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Life Sciences Health Industry Alert

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Massachusetts Releases Final Restrictions on Drug and Device Marketing Activities, Annual Financial Disclosure Requirement

On March 11, 2009, the Massachusetts Department of Public Health (the "Department") released final regulations that impose restrictions on pharmaceutical and medical device manufacturers' sales and marketing activities.[1] The final regulations—which implement section 14 of the Massachusetts Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the "Act")[2] — also require companies to file annual disclosures of all fees, payments and economic benefits paid to health care professionals that total $50 or more.

Massachusetts now joins seven other jurisdictions that have issued similar requirements. Currently, California and Nevada both require manufacturers to adhere to restrictions on marketing activities, and the District of Columbia, Maine, Minnesota, Vermont and West Virginia all mandate periodic disclosures of payments and other economic benefits to health care professionals. Massachusetts, however, has the broadest regulations in two regards. First, Massachusetts is the only state to include both a marketing code of conduct that is specifically enumerated in detail in the regulations, and annual financial disclosure obligations. Other jurisdictions require adherence to a marketing code or disclosure, but not both. Second, Massachusetts is the first state to require financial disclosure from medical device companies. Financial disclosure requirements in other states currently only apply to pharmaceutical companies.

The following Alert describes the final Massachusetts marketing restrictions and disclosure requirements, including a list of key dates for compliance and a chart detailing the Massachusetts marketing code.

I. Marketing Code of Conduct

A. Overview

As noted above, the final regulations establish a code of conduct ("Marketing Code")[3] that restricts the nature and extent of pharmaceutical and medical device companies' interactions with health care practitioners in Massachusetts. Under the final regulations, any "pharmaceutical or medical device manufacturing company" that "employs or contracts with a pharmaceutical or medical device manufacturer agent" must adopt a marketing code of conduct in compliance with the Massachusetts Marketing Code described in the regulations.

A "pharmaceutical or medical device manufacturing company" is defined as any entity that:

- Is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics or medical devices; or
- Is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices.[4]

A "pharmaceutical or medical device manufacturer agent"—a new term not contained in the proposed regulations—means an employee or agent of the company who:

> [E]ngages in detailing, promotional activities or other marketing or 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.[9]

Companies subject to the Marketing Code must also implement a training program on the Marketing Code. Specifically, such training programs must ensure that all representatives employed by or acting on behalf of the company who "visit" health care professionals have "sufficient knowledge" of the Marketing Code, "general science" and product-specific information. In other words, a sales

representative should be able to provide health care professionals with the most accurate, up-to-date information on the product he or she is selling. Further, any such training program must include regular assessments of employees or agents to ensure that they comply with the Marketing Code and with internal company policies.[5]

B. Changes from Proposed Version

The final Marketing Code contains some notable changes and clarifications from the proposed version issued in December 2008. These include the following:

- **Application to Out-of-State Conduct.** Informal guidance posted to the Department's website provides some clarifications with respect to open issues from the proposed regulations issued by the Department in December 2008. In particular, the Department clarifies in its informal guidance that the Marketing Code provisions apply only to activities that take place in Massachusetts or involve a Massachusetts-licensed health care practitioner.
- **Scholarships to HCPs in Training.** Under the proposed Marketing Code, companies would have been permitted to provide scholarships to allow medical students, residents, fellows, and other HCPs in training to attend major educational, scientific or policy-making meetings of national, regional, or specialty medical associations, so long as the selection of the recipients was made by the trainee's academic or training institution. The final Marketing Code removes this section (although the provision of such scholarships is not specifically prohibited). Based on this deletion, it is unclear whether such scholarships are no longer permitted under the Marketing Code or whether the Department has opted simply not to list the scholarships as a permissible activity. The Department did not address this issue in any informal guidance.
- **Samples, Product Demonstration Units.** Under the proposed regulations, Massachusetts had intended to allow companies to provide "prescription drugs or medical device demonstration and evaluation units to a health care practitioner solely and exclusively for use by and education of the health care practitioner's patients." There was concern in the industry that this provision did not allow for evaluation or demonstration medical device units for health care practitioners to evaluate and assess, but not for use on patients. The final regulations make clear that such units are permitted, specifically allowing for the provision of demonstration and evaluation units to health care practitioners "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."
- **CME Events, Conventions Held in Massachusetts.** The Department clarifies in both the final regulations and in informal guidance posted to its website that the Marketing Code does not prohibit continuing medical education or other scientific or professional meetings and conventions from being held in Massachusetts. The Marketing Code specifically allows for "the use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences." The Department notes that drug and device companies can sponsor or provide payments for such meetings or conferences, so long as they are organized by third-parties who remain responsible for the content, selection of speakers and distribution of funds.
- **Meals at Conventions and Meetings.** The Department's informal guidance also clarifies that drug and device companies may not directly pay for meals outside of a "hospital setting"; however, third-party sponsors of CME or other meetings can use general funds from manufacturers to provide meals to attendees.
- **Charitable Donations.** The final regulations add a provision to the Marketing Code that specifically permits companies to provide charitable donations in the form of financial support to a 501(c)(3) tax-exempt organization or in-kind donations of drugs, biologics or medical devices to support the charity care of patients.

Other provisions of the final Marketing Code, as noted above, remain substantially the same. These include the following:

- **No Kickbacks.** Grants, scholarships, subsidies, consulting arrangements, or other items of value cannot be furnished to health care practitioners in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices, or for a commitment to continue doing so in the future.
- **Meals.** Meals must be modest and occasional, provided in connection with an informational presentation and provided in the health care professional's office or in the hospital setting. The term "hospital setting" includes a company's specialized training facility.

- **Entertainment.** Entertainment or recreational items of any value (e.g., theater tickets, sports equipment, trips, etc.) are strictly prohibited.
- **Reminder Items.** "Complimentary" items such as pens, coffee mugs, gift cards or calendars are prohibited. (Importantly, the Department's final memorandum on the Marketing Code indicates that it declined to impose an across-the-board gift ban—as had been requested by consumer advocacy groups.[6])
- **CME.** Funding for CME can only be provided for events that meet the Standards for Commercial Support of the Accreditation Council for CME ("ACCME") or equivalent standards. Further, a company cannot pay for the cost of travel, lodging, attendance or other personal expenses of non-faculty health care professionals, nor can a company make direct payments for meals at a CME event.
- **Training Costs.** Medical device manufacturers can reimburse health care professionals for reasonable costs necessary for technical training on a medical device, so long as the terms of the reimbursement are subject to a written purchase agreement for the device. (The Department notes in its memorandum on the final regulations that it specifically declined to make changes to this section, even though many in the industry argued that training often predates a sales contract.)
- **Price Concessions.** Price concessions, such as discounts and rebates, are permissible.
- **Reimbursement Assistance.** Companies can provide technical assistance concerning reimbursement information (e.g., identifying appropriate coverage, coding, or billing information).

A chart attached to the end of this Alert provides an expanded and detailed summary of the final Marketing Code.

C. Key Dates for Adopting the Marketing Code

The Department has also clarified key compliance dates for ensuring that a company adopts and adheres to the Marketing Code:

By **July 1, 2009**, pharmaceutical and medical device manufacturers subject to the Marketing Code must:

- Adopt a marketing code of conduct in compliance with the requirements laid out in the final regulations
- Adopt and submit to the Department a description of its training program
- Certify to the best of the company's knowledge, information and belief that it is in compliance with the final regulations
- Adopt and submit to the Department policies and procedures for investigating non-compliance, taking corrective action in response to noncompliance, and reporting instances of noncompliance to appropriate state authorities
- Submit to the Department the name, title, address, telephone number and e-mail address of the compliance officer identified as responsible for certifying compliance with the final regulations, and for implementing, monitoring and enforcing the company's marketing code of conduct[7]

On or before **July 1, 2010**—and on or before July 1 of each year thereafter—a company is also required to certify that it has completed an annual audit of compliance with the final regulations.[8]

II. Financial Disclosure Requirements

A. Overview

In addition to the Marketing Code, the final Massachusetts regulations require any pharmaceutical or medical device manufacturing that employs or contracts with a "pharmaceutical or medical device manufacturing agent" to file annual reports disclosing all payments or items of value worth $50 or more to health care practitioners, with few exceptions.

Annual reports (to be filed on a standardized form developed by the Department) must detail:

- The value, nature, purpose and particular recipient of
- Any fee, payment, subsidy or other economic benefit with a value of at least $50
- Paid directly or through its agents
- To any "covered recipient" (any person authorized to prescribe, dispense, or purchase prescription drugs or medical devices, including hospitals, nursing homes, pharmacists, health benefit plan administrators, or "health care practitioners")[10]

- In connection with the company's "sales and marketing activities."[11]

Whether a payment is disclosable, therefore, turns in part on whether it has been made in connection with "sales and marketing activities." The term "sales and marketing activities" means:

- The provision of any fee, payment, subsidy or other economic benefit with a value of at least $50 to a health care practitioner.
- Advertising, promotion or other activities intended
  - To influence sales or market share
  - 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
  - To evaluate the effectiveness of a company's detailing sales force
- Product education and training
- Research projects designed or sponsored by the marketing division of a drug or device company with marketing product promotion or advertising as their purpose.[12]

The term "sales and marketing activities" does not include:

- Clinical trials and genuine research[13] 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.
- The provision of prescription drugs to a covered recipient solely and exclusively for use by patients
- Demonstration and evaluation units
- The provision of in-kind items used for the provision of charity care
- Confidential price concessions established in contracts between companies and insurers, pharmacies, pharmacy benefit managers, or health plan administrators and their affiliates.[14]

The proposed regulations, by contrast, had originally excluded from reporting only those payments related to the provision of compensation for professional or consulting services in connection with a genuine research project or clinical trial. The other exclusions listed above, such as price concessions, were considered disclosable under the proposed regulations, but are shielded from disclosure under the final version.

Regardless of the addition of these exclusions to the final regulations, the Department's financial disclosure requirements remain fairly broad. The financial disclosure requirements, in essence, mandate reporting of all payments of $50 or more in any form to any Massachusetts health care provider with five exceptions—(1) payments for consulting services in connection with research or clinical trials, (2) drug samples, (3) product demonstration or evaluation units, (4) in-kind items for charity care, and (5) price concessions (e.g., discounts and rebates).

Importantly, the final regulations clarify that the $50 threshold should be computed on a per-event or per-transaction basis and should not be aggregated. In addition, all items disclosed to the state will be posted on a searchable, publicly available database.

B. Open Issues

Informal guidance posted to the Department's website provides some clarity with respect to the financial disclosure requirements.[15] Specifically:

- **Out-of-State Activities.** The disclosure requirements apply to any sales and marketing activity directed at and benefiting a Massachusetts covered recipient, even if they occur outside of the state.
- **Multi-Division Companies.** The Department specifies that while a company must designate a compliance officer, it may submit one overall disclosure report or several reports at the divisional level.

C. Filings

Companies must start tracking payments to health care practitioners **July 1, 2009**. The regulations require companies to file the first annual disclosure reports on or before **July 1, 2010**. The 2010 disclosure report would cover the period of July 1, 2009 through December 31, 2009. Starting **July 1, 2011**, annual disclosures would cover the previous calendar year (Jan. 1 – Dec. 31, 2010).

Reports will be filed on a form to be developed by the state. Finally, each annual report must be accompanied by a $2,000 filing fee and a certification as to the truth and accuracy of the report.[16]

III. Penalties

Under the final regulations, any knowing and willing violation of the Marketing Code or the financial disclosure requirements would be punishable by a fine of $5,000 for each transaction, occurrence or event. The penalties' section of the regulations is also clear that pharmaceutical and medical device companies are subject to a duty of good faith compliance and, further, that companies cannot retaliate in any way against an employee, agent or HCP who has "taken any action in furtherance of enforcement" of the regulations.[17]

The final regulations add a section detailing how fines will be enforced. Ten days prior to the issuance of any fine, the government will provide notice and an informal opportunity to dispute the issuance of the fine. Once a fine has been issued, the manufacturer has the opportunity to seek judicial review in the Massachusetts Superior Court.[18]

IV. Conclusion

With the issuance of its final regulations, Massachusetts becomes the eighth jurisdiction in the United States to issue final rules on pharmaceutical and medical device companies' sales and marketing activities and/or on mandating financial disclosure. As noted in a December 2008 Reed Smith Client Alert on the proposed Massachusetts regulations, it is unclear whether the unique nature of the Massachusetts regulatory scheme—i.e., dual marketing and reporting requirements—will become the model for future state laws in this area.

In addition, it is also unclear how state regulations such as the Massachusetts requirements will be impacted by preemption language contained in the recently reintroduced Physician Payments Sunshine Act by Sen. Charles Grassley (R-Iowa), which would require drug and device companies to disclose financial relationships with health care professionals. If the Grassley bill's preemption language were further expanded to override all state reporting requirements—not simply those state reporting provisions that are identical to those contained in the Grassley bill—this could serve to create a uniform, national approach to both tracking and reporting these payments.

Regardless, companies should begin to take steps to ensure compliance with the final Massachusetts regulations by July 1, 2009.

Summary of the Massachusetts Marketing Code

SUBJECT	FINAL MARKETING CODE GUIDELINES
Meals	• Must be modest and occasional. • No meals that are part of an entertainment or recreational event. • No meals without an informational presentation by a company agent or without an agent present. • No meals outside the health care practitioner's ("HCP's") office or the hospital setting.* • No meals provided to an HCP's spouse or other guest. * "Hospital setting" is expanded to include hospitals and academic medical centers, as well as drug and device companies' specialized training facilities. These are facilities designed to approximate surgical suites or working clinical laboratories, and that are used to provide training on large devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment. (Note: the final regulations remove the requirement that such training include use of human tissue and cadavers.)
Continuing Medical Education **Third-Party Scientific or Educational Conferences** **Professional Meetings**	**Prohibited Payments** • Support for costs of travel, lodging, or other personal expenses of non-faculty HCP attendees, either directly to the individuals or indirectly to the event's sponsor. • Funding to compensate for HCP time spent participating in any CME event, third-party scientific or educational conferences, or professional meetings. • Direct payment for meals at any CME event, third-party scientific or educational conferences, or professional meetings. (A CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a drug or device company toward meals for all participants.) • Sponsorship or payment for CME that does not meet ACCME guidelines or equivalent accrediting standards. • Sponsorship or payment for CME that provides payment directly to an HCP. **Permitted Payments** • Payment for a third-party scientific or educational conference, charitable conference or meeting, or professional meeting paid directly to the conference or meeting organizer. • Compensation or reimbursement to an HCP serving as a speaker, or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting. (Payment must be reasonable, based on fair market value, and comply with accreditation standards.) • 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. Note: The final regulations remove the provision that would have permitted scholarships to permit medical students, residents, fellows, and other HCPs in training to attend major educational, scientific or policy-making meetings of national, regional, or specialty medical associations, so long as selection of recipients is made by academic or training institution. **Purpose of Conference or Meeting** • The gathering must be primarily dedicated, in time and effort, to promoting objective scientific and educational activities and discourse—one or more educational presentations should be the highlight of the gathering. • The main purpose for bringing attendees together is to further their knowledge on the topics being presented. **Control of Content** • Responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference or meeting in accordance with their guidelines. • A "pharmaceutical manufacturing company" cannot provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company.[19] **Venue** • Must be held in a venue that is appropriate and conducive to informational communication and training about medical information. **Separation of Sales and Grant-Making** • A "pharmaceutical manufacturing company" must separate CME grant-making from sales & marketing.[20]
Entertainment and Recreation	• No entertainment or recreational items of any value to HCPs who are not salaried employees (e.g., tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips).

Complimentary Items to HCPs	• No "complimentary" items such as pens, coffee mugs, or gift cards to any HCP, except as compensation for "bona fide services."
SUBJECT	**FINAL MARKETING CODE GUIDELINES**
Other Types of Remuneration	• No cash or cash equivalents, no equity, "in kind" or tangible items to any HCP, except as compensation for "bona fide services." • No 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. • No other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under the Anti-Kickback Statute or the equivalent Massachusetts law.
Payments to HCPs for Bona Fide Services	• Reasonable compensation for "bona fide services"*—or the reimbursement of other reasonable out-of-pocket costs incurred by an HCP directly as a result of performing such services—is permitted. • Compensation and reimbursement must be specified in and paid according to a written agreement. The definition of "bona fide services" includes the following conditions: • Must have written agreement specifying services. • Compensation must be based on fair market value. • Must have a legitimate need for the services clearly identified in advance. • Competence and expertise of the consultant must be connected to the purpose of the arrangement. • Number of HCPs retained to provide services cannot be greater than number reasonably necessary to achieve the purpose of the services. • The company must maintain records concerning the arrangement. • The company must make appropriate use of the services provided. • The venue and circumstances of any meeting with consultants must be conducive to the consulting services, and activities related to the services must be the primary focus of the meeting. • The decision to retain an HCP cannot be "unduly influenced" by sales personnel. * "Bona fide services" includes, but is not limited to, any arrangement for research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to promoting health and preventing disease, and presentations at company-sponsored education and training.
Expenses Necessary for Device Training	• Device companies can pay or reimburse for the reasonable expenses—including travel and lodging—necessary for technical training on the use of a medical device. • Such payment must be paid pursuant to and described under a written agreement between the HCP and the "device vendor for the purchase of the device."
Academic, Scientific and Clinical Information	• Permissible to distribute peer-reviewed journals, or academic, scientific, or clinical information. • Permissible to purchase advertising in peer-reviewed academic, scientific or clinical journals.
Samples; Evaluation and Demonstration Units	• Permissible to provide prescription drugs to an HCP solely and exclusively for the benefit of the HCP's patients. • Permissible to provide reasonable quantities of medical device demonstration and evaluation units to assess the appropriate use and functionality of the product, and to determine whether or not and when to use or recommend the product in the future.
Price Concessions	• Permissible to provide customers with price concessions, including rebates and discounts, in the normal course of business.
Reimbursement Information	• Permissible to provide reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products, or of procedures using those products and information. • Permissible to provide information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products.
Patient Assistance Programs	• Permissible to provide payments or the provision of free outpatient prescription drugs to HCPs for the benefit of low income individuals through established Patient Assistance Programs ("PAPs"). Eligible PAPs would have to meet the criterion for a permissible program in accordance with the relevant published guidance available from the U.S. Health and Human Services Office of Inspector General, or as otherwise permitted under applicable federal laws and regulations (e.g., the Anti-Kickback Statute).

Charitable Donations	• Permissible to make 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 Massachusetts regulations. • "Charitable donation" is defined as 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.
SUBJECT	**FINAL MARKETING CODE GUIDELINES**
Use of Prescriber Data	"Pharmaceutical manufacturing companies" that use non-patient-identified prescriber data must: • Maintain the confidential nature of the data. • Develop policies regarding the use of the data. • Educate employees and agents about these policies. • Designate an internal contact person responsible for inquiries regarding the data. • Identify disciplinary action for misuse of the data. • Comply with any HCP's request not to make data available to sales representatives.[21] In addition, before using prescriber data for marketing purposes, manufacturers must give HCPs the opportunity to request that their data (1) be withheld from sales representatives and (2) not be used for marketing purposes.
Formulary Committee Members	• In all speaker and commercial consultant contracts, "pharmaceutical manufacturing companies" must require HCPs who serve as members of a formulary or clinical guidelines committee, and who also serve as speakers or commercial consultants, to disclose the relationship to the committee.[22] • Disclosure is required for at least two years beyond the termination of any speaker or consulting arrangement.

1 *See* 105 Mass. Code Regs. 970.000, available at http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_pharmacy_medical_devices&csid=Eeohhs2.

2 *See* Mass. S.B. 2863 (July 31, 2008), available at http://www.mass.gov/legis/bills/senate/185/st02pdf/st02863.pdf.

3 *See* 105 Mass. Code Regs. § 970.004-970.008.

4 *Id.* The final regulations removed the vague reference in the definition of "pharmaceutical and medical device manufacturing company" that any such company also "participates in a commonwealth health care program."

5 *Id.* § 970.005.

6 Memorandum from M. Lopes, Deputy General Counsel, Mass. Department of Public Health, to Members of the Public Health Council, dated March 11, 2009, available at http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_pharmacy_medical_devices&csid=Eeohhs2.

7 *Id.*

8 *Id.*

9 *Id.* § 970.004. The proposed regulations were drafted more broadly, applying to drug and device companies that employed any person to sell or market a drug or device in Massachusetts.

10 "Covered Recipient" does not include bona fide employees of a pharmaceutical or medical device company, nor does it include consumers who purchase pharmaceuticals or medical devices. "Health care practitioner" is a catch-all term that means any person who prescribes prescription drugs for any person and is licensed to provide health care in the state. It also includes partnerships or corporations comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course of his/her employment, agency or contract. The term does not include hospitals or full-time employees or board members of drug and device companies. *Id.* § 970.004.

11 *Id.* § 970.009.

12 *Id.* § 970.004. The Department notes in its memorandum on the final regulations that this last provision on research projects was included to specifically require disclosure of expenses associated with "seeding trials," or rather research generally designed or sponsored by a manufacturer's marketing department and not undertaken to answer a scientific question.

13 A "Clinical Trial" is defined as a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug 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. *Id.*

A "Genuine Research Project" is defined as a project intended to add to medical knowledge about the care and treatment of patients that constitutes systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published freely 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. *Id.*

14 *Id.* According to the Department in its memorandum on the final regulations, these additional exclusions—drug samples, demonstration and evaluation units, and rebates and discounts—were included in the final regulations to specifically address concerns raised by the drug and device industry.

15 Mass. Dept. of Public Health, Guide to 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct, available at http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_pharmacy_medical_devices&csid=Eeohhs2.

16 105 Mass. Code Regs. § 970.009.

17 *Id.* § 970.010.

18 *Id.* §§ 970.011-970.012.

19 Note that the guideline only applies to pharmaceutical companies.

20 Note that the guideline only applies to pharmaceutical companies.

21 Note that the guideline only applies to pharmaceutical companies.

22 Note that the guideline only applies to pharmaceutical companies.

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