three key areas:

- First, the regulations establish a marketing code of conduct that applies to both pharmaceutical and medical device companies, with certain limited exceptions.

- Second, the regulations mandate that PMDMCs implement certain training and compliance programs, and provide related certifications to the Department of Public Health ("DPH").

- Third, the regulations require PMDMCs to disclose certain payments and other benefits provided to certain covered recipients, and clarify that these disclosures are limited to sales and marketing activities. The disclosures will be made publicly available for review on a dedicated website.

II. Summary of the Final Regulations

A. Section 970.005: General Requirements

Adoption of Marketing Code of Conduct and Training Programs

- Requires that by July 1, 2009, each PMDMC that "employs or contracts with a pharmaceutical or medical device manufacturer agent" must (a) adopt a code of conduct consistent with the regulations, (b) adopt and submit to DPH a description of a training program for the code, (c) certify compliance with the code "to the best of the company's knowledge", (d) adopt and submit to DPH a program for addressing non-compliance, and (e) identify a compliance officer.

Non-patient Prescriber Data

- Requires pharmaceutical manufacturers using non-patient identified prescriber data to (a) maintain confidentiality, (b) develop policies regarding use of the data and educate employees about such policies, (c) designate an internal contact person for data inquiries, (d) establish appropriate disciplinary

actions for data misuse, (e) withhold the data from sales representatives at the request of health care practitioners ("HCPs"), and (f) give HCPs the opportunity to request that their prescriber data be withheld from company representatives and not be used for marketing purposes.

- Allows PMDMCs to use prescriber data to impart important safety and risk information to prescribers, conduct research, comply with FDA-mandated risk management plans, or track adverse effects of drugs or devices.

Disclosures to Formulary and Clinical Guidelines Committees

- Requires PMDMCs to require any HCP who both (a) serves as a member of a committee that sets formularies or develops clinical guidelines, and (b) serves as a speaker or commercial consultant for the PMDMC, to disclose to the committee the nature and existence of his or her PMDMC relationship.

Annual Audits

- Requires each PMDMC to certify annually to DPH that it has conducted an internal annual audit in compliance with the code. The first certification is required on July 1, 2010.

B. Section 970.006: Provision of Meals

Prohibitions on Certain Meals

- Prohibits PMDMCs that employ or contract with pharmaceutical or medical device agents from providing or paying for meals that are (a) part of an entertainment or recreational event, (b) offered without an informational presentation, (c) provided to a spouse or other guest, or (d) offered outside the "office or hospital setting," where that term is defined as a hospital, an academic medical

center, or a facility that the PMDMC has certified to DPH as being a "specialized training facility."

C. Section 970.007: CME, Third-party Scientific or Educational Conferences, or Professional Meetings ("Events")

Prohibitions on Funding for Certain Events

- Prohibits PMDMCs that employ pharmaceutical or medical device manufacturer agents from:
  - directly or indirectly reimbursing the expenses of "non-faculty" physicians attending Events,
  - compensating physicians for time spent attending Events,
  - paying for meals directly to HCPs at Events (although a CME provider or conference organizer may use PMDMC funding to provide meals for all participants), or
  - sponsoring CME Events not meeting ACCME or equivalent standards.

Reasonable Faculty Compensation

- Permits "reasonable" and "fair market value" compensation or expense reimbursement to HCPs serving as speakers, faculty organizers, or academic program consultants for an Event.

Separation of CME Funding

- Requires pharmaceutical manufacturers to separate their CME grant-making functions from their sales and marketing departments, and prohibits pharmaceutical manufacturers from providing advice or guidance to a CME provider regarding the content or faculty for a CME program funded by the company.

Facilities

- Permits the use of hotel or convention center facilities or other venues for Events.

D. Section 970.008: Other Miscellaneous Payments

Allowable Payments

- Allows certain PMDMC payment activities, including:
  - reasonable compensation or expense reimbursements for "bona fide services," (defined as including research, participation on advisory boards, collaboration with nonprofits dedicated to the promotion of health and the prevention of disease, and presentations at company-sponsored medical education and training as formalized in a written agreement),
  - distribution of peer reviewed academic, scientific or clinical information, and the purchase of advertising in academic, scientific, or clinical journals,
  - free samples of prescription drugs for use by patients,
  - payment for device training expenses pursuant to a written agreement,
  - free medical device demonstration and evaluation units for evaluation purposes,
  - price concessions, rebates or discounts in the normal course of business,
  - reimbursement information concerning products that support accurate billing to Medicare and other payors, so long as the information is not offered to induce physicians to purchase,

lease, or use products,

- payments, or free outpatient prescription drugs, provided through certain established patient assistance programs, and
- certain charitable donations.

Prohibited Payments

- Prohibits certain PMDMC payment activity, including:
  - the provision of entertainment or recreational items to HCPs that are not salaried employees of the PMDMC,
  - payments of any kind, including cash, equity, "in kind" payments, and "complimentary items" such as pens and mugs, except as compensation for bona fide services,
  - grants or scholarships, consulting contracts, educational or practice items provided in exchange for prescribing or using drugs or devices, and
  - any other payment or remuneration, including any rebate or "kickback" that is prohibited under federal or state fraud and abuse laws.

E. Section 970.009: Disclosure of Payments

De Minimis Exception

- Requires PMDMCs that employ marketers to disclose "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."

- Clarifies that 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."

Definition of "Sales and Marketing Activities"

- For the purposes of the disclosure requirement, "sales and marketing activities" include:
    - advertising, promotion or other activity that is intended to be used or is used to (a) influence the sale or the market share of a prescription drug, biologic or medical device, or the prescribing behavior of a covered recipient, (b) to market a drug or device, or (c) to evaluate the effectiveness of a pharmaceutical or medical device detailing sales force.
    - any product education, training, or research project that is designed or sponsored by the marketing division of a PMDMC, or has marketing, product promotion, or advertising as its purpose.

Activities Exempt from Disclosure

- The following are not "sales and marketing activities" for purposes of the disclosure requirement, and are thus exempt from disclosure:
    - 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." ("Genuine research" is defined as 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"),

- clinical trials posted on www.clinicaltrials.gov
- the provision of prescription drugs for use by patients,
- the provision of demonstration or evaluation units,
- in-kind items used for the provision of charity care, and
- 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."

Required Certification and Fees

- Requires PMDMCs to certify their disclosure reports as true and accurate, and to submit with each annual report a $2,000 fee. The first fee is due on July 1, 2009, even though the first report is not due until July 1, 2010.

Reporting Deadlines

- Requires that disclosure reports be filed by July 1, 2010 for payments occurring from July 1, 2009 through December 31, 2009, and annually thereafter (by July 1) for payments occurring during the previous calendar year.

F. Section 970.010: Penalties

Monetary Fines

- Establishes a fine of not more than $5,000 for each knowing and willful violation of the regulations.

Whistleblower Protections

- Establishes whistleblower protections for individuals who take actions in furtherance of the regulations.

III. Comprehensiveness

DPH has stated that these regulations are the most comprehensive of their kind in the nation. Particularly, DPH has noted that, with the adoption of the regulations, Massachusetts is the only state to (a) require adoption of and compliance with a state-authored marketing code of conduct, (b) prohibit certain payments to physicians by both pharmaceutical and medical device manufacturers, and (c) require disclosures by medical device manufacturers. The regulations also make Massachusetts one of two states that make disclosure data part of the public record.

105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct

970.001: Purpose

105 CMR 970.000 is set forth to implement M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care. 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, the regulation 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, s.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:

"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 legitimate need for the services clearly identified in advance;
- a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement;
- the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- 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;

- 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
- 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 the commonwealth, 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. 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 the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and board members of pharmaceutical or medical device manufacturers are not health care practitioners.

"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: (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.

"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 the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices; 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 section 36A of chapter 112, 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 pharmacist registered under section 37 of said chapter 112 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, s. 51, a wholesale drug

distributor licensed under M.G.L. c. 112, s. 36A or a retail pharmacist registered under M.G.L. c. 112, s. 37-39C.

"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.

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 C.M.R. 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:

i. 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:

1. the marketing code of conduct,

2. general science, and

3. product-specific information to provide accurate, up-to-date information, consistent with state law and FDA requirements; and

ii. 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 C.M.R 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 C.M.R. 970.000;

d. adopt and submit to the Department policies and procedures for investigating non-compliance with 105 C.M.R. 970.000, taking corrective action in response to non-compliance 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 C.M.R. 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 :

   i. be withheld from company sales representatives, and

   ii. not be used for marketing purposes.

h. Nothing in this section shall prohibit pharmaceutical manufacturing companies from using prescriber data to:

   i. impart important safety and risk information to prescribers of a particular drug or device;

   ii. conduct research;

   iii. 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

   iv. 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 1 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 C.M.R. 970.000.

970.006: Provision of Meals

1. Except as otherwise provided in 105 CMR 970.000, no pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer 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;

c. are offered, consumed, or provided outside of the health care practitioner's office or a hospital setting; or

d. are provided to a healthcare practitioner's spouse or other guest.

2. Meals provided to health care practitioners in compliance with 105 CMR 970.006 must be modest and occasional in nature.

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 these regulations 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, s. 41 and M.G.L. c. 175H, s. 3.

2. Nothing in these regulations 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 if the commitment to provide such expenses, and the amounts or categories of reasonable expenses to be paid, are described in the written agreement between the health care practitioner and the device vendor for the purchase of the 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 payors and provision of information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products, provided, 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 C.M.R. 970.000.

970.009: Disclosure of Payments

1. Beginning July 1, 2010, and annually on or before July 1 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.

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.

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, the 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 C.M.R. 970.009.

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 C.M.R. 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.

About Foley Hoag LLP

Foley Hoag LLP is a leading national law firm in the areas of dispute resolution, intellectual property, and corporate transactions for emerging, middle-market, and large-cap companies. With a deep understanding of clients' strategic priorities, operational imperatives, and marketplace realities, the firm helps companies in the biopharma, high technology, energy technology, financial services and manufacturing sectors gain competitive advantage. The firm's 225 lawyers located in Boston, Washington, and the Emerging Enterprise Center in Waltham, Massachusetts join with a network of Lex Mundi law firms to provide global support for clients' largest challenges and opportunities. For more information visit foleyhoag.com.

Pat A. Cerundolo

Pat Cerundolo's highly diverse administrative law, litigation and regulatory practice involves representing both private and public sector clients in a variety of local, state and federal regulatory concerns. He has assisted business clients from the energy, biotechnology and transportation industries, and represents telecommunications clients in connection with the regulation of fiber optic and wireless networks, including regulatory compliance, open access issues, and permitting. His work for public entity clients encompasses zoning matters, eminent domain, land use and related litigation.

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Pat A. Cerundolo

Colin J. Zick

Colin Zick's practice is focused on health care and compliance issues, and often involves the intersection of those two subjects in administrative proceedings or litigation. His work has had a particular emphasis on compliance issues related to pharmaceutical and medical device companies, hospitals, practitioners (including physicians, dentists, optometrists, psychologists, veterinarians), and provider organizations. This compliance work includes helping clients establish and maintain effective compliance programs. Colin defends clients in disputes alleging kickbacks, overpayments, and billing and coding problems, and represents before various state health care licensing and regulatory entities.

Click the image below for a full biography.

Colin Zick

Tad Heuer

Tad Heuer's practice focuses on advising both private and public sector clients in two main areas: the development of government strategies at the federal, state, and local levels, and on matters pertaining to real estate, permitting, and land use development. In the field of government strategies, Tad provides advice and guidance to a diverse array of clients – including educational institutions and companies, life sciences companies, and health care providers – on a wide range of federal, state, and local legislative and regulatory matters. Tad brings to Foley Hoag considerable experience in the government and nonprofit sectors, having worked previously for the U.S. Department of Education, the New England Board of Higher Education, the Massachusetts Institute for a New Commonwealth (MassINC), and several Massachusetts state legislators. Tad also holds a doctorate in Social Policy & Administration, with a focus on education regulation.

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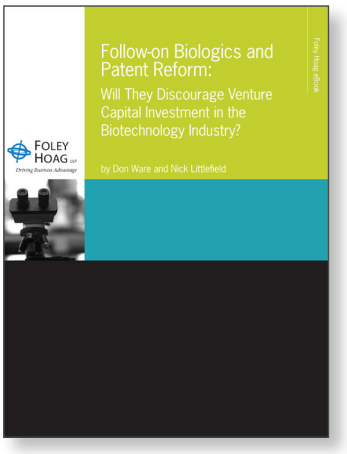

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